No. 2008-1352

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

TRIANTAFYLLOS TAFAS,

Plaintiff-Appellee,

and

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

Plaintiffs-Appellees,

v.

DAVID J. KAPPOS, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, and UNITED STATES PATENT AND TRADEMARK OFFICE,

Defendants-Appellants.

Appeal from the United States District Court for the Eastern District of Virginia in consolidated case nos. 1:07-CV-846 and 1:07-CV-1008, Senior Judge James C. Cacheris.

DECLARATION OF RICHARD B. BELZER, Ph.D IN SUPPORT OF PLAINTIFF TRIANTAFYLLOS TAFAS' APPLICATION FOR ATTORNEYS' FEES AND COSTS

I, **RICHARD B. BELZER**, declare and state as follows:

1. I am over the age of eighteen (18) years and I understand the obligations of an oath.

2. I submit this Declaration in support of Plaintiff Triantafyllos Tafas' Petition for An Award of Fees and Expenses in the above-referenced consolidated action pursuant to 28 U.S.C. § 2412 *et seq*. (the "Equal Access to Justice Act" or "EAJA").

3. Attached hereto as Exhibit A is a genuine and authentic copy of my Declaration dated as of December 27, 2007 that I filed in the District Court in support of the *Amicus Curiae* brief filed by Polestar Capital Associates, LLC ("Polestar") and The Norseman Group ("Norseman")(sometimes referred to herein collectively as "Polestar"), which *amicus* brief was filed in support of the Plaintiffs' motions for summary judgment in the District Court (the "Belzer Declaration" or "Declaration").

4. My previously filed Declaration attached hereto as Exhibit A sets forth my educational background as an economist, as well as my 20 plus years of experience in governmental regulatory analysis, including the ten (10) years I was employed as a professional economist in the United States Office of Management and Budget (OMB) Office of Information and Regulatory Affairs (OIRA). In the interest of brevity and avoiding substantial unnecessary duplication, I beg leave to

incorporate herein by reference the description of my educational background, my professional credentials and experience, as well as my discussion within the Declaration concerning the interplay of many of the applicable operative statutory and regulatory provisions discussed later herein. (*See* Exhibit A).

5. In my Declaration, I describe in significant detail certain interactions with the United States Patent & Trademark Office ("USPTO") and the OMB in connection with my review and analysis of the USPTO's: (a) proposed rule "Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims," ("Proposed Continuations Limit Rule," 71 Fed. Reg. 48 [January 3, 2006]); (b) proposed rule "Changes to Practice for the Examination of Claims in Patent Applications," ("Proposed Claims Limit Rule," 71 Fed. Reg. 61 [January 3, 2006])(sometimes referred to herein collectively as the "Proposed Rules") and (c) the combined final rule "Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications" ("Final Continuations and Claims Limits Rule," 72 Fed. Reg. 46716 [Aug. 21, 2007](sometimes hereinafter referred to collectively as the "Final Rules").

6. In my Declaration, I described what I believe to be the USPTO's lack of adherence to various requirements of Executive Order 12,866, the Information

Quality Act (IQA), the Regulatory Flexibility Act (RFA) and the Paperwork Reduction Act (PRA), which analysis resulted in me concluding, among other things, that: (i) the USPTO did not disclose sufficient information and data to support its certifications of the Proposed Rules and Final Rules under the above referenced requirements, and, (ii) that the USPTO had, in fact, failed to perform a proper analysis concerning the paperwork burdens that would be associated with the Proposed Rules and Final Rules if issued by the USPTO.

7. Nevertheless, in reliance on its greatly flawed and incomplete PRA and RFA analysis, the USPTO improperly certified the Proposed Rules and Final Rules as not having an economically significant impact (including a significant impact on a substantial number of small businesses). An affirmative certification of such effects would not have required much effort had only the USPTO fulfilled its duty under the PRA to produce a "specific, objectively supported estimate of burden." (5 C.F.R. § 1320.8(a)(4).)

8. In my professional opinion, the USPTO failed to abide by principles of regulatory review and impact analysis for major and/or economically significant regulatory actions that have been in place since 1981, and the USPTO seemingly withheld from the OMB certain information that would have made it easy for the OMB to determine: (i) that the Proposed Rules and the Final Rules were likely to have annual effects on the economy exceeding $100 million and thus be

"economically significant" pursuant to Executive Order 12,866 § 3(f)(1); and, (ii) that the Final Rule was "major" pursuant to the Congressional Review Act (5 U.S.C. § 804(2)), which determinations the OMB alone is authorized to make.

9. Before a rule may take effect, a covered Federal agency must submit to each House of Congress and to the Comptroller General a report containing a copy of the rule; a concise general statement relating to the rule, including whether it is a major rule; and the proposed effective date of the rule (5 U.S.C. § 801(a)(1)(A)). On the date of submission of this report, the Federal agency promulgating the rule shall submit to the Comptroller General and make available to each House of Congress (i) a complete copy of the cost-benefit analysis of the rule, if any; the agency's actions relevant to 5 U.S.C. §§ 603, 604, 605, 607, and 609; the agency's actions relevant to sections 202, 203, 204, and 205 of the Unfunded Mandates Reform Act of 1995; and any other relevant information or requirements under any other Act and any relevant Executive orders, such as Executive Order 12,866. If the Federal agency fails to perform a rudimentary economic impact, the OMB may not be able fulfill its statutory responsibility to make major rule determinations.

The USPTO Knew or Reasonably Should Have Known as of January 2008 that Its Failure to Obtain an OMB Control Number Made It Impossible To Implement and Enforce the Final Rules

10. At the time I submitted my above referenced Declaration to the District Court in late December 2007, I strongly suspected, but did not yet have definitive proof, that the USPTO had failed to comply with the PRA including, without limitation, by failing to obtain a valid OMB Control Number for the Final Rules under the Paperwork Reduction Act (44 U.S.C § 3501 *et seq*.).

11. Among other things, under the PRA, the USPTO was required to publish a "60-day notice" along with publication of the Proposed Rules, as well as a "30-day notice" along with the issuance of the Final Rules, each seeking comment from the public on the expected burdens and practical utility of the information collections contained therein. (5 C.F.R. § 1320.11(a) and (h)). These notices were required to be prepared by the USPTO "in a manner that is reasonably calculated to inform the public." (5 C.F.R. § 1320.5(b)(2)(ii)). Both notices must include "objectively-supported" estimates of paperwork burden. (5 U.S.C. § 1320.8(a)(4)).

12. In the USPTO's two (2) applicable notices of rulemaking for the Proposed Rules, the USPTO only minimally complied with the procedural requirements of the PRA. For example, the USPTO's 60-day notices lacked objective support for the *total* reported burden estimates and they included no discussion or itemization of the *incremental* burdens associated with the Proposed Rules. (71 Fed. Reg. 57-58, 66-67). In my professional opinion, it was virtually

impossible for the public to review and/or comment upon the USPTO's 60-day notices in any meaningful or thoughtful way given the dearth of detailed information provided by the USPTO in those notices.

13. As part of my efforts to investigate the sufficiency of the USPTO's adherence to normal procedures, I reviewed most of the public comments on the Proposed Rules. Many of these public comments generally complained of burden and a lack of practical utility, but for the most part the public comments did not use the terminology employed in the PRA and its implementing regulation due to a lack of prior awareness as to the significance of the PRA and the USPTO's self-evident lack of effort to inform the public about it. The USPTO's 30-day notice published concurrent with the issuance of the Final Rules was no better. (72 Fed. Reg. 46835).

14. As required by OMB procedures implementing the IQA, agencies "demonstrate in its PRA clearance packages that each such draft information collection will result in information that will be collected, maintained, and used in a way consistent with the OMB and agency information quality standards." (John D. Graham, Memorandum for President's Management Council: Agency Draft Information Quality Guidelines, June 10, 2002, at 12.). Thus, the USPTO's burden estimates should have been transparent and reproducible, as well as objectively supported as required by the PRA. Although they were neither transparent nor

reproducible, the USPTO certified to the OMB in its Information Collection Request (ICR) dated September 26, 2007, that it had complied with IQA requirements. (USPTO, SF-83 Supporting Statement; Patent Processing (Updating); OMB Control Number 0651-0031, September 26, 2007, at 4.)

15. The USPTO submitted the relevant ICR to the OMB on September 26, 2007, more than one month after promulgating the Final Rule and, barely one month before the planned effective date of November 1, 2007. It is well established that an agency shall not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB Control Number; the agency informs those who are to respond to the collection of information that they are not required to respond to the collection of information unless it displays a currently valid OMB Control Number, and the agency has provided this information in a manner that is reasonably calculated to inform the public. (5 C.F.R. § 1320.5(b)(1)-(2)(ii)).

16. The OMB's regulation implementing the PRA says it "shall provide at least 30 days after receipt of a proposed information collection before making its decision." (5 C.F.R. § 1320.11(e)). Thus, the public comment period on this submission extended until *at least* October 26, 2007 and, therefore, the USPTO could not have properly demanded public compliance with the Final Rule beginning on November 1, 2007, unless the OMB had approved the ICR on or

before that date -- five (5) days after the expiration of the *minimum* public comment period prescribed by regulation -- which the OMB did not do. Nevertheless, the USPTO did not reveal its legal inability to enforce the information collection provisions in the Final Rules to the parties, the public or the Court, continuing to lead all of them to believe that the Final Rules would become effective and enforceable on November 1, 2007, absent the issuance of a preliminary injunction.

17. In order to require patent applicants to provide the USPTO with information in connection with the issuance and implementation of the Final Rule, the PRA requires that the USPTO must first have obtained a valid OMB Control Number. More particularly, notwithstanding any other provision of law, the PRA provides that no person shall be subject to any penalty for failing to comply with a collection of information if the collection of information does not display a valid OMB Control Number or the agency fails to inform the person who is to respond to the collection of information that such person is not required to respond to the collection of information unless it displays a valid OMB Control Number. (44 U.S.C. § 3512(a)).

18. This protection may be utilized in the form of a complete defense, bar, or otherwise at any time during the agency's administrative process or judicial action applicable thereto. (44 U.S.C. § 3512(b)). The OMB's implementing

regulation makes clear that this protection also applies "[w]henever an agency has imposed a collection of information as a means for proving or satisfying a condition for the receipt of a benefit." "The agency shall not treat a person's failure to comply, in and of itself, as grounds for withholding the benefit or imposing the penalty," and "[t]he agency shall instead permit respondents to prove or satisfy the legal conditions in any other reasonable manner. (5 C.F.R. § 1320.6(c)). Although this affirmative defense does not extend to agency collections of information imposed by statute, nothing in the Final Rules qualifies under that exception. (5 C.F.R. § 1320.6(e)).

19. In practical terms, my understanding of the PRA's public protection provision is that any USPTO action that, irrespective of the USPTO's motive or intent, would have penalized a patent applicant for not complying with some paperwork aspect of the Final Rules would be invalid and subject to the affirmative defense. For example, the USPTO would be unable to penalize any patent applicant for exceeding the USPTO's numerical limits on the number of continuations that could be filed and/or for an applicant's failure to provide an Examination Support Document (ESD) as would have been required under the Final Rules but which would have lacked valid OMB Control Numbers.

20. On October 18, 2007, I met with OMB personnel concerning the likely paperwork burdens of USPTO's draft final Information Disclosure Rule

(IDS) (the "IDS Rule"), which had not been accounted for in the September 26, 2007, ICR. Because the draft Final Rule was then under review at the OMB pursuant to Executive Order 12,866, this meeting was organized, staffed, and publicly disclosed in accordance with procedures set forth in § 6(b)(4) as if it concerned regulatory policy matters. Senior USPTO officials were invited to and did attend this meeting. The written materials I provided to the OMB are posted by OMB on its web site and in its PRA docket.[1]

21. Although my focus at this meeting was on the likely but un-estimated paperwork burdens of the IDS Rule, I nevertheless alerted the OMB that the Final Rules also appeared to have paperwork burdens that were substantially greater than had been previously represented by the USPTO. I advised the OMB that these burdens would likely exceed $1 billion per year, thus rendering them both "economically significant" (per Executive Order 12866) and "major" (per the Congressional Review Act). OMB personnel expressed great concern about these burden estimates and appeared to me to have been utterly unaware of their magnitude.

22. I promised the OMB I would provide additional information to support this contention as soon as practicable. OMB personnel promised that they

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1 http://www.reginfo.gov/public/do/DownloadDocument?documentID=57760&version=1.

would withhold any action on the USPTO's September 26, 2007, ICR pending my reasonably prompt submission of these revised estimates. The USPTO personnel present at the meeting did not raise any objection to this delay. Thus, as a practical matter, PTO was effectively barred from enforcing the paperwork requirements of the Final Rules beginning on November 1, 2007, due to the absence of a valid OMB Control Number.

23. Because senior USPTO officials attended the October 18, 2007, meeting, it is certain that the USPTO was aware no later than this date that the Final Rules (as well as the proposed IDS Rules) potentially had billions of dollars in unacknowledged paperwork burdens, that the USPTO was materially out of compliance with the substantive requirements of the PRA. As such, the USPTO knew or should have known that the OMB would not approve the information collections contain in the Final Rules on or before their putative effective date of November 1, 2007.

24. On or about November 27, 2007, I provided the OMB Desk Officer in charge preliminary burden estimates for the IDS Rule, the Final Rule, and one of two other pending USPTO rulemakings. I invited him to share this information with the USPTO to determine if they could identify any material errors in my work.

25. On January 16, 2008, I formally provided to the Administrator of the OMB's Office of Information and Regulatory Affairs (who is responsible for administering the PRA) complete burden estimates for the IDS Rule and the Final Rules, and preliminary estimates of burden for one of the two other pending USPTO rulemakings. These estimates are a matter of public record and are posted on in the OMB's PRA docket. [2] (A genuine copy of my comments provided to the OMB is attached as Exhibit B). My estimates showed the paperwork burden of just one aspect of the Final Rules (i.e., the 5/25 rule) ranged from $10 billion to $22 billion per year, and that the paperwork burden associated with the continuations rule was approximately another $2 billion per year. At the time I submitted these comments to the OMB, I reported that the total paperwork burden for the entire Department of Commerce, of which the USPTO is a sub-agency, was $1.6 billion. (OMB, Information Collection Budget: FY 2006, Table 4.)

26. OMB procedures require the OMB to share my comments with the USPTO and ask it to respond. While I have no first-hand knowledge that the OMB actually provided my comments to the USPTO, it is inconceivable to me, given my own employment experience at the OMB, that it would not have done so.

27. I am unaware if the USPTO responded in writing to the OMB concerning my alternative burden estimates. No such response is logged in the

[2] http://www.reginfo.gov/public/do/DownloadDocument?documentID=57744&version=1.

OMB's PRA docket. Nonetheless, given my own employment experience at the OMB, I believe that one or more written responses exist.

28. On July 1, 2009, the OMB issued an approval for paperwork burdens related to patent processing.[3] This approval does not include any burdens related to the Final Rule. According to the USPTO's revised ICR Supporting Statement internally dated April 22, 2008, these information collection elements were removed "[a]t the direction of OMB." [4]

29. An examination of the OMB's PRA docket reveals unpublished revisions of the ICR Supporting Statement, interally dated April 11, 2008 [5] and January 4, 2008. [6] The April 11, 2008, version omits information collection elements related to the IDS Rule. The January 4, 2008, version omits information collection elements related to the Final Rules. In both cases, the USPTO declares that the removals were performed "[a]t the direction of OMB." Thus, the USPTO knew before January 4, 2008, that it would be unable to enforce the paperwork requirements in the Final Rules even if the Court had rescinded the preliminary injunction issued on October 31, 2007. To the best of my knowledge and belief, the USPTO did not inform the public or the Court of this fact.

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3 http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=200707-0651-005#.

4 http://www.reginfo.gov/public/do/DownloadDocument?documentID=44055&version=4.

5 http://www.reginfo.gov/public/do/DownloadDocument?documentID=44055&version=3.

6 http://www.reginfo.gov/public/do/DownloadDocument?documentID=44055&version=2.

VERIFICATION

I declare under penalty of perjury pursuant to 28 U.S.C. § 1746 under the laws of the United States of America that the foregoing is true and correct.

Executed this 15th day of March 2010, in Alexandria, Virginia.

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RICHARD B. BELZER