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 CORPORATION, et al.,	)	
	)	
Plaintiffs,	)	
	)	Civil Action No. 1:07cv1008 (JCC/TRJ)
v.	)	
	)	
JON W. DUDAS, et al.,	)	
	)	
Defendants.	)	
	)	

DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFFS' REQUESTS FOR A PRIVILEGE LOG ON THE ADMINISTRATIVE RECORD

Defendants Jon W. Dudas and the United States Patent and Trademark Office (collectively "USPTO") respectfully submit this memorandum in response to both "Plaintiff Triantafyllos Tafas's Supplemental Memorandum Addressing Need for the Defendants to Furnish a Privilege Log Concerning Matter Withheld from the Administrative Record Based on Privilege," ("Tafas Mem."), Dkt. No. 73, and "GlaxoSmithKline's Memorandum in Support of Its Motion for Entry of an Order Requiring Defendants to Submit a Privilege Log," ("GSK

Mem."), Dkt. No. 72.[1]

Plaintiffs Triantafyllos Tafas ("Tafas") and GlaxoSmithKline ("GSK") are not entitled to a privilege log identifying the many hundreds, if not thousands, of deliberative documents that the USPTO has properly excluded from the administrative record because such documents do not belong in the administrative record in the first place. This Court should not impose on the USPTO the extraordinary burden of developing such a log absent binding authority requiring the agency to do so.

ARGUMENT

I. THE ORDINARY RULES OF DISCOVERY DO NOT APPLY IN APA CASES.

As this Court is aware, cases that arise under the Administrative Procedures Act ("APA"), 5 U.S.C. §§ 701-706, are not susceptible to the discovery rules that apply in most other civil cases. Most importantly, discovery is the exception, not the rule, in APA cases. See, e.g., Fort Sumter Tours v. Babbitt, 66 F.3d 1324, 1336 (4th Cir. 1995) (citing, inter alia, Camp v. Pitts, 411 U.S. 138, 142 (1973)). Courts generally review APA cases on the administrative record, without discovery. Id.

Tafas and GSK thus err in suggesting that Federal Rule of Civil Procedure 26(b)(5), which governs privilege logs, applies equally to APA cases as to other civil cases. It does not. Rule 26(b)(5) states that it applies "[w]hen a party withholds information **otherwise discoverable** under these rules **by claiming that it is privileged**." Fed. R. Civ. P. 26(b)(5)

[1] The USPTO objects to GSK filing a reply brief in support of its so-called "Motion for Entry of an Order Requiring Defendants to Submit a Privilege Log." Dkt. No. 70. This Court made clear that Plaintiffs' briefs on the privilege log issue were due by close of business on Monday, November 19, and Defendants' response was due by close of business on Tuesday, November 20. Ex. 1, p. 46. The Court authorized no further briefing on this matter.

(emphases added). The rule is thus inapplicable to APA cases for two reasons. First, the documents that the USPTO has excluded from the administrative record are not "otherwise discoverable" under Rule 26(b)(5) because, as noted above, discovery generally is not allowed in APA cases. As the USPTO explained at the November 26, 2007 hearing and will further explain in forthcoming memoranda, Plaintiffs have not established that any of the exceptions to the general rule prohibiting discovery apply.

Second, the USPTO has not withheld documents only because they are subject to the deliberative process privilege, though the withheld documents are subject to that privilege, among others, and their disclosure would represent an "extraordinary intrusion" into the workings of an executive agency. San Luis Obispo Mothers for Peace v. Nuclear Regulatory Comm'n, 789 F.2d 26, 44-45 (D.C. Cir. 1986) (en banc) (explaining that the deliberative process privilege aims to ensure that agencies can engage in "uninhibited and frank" discussions); see also National Labor Relations Bd. v. Sears, Roebuck & Co., 421 U.S. 132, 151 (1975) ("Manifestly, the ultimate purpose of this long-recognized privilege is to prevent injury to the quality of agency decisions."). As explained below, the USPTO also has not included deliberative documents in the administrative record because "they do not belong in the administrative record in the first place." Blue Ocean Inst. v. Gutierrez, 503 F. Supp. 2d 366, 372 n.4 (D.D.C. 2007).

Federal Rule 26(b)(5), like other Federal Rules of Civil Procedure, thus has no application in APA cases.[2] See, e.g., Fed. R. Civ. P. 26(a)(1)(E)(i) (exempting "action[s] for

[2] GSK's assertion that courts have "routinely" required privilege logs in APA cases on Rule 26(b)(5) grounds is hyperbole. GSK Mem. at 2. For this bold proposition, GSK cites a *single* APA case in which a district court directly relied on Rule 26(b)(5) to require a privilege log, Miami Nation of Indians v. Babbitt, 979 F. Supp. 771, 778-79 (N.D. Ind. 1996), and one

review of an administrative record" from the requirement of providing initial disclosures). It should not be surprising, then, that the only case GSK cites for the proposition that "providing a privilege log 'has become, by now, the universally accepted means of asserting privileges in discovery in the federal courts'" is not even an APA case. See GSK Mem. at 2 (quoting Avery Dennison Corp. v. Four Pillars, 190 F.R.D. 1, 1 (D.C. 1999)). Providing a privilege log in APA cases simply is not "standard operating procedure," as Tafas asserts without citation to any legal authority.[3] Tafas Mem. at 5 n. 3.

II. THE USPTO IS NOT REQUIRED TO PRODUCE A PRIVILEGE LOG BECAUSE DELIBERATIVE DOCUMENTS ARE NOT PART OF THE ADMINISTRATIVE RECORD.

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); see also Madison County Bldg. & Loan Ass'n v. Federal Home Loan Bank Bd., 622 F.2d 393, 13 n.3 (8th Cir. 1980) ("Although these [deliberative] documents may have been used by an agency in reaching a decision, they may be excluded from the record because of concerns over proper agency functioning."); Amfac Resorts,

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other district court case citing the first case, People v. U.S. Dept. of Agric., 2006 WL 708914, at *4 (N.D. Cal. 2006). Neither court appears to have considered the arguments above that the plain language of Rule 26(b)(5) renders it inapplicable in APA cases. Moreover, Miami Nation is distinguishable, as the agency in that case included in its record extensive deliberative materials and thus could not explain why some deliberative material was properly included while other such material was not. 979 F. Supp. at 771. The USPTO also respectfully submits that the district courts in these cases committed legal error in requiring the production of materials that simply do not belong in an administrative record.

[3] The Court may find it useful to know, anecdotally, that despite the large number of APA cases handled by the U.S. Attorney's Office each year, none of the undersigned's colleagues in the Alexandria Division has reported submitting a privilege log for an administrative record, either voluntarily or because it was required to do so by the Court.

L.L.C. v. U.S. Dept. of the Interior, 143 F. Supp. 2d 7, 13 ("[D]eliberative inter-agency memoranda and other such records . . . need not be included in the record.").

Deliberative materials do not form part of the administrative record in APA cases because they are irrelevant to the Court's review. See In re Subpoena Duces Tecum Served on the Office of the Comptroller of the Currency, 156 F.3d 1279, 1279 (D.C. Cir. 1998) ("Agency deliberations not part of the record are deemed immaterial."). This is because when a party challenges an agency action as arbitrary or capricious, the reasonableness of the agency's action is judged in accordance with its "stated reasons." Id.; 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"); see Ad Hoc Metals Coal. v. Whitman, 227 F. Supp. 2d 134, 142-43 (D.D.C. 2002) (refusing to include internal agency e-mails in the administrative record because "[j]udicial 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"). "[T]he actual subjective motivation of agency decisionmakers is irrelevant as a matter of law – unless there is a finding of bad faith or improper behavior."[4] In re Subpoena Duces Tecum, 156 F.3d at 1279-80. If the agency decision cannot stand on the reasons articulated in the record it designates, the proper remedy is to remand the case to the agency. See Florida Power & Light Co. v. Lorion, 470 U.S. 729, 743-44 (1985).

Recognizing that deliberative documents do not form part of the administrative record in

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[4] Although Tafas has made various allegations of bad faith in his "Memorandum in Opposition to Defendants' Motion for Issuance of [Proposed] Briefing Schedule in Lieu of a Standard Scheduling Order," Dkt. No. 66, none of those allegations come remotely close to the "strong showing" of bad faith that is required. See Amfac, 143 F. Supp. 2d at 12. As this Court authorized at the November 16, 2007 hearing, the USPTO will further rebut those bad faith allegations in a forthcoming memorandum.

APA cases, the court in Blue Ocean Institute v. Gutierrez, 503 F. Supp. 2d 366, 372 n.4 (D.D.C. 2007), declined to require the Government to produce a privilege log. In doing so, the court observed that "it is unfair to criticize [the government agency] for not claiming a privilege and filing a privilege log as to documents that it claims should not be in the administrative record in the first place." [5] Id.

This Court, too, should deny Plaintiffs' request for a privilege log because deliberative documents simply do not belong in the administrative record. The Final Rules must "stand or fall" on the reasons stated in the USPTO's 127-page Federal Register notice and evident in its nearly 10,000 page record, and Plaintiffs may not contend that some other reason – culled from carefully-selected excerpts of drafts, e-mails, and memoranda among agency staff members in the course of their deliberations – somehow is the agency's "real" rationale. Cf. Vermont Yankee, 435 U.S. at 549.

III. REQUIRING THE USPTO TO COMPILE A PRIVILEGE LOG IS EXTRAORDINARILY BURDENSOME AND SHOULD NOT BE REQUIRED ABSENT COMPELLING AUTHORITY.

The court in Blue Ocean Institute also rejected the plaintiff's demand for privileged documents and a privilege log because of the extraordinary burden it would impose on the Government agency. The court's reasoning merits extended quotation:

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[5] Contrary to GSK's assertion, the holding of Blue Ocean Institute was not limited to deciding "whether the agency should describe with particularity the documents and redacted material it has chosen to withhold." GSK Mem. at 4 n.2. The court also refused to grant the plaintiff's request for a privilege log of withheld deliberative documents. See Blue Ocean Institute, 503 F. Supp. 2d at 372 n. 4; see also Ex. 2, p. 11 (excerpt from Blue Ocean Institute's memorandum showing request for a privilege log).

> [I]t must be recalled that production of the materials Blue Ocean seeks would transform the process of judicial review of administrative decisions greatly even if limited to specific instances of claimed deficiencies in the administrative record. The agency would have to collect all internal communications among agency officials pertaining to the claimed deficiency, catalogue them, and claim the deliberative process privilege where appropriate, which may be as to all of them. The privilege question would have to be resolved before judicial review of the administrative decision could even begin. **Creating such a new burden on the agency, the parties and the court by forcing production of even a limited number of interagency deliberative documents requires a clear command from the court of appeals, particularly in light of the unequivocal statement by that court that such materials are not part of the administrative record when an agency decision is challenged as arbitrary and capricious**.

503 F. Supp. 2d at 372 (footnote omitted).

The D.C. District Court's reasoning applies with equal force to this case. The USPTO has already produced a nearly 10,000 page administrative record that Plaintiffs have been unable to show is incomplete or otherwise deficient. To require the USPTO to now "collect all internal communications among agency officials" regarding a rules package that took more than two years to complete would impose an extraordinary burden on the agency – one that would require between twenty and thirty agency employees to devote countless hours to reviewing and indexing thousands of pages of e-mails, drafts, memoranda, and other types of communications. Id.; see Declaration of Jennifer M. McDowell, Ex. 3, ¶¶ 7-9.

This Court, too, should find that "[c]reating such a new burden on the agency . . . requires a clear command from the court of appeals." Id. Plaintiffs have identified nothing close to a clear command from any Court of Appeals, much less the Federal or Fourth Circuits. As the district court found in Blue Ocean Institute, the only clear pronouncement is the D.C. Circuit's "unequivocal statement . . . that such materials are not a part of the administrative record when

an agency decision is challenged as arbitrary and capricious." Id.

Plaintiffs merely cite distinguishable district court cases. Some of Plaintiffs' cases shed no light on the issue because the agencies in those cases *voluntarily* produced privilege logs – probably because, unlike in this case, the logs contained only a small number of privileged documents. See, e.g., Trout Unlimited v. Lohn, 2006 WL 1207901, at *1 (W.D. Wash. 2006) (noting that the agency's privilege log identified "twenty-two [documents] as protected by the deliberative process privilege"); Center for Biological Diversity v. Norton, 336 F. Supp. 2d 1149, 1157-63 (D.N.M. 2004) (referencing a privilege log that identified "tweny-eight documents withheld from the administrative record on grounds of deliberative process privilege"). Others are not APA cases, and thus are equally unhelpful. E.g., General Elec. Co. v. Johnson, 2007 WL 433095, at *1 (D.D.C. 2007) (CERCLA case); Spiller v. Walker, 2002 WL 1609722, at *3 (W.D. Tex. 2002) (NEPA case); Elkem Metals Co. v. United States, 24 C.I.T. 1395, 1398 (C.I.T. 2000) (international trade case); United States v. Farley, 11 F.3d 1385, 1388-91 (7th Cir. 1993) (Hart-Scott-Rodino Act case).

In sum, while the burden on the USPTO to create a privilege log would be tremendous, Plaintiffs have produced no binding authority, and scant persuasive authority, justifying their demand. In the absence of compelling authority requiring a privilege log in an APA rulemaking case such as this one, the Court should not be the first in this Circuit to order one.

IV. GSK IGNORES THAT THE ADMINISTRATIVE RECORD IS ENTITLED TO A PRESUMPTION OF REGULARITY ABSENT CLEAR EVIDENCE TO THE CONTRARY.

GSK also suggests that the USPTO must be required to produce a privilege log because "[t]he government is not infallible; its lawyers are human too, and they can and do make

mistakes." GSK Mem. at 6. GSK overlooks that "the designation of the Administrative Record, like any established administrative procedure, is entitled to a presumption of administrative regularity." Bar MK Ranches v. Yuetter, 994 F.2d 735, 740 (10th Cir. 1993). Accordingly, "[t]he court assumes the agency properly designated the Administrative Record absent clear evidence to the contrary."[6] Id.; see also Blue Ocean Institute, 503 F. Supp. 2d at 369 ("[T]he agency enjoys a presumption that it properly designated the administrative record and may exclude materials that reflect internal deliberations.").

Neither GSK nor Tafas has presented "clear evidence" that the USPTO has improperly designated the administrative record. To the contrary, the two documents attached to GSK's brief as Exhibits B and C only confirm how careful the USPTO was in its designation of the administrative record. For example, GSK's Exhibit B represents issue papers on various topics related to the Final Rules that were compiled and given to Under-Secretary of Commerce Jon Dudas. See McDowell Decl., Ex. 3, ¶¶ 10-11. Rather than withholding the entire document, the USPTO assiduously redacted only those portions that were deliberative in nature because they provided subjective advice and recommendations to the Under-Secretary. Id.; Sears, Roebuck & Co., 421 U.S. at 150 (explaining that the deliberative process privilege "focus[es] on documents reflecting advisory opinions, recommendations, and deliberations comprising part of a process by which governmental decisions and policies are formulated.") (internal quotation marks omitted).

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[6] Because Plaintiffs have the burden to come forward with evidence that the administrative record is improperly designated, their attempt to analogize a privilege log in this APA litigation to a "Vaughn index" in FOIA litigation is inapt. As the D.C. Circuit has explained, the Vaughn index requirement "is a rule the circuit imposed because FOIA itself places the burden on the agency to sustain the lawfulness of specific withholdings in litigation." Natural Res. Defense Council v. Nuclear Regulatory Comm'n, 216 F.3d 1180, 1190 (D.C. Cir. 2000). Here, by contrast, the burden is directly reversed, and the Plaintiffs' reliance on FOIA cases is thus misplaced. See Tafas Mem. at 3; GSK Mem. at 7.

The USPTO appropriately included in the administrative record all objective data that the Under-Secretary considered in deciding on the Final Rules. See GSK Mem., Ex. B.

Similarly, GSK's Exhibit C reflects that the USPTO included all communications from external sources, even when those communications were critical of the Proposed Rules. The redacted portion of the exhibit merely contains internal "forwarding" e-mails that are transmittal in nature and thus do not fall within the scope of an administrative record. See McDowell Decl., Ex. 3, ¶¶ 12-13; Amfac, 143 F. Supp. 2d at 12 (defining administrative record to include non-privileged materials that "might have influenced the agency's decision").

Thus, far from rebutting the presumption of regularity that attaches to the designation of the administrative record, Exhibits B and C demonstrate the validity of that presumption in this case.[7] The Court should not excuse Plaintiffs' failure to provide the "clear evidence" required before ordering any supplementation of the administrative record, even in the form of a privilege log.

V. GSK'S DESIRE TO ACCELERATE THE FOIA PROCESS IS AN IMPROPER REASON TO REQUIRE A PRIVILEGE LOG.

GSK further errs in arguing that the USPTO should be compelled to create a privilege log because it may eventually be required to produce the identical information in a Vaughn index in the event that it "withholds documents otherwise responsive to GSK's FOIA request." GSK Mem. at 6. GSK's invocation of a Vaughn index in connection with its pending FOIA requests is exceedingly premature, and moreover, is irrelevant to this litigation.

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[7] To the extent that the Court nevertheless has concerns about the USPTO's designation of the administrative record, the USPTO respectfully suggests that the Court should review in camera unredacted versions of selected redacted pages of the administrative record before requiring the USPTO to engage in the extraordinarily burdensome process of creating a privilege log.

The obligation to prepare and produce a Vaughn index – a narrative description of, among other things, documents withheld under one or more of the FOIA's recognized exemptions, see Vaughn v. Rosen, 484 F.2d 820 (D.C. Cir. 1973) – arises only in the context of FOIA litigation and not in connection with a mere FOIA request to an agency. See Natural Res. Def. Council, 216 F.3d at 1190 (explaining that FOIA's Vaughn index requirement "governs litigation in court and not proceedings before the agency"); Schwarz v. U.S. Dept. of Treasury, 131 F. Supp. 2d 142, 147 (D.D.C. 2000) ("[T]here is no requirement that an agency provide . . . a Vaughn index on an initial request for documents. The requirement for detailed declarations and Vaughn indices is imposed in connection with a motion for summary judgment filed by a defendant in a civil action pending in court."). Here, GSK's two FOIA requests are still pending before the USPTO and are not even close to ripening into a matter subject to judicial review. Indeed, GSK submitted its FOIA requests on November 8th and 9th, 2007, merely twelve and eleven days ago, respectively.

The FOIA provides federal agencies with twenty working days from the receipt of the request to decide whether to comply with the request, and to advise the requester of the decision and the agency's supporting reasons for the determination. 5 U.S.C. § 552(a)(6)(A)(i). The twenty-day time limitation may be extended by an additional ten working days if the agency determines that "unusual circumstances" exist. 5 U.S.C. § 552(a)(6)(B). Should the agency decline to comply with the request, the FOIA imposes upon the requester an administrative appeal process before filing a civil action under the FOIA. 5 U.S.C. § 552(a)(6)(A)(ii). The administrative appeal process permits an agency to make a determination regarding an appeal within twenty days following the receipt of the appeal. Id. Once the agency provides the

required information concerning the requester's appeal rights, the requester must comply within the time limits or lose the ability to file suit until the administrative process has been completed. "Courts have consistently confirmed that the FOIA requires exhaustion of this appeal process before an individual may seek relief in the courts." Ogelsby v. U.S. Dep't of Army, 920 F.2d 57, 61-62 (D.C. Cir. 1990); see also, Hamilton v. Dept. of Housing and Urban Development,106 F. Supp. 2d 23 (D.D.C. 2000). Thus it is only after this appeals process may a requester file suit in federal court.

Once the requester files a civil action under the FOIA in federal court, the United States need not respond until thirty days from proper service. 5 U.S.C. § 552(a)(4)(C). Depending upon the allegations in the complaint, this initial response may take the form of an answer, a motion to dismiss, a motion for summary judgment, a motion for an enlargement of time, or a combination of several of these and other possible responses. Generally, if an agency provides a Vaughn index, it will do so in connection with the agency's motion for summary judgment. See Schwarz, 131 F. Supp. 2d at 147.

The administrative process associated with GSK's FOIA request has just begun. The USPTO could not be required to produce a Vaughn index until GSK completely exhausted its administrative remedies and then filed a civil action under FOIA. Even then, the USPTO would likely not submit a Vaughn index until it was prepared to file a motion for summary judgment. In the end, GSK's motion to compel a privilege log simply because the USPTO may, sometime down the road, submit a Vaughn index supporting a motion for summary judgment in a yet-to-be filed FOIA suit lacks any support in the law and is far too speculative to justify a privilege log.[8]

[8] GSK mischaracterizes the scope of its second FOIA request when it suggests that "the PTO will go through the same basic steps in creating its *Vaughn* Index as it will in creating a

Furthermore, GSK's pending FOIA requests are irrelevant to the question of whether the USPTO is required to submit a privilege log in this case. As this Court knows, a FOIA request – and the parties' concomitant rights and obligations in response to that request – is part of a comprehensive administrative process wholly independent of any parallel federal civil or criminal action. See, e.g. Sears, Roebuck & Co., 421 U.S. at 143 n.10 (holding that the right of a plaintiff who brings an action under the FOIA to compel production of agency documents is neither increased nor decreased by the fact that he is a litigant in a pending suit). It is well-settled that FOIA is not a substitute for, or a means of, supplementing discovery procedures available to litigants in federal proceedings. United States Dep't of Justice v. Landano, 508 U.S. 165 (1993); John Doe Agency v. John Doe Corp., 493 U.S. 146, 153 (1989) ("[T]he FOIA was not intended to supplement or displace rules of discovery."); Miller v. Bell, 661 F.2d 623 (7th Cir. 1981) ("It is not purpose of FOIA litigation to benefit private litigants by serving as adjunct or supplement to discovery provisions of Federal Rules of Civil Procedure."); Nix v. United States, 572 F.2d 998, 1002 (4th Cir. 1978) (same); Deering Milliken, Inc. v. Irving, 548 F.2d 1131, 1135 (4th Cir. 1977).

For these reasons, whether GSK is attempting to circumvent the prohibition against discovery in APA actions by resort to the FOIA process, or simply seeking to extend the life of the preliminary injunction in this case by further delaying presentation of the merits to this Court, its FOIA requests have absolutely no bearing on Plaintiffs' unsubstantiated request for a privilege log.

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privilege log." GSK Mem. at 7. GSK's second FOIA requests asks for thousands of documents that would not fall within the scope of a privilege log in this litigation. See, e.g., Ex. 4, request #16 (requesting documents related to "any potential or future rulemakings, or any other initiatives, related to the PTO Rules").

CONCLUSION

In sum, Plaintiffs are not entitled to a privilege log in this case because deliberative documents do not belong in an administrative record, and there is no compelling authority requiring the USPTO to engage in the extraordinarily burdensome process of compiling a privilege log in this APA case.

Respectfully submitted,

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