

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

TRIANTAFYLLOS TAFAS,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 1:07cv846(L) (JCC/TRJ)
)	
JON W. DUDAS, et al.,)	
)	
Defendants.)	
_____)	

CONSOLIDATED WITH

SMITHKLINE BEECHAM CORP.,)	
d/b/a GLAXOSMITHKLINE, et al.,)	
)	
Plaintiffs,)	
)	Civil Action No. 1:07cv1008 (JCC/TRJ)
v.)	
)	
JON W. DUDAS, et al.,)	
)	
Defendants.)	
_____)	

MEMORANDUM IN SUPPORT OF DEFENDANTS’ MOTION TO STRIKE

Defendants Jon W. Dudas and the United States Patent and Trademark Office (collectively “the USPTO”) respectfully submit this memorandum of law in support of their motion to strike exhibits filed by Plaintiff Triantafyllos Tafas, *Amicus Curiae* Ron D. Katznelson, and *Amici Curiae* Polestar Capital and Norseman Group that are not contained in the administrative record, along with the portions of their briefs that rely on those exhibits.¹

¹ As noted in Defendants’ Motion to Strike, the USPTO requests that the Court construe its motion to be a standing objection to any future attempts by the plaintiffs to introduce extra-record materials at later stages of the summary judgment briefing.

INTRODUCTION AND BACKGROUND

In these consolidated cases, Tefas and GlaxoSmithKline (“GSK”) challenge Final Rules published by the USPTO on August 21, 2007.² In addition to other claims that are not material to this motion, both plaintiffs allege that the Final Rules are “arbitrary and capricious” under the Administrative Procedure Act (“APA”), 5 U.S.C. § 706(2)(A), and Tefas alone claims that the USPTO failed to properly comply with the Regulatory Flexibility Act (“RFA”), 5 U.S.C. §§ 601-612, in promulgating the Final Rules. The USPTO denies these allegations, along with Plaintiffs’ other claims.

On October 5, 2007, the USPTO filed the certified administrative record in this case. Dkt. Nos. 21-22. The record contains the 127-page Federal Register notice explaining the basis and rationale for the Final Rules, A9390-A09518, along with nearly 10,000 pages of other materials that the USPTO directly or indirectly considered in formulating the Final Rules.³

In mid-November 2007, Plaintiffs filed numerous briefs seeking discovery beyond the administrative record, claiming that the record was incomplete or otherwise inadequate for a variety of reasons. See Dkt. Nos. 63, 66, 70-73, 77-80. The USPTO opposed these efforts, and after two hearings on the matter, Magistrate Judge Jones denied Plaintiffs’ motions and entered a protective order against all discovery outside the administrative record. Mem. Op. & Order,

² Changes To Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications; Final Rule, 72 Fed. Reg. 46716 (Aug. 21, 2007) (“Final Rules”).

³ On January 18, 2008 and January 22, 2008, the USPTO supplemented the record with eleven additional public comments and a two-page initial RFA certification, after summary judgment briefing revealed that they had been inadvertently omitted from the record. See Dkt. Nos. 240, 248.

Nov. 28, 2007, Dkt. No. 91. Tafas filed objections to Judge Jones’s ruling, Dkt. No. 98-99, and GSK stated that it would “take no position” on Tafas’s objections. Dkt. No. 106.

After another hearing, this Court overruled Tafas’s objections in a lengthy memorandum opinion. See Dkt. No. 226; Tafas v. Dudas, — F. Supp. 2d —, 2008 WL 112043 (E.D. Va. Jan. 9, 2008) (“Tafas II”). The Court observed that “[i]n applying the arbitrary and capricious standard, ‘the focal point for judicial review should be the administrative record already in existence.’” Id. at *3 (quoting Camp v. Pitts, 411 U.S. 138, 142 (1973)). While acknowledging that there are some exceptions to this rule, the Court concluded after considering each of Tafas’s arguments that “Tafas has not made a sufficiently strong or substantial showing of incompleteness to overcome the presumption that the USPTO properly designated the administrative record.” Id. at *7. The Court further considered whether it was appropriate to go beyond the administrative record to consider Tafas’s RFA claim. The Court held that it was not, finding that the record was “sufficient for this Court to determine whether the USPTO made a ‘reasonable, good-faith effort’ to comply with the RFA’s procedural requirements.”⁴ Id. at *9.

On December 20, 2007, the parties filed cross-motions for summary judgment. Attached to Tafas’s memorandum of law are numerous documents that are not contained in the administrative record, which he purports to use to support his claims that the Final Rules are “arbitrary and capricious” under the APA and violate the RFA. See Pl. Triantafyllos Tafas’ Mem. of Law in Supp. of Summ. J. Mot. (“Tafas Mem.”), Dkt. No. 143. Specifically, in arguing that the rules are “arbitrary and capricious,” Tafas relies on the Declaration of Michael A. Rueda,

⁴ On January 18, 2008, Tafas filed a motion for reconsideration of the Court’s January 9, 2008 ruling. The USPTO opposes this motion and intends to file a timely response.

Esq. (“Rueda Declaration”), which purports to authenticate extra-record documents and other multi-media materials. See id. at 33-35, App. C, Rueda Decl. & Exs. 4-27, 43. In relying on those extra-record exhibits, Tafas admits that he “made the same arguments concerning seemingly missing parts of the administrative record (and attached most of the same exhibits)” in briefing on the discovery issues referenced above. Id. at 34 n.12. Tafas also appends to the Rueda Declaration numerous additional exhibits that he never cites in his brief and are not part of the administrative record. Id., App. C, Exs. 29, 33-36, 38, 40.⁵ In support of his RFA claim, Tafas relies on the declaration of Robert N. Fenili, Ph.D. (“Fenili Declaration”), which he cites extensively to support his theory that the USPTO failed to comply with the RFA. See Tafas Mem. at 40-46 & App. B.

Two *amici* also rely on extra-record materials, in part to support Plaintiffs’ “arbitrary and capricious” and/or RFA claims. Mistaking itself for a party to this litigation, *Amici* Polestar Capital and Norseman Group (“Polestar”) raise numerous claims that are not in Plaintiffs’ complaints and support these claims through a variety of extra-record materials. See Br. of *Amici Curiae* Polestar Capital and Norseman Group in Supp. of Pls. (“Polestar Br.”), Dkt. No. 173, Exs. 1-3, 5-9, 12-13, 17, 21-28. *Amicus* Ron D. Katznelson (“Katznelson”) similarly seeks to support Tafas’s RFA claim through extra-record materials. See Mem. of *Amicus Curiae* Ron D. Katznelson in Supp. of Pls. Mots. for Summ. J. (“Katznelson Br.”), Dkt. No. 198, Ex. 1 & App. A-E.

⁵ Many of these exhibits are identical to exhibits that are appended to the Declaration of Triantafyllos Tafas (“Tafas Declaration”), which also are never cited in the brief. See Tafas Mem., App. A, Exs. E-H, J, M. To the extent the Court strikes any of the Rueda exhibits, all copies of the exhibits should be stricken. Exhibits A and K to the Tafas Declaration are also extra-record materials that should be stricken.

Based on this Court's ruling of January 9, 2008, and for the reasons that follow, the Court should strike these extra-record materials and all parts of the briefs that refer to them.

ARGUMENT

I. THE COURT SHOULD STRIKE ALL EXTRA-RECORD MATERIAL RELATED TO THE CLAIM THAT THE FINAL RULES ARE "ARBITRARY OR CAPRICIOUS" UNDER THE APA

The Supreme Court has frequently reiterated that in conducting APA review, "the focal point for judicial review should be the administrative record already in existence, not some new record initially made in the reviewing court." Camp v. Pitts, 411 U.S. 138, 142 (1983); Fla. Power & Light Co. v. Lorion, 470 U.S. 729, 743-44 (1985) ("The task of the reviewing court is to apply the appropriate APA standard of review, 5 U.S.C. § 706, to the agency decision based on the record the agency presents to the reviewing court.") Relying on Camp, this Court has twice made the same observation in this case. Tafas II, 2008 WL 112043, at *3 ("In applying the arbitrary and capricious standard, 'the focal point for judicial review should be the administrative record already in existence.'"); Tafas v. Dudas, 511 F. Supp. 2d 652, 662 (E.D. Va. 2007) ("Tafas I") ("Generally, 'judicial review of agency action pursuant to the APA is confined to the agency's administrative record.'") (quoting Am. Canoe Ass'n, Inc. v. U.S. Envtl. Prot. Agency, 46 F. Supp. 2d 473, 474 (E.D. Va. 1999). Even Tafas himself admits that in APA cases, "the administrative record provides the complete factual predicate for the court's review." Tafas Mem. at 3 (quoting Krichbaum v. Kelley, 844 F. Supp. 1107, 110 (W.D. Va. 1994), aff'd 61 F.3d 900 (4th Cir. 1995) (emphasis added); id. at 4 ("In order, therefore, to prevail by summary judgment, the parties in an APA case, 'must point to facts in the administrative record to factual failings in that record which can support [their] claims under the governing legal standard.'") (quoting Krichbaum, 844 F. Supp. at 110).

Despite this clear rule, Tafas and Polestar seek to introduce materials outside the record to argue that the Final Rules are arbitrary or capricious. The USPTO recognizes that “[e]ven in APA record review cases, circumstances may justify expanding the record,’ 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.’” Tafas I, 511 F. Supp. 2d at 662 (quoting Am. Canoe Ass’n, 46 F. Supp. 2d at 477). Here, however, the plaintiffs had numerous opportunities – including three hearings – to demonstrate that any of these exceptions apply and justify resort to extra-record materials.⁶ See Dkt. Nos. 63, 66, 70-73, 77-80, 98-99. Tafas even acknowledges that he “made the same arguments concerning seemingly missing parts of the administrative record (and attached most of the same exhibits)” in briefing whether he should be allowed discovery outside the administrative record. Tafas Mem. at 34 n.12.

Tafas failed, however, to make the requisite showing. Affirming Magistrate Judge Jones’s decision, this Court concluded in its recent decision that resort to materials outside the administrative record is unjustified because there has been no showing that the record is

⁶ Polestar now suggests that the administrative record should contain materials that private parties submitted to the Office of Management Budget (OMB) in June 2007. Polestar Br. at 14 (citing Ex. 9). As Polestar admits, however, these documents were submitted to OMB “to assist OMB’s review under E.O. 12,866.” Id. at 3 (emphasis added). By June 2007, the USPTO had completed the Final Rules, and they were in the hands of OMB for review under Executive Order 12,866. See Office of Information and Regulatory Affairs (OIRA), Executive Order Reviews Completed between January 1, 2007 to December 31, 2007, at p. 5, available at <http://www.reginfo.gov/public/do/eoHistReviewSearch> (Department of Commerce, 2007) (showing that OMB received the Final Rules on April 10, 2007 and completed its review on July 9, 2007). Having not directly or indirectly considered these OMB documents, the USPTO properly did not include them in the administrative record.

incomplete, or that the USPTO acted in bad faith. See Tafas II, 2008 WL at *7 (“Tafas has not made a sufficiently strong or substantial showing of incompleteness to overcome the presumption that the USPTO properly designated the administrative record.”); id. 2008 WL at *8 (“The minor discrepancies that do exist between the various submissions are ‘woefully inadequate to justify going outside the administrative record.’”). This ruling is now the law of the case. See Christianson v. Colt Indus. Operating Corp., 486 U.S. 800, 816 (1988) (explaining the “law of the case” doctrine, which “posits that when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case”) (internal quotation marks omitted).

Accordingly, the Court should strike all extra-record materials referenced in Tafas’s “arbitrary and capricious” discussion and in Polestar’s brief, along with the parts of their briefs that refer to those materials.⁷ See Tafas Mem. at 33-35 & App. C, Exs. 4-27, 43; Polestar Br. Exs. 1-3, 5-9, 12-13, 17, 21-28; see, e.g., Center for Biological Diversity v. U.S. Fish & Wildlife Serv., 450 F.3d 930, 944 & n.21 (9th Cir. 2006) (affirming district court’s decision to strike extra-record documents, along with portions of brief that refer to them); Walter O. Boswell Mem’l Hosp. v. Heckler, 749 F.2d 788, 792 (D.C. Cir. 1984) (striking extra-record materials of parties and *amici* and parts of brief that discuss them).

⁷ Polestar appears to argue in part that the Final Rules are arbitrary or capricious under 5 U.S.C. § 706(2)(A), and in part that the USPTO acted “without procedure required by law” under 5 U.S.C. § 706(D). Polestar Br. at 1. To the extent Polestar pursues the former, extra-record materials are appropriately struck for the reasons discussed above. To the extent the brief relates to the latter, and specifically to Polestar’s contention that the USPTO violated the Freedom of Information Act, 5 U.S.C. § 552, and failed to follow guidelines promulgated pursuant to the Information Quality Act, 44 U.S.C. § 3516 Note, resort to extra-record materials is additionally inappropriate because these claims are outside the scope of the parties’ complaints. See Tafas I, 511 F. Supp. 2d at 660-61 (“The Court agrees that it may not consider legal issues or arguments not raised by the parties.”). These arguments are further irrelevant to the issues before the Court.

The Court should further strike the extra-record exhibits that Tafas appends to his brief but never cites in his brief, some of which are reproduced as exhibits more than once. See Tafas Mem., App. A, Exs. A, E-H, J, K, M; App. C, Exs. 29, 33-36, 38, 40. These materials not only go outside the administrative record, but are also apparently irrelevant given that they play no role in Tafas’s analysis.

II. THE COURT SHOULD STRIKE ALL EXTRA-RECORD MATERIAL SUBMITTED BY TAFAS AND KATZNELSON RELATED TO THE USPTO’S RFA CERTIFICATION

The Court should strike the declaration of Dr. Robert Fenili and several of Katznelson’s exhibits because they impermissibly introduce into the record materials that were not before the USPTO when it promulgated the Final Rules and are, as a matter of law, irrelevant to the RFA issue.⁸ Tafas Mem., App. B; Katznelson Br., Ex. 1 & Apps. A-E; see, e.g., IMS v. Alvarez, 129 F.3d 618, 624 (D.C. Cir. 1997) (striking litigation affidavits that were not before the USPTO at the time it acted); Walter O. Boswell Mem’l Hosp., 749 F.2d at 792 (striking extra-record affidavits of parties and *amici* and parts of brief that discuss them); Envtl. Def. Fund v. Costle, 657 F.2d 275, 286 (D.C. Cir. 1981) (striking four litigation affidavits). The Court should likewise strike the portions of Tafas and Katznelson’s briefs that rely on these materials.

Most importantly, the Court has already held that Tafas failed to demonstrate that the administrative record in this case needs to be supplemented for purposes of resolving his RFA claim. The Court recognized first that the RFA imposes only procedural requirements on an

⁸ The Fenili declaration also should not be considered because it is biased. Dr. Fenili swears to have been “retained by Kelley Drye & Warren to independently evaluate and provide” expert opinion testimony. Fenili Decl. ¶ 3 (emphasis added). However, Dr. Fenili’s consulting firm, Georgetown Economic Services, is a subsidiary of plaintiff’s law firm, Kelley Drye, a fact not disclosed in Dr. Fenili’s curriculum vitae. See Kelley Drye, “Economic Consulting and Data Services,” www.kelleydrye.com/practice_areas/36 (last visited Jan. 20, 2008).

agency, and that an agency need only “put forth a ‘reasonable, good faith effort’” to fulfill these requirements. Tafas II, 2008 WL 112043 at *9 (quoting U.S. Cellular Corp. v. FCC, 254 F.3d 78, 88 (D.C. Cir. 2001)). The Court then held that “the existing administrative record is sufficient” for “this Court to determine whether the USPTO made a ‘reasonable, good faith effort’ to comply with the RFA’s procedural requirements.” Id., 2008 WL 112043 at *9 (citing 72 Fed. Reg. 46830-35; A07203-A08329); see also Little Bay Lobster Co. v. Evans, 352 F.3d 462, 470-71 (1st Cir. 2003) (conducting RFA review on the administrative record). Dr. Fenilli’s declaration and the Katznelson exhibits raise precisely the kind of substantive points that are irrelevant to an RFA analysis (e.g., arguing that the USPTO ought to have implemented alternative proposals to the Final Rules, or relied upon a different statistical methodology in reaching its certification) and that this Court does not need to resolve the RFA issue.

Contrary to Tafas’s suggestion, none of the limited exceptions allowing extra-record materials justify the Court considering the Fenili Declaration. See Tafas I, 511 F. Supp. 2d at 662 (quoting Am. Canoe Ass’n, 46 F. Supp. 2d at 477). As this Court already determined, the USPTO’s RFA certification is adequately explained in the 1,100+ pages of the administrative record entitled “Information Relating to the Regulatory Flexibility Act.” A07203-A08329. The USPTO does not rely on materials outside the administrative record to support its RFA analysis in its summary judgment motion. Finally, the RFA certification – which need only be evaluated for whether it is procedurally adequate – is not “so complex” that the Court needs more evidence to understand it.⁹ Accordingly, the Court should not resort to materials outside the

⁹ Tafas asserts that a fourth exception – not before recognized by this Court – is applicable to this case: “when the agency failed to consider factors which are relevant to its final decision.” Tafas Mem. at 40 n.16 (quoting Amfac Resorts, L.L.C. v. U.S. Dept. of the Interior, 143 F. Supp. 2d 7, 12 (D.D.C. 2001)). This Court has consistently applied American Canoe

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CERTIFICATE OF SERVICE

I hereby certify that on January 22, 2008, I electronically filed the foregoing, with attachments, with the Clerk of the Court using the CM/ECF system, which will send a notification of such filing (NEF) to the following:

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