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

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

PLAINTIFF TRIANTAYLLOS TAFAS'S MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION FOR ISSUANCE OF EXPEDITED BRIEFING <u>SCHEDULE IN LIEU OF A STANDARD INITIAL SCHEDULING ORDER</u>

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PRELIMINARY STATEMENT

The Plaintiff, Dr. Triantafyllos Tafas ("Plaintiff" or "Tafas"), through his counsel, Kelley Drye & Warren LLP, submits this Memorandum in Opposition to Defendants' Motion for an Expedited Scheduling Order in Lieu of a Standard Initial Scheduling Order dated November

9, 2007 (the "Motion")(Docket No. 60-61).

ARGUMENT

Point I

DEFENDANTS HAVE NOT DEMONSTRATED ANY NECESSITY OR EQUITABLE ENTITLEMENT TO <u>A GREATLY EXPEDITED SCHEDULING ORDER</u>

Here, Defendants are seeking to gain an unfair tactical advantage by trying to force plaintiffs to file their summary judgment motions (which is the functional equivalent of a trial in the present context) by December 20th. This is less than four (4) months after Dr. Tafas first filed his suit and less than 2¹/₂ months since plaintiff Glaxo Smith Kline Beecham ("GSK") filed its case..

First, Plaintiffs are not "stalling." Quite to the contrary, in recent negotiations Plaintiffs jointly proposed to Defendants a greatly expedited case scheduling order, which called for summary judgment briefs to be filed on January 25, 2008 and a final summary judgment hearing on the merits on April 11, 2007. (See Exhibit 1). Defendants unreasonably spurned Plaintiffs' proposal and their motivation is transparently tactical and self-serving -- which is to deny Plaintiffs sufficient time to review and analyze the approximately 10,000 pages in the "administrative record" so as to prejudice their ability to successfully prosecute this case. Defendants suggestion that GSK is somehow bound to the summary judgment briefing schedule originally agreed to between Defendants and Tafas (and now vacated by stipulation) makes no sense at all.

First, Defendants repeatedly and vociferously objected to GSK's request to have the <u>option</u> of participating in the above referenced Tafas schedule. (<u>See</u> Def. Mem. In Opposition to Preliminary Injunction Motion at pp. 1-2 n.1). It is only after losing the preliminary injunction that Defendants have now done an about face and are seeking to rush GSK (and Tafas) to summary judgment as part of a frantic effort to find an early escape hatch to the Federal Circuit.

Second, Defendants have grossly misconstrued the thrust of Attorney Desmarais' statements at the preliminary injunction hearing. GSK's counsel did <u>not</u> stipulate to abide by the Tafas summary judgment schedule in all events. Rather, Attorney Desmarais simply noted that GSK would be willing to abide by the Tafas summary judgment schedule **IF** the Court <u>deemed an early resolution sufficiently important as to make that a **condition** of granting a <u>preliminary injunction</u> in favor of GSK. The grant of a preliminary injunction was not at all a "close call" and the decision was entirely silent as to any timetable for a final hearing nor was the preliminary injunction made conditional on an expedited scheduling order.</u>

Third, various amendments to the Tafas summary judgment schedule included language (<u>inserted at Defendants' insistence</u>) contemplating that the summary judgment schedule would be further enlarged if GSK obtained a preliminary injunction. (<u>See</u> Stipulation and Consent Order dated October 17, 2007, ¶ 9; Docket No. 28). Additionally, the parties subsequently stipulated to vacate the Tafas scheduling order (as amended) altogether by a

Stipulation and Consent Order dated November 8, 2007 (Exhibit 2). This renders moot any alleged commitment to abide by the Tafas schedule.

Notwithstanding that the preliminary injunction order was not conditioned on the entry of an expedited scheduling order, <u>Plaintiffs have still graciously offered to proceed under a greatly expedited schedule</u>. Nonetheless, Defendants persist in insisting that the Court dramatically shrink Plaintiff's time to prepare their cases beyond that which is colorably reasonable giving the importance of the issues. There is no longer any exigency (*i.e.*, the November 1 implementation date for the new rules) mandating such extreme speed.

Defendants have not even filed their Answer yet (and are in default with respect to Tafas). Under all the above circumstances, Defendants have no business trying to stampede plaintiffs into finalizing summary judgment papers at the same time Plaintiffs are still in the process of reviewing and analyzing the administrative record produced to date.

As part of a smoke-screen to distract the Court from the fact that Plaintiffs <u>are</u> <u>prepared to proceed on a greatly expedited basis</u>, Defendants incorrectly suggest that the only reason Plaintiffs are seeking more time is to attempt to take discovery they are not entitled to under the Administrative Procedure Act (APA). Again, Plaintiffs proposed date to submit summary judgment <u>is barely 3 months after GSK commenced this action</u>. The schedule jointly proposed by Plaintiffs is already very aggressive and provides the absolute bare minimum amount of time reasonably necessary to provide for an adequate review and vetting of the administrative record (separate and apart from any discovery that may or may not be allowed by <u>the Court</u>).

Of course, the Court should not decide whether to permit discovery based on "scheduling considerations". Here, Defendants obvious motive is to effectively eliminate the

possibility of discovery (whether through FOIA requests, formal discovery under the Federal Rules of Civil Procedure, or otherwise) by propounding a proposed scheduling order purposefully crafted to deprive Plaintiffs of any time to conduct discovery.

Point II

THE COURT SHOULD NOT ISSUE A BLANKET PROHIBITION ON DISCOVERY IN THIS CASE

As set forth below, Defendants have failed to carry their burden of demonstrating good cause for the issuance of a protective order quashing the proposed depositions of four (4) senior USPTO personnel (including Defendant Jon W. Dudas). Each of the 4 proposed deponents are reasonably believed to have been extensively involved in the underlying rulemaking process and ultimate decision to promulgate the Revised Rules. Regardless of what the Court ultimately decides with respect to these particular depositions, the Court should certainly not issue a blanket prohibition against any discovery in this action at the present time as Defendants have suggested.

Here, Defendants engaged in a biased, results oriented rule-making process with respect to the Revised Rules. Tafas respectfully submits that there is sufficient indicia of bad faith and withholding of factual information and documents from the administrative record as to provide a reasonable ground for affording some discovery concerning the rule-making process. Moreover, proof of a *bad faith* certification is also a substantive element of Tafas' Regulatory Flexibility Act (RFA) claim. Finally, in addition to Tafas' claims of "arbitrary and capriciousness" rule-making by the USPTO under the APA, Tafas has also asserted *constitutional claims* based on the Patent Clause and Fifth Amendment, which claims are legitimately subject to discovery.

A. <u>APPLICABLE LEGAL STANDARD</u>

Under the Federal Rules of Civil Procedure, a court may grant a protective order if it is required to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense. FED.R.CIV.P. 26(c). The burden of proof in obtaining a protective order is on the moving party. <u>Great American Ins. Co. v. Gross</u>, 2007 WL 1577503 *12 (E.D. Va. 2007)(the moving party must show the necessity of a protective order and "stereotyped and conclusory statements" will not suffice). Notwithstanding the so called administrative record limitation on discovery, the burden is still on the moving party to establish the need to withhold extra-record evidence during pre-trial discovery. ¹ <u>E.g., In re Terra Int'l, Inc.,</u> 134 F.3d 302, 306 (5th Cir. 1998); <u>Save Our Wetlands, Inc. v. Connor</u>, 1999 WL 508365 at *1 (E.D.La. 1999).

Of course, Tafas is well aware that extensive discovery is not the norm in the APA

context. However, as this Court itself recognized in its preliminary injunction decision, there

are well-established exceptions that permit discovery in APA cases:

Generally, "judicial review of agency action pursuant to the APA is confined to the agency's administrative record."... However, "[e]ven in APA record review cases, circumstances may justify expanding the record or permitting **discovery**," including "such a failure in the **record** to explain **administrative** action as to frustrate judicial review, the agency's reliance on materials or documents not included in the administrative record, or the need to supplement the record to explain or clarify technical terms or other difficult subject matter included in the record."<u>*Id.*</u> at 477 (internal citations omitted); ...

Tafas v. Dudas, 2007 WL 3196683 at * 6 (E.D.Va. 2007). (Citations omitted).

¹ In the face of relevancy objections to discovery requests, courts have taken the position that "relevance, in the realm of discovery, ought to be broadly and liberally construed." <u>Breon v.</u> <u>Coca-Cola Bottling Co. of New York</u>, 232 F.R.D. 49, 52 (D. Conn. 2005); <u>Watson v.</u> <u>Lowcountry Red Cross</u>, 974 F.2d 482 (4th Cir. 1992). On relevancy matters, the trial court has broad discretion."). A request for discovery should be considered relevant if there is *any possibility* that the information sought might be relevant to the claim or defense of any party. <u>Breon</u>, at 52, quoting <u>Favale v. Roman Catholic Diocese of Bridgeport</u>, 2005 WL 3017959 at *3 (D.Conn. 2005).

Discovery is permissible in the APA context where the administrative record is incomplete or where it appears that the agency may have relied on documents or facts not included in the record (including situations where the agency excluded pertinent but unfavorable factual information). <u>E.g.</u>, <u>Public Power Council v. Johnson</u>, 674 F.2d 791, 794 (9th Cir. 1982) (permitting discovery where issues were complex and based on allegations that additional memoranda and notes of internal agency meetings were not part of the record). As the <u>Johnson</u> court noted:

[T]here is a further exception to the general rule that...arises when it appears that the agency has relied on documents or materials not included in the record ... Some courts have thus permitted discovery when those challenging agency action have contended the record was incomplete, in order to provide a record of all documents and materials directly or indirectly considered by the agency decision-makers.

Id. at 794 (citations omitted) (Emphasis added).

The seminal case recognizing that discovery beyond the administrative record is permissible when the record is incomplete or inadequate is <u>Citizens to Preserve Overton Park v.</u> <u>Volpe</u>, 401 U.S. 402, 420 (1971)("<u>Overton Park</u>"). The Supreme Court held that while "review is to be based on the full administrative record that was before the Secretary at the time he made his decision ... [that] since the bare record may not disclose the factors that were considered or the Secretary's construction of the evidence it may be necessary for the [d]istrict [c]ourt to require some explanation in order to determine if the Secretary acted within the scope of his authority ... [and] ... may require the administrative officials who participated in the decision to give testimony explaining their action[s]." <u>Id</u>. at 420.

As noted in Johnson and Overton Park, discovery may be permitted in APA cases if all matters considered by agency decision-makers are not made part of the administrative record. ² <u>E.g., Appalachian Power Co. v. Environmental Protection Agency</u>, 477 F.2d 495, 507 (4th Cir. 1973) (the whole record is not necessarily those documents that the agency has compiled and submitted as the administrative record and the court must look to all the evidence that was before the decision-making body).

Another well-established exception that provides a basis for discovery in an APA proceeding is alleged *bad faith* or improper behavior by agency officials.³ E.g., U.S. v. Shaffer Equip., 11 F.3d 450, 460-61 (4th Cir. 1993); Palmico-Tar River Foundation v. U.S. Army Corps of Engineers, 329 F.Supp.2d 600, 609-610 (E.D.N.C. 2004)(administrative record may be supplemented through discovery in order to show that agency failed to consider certain relevant

² <u>See also Tenneco Oil Co. v. Dept. of Energy</u>, 475 F.Supp. 299, 317 (D. Del. 1979) ("It strains the Court's imagination to assume that the...decision-makers reached their conclusions without reference to a variety of internal memoranda, guidelines, directives and manuals ..."); <u>Franklin Savings Ass'n v. Ryan</u>, 922 F.2d 209, 210 (4th Cir. 1991)(discovery permitted after preliminary showing that the administrative record as presented may be incomplete and that there may have been documents or evidence available for review by agency that were not reviewed, or which were reviewed and not relied upon by agency, or which were reviewed and relied upon by agency but not contained in the administrative record); <u>Fund for Animals v. Williams</u>, 245 F.Supp.2d 49, 55 (D.D.C. 2003)(agency may not skew the record in its favor by excluding pertinent but unfavorable information from the administrative record designated for judicial review, nor may agency exclude information on the grounds that it did not "rely" on the excluded information in its final decision).

³ The lower court proceedings in <u>Maritime Management v. U.S.</u>, 242 F.3d 1326, 1329-1330 (11th Cir. 2001)("<u>Maritime Mgmt."</u>) illustrate the well-established exception of bad faith on an agency's part as providing the basis for discovery in the APA context. That Court found that "[1]imited discovery was indeed proper because of the Government's 'failure to include relevant documents in the report to the GAO and in light of the negative nature of those documents purposefully excluded from the report. Such evidence constitutes a showing of bad faith or improper behavior on the part of Defendant justifying additional discovery." <u>Id</u>. at 1330.

evidence; to show that an agency, in bad faith, failed to include certain information in the record; or, to demonstrate bad faith in the agency's decision making process).

Additionally, the assertion of a *constitutional* claim is another recognized exception to the general practice of limiting judicial review to the existing administrative record.⁴ In such an instance, the court may allow discovery so that the claimant may attempt to establish any facts potentially relevant to the constitutional claim. <u>Webster v. Doe</u>, 486 U.S. 592, 603- 604 (1988)("<u>Webster</u>"); <u>National Medical Enterprises</u>, Inc. v. Shalala, 826 F.Supp. 558, 565 (D.D.C. 1993)("<u>National Medical</u>"). In <u>National Medical</u>, although the court ultimately rejected the plaintiff's equal protection challenge, the court noted that there were a number of exceptions to the general practice of limiting judicial review to the existing administrative record. One of those exceptions is if the claim was a constitutional one. <u>Id</u>. 826 F. Supp. at 565. When a court reviews a constitutional claim concerning an agency's decision, the court may go beyond the administrative record and "make an independent assessment of the facts and the law" and "may consider additional affidavits which were not before the agency upon administrative review." <u>Id</u>. at 565 (quoting <u>Rydeen v. Quigg</u>, 748 F.Supp. 900 (D.D.C. 1990)).

B. DISCOVERY SHOULD BE PERMITTED BECAUSE THE ADMINISTRATIVE RECORD <u>IS INCOMPLETE</u>.

The Revised Rules at issue in this Action were first formally proposed by the USPTO in the Federal Register on January 3, 2006. <u>See</u> "*Changes to Practice for Continuing Applications, Requests for Continuing Applications, Requests for Continued Examination Practice, and*

⁴ When a constitutional claim is involved, the court's decision-making criteria differs from its treatment of a typical APA claim. For a typical APA claim, the court simply determines whether the agency had a rational basis in the record to support its administrative action. If the agency had a rational basis, then the court leaves the agency's decision undisturbed and does not permit discovery. <u>Puerto Rico Public Housing Administration v. U.S. Department of Housing and</u> <u>Urban Development</u>, 59 F.Supp.2d 310, 327 (D. Puerto Rico 1999).

Applications Containing Patentably Indistinct Claims" and "Changes to Practice for the Examination of Claims in Patent Applications." 71 Fed. Reg. 48 and 61 (the "Proposed Rules"). Copies of the Proposed Rules are attached hereto as Exhibits 3 and 4, respectively.

While the Final Rules did contain some material changes (which are the subject of Tafas' "logical outgrowth" APA claim in his Amended Complaint), in most respects the basic elements, contours and thrust of the Final Rules closely track the Proposed Rules. Consequently, logic and common sense make it reasonable to infer that the vast majority of the <u>true</u> "administrative record" reflecting the formation of the rules; the facts considered directly or indirectly by the rulemakers; facts the USPTO's rationale and factual foundation for same should logically predate the publication of the Proposed Rules on January 3, 2006. Upon information and belief, the USPTO had been extensively studying and internally debating promulgating the Proposed Rules for many years prior to this.

As is reflected in the highlighted portions on the USPTO's index to the administrative record, it is greatly surprising (to say the least) that only approximately 55 documents out of the approximately 846 documents listed in the USPTO's index were created prior to the publication date of the Proposed Rules.⁵ (See Index at Ex. 5; Bates Nos. A3200-A4404; A7203-7477; and A8454-8487). Of these 55 documents, the majority consisted of internally generated statistical data. The data consisted primarily of statistical breakdowns on such areas as the filing of claims and independent claims, claim fee analysis and the issuance of patents, but did not appear to be accompanied by any meaningful analysis or commentary discussing the importance of this data in connection with the Proposed Rules.⁶ In sum, the

⁵ 119 documents listed on the index are undated. <u>See Exhibit 5</u>.

⁶ Furthermore, a significant number of these 55 documents consisted of publicly available articles, reports and surveys. For example, the documents contained several yearly Economic Survey Reports by the American Intellectual Property Law Association (AIPLA) and a report by

administrative record is devoid of any meaningful information or documents reflective of how the USPTO actually devised the Proposed Rules -- despite the obvious fact that most of the significant decisions and weighing to be performed by the agency rule-makers in formulating the Proposed Rules would necessarily have preceded the publication date of the Proposed Rules.

Similarly, the administrative record (excluding public comments) for the period after January 3, 2006 is similarly devoid of any substantial amount of internal USPTO memoranda, email or other substantive summary documents that are reflective in any meaningful way of the weighing process (if any) employed by the USPTO decision-makers.

Tafas believes that there were two (2) disconnected decision making processes at work. The <u>real</u> decisions and deliberations were done by the USPTO in a private "back-room" decision making process from which the public has been entirely excluded and which is not reflected within the administrative record.⁷ The "public" rule-making process (including the notice and comment) was essentially nothing more than an elaborate but meaningless public show in that the USPTO's senior managers had, upon information and belief, already irrevocably decided to impose its Proposed Rules -- regardless of any public outcry or information being brought to its attention that might call into question the legitimacy or wisdom of same.

Congress on how the USPTO expects to confront the challenges of the 21st Century. The articles, reports and surveys were general in nature and contained little in serious analytical or direct relevance as to the USPTO creative process in devising the Proposed Rules.

⁷ To the extent that any meaningful debate among the USPTO's decision-makers concerning the overwhelming amount of negative public comment on the Proposed Rules was engaged in after January 2006, the administrative record is largely devoid of any evidence of same. While it is possible that the USPTO may be intending to claim a deliberative process privilege for such materials (which Tafas would likely challenge under the circumstances), no privilege log has yet been produced by Defendants that would permit the parties or the Court to assess the validity of any such claimed privilege.

Depositions are also needed here because in the explanatory preamble to the Final Rules the USPTO purported to justify the new rules by repeatedly citing to the USPTO's past "experience". (See highlighted excerpts from "*Changes to Practice for Continued Examination of Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications.*" 72 Fed. Reg. 161 at pp. 46744, 46782, 46787, 46795, 46806-807, 46822) attached as Exhibit 6. Tafas respectfully submits that the only way to adequately probe the USPTO's "**experience**" (which was admittedly a substantial basis that upon which is USPTO directly or indirectly relied in promulgating its Revised Rules), as well as to determine whether the USPTO's reliance on its experience was arbitrary and capricious, is by deposing the key USPTO personnel with primary responsibility within the relevant experiential areas. ⁸

C. DISCOVERY SHOULD BE PERMITTED BECAUSE OF BAD FAITH IN THE RULE <u>MAKING PROCESS</u>

The bedrock of the USPTO's new rules package is amply explained by the

USPTO's own Deputy General Counsel and Solicitor (now retired), John Whealan, who acknowledged in a speech he made at Duke Law school in February 2006 that the USPTO is changing the "patent system" through the promulgation of "rules," without the need for the USPTO to turn to the courts or the legislature for permission:

I went to the patent office to argue cases at the Federal Circuit, and after doing that for a while, you realize well, that's interesting, but its hard to make policy

⁸ Further evidence of documents that the USPTO should have placed in the administrative record and seemingly did not (or which logically should be found in the Administrative Record in light of the nature rule-making and the USPTO's proffered justifications for same) is described in GSK's Memorandum In Opposition to Defendant's instant motion dated November 13, 2007 at pp. 4-7, and Ex. D and E). Tafas is in accord with GSK concerning the missing items and begs leave to incorporate GSK's discussion of these items by reference in the interests of brevity. This material should be provided to Plaintiffs forthwith (either through FOIA or discovery in this action, or both).

that way because you have to get a case up, win it, and get them to write it your way.

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. That is what I am going to talk about.

Brian did a nice job in referring to some <u>patent legislation up on the hill – that is</u> <u>stalled. We don't have that problem. We write rules</u>, and they issue, <u>and maybe</u> <u>they get overturned</u>, but we can actually try to move forward and I think it would be irresponsible not to do that. (emphasis added) (Exhibit 11 – Video 1).

As set forth below, Tafas, asserts that in their sprint to "change policy," the USPTO has

taken a number of initiatives to "hide the ball" in respect of its administrative record provided in

this case. Tafas seeks discovery to uncover it.

A. There is strong appearance of bad faith on the part of USPTO Officials With <u>Respect to its Changes to the Examination of Claims</u>

1. Irrespective of Statements Made to The Public and This Court, Statements of Former USPTO Executives Indicate That the USPTO Designed its Examination Support Document (ESD) Rule to Seriously Restrict the Number of Claims

Under §1.75(b)(1) of the Enjoined Rule, if an application contains, or is amended to

contain, more than five independent claims or more than twenty-five total claims (the "5/25"

threshold), an applicant must file an Examination Support Document ("ESD") in compliance

with § 1.265 that covers each claim (whether in independent or dependent form) before the

issuance of a first Office action on the merits of the application. The USPTO has repeatedly

reassured applicants of the fact that the ESD places no effective limits on the number of claims

applicants can file:

"The applicant is free to file as many claims as necessary to adequately protect the invention." 72 Fed. Reg. 46791, col. 1, \P 5.

"Section 1.75 does not limit the number of claims that [an] applicant can present in one application." 72 Fed. Reg. 46790. col. 1, paragraph 2; Cf., 72 Fed. Reg. 46791, col. 1., \P 4.

"Plaintiffs misconstrue the ESD requirement to suggest there is a limit, that it's

only 5/25." Transcript of Preliminary Injunction Hearing at pp. 56 lines 14-15.

Thus, the USPTO has repeatedly asserted to the public, and this Court, that its Rule 1.75 does not erect a prohibitive barrier with which applicants must contend in filing all the claims the applicant "consider[s] necessary or desirable" to file. Such assertion is not surprising given the CCPA decision of <u>In re Wakefield</u>, 57 C.C.P.A. 959, 962, 164 U.S.P.Q. 636 (1970) wherein the court (the predecessor to the Federal Circuit) asserted that statutorily an applicant is "allowed to determine the necessary number and scope of claims."

According to USPTO's own information⁹, some 30% of applications exceed the 5/25 claims limit. Given that the USPTO predicts that it will receive 479,200 patent applications in FY 2008¹⁰, by simple calculation one can determine that 143,760 (479,200 × 0.3) applications would be subject to the 5/25-rule and would require a submission of an ESD. Given further that this Enjoined Rule was to be applied retroactively to the back-file (and to any new application received by November 1, 2007), at least another 212,400 (708,000 × 0.3) applications would be subject to the 5/25-rule. While the USPTO has asserted a benign effect of the ESD on total claims, its own information supplied to the Office of Management and Budget (OMB), estimates that no more than 5000 applicants (all large entity filers) will make use of the ESD procedure (See Table I, infra at p. 15). The administrative record provided in this case is devoid, however, of a reason for such a low estimate of applicants who will make use of the ESD.

⁹ Email from Robert Bahr to Gregory Morse, dated March 22, 2007, A05028 (indicating that 30% of the applications in the back-file which had no first office action exceed the 5/25 threshold). The Final Rule text (at 46788, Col. 2) indicates that only 24% of the applications filed in FY 2006 exceed the 5/25 threshold. It ignores, however, that due to the long pendency, the back-file applications being examined first, would dominate triggering possible ESD submissions for FY 2008 and FY 2009.

¹⁰ See USPTO, FY2008 President's Budget Request, (February 2007), p. 20. at <u>http://www.uspto.gov/web/offices/ac/comp/budg/fy08pbr.pdf</u>

Statements by USPTO executives at the time of the proposed and revised rules shed some light of the discrepancy between the USPTO's assertions to the public, the and this Court, and its own internal beliefs. For example, Robert J. Spar, the Former Director of the Office of Patent Legal Administration and Deputy Commissioner for Patent Examination Policy, who was the Certifying Officer of the USPTO's information collection request to the OMB in 2005 and 2006, asserted at an SDIPLA Meeting, October 11, 2007 (after his retirement):

"An ESD will be required to aid in the examination, <u>but it is expected that most</u> <u>applicants will not file an ESD</u>" Slide 15 SDIPLA Meeting October 11, 2007 (Exhibit 23)

Likewise, in a presentation made on October 11, 2007 (after his retirement) at indicates that the

Duke Law school made by the USPTO's former Deputy General Counsel for Intellectual

Property and Solicitor, John M. Whealan, (while he was still the Deputy General Counsel and

Solicitor for the USPTO) concerning the Proposed Rules, Mr. Whealan admits that attorneys

most likely would not file ESD's due to a fear of inequitable conduct charges that could be

raised: :

"And if you want your claims examined up front, you can have it done – but it is going to cost you. Your are going to have to do some work, which in the current law of inequitable conduct, <u>nobody is going to want to do this</u>. (emphasis added) Exhibit 11 - Video 2.

This statement is clearly contrary to the USPTO's position that "The submission

of an examination support document ... does not expose an applicant to a greater risk of

inequitable conduct." (emphasis added) 72 Fed. Reg. 46801, Col. 3, last paragraph.

2. Data Supplied to the Office of Management and Budget Concurrent With Its Statements to the Public on the Non-Limiting Nature of its 5/25 ESD Rule Indicate the USPTO Knew that Its Rule Would Severely Restrict An <u>Applicant's Right to File More than 5 Independent Claims or 25 Claims</u>

The purported benign effect of the USPTO's 1.265 examination support

document requirement is also belied by the USPTO's own data supplied to the OMB under the

Paper Reduction Act as set forth in tabulated form in Table 1. The USPTO withheld such

estimates from the public rulemaking proceeding. Indeed, had it been disclosed in the January 3,

2006 Notice that USPTO expected only 2,900 ESD submissions per year under the proposed

rules, it may have received very different comments from the public.

	Submission Date	22-Dec-05	13-Mar-07	22-Jun-07	26-Sep-07
	ICR Ref No.	200512-0651-002	200703-0651-001	200706-0651-004	200707-0651-005
Produced by USPTO in the "Administrative Record"		A07328	A08209	NO	NO
USPTO person submit	ting the ICR	Robert Spar	Robert Bahr	Samual Broda	Samual Broda
		Aproved with	Aproved with		Pending with
OMB Conclusion	Action	31-Jul-06	30-Sep-07	Disaproved	temporary
OWB COnclusion		expiration	expiration		extension
	Date	22-Feb-06	30-Mar-07	26-Jul-07	
Collection Ite	-				
	Resp./Yr	4,500	1,000	1,000	1,000
Petition for a second RCE with a	Resp./Yr (Small Entiy)	0	0	0	0
showing	Unit burden (hrs)	2	4	4	4
	Yearly burden (hrs)	9,000	4,000	4,000	4,000
Petition for a second	Resp./Yr	5,700	2,000	2,000	1,000
continuation or continuation-in-	Resp./Yr (Small Entiy)	0	0	0	0
part application with a showing	Unit burden (hrs)	2	4	4	4
pa	Yearly burden (hrs)	11,400	8,000	8,000	4,000
	Resp./Yr	2,900	10,000	10,000	5,000
Examination Support Document	Resp./Yr (Small Entiy)	0	0	0	0
including listing of references	Unit burden (hrs)	12	24	24	24
	Yearly burden (hrs)	34,800	240,000	240,000	120,000
Listing of Commonly Owned	Resp./Yr	20.000			20.000
Applications and Patents 37 CFR	Resp./Yr (Small Entiv)	20,000			20,000
1.78(f) & Explanations as to claim	Unit burden (hrs)	0			0
distinctions; Paper & EFS-Web	Yearly burden (hrs)	20,000			20,000
distinctions; Faper & EFS-web		20,000			20,000
	Resp./Yr				16,500
	Resp./Yr (Small Entiy)				3,930
Notice of Appeal	Unit burden (hrs)				0.2
	Yearly burden (hrs)				3,300
		1			5,500
	Resp./Yr				56.000
Request for Continued	Resp./Yr (Small Entiy)				11,200
Examination (RCE) Transmittal;	Unit burden (hrs)				0.2
Paper & EFS-Web	Yearly burden (hrs)				11,200

UPTO Information	Collection Re	quests under OMI	3 Control No. 0651-0031

Table 1

Table 1 shows four different Information Collection Requests ("ICR") (Exhibitss 27 -

30) related to the Enjoined Rule that USPTO filed pursuant to OMB rules¹¹ in order to get

¹¹ 5 C.F.R. § 1320.5.

OMB's approval under the Paperwork Reduction Act¹² ("PRA"). In its latest submission on the ESD item¹³, the USPTO estimates only 5,000 ESD submissions per year from large entities and <u>none (0)</u> from small entities (a class which the USPTO assert in its Certification Analysis under the Regulatory Flexibility Act will not be substantially impacted by the rule changes!). As shown in Table 1, this recent estimate was made after the USPTO whip-sawed its ESD estimates from a mere 2,900 (proposed rule) submissions to 10,000 (new rule), then down to 5,000 (new rule). Calculations based on USPTO data provided in the administrative record at A03554 (Exhibit 12), show that this reduction amounts to about 2.5 Million claims per year!

3. Data Manipulation at the OMB with Respect to the Impact of the Rules Brings into Question the Entire Statistical Analysis Relied Upon by the USPTO in Formulation of Its Rules Package

Table 1 shows that only two of the ICR's filed with OMB were produced in the "Administrative Record" to Plaintiffs. No records of the USPTO ICR submissions of June 22, 2007 and September 26, 2007 were produced in this case, despite their availability at USPTO prior to its October 5, 2007 production of documents in this case.

The supporting statement from the March 13, 2007 ICR explains the change in the information collection burden estimates due to modification of the proposed rules to the new rules. Thus, there is no question that the USPTO expected to receive 10,000 ESDs per year, each including a listing of references and the related analysis. The ESD collection item was included as a single item in the ICR. No changes to the collection items were made in the subsequent ICR of June 22, 2007 (which was subsequently disapproved by OMB due to its finding that "[t]he

¹² 44 U.S.C. § 3501 et seq.

¹³ Examination Support Document Transmittal, PTO/SB/216. Available online at <u>http://www.reginfo.gov/public/do/PRAViewIC?ref_nbr=200707-0651-005&icID=178966</u>

requested change is material and substantive and cannot be in this action".¹⁴)

The USPTO's September 26, 2007 ICR (which was absent from the Administrative Record) raises the specter of "rabbit out of the hat" data manipulation. Five weeks after the USPTO published its final Enjoined Rule in August 21, 2007, the USPTO changed its estimate for the annual number of ESDs it will receive from 10,000 to 5,000, and the annual number of petitions for exceeding the limit of continuation applications from 2,000 to 1,000. These new estimates substantially reduced the information collection burdens the USPTO now requests OMB to approve. The explanation of such change is set forth in the September 26, 2007 supporting statement for its OMB submission (SF-83¹⁵ - Exhibit 26). Such statement, respectively, lacks credible statistical explanation for such a decrease in burden:

The USPTO has created <u>two new forms</u> for an *existing* requirement. These forms are "Examination Support Document Transmittal" and "Examination Support Document Listing of References 37 CFR 1.265(c)" as a result of a rulemaking. The 10,000 responses *for the two forms were split evenly* but the hours were not, so the burden has decreased by half. The USPTO estimates that it will take 22 hours to complete one form and 2 hours to complete the other. Therefore, this submission takes a burden decrease of 120,000 hours *as a program change*. (Emphasis supplied)

Thus where there was 10,000 ESDs before, and by creating two forms for submission of an ESD, there are now only 5,000 ESDs. That is, by creating two forms instead of one, the paperwork burden was shrunk by a factor of two, and the number of applicants affected by the requirement decreased by two! Such statement clearly does not support a "program change." No good faith reason for such manipulation can be divined.

The September 26, 2007 ICR Supporting Statement also contains on Page 11 under the

heading "Consultation Outside the Agency", the following statement:

¹⁴ OMB's disapproval of ICR at <u>http://www.reginfo.gov/public/do/DownloadNOA?</u> requestID=208167.

¹⁵ *See* SF-83 at

http://www.reginfo.gov/public/do/DownloadDocument?documentID=44055&version=0.

The USPTO has long-standing relationships with groups from whom patent application data is collected, such as the American Intellectual Property Law Association (AIPLA), as well as patent bar associations, inventor groups, and users of our public facilities. Their views are expressed in regularly scheduled meetings and considered in developing proposals for information collection requirements. There have been *no comments or concerns* expressed by these or similar organizations concerning the time required to provide the information required under this program. (Emphasis added).

This certified statement is remarkable coming after hundreds of comments in the

rulemaking proceeding raising concerns regarding the burdens that the ESD would impose on

applicants. For example, the very group that the USPTO mentions in its statement (AIPLA) has

specifically commented and expressed serious concerns on the burdens and costs of preparing

and filing an ESD.¹⁶ This USPTO statement to OMB in an attempt to obtain its approval for the

information collection burdens associated with the Enjoined Rule constitutes a material

misrepresentation of the facts surrounding its "consultation outside the agency."

B. There is strong appearance of bad faith on the part of USPTO Officials With Respect to its Changes to Practice for Continued Examination Filing

1. The Foundation for Passing the Changes to Practice for Continued Examination Filings is Flawed in a Manner that is Readily Apparent

The basis for the entire rule package related to continued examination filings

relates to the Offices position that continuation filings comprise "rework":

"Last year [2004], more than 100,000 applications of our newly received application workload of 35,000 applications were some form of application that had been previously been before an examiner in the examination process. This rework presents a significant obstacle to the ability of our examiners to reach new applications that have not been examined...The continuing and expanding churn of rework by or examiners is a very real limitation on our ability to examine the

¹⁶ See AIPLA comments at <u>http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_claims/aipla.pdf</u>, at 11-12, ("The requirements for the [ESD] are so onerous and fraught with dangers for the patent applicant that few practitioners would recommend this approach to their clients. ... In addition, the search and analysis necessary to prepare an [ESD] would add significant cost to the preparation of an application, a burden that would significantly disadvantage independent inventors and small businesses. ... The necessary legal analysis to prepare an [ESD] would add substantial costs - far in excess of the cost of the underlying search").

new innovations that are filed every year..." Testimony under Oath of Jon W. Dudas before the Subcommittee on Intellectual Property, Committee on the Judiciary "The Patent System: Today and Tomorrow," April 21, 2005 (Exhibit 31)

"In fiscal year 2005, more than 85,000 of the USPTO's 400,000 new patent applications were a continued prosecution of an application that had been previously been before an examiner in the examination process. <u>That is almost one-quarter of the applications that examiners had to review were ones they had previously rejected</u>. <u>Our proposed changes will not limit the ability of an applicant to file</u> ... [although] requests for continuations would be subject to a more stringent review process before the requests are granted." Testimony under Oath of Jon W. Dudas before the Subcommittee on Courts, The Internet, and Intellectual Property, Committee on the Judiciary. "Patent Quality Enhancement in the Information-Based Economy."

(Exhibit 32)

The problem with such assertions is that they are in the very least misleading.

First, the vast majority of continuation applications, as opposed to "requests for continued examination" ("RCEs") can not be said to be "rework." An RCE cannot be filed to obtain an "examination on the basis of claims that are independent and distinct from the claims previously claimed and examined as a matter of right (*i.e.* applicant cannot switch inventions)." Manual of Patent Examining Procedure ("MPEP") at 706.07(h). A continuation application, on the other hand, often (if not usually) claims a distinctly <u>different</u> invention that is distinct and independent from the invention first claimed, and therefore cannot be said to comprise just "rework," nor comprise applications that examiners "had previously rejected."

Second the numbers cited by the Director do not correspond to the data supplied in the administrative record at A03528 (Exhibit 13). The first statement made in 2004 apparently includes continuation-in-part applications, which disclose and often claim new subject matter, in its "rework" analysis, while the second statement made in 2005 apparently does not. In any case there is no analysis provided by the administrative record which supports these statements, statements that are key to an understanding of the entire rule package on continuation applications. Lastly as set forth below, the statement that continuation applications would be "subject to a more stringent review process before the requests are granted" was at best an extreme understatement -- something well understood by USPTO executives when the statement was made.

2. Data Supplied to the Office of Management and Budget Concurrent with Its Statements to the Public of the Non-Limiting Nature of its Changes to Practice for Continued Examination Indicate that the USPTO Knew Its Rule Would Severely Restrict an Applicant's Right to File More than Two Continuations

The Office has consistently maintained to the Public and this Court that its

continuation rules do not limit the number of continuation applications. As discussed in Tafas's

Motion for Preliminary Injunction filed August 22, 2007 with this Court, such assertions are not

unexpected given the recognition by the US Supreme Court in Godfrey v. Eames, 68 U.S. 317,

323-325 (1863), In re Hogan, 559 F.2d 595 (CCPA 1977), and In re Henricksen, 399 F.2d 262

(CCPA 1968), Ricoh Company Ltd. v. Nashua Corp, 185 F.3d 844, at 3 (Fed. Cir. 1999)(non-

precedential opinion), of the right of an applicant to file continuation applications.

"Th[e] final rule ... does not place any absolute limits on the number of continuing applications and requests for continued examination." 72 Fed. Reg. 46757, col. 1, \P 3.

"[T]here is no absolute limit on the number of continuing applications an applicant must file; he or she must simply meet the petition and showing requirement."

Def. Opposition to Plaintiff's Motion for TRO and Preliminary Injunction at p. 26.

As shown in USPTO own internal memorandum, supplied in the Administrative

Record at A08227 (Exhibit 14), 11,326 applicants filed in Fiscal Year 2006 a third or more

continuation application. Of these 3,320 were application by small entities, and 8,006 were from

large entities. Yet, the USPTO represented to the OMB in early 2007 (see Table I) that it

expected 2000 petitions, and later in 2007 only 1000 petitions (with none (0) by small entities).

While the present representation to OMB comprises a mere 8% of all third or more continuations that occurred in just the fiscal year 2006 (it does not take into account the number of second or more continuations sitting in its backlog, or which were filed previously but not yet examined), it asserted to the public and this court that they were not limiting continuation practice. The estimate of petitions that would be filed appears to have been entirely arbitrary chosen (See A04546 (Exh. 15) wherein it is noted "the best estimate is that between 5 and 30 percent of second/subsequent continued examination filings will still be filed now with a petition").

The true understanding of USPTO's administration as to the practical implication of their new continuation rule is that few if any of such applications would be filed by applicants after the Rules went into full effect against all applications: "<u>New Ground rule: max of 3 patents</u>, with 15/75 claims per invention!" – Slide 23 of SDIPLA Meeting October 11, 2007, Robert J. Spar, the Former Director of the Office of Patent Legal Administration and Deputy Commissioner for Patent Examination Policy, who was the Certifying Officer of the USPTO's information collection request to the OMB in 2005 and 2006 (Emphasis added).

3. Data Supplied to the Office of Management and Budget Concurrent with Its Statements to the Public of the "Flexible Nature" of its New Proposed Petition Process with Respect to Third or more Continuations Requests Indicate that the <u>USPTO Knew That It Would Not Deliberately Consider Petitions</u>

The USPTO has maintained to the public and this court that due consideration

would be applied to all petitions filed seeking a third or more continuation:

"[T]he USPTO will review petitions "on a case-by-case basis" to determine whether a satisfactory showing is made." Def. Opposition to Plaintiff's Motion for TRO and Preliminary Injunction at 26, fn. 20.

"[T]his is not the mechanical rule that plaintiffs describe ... this is not simply a yes or no mechanical rule which says two continuations and one RCE. This is a flexible rule where the agency will look at the petition and decide on a case-by-case basis." Transcript of Motion Hearing Dated October 31, 2007, pg. 50, ln. 16

– pg. 51, ln. 4.

"The Office will decide these petitions on a case-by-case basis based on the prosecution history of the prior-filed application ... will consider the showing of why the new subject matter sought to be entered could not have been previously submitted in the prior application ... [and] will also consider the amendment including any new claims." 72 Fed. Reg. 46722, col. 2, \P 4.

Such statements run counter to the USPTO's own representation to the OMB in its September 26, 2007 submission (SF-83, Exhibit 26, Supporting Statement to OMB Control Number 0651-0031), that the USTO anticipated that it would take the office only 0.10 hours to handle a "petition of a second continuation or continuation-in-part application showing why the amendment, argument, or evidence could not have been submitted prior to the close of prosecution in the prior-filed application." (some fast read of a file history!). It also runs counter to commentary provided in the Federal Register upon publication of the rules wherein the office urged that a petition would not be granted in nearly every situation raised (except in one narrow circumstance) including if the applicant became disabled for a lengthy time during pendency of the application! 37 Fed. Reg. 46777, col. 2, \P 4.

4. The USPTO in Bad Faith did Not Disclose to the Public and the Office of Management and Budget its Anticipated Significant Restrictions on the Right to Appeal in Conjunction with its Limitations on Continuation Filings

The USPTO has continually maintained since promulgation of its proposed rules that the appeal process would be an outlet for applicants who wished resolution of a dispute with the

Examiner over patentability without the need to resort to a continuation filing:

"[T]he appeal process offers a more effective resolution than seeking further examination before the examiner." USPTO Notice of Proposed Rulemaking, 71 Fed. Reg. 48.

"Upon receipt of a final rejection, an applicant [may] ... appeal to the Board of Patent Appeals and Interference." Def. Opposition to Plaintiff's Motion for TRO and Preliminary Injunction at 5.

"If applicant disagrees with the examiner's rejections, applicants should file appeal rather than filing a continuation application or a request for continued examination." 72 Fed. Reg. 46763, Col. 2, $\P 2$.

The opportunity to appeal was backed up with USPTO statements in the proposed rules to the effect that the "Board of Patent Appeals and (BPAI) has radically reduced the inventory of pending appeals from 9,201 at the close of fiscal year 1997 to 882 at the close of fiscal year 2005." Proposed Rules, 71 Fed. Reg. 48. However, the USPTO knew at the time of its proposed rules, and during the notice and comment period on the proposed rules, that it was about to promulgate a set of proposed rules that would place significant burdens on applicants seeking to use the appeals route. The USPTO, however, chose to hide such information from the public, and the Office of Management and Budget, and to submit such a rule package shortly after (July 30, 2007) OMB Review had concluded on the Continuation Rules package (July 9, 2007).

The USPTO budget clearly sets forth the USPTO actual assumptions related to appeals given its new Rules package:

"[D]uring fiscal year 2007, the Board of Patent Appeals and Interferences (BPAI) anticipates it will begin to receive an increased level of appeals <u>following</u> <u>continuation rulemaking</u> ... Based on existing assumptions, the office anticipates BPAI's appeal <u>work load to increase by approximately one-third</u>."

USPTO 2007 Budget, note 27 at 32 (emphasis added)

As indicated in an excellent and detailed analysis by Dr. Ron D. Katznelson filed with the

OMB (http://www.uspto.gov/web/offices/pac/dapp/opla/comments/bpai/katznelson.pdf)

(Exhibit. 16), what was known to the USPTO was that substantial costs were about to placed on applicants who sought to seek appeal rather than using one of their limited continuations, or only RCE, to proceed with prosecution. Irrespective of the USPTO's acknowledgment to Congress that it expected an increase of appeals due to its continuation rules, as late as its September 26, 2007 submission to OMB (*See* Table I) it did not update its notice of appeals submissions to the OMB by thirty percent, again leading to a lower public burden which improved its approval chances in front of the OMB.

D. DISCOVERY SHOULD BE PERMITTED IN CONNECTION WITH THE USPTO'S REGULATORY FLEXIBILITY ACT CERTIFICATION.

Tafas should also be permitted to proceed with the depositions because one of his substantive claims is that Defendant Jon W. Dudas (through his deputies) made erroneous and *bad faith* certifications under the Regulatory Flexibility Act that the Proposed Rules and Final Rules would not have a substantial economic impact on a substantial number of small entities. (See Amended Complaint, Fourth Count, ¶¶ 74-86, Ex. 7). ¹⁷

The complete lack of an adequate factual basis for the USPTO's two (2) certifications and the resulting un-mistakable inference of bad faith¹⁸ is particularized in the Amended Complaint. (See Amended Complaint, Fourth Count, ¶¶ 81-85). Here, Tafas does not believe that there was an adequate factual basis for the two (2) RFA certifications and that the resulting inference that should be drawn is bad faith on part of Defendants. For example, the USPTO's initial certification purporting to exempt itself from conducting an initial RFA was only 3 pages long. (See Memorandum from B. Knight to T. Sullivan dated November 25, 2005; Ex. 8; A7325-327). Incredibly, Mr. Knight was able to make a sweeping certification of no substantial economic impact for all small business entities in the entire United States despite the fact that the RFA Index produced by the USPTO only included four (4) documents that preceded

¹⁷ Defendants did not challenge the legal sufficiency of this court pursuant to Rule 12(b)(6) in their Partial Motion to Dismiss dated October 4, 2007 (now withdrawn).

¹⁸ It is well established that "good faith" is a central ingredient in an agency head properly certifying pursuant to 5 U.S.C. § 605(b) that there is no need for the agency to engage in an initial or final Regulatory Flexibility Act analysis. <u>E.g.</u>, <u>Alenco Communications Inc.</u>, v. Fed. <u>Communications Comm'n</u>, 201 F.3d 608, 625 (5th Cir.2000); <u>National Women</u>, <u>Infants</u>, and <u>Children Grocers Ass'n v. Food and Nutrition Service</u>, 416 F.Supp.2d 92, 108 (D.D.C., February 23, 2006)

the certification date -- none of which could have possibly provided the basis for the certification. (Compare Ex. 5, p. 25; A7203-7324 and Ex. 8). In essence, the USPTO's sweeping initial and conclusory RFA certification appears to have emerged "out of thin air." The only way to effectively challenge the USPTO's good faith on this point is to have the opportunity to confront and examine the agency officials ultimately responsible for making the certification (*e.g.*, Commissioner Dudas).¹⁹

With respect to the final RFA certification made by Mr. Covey on behalf of Defendants by letter dated July 10, 2007 (Exhibit 9), this letter is suggestive of bad faith in that the USPTO purports to have considered the many negative comments concerning the Proposed Rules, but in fact as a practical matter ignored them in actuality and played "ostrich" concerning any facts suggestive of a substantial negative impact on small business inventors. Moreover, it is apparent from Mr. McCovey's letter that the USPTO essentially outsourced almost the entire certification process to an outside private contractor (*i.e.*, ICF International) and simply accepted its conclusions at face value.²⁰ (See Ex. 9 at p. 2-9 and ICF Report at Exhibit 10).

¹⁹ The deliberative process privilege may be overcome when improper behavior on the part of the decision-makers is an issue in the case. For example, when a complaint alleges that the real motive for a facially neutral decision was intentional discrimination, the subjective intent of the decision-makers is relevant. North Pacifica LLC v. City of Pacifica, 274 F.Supp.2d 1118, 1122-1124 (N.D.Cal.2003) (city council's motive and intent "central to [plaintiff's] equal protection claim, and at issue is alleged government misconduct").

²⁰ Putting aside the issue of whether the USPTO is lawfully permitted to delegate its duty to evaluate these questions to a private company, Tafas should be entitled, at a minimum, to take discovery from ICF to find out: (i) what information it considered in conducting this analysis; (ii) any instructions or agenda it was provided with by the USPTO; (iii) the division of responsibilities between the USPTO and ICF; and (iv) how much of the administrative record was considered by ICF as part of its analysis and in what respect -- to name just a few categories. Of course, any RFA analysis performed by a private sector firm is not entitled to any presumption of regularity in an APA proceeding and should be freely discoverable.

a. The USPTO has Depended on a Flawed 15/75 Composite Claim Analysis in Making its Certification of No Significant Economic Impact of the Rules on a Substantial Number of Small Entities

Having made its decision to cut off submission of claims beyond the 5/25 threshold, the USPTO attempts to rationalize its action by a tortured exercise of "analytical" obfuscation. In an attempt to downplay and minimize the effect of its 5/25 Rule, the USPTO asserts that applicants have three opportunities in a chain or family of applications to file up to 5/25 claims without an ESD, resulting in a total of 15 independent or 75 total claims (15/75 threshold). The USPTO then leaps to a conclusion that by examining the number of single applications which have more than 15/75 claims, it can analytically predict the number of cases that would be impacted by the 5/25 Rule. This tortured 15/75 analysis assuming combination of claims from a family of three applications was also the basis of USPTO's in its Certification Analysis under the Regulatory Flexibility Act (See page 13 of Analysis – Exhibit 17). This is patently wrong, as the Enjoined Rule does not set a limit of 15/75 to a family of applications. This erroneous and flawed statistical approach analyzes claim distributions in a single application drawn from the ensemble of all applications. It ignores the fact that the distribution of the composite claim numbers made up of the sum of claims from three different applications within the ensemble will exceed the 15/75 limit in many more cases than those found to exceed this limit in a single application.

b. The ESD Cost Analysis is Wholly Without Foundation

The foundation of the Examination Support Document analysis in the Certification Analysis under the Regulatory Flexibility Act rests on numbers obtained from the AIPLA Report of Economic Survey 2005 (covering the year 2004). The Analysis asserts that such numbers indicate that "the cost of a patent search ranges from approximately \$1,000 for a relatively simple patent application up to approximately \$2,500 for a relatively complex patent

application." Cert. Analysis at 16. The problem evident with such statement is clearly seen when one turns to the data used to provide such statement – that is to page I-100 (Exhibit 18). <u>Clearly</u> there is no suggestion in such chart that \$1000 figure applies to a simple application and \$2500 to a relatively simple patent application. Clearly the number references First Quartile and Third Quartile charges with respect to the subject matter as set forth in Question 39(o) of the survey:

"Assuming a typical case <u>with no unusual complications</u>, what would you have expected to charge or be charged, in 2004, <u>for legal services only</u> (including search fees, but not including copy costs, drawing fees, or government fees) in each of the following types of U.S. matters Utility Patent Novelty Search, Analysis and Opinion." AIPLA Report of the Economic Survey 2005, Appendix B, pp. 4 - 5 (Exhibit 19)

Clearly, the question is at best ambiguous in that, as is known in the art, most attorneys simply do not perform patentability searches, but rather use outside search firm. It would be anticipated that at least a large percentage of attorneys would not consider a cost disbursement as "part of their legal services." Further, and most disconcerting, is that this question is directed to "a typical case" which even the USPTO in promulgating its rules admits would not include applications having more than 5 independent and/or 75 total claims, the particular class of applications which are actually in play when performing an ESD.²¹ Further the analysis of ESD costs takes into no account the cost in obtaining documents for review or the initial reading of the documents before any analysis occurs.²²

²¹ It is unclear whether this issue plagued the office in respect of its Certification given the communication from Elizabeth Gormsen to John Collier (and copied to Robert Bahr) at A08244-A08247 (Exhibit 20) wherein Ms. Gormsen (of ICF that performed the study) asks for clarification of what the AIPLA means by "minimal complexity (Mr. Bahr responds – applications having a "10 page specification, 10 claims.").

²² The Certification Analysis Under the Regulatory Flexibility Act document produced by ICF further makes note that its higher figures set forth at Exhibit 4-2 of the analysis (page 18 – Exhibit 17) covers "50 independent claims or 350 total claims." No materials, however, can be located in the administrative record to support that ANY survey was undertaken to determine if such was the case. The analysis uses a "blended composite wage data based on data from the AIPLA report … 2005" as a composite "attorney and paralegal wage rate" even though the

Attached at Exhibit 21 is an examination support document request made to one of the most reputable search firms in the United States – Nerac, with respect to an software application having 10 independent and 55 dependent claims. As can be seen the estimate is in the range of \$46,000, not \$5,170 - \$13,121 as set forth in the analysis.

c. Using a Calculation of the Annualized Increment Cost to a Hypothetical Small Entity Over a 20 Year Period to Determine Significant Impact Shocks the <u>Conscience</u>

The Certification Analysis Under the Regulatory Flexibility Act document produced by ICF determines impact of the rules on a hypothetical sole proprietor making \$75,000 per year (which ICF asserts as the minimum need to "support an individual's living expenses, as well as his/her patent filing and maintenance costs," (Cert. Analysis, Exhibit 20, at page 23) rather than looking at the effect of the rules on small entities as a whole. The report asserts that the "revenue" number for the sole proprietor is set higher than the U.S. median income as "it seems reasonable in light of the creative/technical abilities of an individual seeking a patent" that they would be higher in median income. Id. No basis is provided on how this hypothetical person scenario applies to all small entities as a group.

The Certification Analysis then allocates the cost of obtaining a patent to the "20-year life of the resulting patent." Cert. Analysis, Exhibit 20, at page 20 (see also page 22: "The incremental costs are annualized over a period of 20 years (to coincide with the life of the patent)). Of course, patents do not have a 20-year life, but rather a substantially shorter life span based on how long it takes the application to issue from the patent office (that is, if it issues).

AIPLA report of 2005 does not include paralegal wage rates, and even though it is not clear by any means who a paralegal can do the legal functions set forth in the certification's Exhibit 4-1, (or for that matter that paralegals of the type of training ICF envisions are even available in number to allow for such a composite rate). Although the survey says it updates the composite wage rate to 2006 dollars using the Consumer Price Index, a quick review of the 2007 AIPLA Report Survey (setting forth 2006 numbers) clearly demonstrates a mean attorney rate considerably higher than the purported blended rate (mean billing rate over \$300 per hour).

Using an "Incremental Cost as a Percent of Revenue" analysis (although income in this case does not represent revenue from a patent), the study finds no effect. No explanation is given as to whether the applicant would be blocked from initial filing due to the costs needed to be upfront, or the need to file multiple applications due to claim limitation (how many home owners cannot afford a down payment on house because they need the money upfront!). Nor is any analysis taken up to determine the cost of appeals which a small entity would be faced with if a filing was ever made.

E. DISCOVERY SHOULD BE PERMITTED ON TAFAS' CONSTITUTIONAL CLAIMS.

In Count Two of his Amended Complaint, Tafas claimed that the Final Rules violated the Patent Clause (Art. I, Sec. 8, Cl. 8) and the Fifth Amendment to the Constitution (by implementing rules that retroactively deprive Tafas of his property rights without due process of law). (See Amended Complaint, Count Two, ¶¶ 60-61) (Ex.7). As concerns the Patent Clause, Tafas asserts, *inter alia*, that actions taken by the USPTO, as a body of the Executive Branch, exceed the limitations set forth in the Constitution because under the Patent Clause, only Congress has the power to pass <u>substantive</u> laws setting down the terms and conditions for patent eligibility. Second, the USPTO is certainly subject to the same limitations imposed upon Congress under the Patent Clause in exercising its delegated power.²³ Likewise, the Patent Clause imposes the same constitutional standard on the USPTO in performing its patent processing role as it does on Congress. <u>A.F. Stoddard & Co., LTD v. Dann</u>, 564 F.2d 556, 563-564 (D.C. Cir. 1977) (overturning USPTO's decision to reject an amended continuation application because to do so "would frustrate the constitutional objective" underlying the Patent

²³ The Patent Clause places a substantive limitation on Congress's power, which is qualified authority, "limited to the promotion of advances in the 'useful arts.'" <u>Graham v. John Deere Co.</u> <u>of Kansas City</u>, 383 U.S. 1, 5 (1966) (the Patent Clause constitutes both a grant of power and a <u>limitation</u>).

Clause). The Patent Clause is the very basis on which the USPTO was established. ²⁴ Sperry v. <u>Florida</u>, 373 U.S. 379, 403 (1962).

Tafas alleges in his Amended Complaint that the USPTO failed in its constitutional duty to appropriately consider and adequately weigh in its rule-making whether the Final Rules would promote the progress of science and the useful arts in accordance with the constitutional command. (Amended Complaint, Count Two, \P 60). Here, the Revised Final Rules are invalid under the APA because they contravene the primary purpose of the Patent Clause -- to promote the progress of the science and the useful arts. The Final Rules not only do not promote this constitutional objective, but in fact retard it, rendering them unconstitutional. Defendants moved to dismiss this constitutional claim pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure and later withdrew the motion. (*USPTO's Memorandum in Support of Defendant's Partial Motion to Dismiss*, dated October 4, 2007, p. 5 and 27-29) (Docket No. 18).

Under the reasoning in <u>Webster</u> and <u>National Medical</u> (infra at pp. 8-9), Tafas should be permitted to take discovery in support of his Patent Clause claim because the standard of judicial review is not strictly limited to whether the USPTO's rule-making was arbitrary and capricious, but rather is also focused on whether and to what extent an adequate constitutional weighing process was actually performed. Tafas is entitled to take discovery to establish that the USPTO's senior decision-makers purposefully sought to circumnavigate around and/or to overreach their limited constitutional authority under the Patent Clause.

²⁴ The Constitution is the supreme law, and, therefore, no regulation established by the USPTO may be inconsistent with it. U.S. Const. Art. VI. The Constitution commands that the system Congress establishes must be to 'promote the Progress of ...useful Arts.' <u>Graham</u>, 383 U.S. at 5-6. ("It is the duty of the Commissioner of Patents...in the administration of the patent system to give effect to the constitutional standard by appropriate application...of the statutory scheme of the Congress.") <u>Id.</u> at 6. Thus, compliance with the Patent Clause is an independent non-APA factor that the USPTO must "weigh" when establishing regulations under the patent system.

Dated: November 14, 2007

Respectfully submitted,

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