

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

SMITHKLINE BEECHAM )  
CORPORATION, )  
d/b/a GLAXOSMITHKLINE, )  
SMITHKLINE BEECHAM PLC, and )  
GLAXO GROUP LIMITED, )  
d/b/a/ GLAXOSMITHKLINE, )  
 )  
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 No. 1:07cv1008 (JCC/TRJ)  
[Consolidated with No. 1:07cv846]

**REPLY MEMORANDUM IN SUPPORT OF DEFENDANTS’ MOTION TO STRIKE  
EXHIBIT E OF THE MEMORANDUM IN SUPPORT OF PLAINTIFF’S MOTION FOR  
A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION**

Defendants Jon W. Dudas and the United States Patent and Trademark Office (collectively the “USPTO”), respectfully submit this reply memorandum in support of their motion to strike Exhibit E (Dkt. No. 16) of the Memorandum in Support of Plaintiffs’ Motion for a Temporary Restraining Order and Preliminary Injunction (“Plaintiffs’ Memorandum”) filed by Plaintiffs SmithKline Beecham Corp., d/b/a GlaxoSmithKline, SmithKline Beecham PLC, and Glaxo Group Limited, d/b/a GlaxoSmithKline (collectively “Plaintiffs”). Exhibit E is the declaration of Harry F. Manbeck, Jr.

## INTRODUCTION

Perhaps recognizing the impropriety of proffering expert opinion testimony on the ultimate legal questions in this case, Plaintiffs have resorted to asserting the ipse dixit justification that Manbeck's testimony merely provides "context" and "background information" to assist the court. Even the most cursory review of the Manbeck declaration – with its extensive legal citations, legal arguments, and ultimate legal conclusion that the USPTO's Final Rules are legally deficient – reveals that the testimony contained therein does not simply provide "context" or "background," but overwhelmingly constitutes a multifaceted legal attack on the legitimacy of the Final Rules. As the USPTO demonstrated in its opening memorandum, such expert testimony is entirely improper because it: (1) usurps the role of the Court to resolve the ultimate legal questions presented in this case; (2) supplements the administrative record in a manner that does not fall within the three narrow circumstances when such supplementation is permissible; and (3) blatantly circumvents the page limitations to opening legal memoranda imposed by Local Civil Rule 7(F)(3).

Plaintiffs' opposition memorandum, which includes citation to inapposite legal authority, irrelevant references to the USPTO's use of the Karen Young declaration, and bald assertions that the Manbeck declaration provides mere "context" and "background" are simply not bases upon which this Court may admit and rely on Manbeck's testimony. For the reasons set forth in the USPTO's opening memorandum and those contained herein, this Court should strike the Harry F. Manbeck Jr. declaration.

## ARGUMENT

### **I. THE MANBECK DECLARATION IMPROPERLY OPINES ON THE ULTIMATE LEGAL QUESTIONS PENDING BEFORE THIS COURT.**

In its opening memorandum, the USPTO relied on the unassailable proposition that Rule 702 of the Federal Rules of Evidence limits the use of expert testimony to circumstances in which the expert “will assist the trier of fact to understand the evidence or to determine a fact in issue.” Fed. R. Evid. 702 (emphasis added). To this end, the USPTO cited the well-settled principle that experts may not offer opinion testimony that seeks to resolve the ultimate legal issues in a particular case, thereby usurping the traditional role of the trial judge or jury. See, e.g., LLC v. U.S. Search.com, Inc., 300 F.3d 517, 522 n.4 (4th Cir. 2002) (affirming trial court’s decision to deny use of expert legal opinion testimony on trademark law issues); Peterson v. City of Plymouth, 60 F.3d 469, 475 (8th Cir. 1995) (“[The expert’s] testimony was not a fact-based opinion, but a statement of legal conclusion. These legal conclusions were for the court to make.”); United States v. Duncan, 42 F.3d 97, 101 (2d Cir. 1994) (“Generally, the use of expert testimony is not permitted if it will usurp either the role of the trial judge in instructing the jury as to the applicable law or the role of the jury in applying the law to the facts before it.”). Because the Manbeck declaration consists primarily of legal analysis aimed at supporting Manbeck’s personal legal opinion that the Final Rules exceed the USPTO’s rulemaking authority, contradict certain provisions of the Patent Act, and are unconstitutionally vague – i.e., the identical legal issues this Court must resolve in this case – the USPTO properly filed this motion to strike.

Plaintiffs mistakenly dismiss the USPTO’s contentions as a trivial evidentiary matter calculated to distract this Court’s attention from the true legal issues in this case, and argue that

the USPTO has misapprehended the function of Fed. R. Evid. 702. In support of their argument, Plaintiffs cite to four unpublished district court cases from outside the Fourth Circuit in which expert testimony was permitted in various patent infringement cases. See Pl. Opp'n Mot. to Strike at 6-9. Not one of these cases, however, provides any support for allowing Manbeck's testimony in this case. These decisions each involved patent infringement cases in which the Court permitted fact-based testimony from experts describing the generic procedures the USPTO applies in examining patent applications. None of these cases involved a record review under the Administrative Procedure Act ("APA"), 5 U.S.C. § 701, et seq., and none of these cases involved any legal challenge to the propriety of the USPTO's examination procedures. As such, none of the experts in those cases opined on the legality of such procedures. Furthermore, in none of the cited cases did the court permit the expert to opine on the ultimate legal question at issue. In fact, the District Court in two of the cases cited, Chamberlain Group, Inc. v. Interlogix, Inc., 1C6147, 2002 WL 653892 (N.D. Ill. Apr.19, 2002), and Revlon Consumer Prods. Corp., No. 96-192, 1997 WL 158281 (D. Del. Mar. 26, 1997), expressly noted that it would be improper to allow the expert to offer opinion testimony on the ultimate legal question presented. See Chamberlain Group Inc., 2002 WL 653892 \*1 (noting that experts should not provide opinion testimony "on the interpretation of a claim as a matter of law"); Revlon Consumer Prods. Corp., 1997 WL 158281 (holding that if it permitted the expert to testify on the ultimate legal issue in the case, the expert "would usurp the respective functions of the jury and the Court").

The three additional cases Plaintiffs cite in which Manbeck provided expert testimony are equally inapposite. None of these three cases involved the question of whether Manbeck was permitted to testify on the ultimate legal issue before the Court. Indeed, Manbeck merely

provided fact-based testimony on the generic patent examination procedures used at the USPTO in each of those cases. In short, not one of the cases cited by Plaintiffs even remotely stands for the proposition that an expert may offer opinion testimony on the ultimate legal issue before the court.

In the end, Manbeck opines on the pure legal issues of whether the Final Rules exceed the USPTO's rulemaking authority, conflict with certain provisions of the Patent Act, or violate the Due Process clause for vagueness. Manbeck's declaration in this regard "offer[s] nothing more than a legal conclusion- i.e., [his] testimony [] does little more than tell the jury what result to reach," which of course "is properly excluded under the Rules." United States v. Barile, 286 F.3d 749, 760 (4th Cir. 2002). For these reasons, the Manbeck declaration should be stricken from Plaintiffs' motion for preliminary injunction.<sup>1</sup>

## **II. MANBECK'S PROFFERED TESTIMONY ON THE MERITS OF THE FINAL RULES IMPERMISSIBLY AUGMENTS THE ADMINISTRATIVE RECORD.**

The USPTO next demonstrated in their opening memorandum that the Manbeck declaration improperly operates to supplement, without leave of court, the administrative record. The USPTO noted that courts review agency actions under the APA using the administrative

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<sup>1</sup> Plaintiffs also assert that the USPTO "incorrectly predict[s]" that Plaintiffs will base their entire legal challenge to the Final Rules on Manbeck's declaration. Plaintiffs have misapprehended the USPTO's argument. The USPTO asserted that without the Manbeck declaration, Plaintiffs lack competent authority for many of their most significant legal assertions. See Defs. Mem. at 3 n.2. A review of Plaintiffs' memorandum in support of their motion for preliminary injunction demonstrates that they have cited extensively to the Manbeck declaration for many of their legal assertions. Moreover, Plaintiffs' extensive citation to Manbeck's declaration underscores the USPTO's arguments that the declaration is a legal memorandum, and that it is being proffered as an expert opinion on the ultimate legal issues that this Court – not a hired expert – must resolve.

record before the agency. See Camp v. Pitts, 411 U.S. 138, 142 (1973). As previously explained, the fundamental principle of record review is that the administrative record consists of the materials before the agency at the time the decision was made. Am. Canoe Ass'n, Inc. v. U.S. Env'tl. Prot. Agency, 46 F. Supp. 2d 473, 474 (E.D. Va. 1999) (Ellis, J.). The rationale for this rule is that a reviewing court should determine agency compliance with the law solely on the record on which the agency made the decision. See Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 419 (1971). Finally, USPTO noted that the courts recognize three limited circumstances in which a court may supplement the administrative record – not one of which is applicable here. See Am. Canoe Ass'n, Inc., 46 F. Supp. 2d at 473.

Plaintiffs assert that the Manbeck declaration is permissible because Manbeck's unique experience and expertise<sup>2</sup> properly assists the court by explaining complex material implicated by the Final Rules.<sup>3</sup> The USPTO recognizes that there are circumstances in which courts may

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<sup>2</sup> Plaintiffs criticize the USPTO for ostensibly not being sufficiently impressed with Manbeck's credentials. See Pl. Opp. Mot. to Strk. at 4 n.2 ("Defendants' motion to strike is the second instance in which Defendants have failed to acknowledge that Harry F. Manbeck Jr. served as [a former director of the USPTO]"). Manbeck's credentials are irrelevant. As thoroughly discussed herein and in the USPTO's opening memorandum, the basis of this motion to strike has nothing to do with Manbeck's qualifications as an expert. Rather, Manbeck's testimony is improper because it consists primarily of legal argument, opines on the ultimate legal issue in this case, supplements the administrative record, and circumvents the page limitations under this Court's Local Civil Rule 7(F)(3). The USPTO does note, however, that having not worked at the USPTO in fifteen years, Manbeck has no particular expertise regarding the Final Rules at issue. Plaintiffs' use of attorney Manbeck is no different – or more helpful – than if the USPTO were to proffer the testimony of its own agency counsel, or the present head of the USPTO, on their interpretation of the Final Rules and whether as a matter of law the rules are proper.

<sup>3</sup> Plaintiffs raise two entirely irrelevant points in the background of their opposition memorandum. First, Plaintiffs fault the USPTO for its tremendous effort to promptly issue explanatory guidance on the Final Rules. This official guidance, which Plaintiffs have attached to their opposition memorandum, explains multiple aspect of the Final Rules package to ensure the public understands, and is well prepared for, the Rules when they come into effect on

supplement the administrative record in an APA action, and that it is proper to supplement such record when it is necessary to explain or clarify technical terms. See id. Plaintiffs’ assertion that the Manbeck declaration falls within this narrow exception, however, is without merit. Although the USPTO acknowledges that Manbeck has defined a few technical terms<sup>4</sup> – indeed, the USPTO noted as such in their opening memorandum, see Mem. Supp. Mot. Strk. at 7 n.4 – the overwhelming majority of the declaration is devoted to expressing his personal views of the Patent Act and the Final Rules. Significantly, Plaintiffs do not even attempt to articulate which material in the administrative record Manbeck’s eighteen-page, fifty-three paragraph declaration purports to explain or clarify. Nor do Plaintiffs explain how exactly Manbeck’s extensive citation to Federal Circuit precedent, extensive legal argument supporting Plaintiffs’ legal position in this case, or ultimate legal opinion that “[the USPTO] ha[s] exceeded their statutory authority in promulgating the Final Rules, that the Final Rules exceeded the plain language of the Patent Act, and that the Final Rules’ ESD requirement hopelessly lacks guidance,” see Manbeck Decl. at 18, even remotely “explains or clarifies” complex material. Further, it strains credulity

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November 1, 2007. The Office’s issuance of such guidance is routine with the promulgation of new rules. Second, Plaintiffs reference to an internal and harmless error when, prior to the implementation of the Final Rules, the USPTO began to identify applications that contained more than five independent or twenty-five total claims for purposes of requiring such applications to submit an examination support document. The USPTO cured this internal error, and accordingly, Plaintiffs have suffered not harm as a result.

<sup>4</sup> As the USPTO also asserted in their opening memorandum, Plaintiffs have not demonstrated why Manbeck even needs to define such technical terms. Plaintiffs have already incorporated into their Verified Amended Complaint a portion of the USPTO’s motion to dismiss memorandum filed in Tafas v. Dudas, et al. (now consolidated with this action), which provides a far more exhaustive explanation of the patent concepts at issue. See Verified Amended Complaint, p. 14 n.1 & Ex. A. Plaintiffs incorporation of the USPTO’s explanation of these concepts is conclusive evidence that they did not dispute the USPTO’s explanation of the examination process and definitions of technical terms.

that Plaintiffs would have paid Mr. Manbeck \$700 per hour merely to explain technical terms that Plaintiffs themselves could have explained in their brief, had they requested a page extension from the Court. See Manbeck Decl., ¶ 2.

Plaintiffs' reference to the USPTO's use of the declaration of Karen Young is inapposite. Plaintiffs ostensibly argue that because the USPTO included a declaration in the Tafas litigation, which also is an action under the APA, Plaintiffs' use of the Manbeck declaration in this litigation must be equally permissible. Plaintiffs are comparing apples and oranges. The USPTO's use of the Young declaration was to provide a factual basis to support its challenge of Plaintiff Tafas's constitutional and prudential standing to raise certain legal claims in his complaint. In this respect, it is well-settled in this circuit that when a defendant challenges subject matter jurisdiction via a Rule 12(b)(1) motion, as was the case in Tafas, it is proper for the District Court to consider evidence outside the pleadings. See, e.g., Velasco v. Gov't of Indon., 370 F.3d 392, 398 (4th Cir. 2004); Adams v. Bain, 697 F.2d 1213, 1219 (4th Cir. 1992). Furthermore, a brief review of the Young declaration readily reveals that it is not a self-serving legal memorandum that attempts to offer an expert opinion on the ultimate legal issues in this case. Any suggestion to the contrary lacks merit.

Finally, the USPTO is not suggesting that all declarations in support of a preliminary injunction motion are improper. If that was the USPTO's position, it would have moved to strike the declaration of Sherry M. Knowles. See Ex. B, Pl. Mem. Supp. Mot. for Prel. Inj. It did not. Unlike the Manbeck declaration, the Knowles declaration is proper because it primarily speaks to the factual question of whether there is harm, not the ultimate legal questions in this case. This is also why the declarations the USPTO has submitted with its opposition to Plaintiffs' preliminary



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**CERTIFICATE OF SERVICE**

I hereby certify that on October 30, 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:

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