

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

**TRIANAFYLLOS TAFAS,**

**Plaintiff,**

v.

**JON W. DUDAS, in his official capacity as Under-Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, and the UNITED STATES PATENT AND TRADEMARK OFFICE,**

**Defendants.**

**CIVIL ACTION: 1:07cv846 (JCC/TRJ)  
and Consolidated Case (below)**

**SMITHKLINE BEECHAM CORPORATION,**

**Plaintiff,**

v.

**JON DUDAS, in his official capacity as Under-Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, and the UNITED STATES PATENT AND TRADEMARK OFFICE,**

**Defendants.**

**CIVIL ACTION: 1:07cv1008 (JCC/TRJ)**

**PLAINTIFF TRIANAFYLLOS TAFAS' SUPPLEMENTAL  
MEMORANDUM ADDRESSING NEED FOR THE DEFENDANTS TO  
FURNISH A PRIVILEGE LOG CONCERNING MATTER WITHHELD  
FROM THE ADMINISTRATIVE RECORD BASED ON PRIVILEGE**

**PRELIMINARY STATEMENT**

As requested by the Court (*per* the Hon. Judge Thomas Rawles Jones, Jr.), the Plaintiff, Dr. Triantafyllos Tafas ("Plaintiff" or "Tafas"), through his counsel, Kelley Drye & Warren LLP, submits this supplemental memorandum identifying legal authority for Tafas' assertion that the Defendants should be required to provide a privilege log to Plaintiffs identifying any documents or information withheld from the administrative record based on

privilege (including, without limitation, attorney-client, attorney-work product and the so called “deliberative process” privileges).

ARGUMENT

**DEFENDANTS ARE NOT PERMITTED TO SIMPLY WITHHOLD  
INFORMATION OR DOCUMENTS FROM THE ADMINISTRATIVE  
RECORD BASED ON PRIVILEGE WITHOUT PROVIDING A  
LOG SUBSTANTIATING THE CLAIMS OF PRIVILEGE**

There is no merit to Defendants’ unusual assertion that they may withhold allegedly “privileged” documents or information from the administrative record that may have been “directly or indirectly” relied upon by agency decision-makers in formulating the rules at issue in this case without providing a privilege log or otherwise substantiating each and every claim of privilege. As is discussed briefly below, the mere fact that this case involves judicial review of agency rules under the APA does not obviate the general rule that privileges are to be narrowly construed and that all claims of privilege must be substantiated by the proponent of the privilege in a manner that provides the opposing party a reasonably opportunity to probe and challenge the assertion of privilege.

First, as a rule of general applicability, Rule 26(b)(5)(A) of the Federal Rules of Civil Procedure mandates that a party in any federal court proceeding subject to the Federal Rules of Civil Procedure is required to produce a privilege log or its functional equivalent:

When a party withholds information otherwise discoverable under these rules by claiming that it is privileged or subject to protection as trial-preparation material, the party shall make the claim expressly and shall describe the nature of the documents, communications, or things not produced or disclosed in a manner that, without revealing information itself privileged or protected, will enable other parties to assess the applicability of the privilege or protection.

Fed. Rules Civ P. 26(b)(5)(A)(Emphasis Added). Plaintiff is aware of no exception to this

general rule for APA cases.

Second, it is well established that government agencies need to substantiate any claims of privilege in response to Freedom of Information Act (FOIA) requests made pursuant to 5 U.S.C. § 552 even when the initial FOIA requests are made in a non-judicial setting. In this regard, when objections based on privilege have subsequently been judicially challenged, courts have routinely required the agency to substantiate its privilege claims through a combination of producing privilege logs or affidavits and/or through the court utilizing *in camera* review of allegedly privileged materials. E.g. Nevada v. Doe, 2007 WL 2821442 at \*6-7 (D.Nev. 2007); Ethyl Corp. v. U.S. Env't'l Protection Agency, 25 F.3d 1241, 1244 (4<sup>th</sup> Cir. 1994). The same should hold equally or more true in the present context. If agencies commonly provide privilege logs or affidavits or submit documents for *in camera* review even in the context of simple FOIA requests, certainly the same should hold true in a judicial proceeding where the completeness and integrity of the administrative record is of paramount importance in terms of enabling the court to conduct its statutory duty of judicial review.

Third, courts hearing APA challenges to agency rule-making and/or other agency action have routinely required the production of privilege logs and reviewed documents *in camera* in connection with disputes as to whether documents allegedly subject to the so called *deliberative process privilege*<sup>1</sup> were properly excluded from the administrative record the agency

---

<sup>1</sup> To fall within the deliberative process privilege, the materials must be pre-decisional and must also form part of the agency's deliberative process. Center for Biological Diversity v. Norton, 336 F.Supp.2d 1149, 1153 (D.N.M. 2004); Modesto Irrigation District v. Gutierrez, 2007 WL 763370 (E.D. Cal. 2007). To be pre-decisional, the materials must have been generated before the adoption of a policy or decision. North Pacifica v. City of Pacifica, 274 F.Supp.2d 1118, 1121 (N.D. Cal. 2003) (citations omitted). The documents claimed as privileged must be ones that were prepared to "assist an agency decision-maker in arriving at his decision ... and may include recommendations, draft documents, proposals, [and] suggestions ..." Center for Biological Diversity, 336 F.Supp.2d at 1153. However, the materials that can be claimed as

provided to litigants in APA cases. E.g., Center for Biological Diversity v. Norton, 336 F.Supp.2d 1149, 1157-1163 (D.N.M. 2004)(the government has the burden of establishing all the elements of the deliberative process privilege and, to fulfill this burden, agencies typically submit declarations or affidavits explaining in detail why the privilege applies); Elkem Metals, 24 C.I.T., 1395, 1398 (C.I.T. 2000)(same); Greenpeace v. National Marine Fisheries Serv., 2000 WL 151915 (W.D.Wash. Feb 02, 2000)(it is important for the attorney-client privilege or deliberative process privilege to be substantiated by agency in judicial challenge to administrative action so the privilege is not used as shield for potentially improper agency conduct); Trout Unlimited v. Lohn, 2006 WL 1207901 at \*5 (W.D. Wash. 2006)(requiring production of privilege log and *in camera* review)<sup>2</sup>; Eugene Burger Mgmt. Corp. v. U.S. Dept. of Housing and Urban Development, 192 F.R.D. 1 (D.D.C. Jul 12, 1999)(agency required to produce privilege log and court utilized *in camera* review concerning whether material was

---

privileged are not limited to written documents. The second requirement to falling within this privilege is that the materials must form part of the agency's deliberative process. This means that the materials relate to the agency's decision-making and their disclosure to the public would expose the agency's decision-making process in a way that would discourage candid discussion within the agency and undermine the agency's ability to perform its functions. Center for Biological Diversity, 336 F.Supp.2d at 1153. Even if the government successfully asserts this privilege and the court deems the privilege to apply, the other party can overcome it if its need for the privileged materials and the need for accurate fact-finding overrides the government's interest in non-disclosure. Id. at 1153. In making this ultimate determination, the court considers various factors, and among those is whether there was improper behavior by the agency. Modesto Irrigation, 2007 WL 763370 at \*11.

<sup>2</sup> In Trout Unlimited, the plaintiffs brought an action challenging the National Marine Fisheries Service's ("NMFS") promulgation of its "Hatchery Listing Policy," which was to be codified at 50 C.F.R. pts. 223 and 224. Trout Unlimited, 2006 WL 1207901 at \*1. The defendants submitted a privilege log identifying and describing the documents they were withholding from the record based on a claim of deliberative process privilege. Id. at \*5. There was no question in Trout Unlimited about whether or not the defendants should or would be submitting a privilege log to substantiate its claim of deliberative process privilege. Id. at \*5. The parties treated the submission of a privilege log in that context as par for the course. The defendants did not argue that because they were in the APA rule-making context, they should be exempt from the general requirement under FRCP 26(b)(5)(A) of having to submit a privilege log to substantiate its privilege claims. Id. at \*5.

appropriately redacted from administrative record based on attorney-client and deliberative process privileges<sup>3</sup>; U.S. v. Farley, 11 F.3d 1385, 1388-1391 (7th Cir.(Ill.) 1993)(approving of district court’s use of privilege log and *in camera* review to determine challenges to agency’s assertion of attorney-client and deliberative process privilege).

In People of State of Cal. ex rel. Lockyer v. U.S. Dept. of Agriculture, 2006 WL 708914 (N.D.Cal. Mar 16, 2006)(“Lockyer”), the Lockyer Court stressed the importance of a governmental agency producing a privilege log to substantiate its claims of privilege in the face of a contention that that administrative record was incomplete:

Plaintiffs have also shown that the record is incomplete because it lacks internal and external agency documents relating to the decision-making process for the State Petitions Rule. Specifically, Plaintiffs believe that the Forest Service is withholding correspondence between and among the parties involved, e-mail messages, agency meeting notices, draft analyses, assessments of alternatives and discussions of the impacts of scientific uncertainties on the selection of each alternative.

\* \* \* \*

[E]ven under the correct standard, some agency documents, such as purely internal deliberative materials, may be protected from inclusion in the administrative record, **but Defendants must make a specific showing establishing the application of a privilege for each document that it contends that it may withhold based on privilege.** Arizona Rehabilitation Hospital, Inc. v. Shalala, 185 F.R.D. 263, 267 (D.Ariz.1998) (recognizing the deliberative process privilege: “This privilege protects the consultative functions of government by maintaining the confidentiality of

---

<sup>3</sup> Likewise, in Eugene Burger Mgmt., the Department of Housing and Urban Development (HUD)’s submission of a privilege log was treated as routine practice. Eugene Burger Management Corporation, 192 F.R.D. at \*4. In fact, the court had ordered the HUD in an earlier motions hearing to submit the withheld materials for *in camera* review, even though there was a privilege log to work with. Id. at \*4. In any case, the point is that submission of a privilege log, even in the APA context of judicial review of agency action, is standard operating procedure. Here, the USPTO has withheld information from the record on the basis of a deliberative process privilege claim, but have failed to substantiate that claim with a privilege log. The Federal Rules of Civil Procedure mandate that a privilege log must be submitted, and case law shows that being in the APA rulemaking context does not change that requirement.

advisory opinions, recommendations and deliberations comprising part of a process by which governmental decisions and policies are formulated.”); see also Amfac Resorts, L.L.C. v. Department of Interior, 143 F.Supp.2d 7, 12 (D.D.C.2001) ( “However, deliberative intra-agency memoranda and other such records are ordinarily privileged, and need not be included in the record.”); Miami Nation, 979 F.Supp. at 778-79 (requiring agency to make a specific showing, “in the spirit of *Fed.R.Civ.P.* 26(b)(5) [requiring a **privilege log**],” for the materials that it sought to protect with the **deliberative process** privilege); cf. FTC v. Warner Communications, Inc., 742 F.2d 1156, 1161 (9th Cir.1984) ( “Purely factual material that does not reflect **deliberative processes** is not protected.”).

Lockyer, 2006 WL 708914 at pp. 3-4 (Emphasis Added).

### CONCLUSION

For all the foregoing reasons, Defendants should be required to provide Plaintiffs with a detailed privilege log to substantiate each and every deletion from the administrative record predicated on privilege (regardless of the nature of the privilege asserted).

Dated: November 19, 2007

Respectfully submitted,

/s/ Joseph D. Wilson  
Joseph D. Wilson (VSB # 43693)  
Steven J. Moore, Esq. (*pro hac vice*)  
James E. Nealon, Esq. (*pro hac vice*)  
KELLEY DRYE & WARREN LLP  
Washington Harbor, Suite 400  
3050 K Street, NW  
Washington, DC 20007  
Telephone: (202) 342-8400  
Facsimile: (202) 342-8451  
E-mail: [jwilson@kelleydrye.com](mailto:jwilson@kelleydrye.com)  
[smoore@kelleydrye.com](mailto:smoore@kelleydrye.com)  
[jnealon@kelleydrye.com](mailto:jnealon@kelleydrye.com)

*Counsel for Plaintiff Triantafyllos Tafas*

**CERTIFICATE OF SERVICE**

I hereby certify that on November 19, 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:

Elizabeth Marie Locke  
Kirkland & Ellis LLP  
655 15<sup>th</sup> Street, NW  
Suite 1200  
Washington, DC 20005  
Email: [elocke@kirkland.com](mailto:elocke@kirkland.com)

Craig Crandell Reilly  
Richard McGettingan Reilly & West PC  
1725 Duke Street  
Suite 600  
Alexandria, VA 22314  
Email: [craig.reilly@rmrwlaw.com](mailto:craig.reilly@rmrwlaw.com)

Daniel Sean Trainor  
Kirkland & Ellis LLP  
655 15<sup>th</sup> Street, NW  
Suite 1200  
Washington, DC 20005  
Email: [dtrainor@kirkland.com](mailto: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 Avenue, NW  
Washington, DC 20004  
Email: [to'brien@morganlewis.com](mailto:to'brien@morganlewis.com)

*Counsel for Putative Amicus American Intellectual  
Property Lawyers Association*

Dawn-Marie Bey  
Kilpatrick Stockton LLP  
700 13<sup>th</sup> Street NW  
Suite 800  
Washington, DC 20005  
Email: [dbey@kslaw.com](mailto:dbey@kslaw.com)

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

James Murphy Dowd  
Wilmer Cutler Pickering Hale & Dorr LLP  
1455 Pennsylvania Avenue NW  
Washington, DC 20004  
Email: [james.dowd@wilmerhale.com](mailto: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](mailto: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](mailto:Rebecca.carr@pillsburylaw.com)

Scott J. Pivnick  
Pillsbury Winthrop Shaw Pittman  
1650 Tysons Boulevard  
McLean, Virginia 22102-4856  
[Scott.pivnick@pillsburylaw.com](mailto:Scott.pivnick@pillsburylaw.com)

*Counsel for Putative Amicus Elan  
Pharmaceuticals, Inc.*

Lauren A. Wetzler  
Assistant United States Attorney  
Justin W. Williams U.S. Attorney's Building  
2100 Jamieson Avenue  
Alexandria, Virginia 22134  
Tel: (703) 299-3752  
Fax: (703) 299-3983  
[Lauren.Wetzler@usdoj.gov](mailto:Lauren.Wetzler@usdoj.gov)

*Counsel for All Defendants*

/s/ Joseph D. Wilson

Joseph D. Wilson (VSB # 43693)

KELLEY DRYE & WARREN LLP

Washington Harbor, Suite 400

3050 K Street, NW

Washington, DC 20007

Telephone: (202) 342-8400

Facsimile: (202) 342-8451

E-mail: [jwilson@kelleydrye.com](mailto:jwilson@kelleydrye.com)

*Counsel for Plaintiff Triantafyllos Tafas*