

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

TRIANAFYLLOS TAFAS,)
)
Plaintiff,)
)
v.)
)
JON W. DUDAS, et al.,)
)
Defendants.)
_____)

Civil Action No. 1:07cv846(L) (JCC/TRJ)

CONSOLIDATED WITH

SMITHKLINE BEECHAM)
CORPORATION, et al.,)
)
Plaintiffs,)
)
v.)
)
JON W. DUDAS, et al.,)
)
Defendants.)
_____)

Civil Action No. 1:07cv1008 (JCC/TRJ)

**DEFENDANTS' OMNIBUS MEMORANDUM IN OPPOSITION TO PLAINTIFFS'
REQUESTS FOR DISCOVERY BEYOND THE ADMINISTRATIVE RECORD**

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INTRODUCTION

In the interest of economy, Defendants Jon W. Dudas and the United States Patent and Trademark Office (collectively “USPTO”) respectfully submit this omnibus memorandum in opposition to Plaintiff Triantafyllos Tafas (“Tafas”) and Plaintiff GlaxoSmithKline’s (“GSK”) multiple submissions attempting to seek discovery and supplementation of the administrative record in this Administrative Procedures Act (“APA”), 5 U.S.C. §§ 701-706, case. See Dkt. Nos. 63, 66, 77, 78, 79.¹ Despite five opportunities to do so, Plaintiffs have not met their burden to justify discovery beyond the administrative record.

Plaintiffs argue that discovery is warranted in these consolidated APA cases on two main grounds: that the nearly 10,000 page record is incomplete and that the USPTO acted in bad faith. Plaintiffs have adduced no evidence, however, showing the record to be so bare as to frustrate judicial review, and they have not come close to revealing the kind of deliberate and wanton misconduct necessary to establish bad faith. Tafas further has not shown that one of his constitutional claims merits discovery beyond the administrative record.

Consequently, Tafas has not justified probing the policy choices and decision-making processes of high-level USPTO officials through wide-ranging depositions, and GSK has not justified its desire to serve interrogatories and sweeping document production requests on the

¹ These submissions are: (1) GlaxoSmithKline’s Memorandum in Opposition to Defendants’ Motion for Issuance of Proposed Briefing Schedule in Lieu of a Standard Initial Scheduling Order (“GSK Opp. Mem.”), Dkt. No. 63; (2) Plaintiff Triantafyllos Tafas’s Memorandum in Opposition to Defendants’ Motion for Issuance of Expedited Briefing Schedule in Lieu of a Standard Scheduling Order (“Tafas Opp. Mem.”), Dkt. No. 66; (3) GlaxoSmithKline’s Memorandum in Support of Its Motion to Compel Limited Discovery from the Defendants to Complete the Administrative Record (“GSK Compel Mem.”), Dkt. No. 77; (4) Plaintiff Triantafyllos Tafas’s Supplemental Memorandum Concerning Presumption of Regularity in APA Proceedings and Availability of Discovery on Constitutional Claims (“Tafas Supp. Mem. re Const. Claims”), Dkt. No. 78; and (5) Plaintiff Triantafyllos Tafas’ Supplemental Memorandum in Support of Notices for Depositions of Senior Officials (“Tafas Supp. Mem. re Depos.”), Dkt. No. 79.

USPTO – document requests that are so broad as to be incongruous with the narrow defects GSK purports to identify in the record. In the end, Plaintiffs’ multiple briefs merely confirm that what they seek is a fishing expedition and a delay in this litigation.

The time has come for the Court to enter a clear and final order denying discovery and setting a summary judgment briefing schedule that will allow for the expeditious resolution of the merits of this matter without further interruption. As the USPTO has noted before, both GSK and Tafas previously represented that they were ready and willing to have this case argued on the merits in December. See Memorandum in Support of Defendants’ Motion for Issuance of Proposed Briefing Schedule in Lieu of a Standard Scheduling Order, Dkt. No. 61, pp. 1-2, 4-5. Their calls for discovery now ring hollow. The USPTO thus asks the Court to enter the Order previously agreed to by GSK and USPTO counsel, which the USPTO provided to the Court at the November 16, 2007 hearing and provides again with this submission.²

² Pursuant to the Court’s order at the November 16, 2007 hearing, the USPTO has considered in good faith whether it will voluntarily provide any of the excessive materials requested by Plaintiffs and has concluded that Plaintiffs have not established their entitlement to any discovery. Nevertheless, the USPTO would not seriously object to providing Plaintiffs with two items – not as a supplementation of the record, but merely as background information. The first is a one-page document that explains the USPTO’s budget model, which may be partially responsive to GSK’s first interrogatory. See GSK Compel Mem., Ex. B. The document does not appear in the administrative record because it was not developed for the rulemaking under review but was previously developed as a basic explanation for the public of the USPTO’s budget model. The second is the “task orders” provided to ICF International (“ICF”) in connection with the Regulatory Flexibility Act analysis it performed. See id. at 11; Tafas Opp. Mem. at 25 n.20.

At the hearing, the Court alluded to Shipbuilders Council of Am., Inc. v. U.S. Dep’t of Homeland Security, No. 1:07cv665 (E.D. Va), and GSK has since relied upon – and misapprehended – that case. See GSK Compel Mem. at 5. Shipbuilders is very different from this case. As a preliminary matter, Shipbuilders involves a challenge to a single, discrete adjudicatory decision by the U.S. Coast Guard, which is accompanied by a 115 page administrative record. By contrast, this case involves a broad challenge to a comprehensive rulemaking, which is accompanied by a correspondingly comprehensive, 10,000 page record. Furthermore, this Court in Shipbuilders did not order any discovery from the Government.

(Cont’d)

ARGUMENT

I. WELL-SETTLED PRINCIPLES OF ADMINISTRATIVE LAW REQUIRE DENYING DISCOVERY IN THIS APA CASE.

The background principles that animate APA record review militate against discovery in these consolidated APA cases.

A. The Court’s Task in Conducting APA Review Is Limited.

In their amended complaints, Plaintiffs have asked the Court to decide whether the Final Rules published by the USPTO on August 21, 2007³ exceed the agency’s statutory authority, violate the Constitution, are “arbitrary” or “capricious,” or are otherwise unlawful under the APA, 5 U.S.C. § 706.⁴ See First Amended Complaint for Declaratory and Injunctive Relief and Petition for Review of Rulemaking, 1:07cv846, Dkt. No. 14; Verified Amended Complaint, 1:07cv1008, Dkt. No. 5. Only “final agency action” is reviewable under the APA. 5 U.S.C. § 704. Therefore, the Court’s task is to review the Final Rules, not the Proposed Rules published

Rather, the Court ordered the Intervenor defendant to produce a response (and any supporting documents) to a single interrogatory that the Court itself had prepared. In a good-faith effort to resolve all discovery disputes and proceed to the merits in that case as quickly as possible, the Government voluntarily produced all ten documents it had in its possession that were responsive (but nevertheless legally irrelevant) to the plaintiffs’ discovery requests, with the exception of documents that were clearly protected by the attorney-client and deliberative process privileges. The Court simply ordered the Government to create a privilege log in connection with its assertion of privilege on the documents it voluntarily provided. Importantly, the Government never conceded, and the Court did not order, that the wide-ranging discovery of the Government was appropriate.

³ See 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. No. 46716 (Aug. 21, 2007).

⁴ The USPTO will address Tafas’s claim under the Regulatory Flexibility Act (“RFA”), 5 U.S.C. §§ 601-612, infra Part IV.

on January 3, 2006.⁵

The vast majority of Plaintiffs' claims implicate pure questions of law that do not require discovery to be resolved. See, e.g., Zeneca Inc. v. Shalala, No. WMN-99-307, 1999 WL 728104, at *4 (D. Md. 1999) (holding that because a document sought in discovery "addresses a purely legal question that the Court must ultimately decide, its inclusion in the record would be unnecessary"); Sathianathan v. Smith Barney, Inc., 2007 U.S. Dist. LEXIS 64880, at *8 (N.D. Cal. Aug. 24, 2007) ("Plaintiff's argument on that issue is based entirely on a question of law and no discovery is necessary."); see also Marshall County Health Care Auth. v. Shalala, 988 F.2d 1221, 1226 (D.C. Cir. 1993) ("[W]hen an agency action is challenged . . . [t]he entire case on review is a question of law, and only a question of law"). These issues include, for example: whether Congress has delegated the USPTO authority to promulgate the Final Rules; whether the Final Rules conflict with the Patent Act, 35 U.S.C. §§ 1 et seq.; whether they are retroactive; whether they are impermissibly vague; and whether the USPTO has violated the Patent and Copyright Clause of the U.S. Constitution, Art. I, § 8, cl. 8. See 5 U.S.C. § 706(2)(B), (C).

The primary question that requires review of the administrative record is the determination of whether the USPTO acted in an "arbitrary" or "capricious" manner when it promulgated the Final Rules. 5 U.S.C. § 706(2)(A). "To make this finding, the court must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971). The APA commands that this question be decided on the "whole record,"

⁵ See Changes to Practice for Continuing Applications, Requests for Continuing Applications, Requests for Continued Examination Practice, and Applications Concerning Patentably Indistinct Claims, 71 Fed. Reg. 48 (Jan. 3, 2006); Changes to Practice for the Examination of Claims in Patent Applications, 71 Fed. Reg. 61 (Jan. 3, 2006).

id. § 706 – that is “the administrative record already in existence, not some new record initially made in the reviewing court.” Camp v. Pitts, 411 U.S. 138, 142 (1973); see also Fort Sumter Tours v. Babbitt, 66 F.3d 1324, 1335 (4th Cir. 1995) (“Judicial review of administrative action is generally confined to the administrative record.”).

In reviewing the record, the Court’s task is to determine the reasonableness of the agency’s action based on the agency’s “stated reasons.” In re Subpoena Duces Tecum Served on the Office of the Comptroller of the Currency, 156 F.3d 1279, 1279 (D.C. Cir. 1998) ; Vermont Yankee Nuclear Power Corp. v. NRDC, 435 U.S. 519, 549 (1978) (explaining that agency decision must “stand or fall on the propriety of that finding”). Accordingly, “the actual subjective motivation of agency decisionmakers is irrelevant as a matter of law – unless there is a finding of bad faith or improper behavior.”⁶ In re Subpoena Duces Tecum, 156 F.3d at 1279-80; see also Ad Hoc Metals Coal. v. Whitman, 227 F. Supp. 2d 134, 143 (D.D.C. 2002) (“Judicial review of agency action should be based on an agency’s stated justifications, not the predecisional process that led up to the final, articulated decision”).

If the agency’s decision cannot stand on the reasons articulated in the record it designates, the remedy is to remand the matter to the agency. See Fla. Power & Light Co. v. Lorion, 470 U.S. 729, 743-44 (1985). Here, the USPTO has stated its reasons for the Final Rules in its 127-page Federal Register notice and has substantiated those reasons in its nearly 10,000 page administrative record.⁷

⁶ As explained infra Part III, there is absolutely no evidence that the USPTO acted in bad faith.

⁷ The USPTO has attached for the Court’s convenience the thirty-page Index of Administrative Record that it filed with the administrative record on October 5, 2007. Ex. 1.

B. The USPTO Has Correctly Designated the Administrative Record and Has Properly Excluded Deliberative Materials

An agency's administrative record properly consists of "all documents and materials directly or indirectly considered by the agency," Bar MK Ranches v. Yuetter, 994 F.2d 735, 739 (10th Cir. 1993), including "all materials that 'might have influenced the agency's decision.'" Amfac Resorts, L.L.C. v. U.S. Dep't of Interior, 143 F. Supp. 2d 7, 12 (D.D.C. 2001) (quoting Bethlehem Steel v. E.P.A., 638 F.2d 994, 1000 (7th Cir. 1980)). The administrative record does not, however, include privileged materials, such as documents that fall within the deliberative process privilege, attorney-client privilege, and attorney work product privilege. See, e.g., Town of Norfolk v. U.S. Army Corps of Eng'rs, 968 F.2d 1438, 1456-58 (1st Cir. 1992).

As the D.C. Circuit and other courts have long held, "internal memoranda made during the decisional process . . . are never included in the record." Norris & Hirshberg, Inc. v. SEC, 163 F.2d 689, 693 (D.C. Cir. 1947) (emphasis added); In re Subpoena Duces Tecum, 156 F.3d at 1279 (D.C. Cir. 1998) ("Agency deliberations not part of the record are deemed immaterial."); see also Grand Cent. P'ship, Inc. v. Cuomo, 166 F.3d 473, 482 (2d Cir. 1999) (explaining that the deliberative process privilege covers all "recommendations, draft documents, proposals, suggestions, and other subjective documents which reflect the personal opinions of the writer rather than the policy of the agency") (internal quotation marks omitted). There are at least two reasons deliberative process materials are excluded. First, such materials are irrelevant because, as noted above, the reasonableness of the agency's action is judged in accordance with its "stated reasons" since "the actual subjective motivation of agency decisionmakers is irrelevant as a matter of law" See In re Subpoena Duces Tecum, 156 F.3d at 1279. Second, requiring an agency to include deliberative materials in its administrative record would represent an

“extraordinary intrusion” into the workings of an executive agency and would chill “uninhibited and frank” discussions. San Luis Obispo Mothers for Peace v. Nuclear Regulatory Comm’n, 789 F.2d 26, 44-45 (D.C. Cir. 1986) (en banc); Ad Hoc Metals Coalition, 227 F. Supp. 2d at 143 (noting that require agencies to turn over deliberative materials threatens to “hinder candid and creative exchanges regarding proposed decisions and alternatives, which might . . . lead to an overall decrease in the quality of decisions.”). Internal memoranda, drafts, e-mails, and other such deliberative materials no more belong in an agency’s administrative record than similar documents created by district court judges or their law clerks belong in a record on appeal. See San Luis Obispo Mothers, 789 F. 2d at 45 (“We think the analogy to the deliberative processes of a court is an apt one. Without the assurance of secrecy, the court could not fully perform its functions.”).

Furthermore, the deliberative process privilege applies equally to *inter-agency* and *intra-agency* materials. See Dept. of Interior v. Klamath Water Users Protective Ass’n, 532 U.S. 1, 8-9 (2001); see also EPA v. Mink, 410 U.S. 73, 87 (1973). Thus, not only deliberative communications within the USPTO, but also between the USPTO and other executive agencies (such as the Office of Management and Budget (“OMB”) and the Small Business Administration (“SBA”)), may fall within the scope of the privilege.

In this case, the USPTO has provided a nearly 10,000-page record that was compiled in accordance with these well-settled principles. See Certification of the Administrative Record by the United States Patent and Trademark Office, Dkt. No. 21-2; Decl. of Jennifer M. McDowell, Dkt. No. 74, Ex. 3 (explaining that “[t]he USPTO included in its administrative record all non-privileged materials and documents that the agency decision-maker indirectly or directly considered in connection with the Final Rules”). Plaintiffs are not entitled to discovery into the

agency's deliberative process – particularly through deposition, see United States v. Morgan, 313 U.S. 409 (1941)⁸ – as allowing discovery into such materials would chill the USPTO's deliberations in future rulemakings, and such materials are, in any event, irrelevant to the question of whether the USPTO acted in an arbitrary or capricious manner.

C. Exceptional Circumstances Do Not Exist that Would Warrant Discovery Beyond the Voluminous Administrative Record.

“[T]he designation of the Administrative Record, like any established administrative procedure, is entitled to a presumption of administrative regularity.” Bar MK Ranches, 994 F.2d at 740; see Mullins v. U.S. Dept. of Energy, 50 F.3d 990, 993 (Fed Cir. 1993) (“There is an assumption that government officials perform their duties properly and in good faith.”). Accordingly, “[t]he court assumes the agency properly designated the Administrative Record absent clear evidence to the contrary.” Bar MK Ranches, 994 F.2d at 740; see also Blue Ocean Inst. v. Gutierrez, 503 F. Supp. 2d 366, 369 (D.D.C. 2007) (“[T]he agency enjoys a presumption that it properly designated the administrative record and may exclude materials that reflect internal deliberations.”). In order to rebut this presumption, “a party must make a significant showing – variously described as a ‘strong,’ ‘substantial,’ or ‘prima facie’ showing – that it will

⁸ As the USPTO has previously explained, depositions of high-level officials are impermissible except in “exceptional circumstances.” In re Office of Inspector Gen., 933 F.2d 276, 278 (5th Cir.1991); see Memorandum in Support of Defendants’ Motion for Issuance of Proposed Briefing Schedule in Lieu of a Standard Scheduling Order, Dkt. No. 61, pp. 13-16 (citing, inter alia, Morgan, 313 U.S. at 422; Simplex Time Recorder Co. v. Sec’y of Labor, 766 F.2d 575, 586 (D.C. Cir.1985)). “Before the involuntary depositions of high ranking government officials will be permitted, the party seeking the depositions must demonstrate that the particular official’s testimony will likely lead to the discovery of admissible evidence and is essential to that party’s case.” Warzon v. Drew, 155 F.R.D. 183, 185 (E.D.Wis.1994) (citing Sweeney v. Bond, 669 F.2d 542, 546 (8th Cir.1982)) (emphasis added). In addition, “the evidence must not be available through an alternative source or via less burdensome means.” Id. Plaintiffs have not shown that these circumstances exist.

find material in the agency’s possession indicative of bad faith or an incomplete record.” Amfac Resorts, 143 F. Supp. 2d at 11 (quoting Overton Park, 401 U.S. at 420; San Luis Obispo, 751 F.2d at 1327; Natural Res. Def. Council v. Train, 519 F.2d 287, 291 (D.C. Cir. 1975)). Important separation of power principles underlie the requirement that Plaintiffs make a strong showing before the Court should supplement the administrative record: “Were courts cavalierly to supplement the record, they would be tempted to second-guess agency decisions in the belief that they were better informed than the administrators empowered by Congress and appointed by the President.” San Luis Obispo Mothers, 751 F.2d at 1325-26.

Merely saying that an administrative record is “incomplete” does not justify discovery. Plaintiffs would have to demonstrate that the record is so bare as to “frustrate judicial review.” Am. Canoe Ass’n, Inc. v. U.S. Env’tl. Prot. Agency, 46 F. Supp. 2d 473, 477 (E.D. Va. 1999) (Ellis, J.); see Voyageurs Nat’l Park Ass’n v. Norton, 381 F.3d 759, 766 (8th Cir. 2004) (observing that the exception is “very narrow” and finding that the “ten-thousand pages of reports, correspondence, studies and analyses – is fully sufficient to facilitate judicial review without discovery”); Cnty. for Creative Non-Violence v. Lujan, 908 F.2d 992, 998 (D.C. Cir. 1990) (“Only in the rare case in which the record is so bare as to frustrate effective judicial review will discovery be permitted under the second exception noted in Overton Park.”). Moreover, it is not enough to theorize that some other documents may exist. As the court held in Blue Ocean Institute, “theorizing that the documents *may* exist . . . fails to overcome the presumption that the record is complete.” 503 F. Supp. 2d at 371 (emphasis original). At the preliminary injunction stage, this Court had little difficulty finding, based on the record already in existence, that “the PTO’s rationale appears to be sufficient to satisfy arbitrary and capricious review, and the Court will find that GSK has not shown a real likelihood of success on the

merits.” Tafas v. Dudas, – F. Supp. 2d –, 2007 WL 3196683, at *12 (E.D. Va. Oct. 31, 2007).

Similarly, bald allegations of “bad faith” are inadequate to overcome the presumption that the Court must confine its review of agency action to the record. As noted above, there is a presumption that government officials perform their duties properly and in good faith. See Mullins, 50 F.3d at 993; Spezzaferro v. Federal Aviation Admin, 807 F.2d 169, 173 (Fed. Cir. 1986); Gonzales v. Def. Logistics Agency, 772 F.2d 887, 889 (Fed. Cir. 1985). Thus, in order to obtain discovery beyond the administrative record, there must be a “strong preliminary showing,” supported by specific facts, that the challenged action was reached because of bad faith or improper behavior. Nat’l Nutritional Foods Assoc. v. Food & Drug Admin., 491 F.2d 1141, 1145 (2d Cir. 1974). Although courts have not developed a “bright-line” test to identify what alleged conduct constitutes a “strong preliminary showing” of bad faith or improper behavior, they have uniformly imposed a high standard for plaintiffs seeking to demonstrate bad faith. See, e.g., Mullins, 50 F.3d at 993 (finding no bad faith absent a showing of “fraud or clear wrongdoing”); United States v. Shaffer, 11 F.3d 450, 460-61 (4th Cir. 1993) (finding bad faith where agency employee created fraudulent documents and “perjured himself repeatedly”); Mar. Mgmt. v. United States, 242 F.3d 1326, 1330-31 (11th Cir. 2001) (permitting discovery only after finding that the Government had “purposefully” excluded documents that were unfavorable to its conclusions); Sher v. United States VA, 488 F.3d 489, 497-98 (1st Cir. 2007) (finding no bad faith when plaintiff failed to proffer evidence of intentional misconduct on the part of the federal agency); Newton County Wildlife Ass’n v. Rogers, 141 F.3d 803, 807-08 (8th Cir. 1998) (finding allegation of bad faith “woefully inadequate to justify going outside the administrative record” where the plaintiff identified a particular discrepancy in the agency’s conduct as evidence of bad faith). Here, by contrast, there is no evidence even remotely approaching fraud, perjury,

or intentional delay to avoid judicial review. Nor has Tafas shown that the USPTO purposefully excluded unfavorable documents from the record.

II. PLAINTIFFS HAVE NOT REBUTTED THE PRESUMPTION THAT THE ADMINISTRATIVE RECORD IS COMPLETE.

Even though the USPTO has filed an administrative record containing a 127-page Federal Register notice explaining the Final Rules, along with nearly 10,000 pages of public comments, presentations, data, RFA materials, correspondence, and other documents, Plaintiffs allege that there are items missing from the record as to justify discovery.⁹ Plaintiffs have not come close to showing that the record is incomplete, much less that it is so bare as to frustrate judicial review. If anything, GSK's and Tafas's allegations underscore just how carefully the USPTO compiled the record and how comprehensive the record truly is.

⁹ At the hearing on November 16, 2007, GSK counsel stated that GSK was not seeking discovery at the present time because it was waiting for answers back from its two FOIA requests and "depending upon what the answers are, that may lead to targeted discovery that we may need to do at that point." Ex. 2, Tr. p. 33. GSK further asked the Court not to make a "blanket" ruling on discovery and to "take the discovery requests as they come up." *Id.* GSK then changed course and moved to compel discovery just before Thanksgiving. Dkt. No. 75.

GSK has now had ample opportunity to tell this Court what discovery it wants, and it is inappropriate for this Court to hold up ruling definitively on discovery until the FOIA process runs its course. As explained in "Defendants' Memorandum in Opposition to Plaintiffs' Requests for a Privilege Log on the Administrative Record," Dkt. No. 74, pp. 10-13, GSK's FOIA requests are far from wending their way through the administrative process, and the FOIA process cannot be used as a discovery tool in this litigation. Moreover, even if GSK were, unexpectedly, to uncover some material through its FOIA requests that were inadvertently omitted from the administrative record, this alone would not justify discovery. *See TOMAC v. Norton*, 193 F. Supp. 2d 182, 195 (D.D.C. 2002) ("The fact that TOMAC has identified three documents that it asserts should have been included in the administrative record – among 5,000 pages of information obtained through FOIA – is not strong evidence of bad faith or an incomplete record."). The discovery issue is now fully briefed and ready for this Court's final resolution.

A. GSK’s Five Alleged Categories of Missing Documents Fail to Establish that the Record Is Incomplete¹⁰

1. Documents Explaining the Proposed Rules

GSK first argues that the record is incomplete because “it contains fewer than 400 pages dated before the PTO published the [Proposed] Rules.”¹¹ GSK Compel Mem. at 1. Tafas makes a similar argument. See Tafas Opp. Mem. at 9; Tafas Supp. Mem. re Depos. at 3 (bullet 3). This argument fails for several reasons. First, many of the materials Plaintiffs speculate should be in the record are deliberative in nature and, as explained above, do not belong in the record for that reason. See, e.g., GSK Compel Mem. at 7 (complaining that “[t]here are no e-mails to support that fact or any communications contemporaneous with that original data run”).

Second, the Final Rules are the “final agency action” this Court must review. See 5 U.S.C. § 704. The existing record allows for judicial review of that action, and many of the issues Plaintiffs suggest are missing with regard to the Proposed Rules are irrelevant to review of the Final Rules. See, e.g., GSK Compel Mem. at 7 (seeking discovery about the USPTO’s rationale for using a ten representative claims approach in the Proposed Rules, even though the Final Rules did not adopt that approach).

In any event, to the extent that the USPTO has non-deliberative materials that were generated before the Proposed Rules were published, the USPTO has already included those

¹⁰ In the event this Court were to allow GSK to take discovery, it should at least prohibit GSK from propounding its proposed document production requests. See GSK Compel Mem., Ex. B. These sweeping document requests are grossly disproportionate to the narrow defects GSK purports to identify in the record.

¹¹ In GSK’s memorandum, the bracketed word “[Proposed]” is “Final.” GSK Compel Mem. at 1. The USPTO assumes this was a typographical error, as the statement is otherwise incorrect.

materials in the record. See GSK Compel Mem. at 1 (admitting that the record contains 400 pages dated before the Proposed Rules were published). Contrary to Plaintiffs’ contention, for example, the administrative record contains extensive data that the USPTO studied in arriving at – and later deciding against – the ten representative claims approach. See, e.g., A03545-A03620,¹² A03652-A03653, A03655-A03678, A03767-A03771, A03789-A03795, A03798-A03824, A04333-A04338, A04369-A04371, & A04399-A04402. The administrative record also contains data that the USPTO considered before publishing the Proposed Rules with regard to the ESD requirement. See, e.g., A04330-04332; A04357-04359. Plaintiffs are “reduced to theorizing that [additional] documents may exist,” but such speculation “fails to overcome the presumption that the record is complete.” Blue Ocean Institute, 503 F. Supp. 2d at 371.

2. *Information Regarding Changes from the Proposed Rules to the Final Rules.*

GSK’s claims in this second category do not merit discovery for at least three reasons. See GSK Compel Mem. at 7-9. First, the vast majority of GSK’s assertions are simply arguments for remand. See Fla. Power & Light, 470 U.S. at 743-44. GSK should make these arguments at the summary judgment stage if it believes that the record cannot support the Final Rules; they are not arguments for discovery. See, e.g., GSK Compel Mem. at 8-9 (arguing that the record “includes little information on the alternatives that the PTO considered,” “lacks key analyses (including assumptions, models, populations considered, and the like),” and fails to support certain conclusions on time estimates for ESDs).

Second, a large number of GSK’s questions could be answered only through deliberative

¹² Documents from the administrative record are designated A____.

materials. For example, GSK argues that “there is no discussion in the Record that purports to even consider the strong negative response to the proposed RCE rule,” or that explains the shift from a ten representative claims approach to the 5/25 rule. Id. at 8. Certainly, the USPTO internally discussed the public’s response to some of the Proposed Rules and debated its shift in approach, but these deliberative materials do not belong in the record.

Third, many of the items that GSK claims are missing from the record are in fact present. For example, the administrative record clearly contains “key analyses (including assumptions, models, populations considered, and the like),” GSK Compel Mot. at 8. See, e.g., A07195-7201; A07202; A05641-A05721. The record also shows that the USPTO considered the public’s response to the proposed RCE rule. See, e.g. 72 Fed. Reg. at 46766-67 (comments 61-64). It further contains detailed evidence of how the USPTO accounted for its ESD time estimates. See, e.g., A08304. In the face of these and other examples, Plaintiffs have not met their burden to show that the record is incomplete.

3. *Documents Concerning the PTO’s Post-Promulgation Guidance on the ESD Requirement*

In its final Federal Register notice, which is contained in the administrative record, the USPTO explained how an applicant could satisfy the preexamination search standards of Final Rule 265's ESD requirement, and further promised that applicants would soon be able to find supplemental guidance on the USPTO’s website. See 72 Fed. Reg. at 46741, 46800; see also A09390, A09416, A09475. The USPTO has since provided such supplemental guidance, and the USPTO included these documents as attachments to Exhibit 4 of Defendants’ Opposition to Plaintiffs’ Motion for a Temporary Restraining Order or Preliminary Injunction Motion. See Dkt. No. 46-7. Given that administrative records close with the publication of final rules, it is

inconceivable how GSK could suggest that documents that the USPTO created and then publicized after the Final Rules published represent “holes” in the administrative record.

GSK’s request for discovery regarding these documents is also meritless because the issue of whether the ESD requirement is unconstitutionally vague, a proposition that GSK contends is underscored by the issuance of these documents, involves a pure question of law. As set forth above, discovery is generally unnecessary to resolve purely legal questions. Zeneca Inc., 1999 WL 728104, at *4; Sathianathan, 2007 U.S. Dist. LEXIS 64880 (“Plaintiff’s argument on that issue is based entirely on a question of law and no discovery is necessary.”). In any event, Plaintiffs do not need additional discovery of these documents because they now have them in their possession, and moreover, they are publically available on the USPTO’s website. See, e.g., Guidelines for Examination Support Document (“ESD”) under 37 CFR 1.265, at www.uspto.gov/web/offices/pac/dapp/opla/presentation/esdguidelines090607.pdf.

4. *Documents Concerning Communications with Third Parties*

GSK erroneously speculates that certain USPTO communications with third parties are “conspicuously absent” from the administrative record. See GSK Compel Mem. at 10. In fact, the record already contains all non-privileged documents in the USPTO’s possession reflecting communications between the USPTO and third parties regarding the Final Rules. Indeed, in addition to the 2,600 pages of documents reflecting the public comments on the Proposed Rules, see A00591-03199, the record includes communications between USPTO and Congress,¹³ other

¹³ See A08345-A08364 (letter exchange between USPTO and Senator Boxer); A08516-A08524 (Congressional Review Act letters and form).

Executive Branch agencies,¹⁴ and members of the media, commentators, professors, and the business community¹⁵. See GSK Compel Mem. at 10.

Furthermore, most of the communications that GSK speculates are absent either do not exist, or are deliberative in nature and, therefore, properly excluded from the administrative record. For example, referencing an e-mail included in the record between ICF and the USPTO, GSK complains that the record lacks documents reflecting how ICF learned of certain information regarding the expected effect of the claims rule or why the USPTO as of January 2007 had contemplated not enacting the rule related to requests for continued examination. See id. Every substantive document in the USPTO's possession concerning communications with ICF about the Final Rules is included in the record. See, e.g., A07478-07483, A08228-A08269. GSK further complains, for example, "the PTO has not included the old language it sent to SBA or the SBA's prior 'comments or changes' in the Administrative Record." Id. at 11-12. The USPTO's proposed drafts, as well the SBA's comments on these pre-decisional materials, are deliberative and do not belong in the administrative record.¹⁶ See, e.g., Klamath Water Users

¹⁴ See A07325-A07327 (communication between USPTO and the SBA regarding the certification for the Notice of Proposed Rule Making); A07328-A07477 (communication between USPTO and OMB regarding submission of Paperwork Reduction Act collection); A08307-A08315 (communication between USPTO and SBA regarding certification for Final Rules); A08505 (correspondence from SBA); A08506 – A08515 (communication between OMB to USPTO regarding budget effect of rules).

¹⁵ See A08330-A08344, A08365 (reflecting correspondence from several organizations inviting USPTO to discuss the rules and the USPTO accepting or declining those invitations).

¹⁶ It should also be noted that the Task Orders to IFC and the Patenting Trend Report about which GSK complains, see GSK Compel Mem. at 11, were not included in the record because the materials themselves did not "directly or indirectly" influence the decisions that led to the Final Rules. See Amfac Resorts, 143 F. Supp. 2d at 11 (limiting the administrative record to material that directly or indirectly influenced the agency decision-maker).

Protective Ass'n, 532 U.S. at 8-9; Mink, 410 U.S. at 87 (applying the deliberative process privilege to inter-agency materials).

5. *Analyses or Discussions Regarding Alternative Claims Rules that the PTO Considered.*

GSK's assertion that this category of documents is missing from the administrative record is, like many of its prior assertions, incorrect. For example, the USPTO included in the administrative record documents that reflected its consideration of: (1) increasing the number of continued examination filings without requiring a petition, see 72 Fed. Reg. at 46833; (2) increasing the number of claims that would be examined without an ESD, see id.; (3) declining to apply the claims changes to previously filed applications, see id., see also A04732-A04733, A04743-A04747; and (4) hiring more examiners to ameliorate some of the difficulties the Final Rules are intended to address, see Fed. Reg. 46817-18; see also A04721-A04731, A07082, A07097, A07101-A07105, A07107, A07130-A07134, A07141-A07142, A07168. Furthermore, GSK's assertion that "the Administrative Record also does not contain any analysis or discussion of the vast difference in impact between the proposed ten 'representative' claims rule (1.2% of applications) and the 5/25 claim limit in the Final Rules (25% of applications)" is also incorrect. See GSK Compel Mem. at 12. There are numerous documents in the administrative record reflecting this analysis in connection with the USPTO's initial RFA certification, see, e.g., A07325- A07327, and its final report and final certification, see, e.g., A08270-A08315.

In light of these and other examples, GSK has failed to demonstrate that the administrative record is incomplete. Instead, its allegations suggest that GSK merely seeks to undertake a fishing expedition and delay the litigation while a preliminary injunction is in place.

B. Tafas’s Additional Arguments for Why the Administrative Record is Incomplete Are Baseless

In the bullet points and attached deposition outlines of his “Supplemental Memorandum in Support of Notices of Depositions of Senior USPTO Officials,” Dkt. No. 79, Tafas identifies numerous areas that he would like to explore in wide-ranging depositions of high-level agency officials.¹⁷ These areas fall into three categories: (1) requests showing that Tafas is fishing for deliberative materials; (2) requests showing that Tafas has failed to review the record carefully enough to realize that the materials he seeks are already there;¹⁸ and (3) requests showing that Tafas is looking for information that is otherwise legally irrelevant. Each of these efforts is clearly inappropriate and underscores that Tafas, like GSK, seeks a fishing expedition.

1. Requests for Deliberative Information

Much of the information that Tafas seeks is deliberative process material, which does not belong in the record, see In re Subpoena Duces Tecum, 156 F.3d at 1279, and is particularly inappropriate to obtain through depositions, see Morgan, 313 U.S. at 420. Tafas speculates, for example, that the record is missing “substantive internal written communications among the

¹⁷ Tafas also indicates that he may want to depose Jennifer McDowell, who certified the administrative record, and that he would like to take a Rule 30(b)(6) deposition to “obtain, inter alia, an identification of each USPTO official involved in formulating and approving the Rules, as well as a detailed explanation concerning how the administrative record was put together.” Tafas Supp. Mem. re Depos at 2 n.2. Tafas has provided no justification for why these depositions might be appropriate, and they are not. The Court should make clear that these depositions are likewise impermissible.

¹⁸ Tafas notes more than once that his counsel have “reviewed the entire administrative record.” Tafas Supp. Mem. re Depos. at 3. Given that counsel admits to having already completed this task, it is difficult to make sense of Tafas’s complaint that “[t]he schedule jointly proposed by Plaintiffs . . . provides the absolute bare minimum amount of time reasonably necessary to provide for an adequate review and vetting of the administrative record.” Tafas Opp. Mem. at 3.

Deponents themselves, or for that matter, between the Deponents and any other senior USPTO officials,” Tafas Supp. Mem. re Depos at 4 (bullet 8) (emphasis added), and that it is missing “any internal USPTO email, correspondence, summaries, drafts, work in progress or analysis, evidencing the USPTO’s initial formulation of the rules or, for that matter, reflecting of any internal struggle,” id. at 6 (bullet 15) (emphasis added). Tafas seeks classic deliberative materials – exactly the kind of materials that the court refused to provide in Blue Ocean Institute, reasoning that if such materials were permitted, “there would be no presumption of a complete record because the possibility that internal, deliberative documents exist would occur in every APA case since the employees of agencies must communicate with each other in the process of promulgating a final rule.” 503 F. Supp. 2d at 371.

Tafas further complains that there is “essentially nothing in the administrative record evidencing any ‘spade work’ that would provide a basis for the USPTO’s final commentary and rejection of any negative comments,” id. at 4 (bullet 5), and that “Tafas’ undersigned counsel did not see more than a handful of documents (if that) reflecting that any of the Deponents even reviewed the extensive public comments,” id. at 3 (bullet 4) (emphasis removed). Yet the final Federal Register notice contains eighty-six pages in which the USPTO responded to hundreds of public comments. See 72 Fed. Reg. at 46744-46830. It is these “stated reasons” that the Court must review when performing arbitrary and capricious review. In re Subpoena Duces Tecum, 156 F.3d at 1279. Any deliberative “spade work” the USPTO might have done is irrelevant.

2. *Requests for Materials that Are Already in the Record*

Tafas also seeks to have the deponents spoon-feed him information that is already in the record. For example, Tafas argues that there are numerous “public reports” in the administrative record but that he would “like to question the Deponents as to what, if anything, in these public

reports the USPTO credited (or discounted) in promulgating the Revised Rules.” Tafas Supp. Mem. re Depos at 4 (bullet 7). The USPTO has already demonstrated how it used public reports in its final Federal Register notice. See, e.g., 72 Fed. Reg. at 46758 (citing “To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, A Report by the Federal Trade Commission (2003),” which is at A03202-03516); 72 Fed. Reg. at 46815 (citing to USPTO “Performance and Accountability Report Fiscal Year 2005,” which is at A04509); 72 Fed. Reg. at 46831 (citing to “AIPLA Report of the Economic Survey 2003,” which is at A03200).

Tafas also *speculates* that “only some” presentations were included in the administrative record, but he fails to provide any evidence to rebut the presumption that the USPTO has, in fact, included all such presentations. Tafas Supp. Mem. re Depos at 3 (bullet 1); see Blue Ocean Institute, 503 F. Supp. 2d at 371 (“Blue Ocean is reduced to theorizing that the documents *may* exist, which fails to overcome that the record is complete.”). Tafas is not entitled to undertake a fishing expedition in search of documents that he *hypothesizes* may have been left out of the record. Moreover, his claim that there is “no source material that would explain or provide a basis for the substantive content of these presentations” is baseless. Tafas Supp. Mem. re Depos at 3 (bullet 2). The administrative record contains 4,000 pages of data that agency officials drew upon in their presentations. See A03200-A07202. The law does not require the USPTO’s busy executive officials to sit down with Tafas counsel in order to explain how they assimilated all of this data into presentations.

3. *Requests for Other Legally Irrelevant Materials*

Tafas’s proposed deposition outlines reveal that he further misunderstands the nature of this Court’s task at summary judgment. To take just two examples, Tafas would like to ask

Under-Secretary Dudas whether he has a “good faith belief that the New Rules do not violate the Constitution,” see Tafas Supp. Mem. re Depos, Ex. 1 (#3), and he would like to ask Deputy Commissioner for Patent Examination Policy John Love whether he has a “good faith belief . . . in respect of [the USPTO’s] assertion that the final rules are a logical outgrowth of the proposed rules,” id. Ex. 3 (#4). The question at summary judgment, however, is whether, as a purely legal matter, the Final Rules violate the Constitution and whether they are a logical outgrowth of the Proposed Rules. Agency officials’ personal views on the Final Rules’ legality are irrelevant.

Tafas also repeatedly seeks information on agency officials’ “good faith” basis for their findings on the effects of the Final Rules on patent applicants. See, e.g., id., Ex. 2 (#4) (seeking to ask Commissioner of Patents John Doll “whether the USPTO has a good faith belief that the continuation rules will reduce its backlog without affecting substantive rights”); Ex. 2 (#5) (inquiring into the “good faith basis for asserting that less than 10% of applicants will seek to file a petition to file a continuation”). In particular, Tafas focuses on the USPTO’s “good faith” basis for its submissions to the Office of Management and Budget (“OMB”) under the Paperwork Reduction Act of 1995 (“PRA”), 44 U.S.C. § 3501 et seq. See, e.g., id. Ex. 1 (#2); Ex. 4 (#1). Agency officials’ “good faith” beliefs regarding these matters are irrelevant because, as explained in Part III, infra, Tafas has not shown that agency officials acted in “bad faith,” and he thus has not rebutted the presumption of regularity to which the agency is entitled. Overton Park, 401 U.S. at 420 (requiring “strong showing” of bad faith to justify discovery).

For all of these reasons, the Court should deny discovery on the ground that the record is incomplete. Plaintiffs have not come close to showing that the administrative record is so bare as to “frustrate judicial review.” Am. Canoe Ass’n, 46 F. Supp. 2d at 477.

III. THERE IS NO EVIDENCE OF BAD FAITH ON THE PART OF THE USPTO.

Tafas also attempts to justify his requests for discovery by theorizing that the Final Rules must have been promulgated in “bad faith” because they are at odds with his own policy preferences. See Tafas Opp. Mem. at 11-24. Yet a difference in policy does not satisfy the “strong showing” of bad faith required to justify discovery in a record review case, Overton Park, 401 U.S. at 420, nor does it come close to providing the extraordinary circumstances necessary to allow the depositions of high-level agency officials, see Morgan, 313 U.S. at 422. The vast majority of Tafas’s allegations are either red herrings or arguments for his contention that the Final Rules are arbitrary and capricious – arguments that he may present at summary judgment but that do not justify discovery.

A. Tafas’s References to the USPTO’s Submissions to OMB Are a Red Herring

Tafas’s central charge of “bad faith” revolves around allegations that the USPTO excluded from the administrative record documents that it submitted to the OMB on June 22, 2007 and September 26, 2007 pursuant to the PRA, 44 U.S.C. § 3501, et seq. See Tafas Opp. Mem. at 13-17, 20-22. The absence of these documents from the administrative record is easily explained and does not remotely suggest bad faith.

The USPTO did not include its June 22, 2007 PRA submission in the record because that submission related to a completely different USPTO initiative. As Tafas’s own exhibit shows, the June PRA submission was “[n]ot associated with rulemaking” and instead was precipitated by a USPTO initiative related to pre-first Office action interviews. See Tafas Opp. Mem., Ex. 29, pp. 2 (“Stage of Rulemaking” & 3 (“Short Statement”). OMB’s disapproval of this June 2007 PRA submission was thus unrelated to the Final Rules under review in this case. See id. As Tafas’s own table shows, see Tafas Opp. Mem. at 15, Tbl. 1, OMB approved the USPTO’s

two thorough PRA submissions that related to the Final Rules, and those submissions were appropriately included in the administrative record, see A07328, A08209.

The USPTO did not include the September 26, 2007 PRA submission in the administrative record because it was published after the Final Rules were published on August 21, 2007, and thus after the administrative record in this case closed. See Tafas, Tafas Opp. Mem, Ex. 30. Nothing after August 21, 2007 constitutes material that the USPTO could have “directly or indirectly considered” in promulgating its Final Rules, and thus, such material does not belong in the administrative record. Bar MK Ranches, 994 F.2d at 739.

Moreover, even if the September 2007 PRA submission contains estimates that differ from the USPTO’s prior PRA estimates, any such difference is irrelevant to this lawsuit. Tafas has not brought suit to challenge whether the USPTO has properly complied with the PRA, which is all that his arguments implicate. Indeed, there is no private right of action available for violation of the PRA, even if Tafas had sought to raise one. See Ass’n of Am. Physicians & Surgeons, Inc. v. U.S. Dept. of Health & Human Servs., 224 F. Supp.2d 1115, 1129 (S.D. Tex. 2002) (“The PRA does not create a private right of action.”); Tozzi v. EPA, 148 F. Supp. 2d 35, 43, 47 (D.D.C. 2001). If Tafas believes that the USPTO’s September 2007 PRA submission contains errors, his recourse is to alert the Director of OMB, not to seek discovery in this lawsuit.

In any event, Tafas has not shown that the USPTO attempted, in bad faith, to “skew the record in its favor by excluding pertinent but unfavorable information,” Fund for Animals v. Williams, 391 F.Supp.2d 191, 197 (D.D.C. 2005), or by “purposefully” excluding unfavorable documents. See Mar. Mgmt., 242 F.3d at 1330-31. Indeed, if the USPTO had wanted to skew the record in its favor, it should have included, not excluded, the September 2007 PRA submission, as the data in that submission make the Final Rules appear to affect fewer applicants,

thereby muting Plaintiffs' complaints about its widespread effects.¹⁹ Instead, Tafas has at most alleged a minor discrepancy that is irrelevant to this lawsuit and is "woefully inadequate to justify going outside the administrative record." Newton County Wildlife Ass'n, 141 F.3d at 807-08 (rejecting claim of bad faith based on a similar alleged discrepancy).

B. Tafas's Remaining "Bad Faith" Arguments Relate to Why He Believes the Final Rules Are Arbitrary and Capricious and Do Not Demonstrate Bad Faith.

Tafas's remaining arguments represent reasons why he may choose to argue at summary judgment that the Final Rules are arbitrary and capricious, but they do not come close to showing the "fraud or clear wrongdoing" that would be indicative of bad faith. Mullins, 50 F.3d at 993. For example, Tafas's statistical arguments about ESD use, see Tafas Mem. Opp. at 13; his disagreement with the USPTO over whether people will be deterred from submitting ESDs due to fears of inequitable conduct, id. at 14; his dispute over the USPTO's understanding of the term "rework," id. at 19; and his arguments about the USPTO's appeal statistics, id. at 22-23, may provide reasons for Tafas to argue that the Court should remand the Final Rules to the USPTO, but they do not remotely suggest bad faith or improper behavior by USPTO officials.

In short, Tafas has not made any showing – much less a "strong showing" – of bad faith as to justify discovery. Overton Park, 401 U.S. at 420.

IV. TAFAS'S REGULATORY FLEXIBILITY ACT CLAIM DOES NOT NECESSITATE OR JUSTIFY DISCOVERY.

Tafas's arguments concerning the RFA, 5 U.S.C. §§ 601-612, offer a welcome preview of

¹⁹ Besides raising irrelevant points about the USPTO's PRA submissions, Tafas misunderstands them. Tafas's Table 1 assumes that PRA submissions separately break out responses per year by large and small entity respondents; they do not. Moreover, the USPTO's estimate of using 0.10 hours to handle petitions under Final Rule 178 represents only the time it would take the USPTO to process the petition paperwork and does not include the time for deciding the petition.

his merits arguments at summary judgment, but they do not suggest that the USPTO acted in bad faith when making its certification pursuant to § 605(b), nor do they even remotely show why Tafas would need discovery. See Tafas Opp. Mem. at 24-29; Tafas Supp. Mem. re Depos. at 5 (bullet 13). If anything, Tafas shows that the existing record provides ample material for him to challenge the USPTO's RFA certification.

At oral argument on November 16, 2007, Tafas counsel argued that he needed discovery because he needed to show that the USPTO acted in "bad faith" to make out his RFA claim. Tafas misapprehends the nature of the RFA inquiry. As explained in the USPTO's opening brief, "[t]he RFA imposes no substantive requirements on an agency; rather, its requirements are 'purely procedural' in nature." Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. U.S. Dep't of Agric., 415 F.3d 1078, 1100 (9th Cir. 2005) (quoting U.S. Cellular Corp. v. FCC, 254 F.3d 78, 88 (D.C. Cir. 2001)). Indeed, even in the case upon which Tafas primarily relies, Alenco Committees Inc. v. FCC, 201 F.3d 608, 625 (5th Cir. 2000), the Fifth Circuit confirmed that "[t]he RFA is a procedural rather than substantive agency mandate." The Court thus needs nothing more than the Federal Register notice, 72 Fed. Reg. at 46830-46835, and the 1,100 pages dedicated to the RFA in the administrative record, A07203-A08329, to determine whether the USPTO reasonably followed the RFA's procedures when it issued a certification pursuant to § 605(b). See, e.g., Little Bay Lobster Co. v. Evans, 352 F.3d 462, 470-71 (1st Cir. 2003) (conducting RFA review on the administrative record). Tafas's desire to undertake a fishing expedition that would delve into high-level officials' subjective motivations is plainly unwarranted.

V. TAFAS'S CONSTITUTIONAL CLAIM NEITHER NECESSITATES NOR ENTITLES HIM TO DISCOVERY.

Tafas's claim that the USPTO violated the "Patent and Copyright Clause" of the Constitution, Art. I, § 8, cl. 8, does not entitle him to discovery in this APA action. First, as other courts have recognized, the presence of a constitutional claim in an APA action does not alter the well-settled proposition that courts must confine their review to the administrative record. See Harvard Pilgrim Health Care of New Eng. v. Thompson, 318 F. Supp. 2d 1, 9 (D.R.I. 2004) (citing Marine Mammal Conservancy, Inc. v. Dep't of Agric., 134 F.3d 409, 413 (D.C. Cir. 1998)); Bailey v. United States Army Corps of Eng'rs, No. 02-639, 2003 WL 21877903, at *2 (D. Minn. Aug. 7, 2003); Alabama-Tombigbee Rivers Coal. v. Norton, No. CV-01-S-0194-S, 2002 WL 227032 (N.D. Ala. 2002). Indeed, courts have acknowledged that the APA's restriction of judicial review to the administrative record would be "meaningless" if any party seeking review based on a constitutional claim was entitled to broad-ranging discovery. See, e.g., Harvard Pilgrim, 318 F. Supp. 2d at 9; Malone Mortgage Co. Am. Ltd. v. Martinez, No. 3:02-CV-1870-P, 2003 WL 23272381, at *2 (N.D. Tex. 2003); see also P.R. Pub. Hous. Admin. v. United States HUD, 59 F. Supp. 2d 310, 327 (D. P.R. 1999) (noting that even when constitutional claims are present, a court reviewing an administrative record should not blindly authorize wide-ranging discovery).

Tafas tries to distinguish Harvard Pilgrim, Malone Mortgage, and Alabama-Tombigbee on the basis that the plaintiffs in those case, unlike Tafas in this case, did not raise bad faith as a basis to obtain discovery beyond the administrative record. See Tafas Supp. Mem. re Const. Claims at 3. As set forth above, the USPTO has already demonstrated that Tafas has failed to show bad faith, and accordingly, he is not entitled to discovery on the basis. His efforts to distinguish these cases on this basis are thus futile.

Tafas misapprehends the Supreme Court’s holding in Webster v. Doe, 486 U.S. 592 (1988), which he cites for the proposition that an “assertion of a constitutional claim is an exception to APA limits on discovery outside of the administrative record.” Tafas Supp. Mem. re Const. Claims at 2. In Webster, the Supreme Court confronted the issue of whether judicial review of the plaintiff’s claims challenging his termination from the Central Intelligence Agency was entirely unavailable in light of the limitations of the National Security Act and alternatively, whether such review should be barred because it would entail extensive intrusions into the agency’s affairs. See id. at 603-04. The Court held that while the plaintiff could not pursue relief under the APA itself, the National Security Act did not “preclude consideration of colorable constitutional claims arising out of the actions of the Director” brought pursuant to the APA. Id. at 603. Here, by contrast, there is nothing stopping Plaintiffs from seeking relief under the APA. Moreover, the Court’s notation that the federal court could control the discovery process on remand was mere dictum, as that discussion was not necessary to the Court’s holding that the Act did not bar the federal court’s jurisdiction to review the constitutional claims in accordance with the APA. Id. In any event, nothing in Webster supports Tafas’s position that he should be allowed discovery in this case simply because he has asserted a constitutional claim.

Furthermore, Tafas is not entitled to discovery on this claim to the extent he contends that the USPTO has violated the Patent and Copyright Clause by exceeding the authority delegated to it by Congress.²⁰ This claim is purely a question of law, which is duplicative of his statutory APA claims, and for which discovery is unnecessary. Zeneca Inc., 1999 WL 728104, at *4;

²⁰ Notably, Tafas did not even raise this claim in his First Amended Complaint for Declaratory and Injunctive Relief and Petition for Review of Rulemaking (“Am. Compl.”), Dkt. No. 14. There, his only claim under the Patent and Copyright Clause is that the USPTO violated that clause by “failing to appropriately weight the effect of its regulations on the promotion of the progress of science and the useful arts.” Am. Compl., ¶ 60.

Sathianathan, 2007 U.S. Dist. LEXIS 64880 (“Plaintiff’s argument on that issue is based entirely on a question of law and no discovery is necessary.”).

Finally, Tafas is not entitled to discovery on this claim because, to the extent that he is allowed to rely on the Clause’s preambular language to challenge the USPTO’s rulemaking – a proposition the USPTO contests – all that would be required is a “rational basis” for the conclusion that the USPTO’s Final Rules “promot[e] the progress of science.” Eldred v. Ashcroft, 537 U.S. 186, 212, 213 (2003); Figuroa v. United States, 466 F.3d 1023, 1031-32 (Fed. Cir. 2007). The administrative record includes all the documents Tafas requires to determine whether the USPTO has established a rational basis for the Final Rules. See, e.g., 72 Fed. Reg. 46719 (explaining that the Final Rules will “(1) [l]ead to more focused and efficient examination, improve the quality of issued patents, result in patents that issue faster, and give the public earlier notice of what the patent claims cover; and (2) address the growing practice of filing . . . multiple applications containing patentably indistinct claims.”). Indeed, the record was sufficient to allow Judge Cacheris to find, at the preliminary injunction stage, that “the PTO’s rationale appears to be sufficient to satisfy arbitrary and capricious review, and the Court will find that GSK has not shown a real likelihood of success on the merits.” Tafas, – F. Supp. 2d –, 2007 WL 3196683, at *12. Tafas’s constitutional claim thus fails to afford him a basis for seeking discovery.

CONCLUSION

In sum, Plaintiffs have failed – after five attempts – to show that discovery beyond the administrative record is necessary or appropriate. The Court should thus deny Plaintiffs’ various efforts to obtain discovery and enter the attached proposed order, which the USPTO and GSK have agreed upon in the event the Court denies discovery.

Respectfully submitted,

CHUCK ROSENBERG
UNITED STATES ATTORNEY

By: _____ /s/

Lauren A. Wetzler
Ralph Andrew Price, Jr.
R. Joseph Sher
Assistant United States Attorneys
Attorneys for All Defendants
Justin W. Williams U.S. Attorney's Building
2100 Jamieson Avenue
Alexandria, Virginia 22314
Tel: (703) 299-3752
Fax: (703) 299-3983
Lauren.Wetzler@usdoj.gov

OF COUNSEL:
James A. Toupin
General Counsel

Stephen Walsh
Acting Deputy General Counsel
and Solicitor

William Covey
Deputy General Counsel

William G. Jenks
Janet A. Gongola
William LaMarca
Associate Solicitors

Jennifer M. McDowell
Associate Counsel

United States Patent and Trademark Office

CERTIFICATE OF SERVICE

I hereby certify that on November 26, 2007, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send a notification of such filing (NEF) to the following:

Joseph Dale Wilson, III
Kelley Drye & Warren LLP
Washington Harbour
3050 K Street NW
Suite 400
Washington, DC 20007
Email: jwilson@kelleydrye.com

Joanna Elizabeth Baden-Mayer
Collier Shannon & Scott PLLC
3050 K St NW
Suite 400
Washington, DC 20007-5108
E-mail: jbaden-mayer@kelleydrye.com

Counsel for Plaintiff Triantafyllos Tafas, 1:07cv846

Elizabeth Marie Locke
Kirkland & Ellis LLP
655 15th St NW
Suite 1200
Washington, DC 20005
Email: elocke@kirkland.com

Craig Crandell Reilly
Richard McGettigan Reilly & West PC
1725 Duke St
Suite 600
Alexandria, VA 22314
Email: craig.reilly@rmrwlaw.com

Daniel Sean Trainor
Kirkland & Ellis LLP
655 15th St NW
Suite 1200
Washington, DC 20005
Email: dtrainor@kirkland.com

Counsel for Plaintiffs SmithKline Beecham Corp. d/b/a GlaxoSmithKline, SmithKline Beecham PLC, and Glaxo Group Limited, d/b/a GlaxoSmithKline

Thomas J. O'Brien
Morgan, Lewis & Bockius
1111 Pennsylvania Ave, NW
Washington, DC 20004
Email: to'brien@morganlewis.com

Counsel for Amicus American Intellectual Property Lawyers Association

Dawn-Marie Bey
Kilpatrick Stockton LLP
700 13th St NW
Suite 800
Washington, DC 20005
Email: dbey@kslaw.com

Counsel for Amicus Hexas, LLC, The Roskamp Institute, Tikvah Therapeutics, Inc.

James Murphy Dowd
Wilmer Cutler Pickering Hale & Dorr LLP
1455 Pennsylvania Ave NW
Washington, DC 20004
Email: james.dowd@wilmerhale.com

Counsel for Putative Amicus Pharmaceutical Research and Manufacturers of America

Randall Karl Miller
Arnold & Porter LLP
1600 Tysons Blvd
Suite 900
McLean, VA 22102
Email: randall_miller@aporter.com

Counsel for Putative Amicus Biotechnology Industry Organization

Rebecca M. Carr
Pillsbury Winthrop Shaw Pittman, LLP
2300 N Street, NW
Washington, DC 20037
Rebecca.carr@pillsburylaw.com

Scott J. Pivnick
Pillsbury Winthrop Shaw Pittman
1650 Tysons Boulevard
McLean, Virginia 22102-4856
Scott.pivnick@pillsburylaw.com

Counsel for Amicus Elan Pharmaceuticals, Inc.

/s/

LAUREN A. WETZLER
Assistant United States Attorney
Justin W. Williams U.S. Attorney's Building
2100 Jamieson Avenue
Alexandria, Virginia 22314
Tel: (703) 299-3752
Fax: (703) 299-3983
Lauren.Wetzler@usdoj.gov

Counsel for All Defendants