

**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,)

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

Plaintiffs,)

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)

UNITED STATES PATENT AND)
TRADEMARK OFFICE,)

Defendants.)

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

Defendants 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 (collectively “the USPTO”) respectfully submit this memorandum of law 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 (“Plaintiff’s Memorandum”) filed by Plaintiffs SmithKline Beecham Corp. d/b/a GlaxoSmithKline, SmithKline Beecham PLC, and Glaxo Group Limited, d/b/a GlaxoSmithKline (collectively “Plaintiffs”).

INTRODUCTION AND BACKGROUND

On October 11, 2007, Plaintiffs filed a Verified Amended Complaint challenging, under the Administrative Procedures Act (“APA), 5 U.S.C. §§ 701-706, a package of rules published by the USPTO on August 21, 2007. See 72 Fed. Reg. 46716 (Aug. 21, 2007) (“Final Rules”).

Among other allegations, Plaintiffs claim that the USPTO lacks statutory authority to issue the Final Rules (Count One), that the Final Rules are contrary to the Patent Act, 35 U.S.C. § 1 et seq., (Counts 2, 4, 5), and that one of the Final Rules is unconstitutionally vague (Count 6). (Dkt. No. 5). The USPTO denies these allegations.

On October 15, 2007, Plaintiffs moved the Court for a temporary restraining order and preliminary injunction of the Final Rules. (Dkt. Nos. 12-16). Plaintiffs appended to the thirty-page memorandum in support of their motion a document designated “Exhibit E,” which is an eighteen-page “declaration” of Attorney Harry F. Manbeck, Jr. (“Manbeck Declaration”). (Dkt. No. 16). In his declaration, Mr. Manbeck asserts that because he is a lawyer, who has experience in patent and trademark law, and is familiar with the Patent Act and the USPTO’s Final Rules, he is qualified to opine on the central legal questions that Plaintiffs have asked this Court to decide.¹ After discussing the Patent Act and the Final Rules, Mr. Manbeck offers his legal conclusions, stating, “it is my opinion that the Director and the PTO have exceeded their statutory authority in promulgating the Final Rules, that the Final Rules exceed the plain language of the Patent Act,

¹ Apparently seeking to satisfy the expert disclosure requirements of Federal Rule of Civil Procedure 26(a)(2), Mr. Manbeck states that he is being paid \$700 per hour for his time, and that he has attached to his “report” his “curriculum vitae (Exhibit A); a list of publications that [he has] authored or co-authored (Exhibit B); and a list of the intellectual property cases in which [he has] testified in court or in deposition as an expert in the last four years (Exhibit C).” Plaintiffs’ Memorandum, Ex. E, ¶ 2. None of these documents are actually attached to the declaration or filed with the Court, nor would they be even remotely relevant if they had been provided.

and that the Final Rules' ESD requirement hopelessly lacks guidance." See Plaintiffs' Memorandum, Ex. E, p. 18.

The Court should strike the Manbeck Declaration for at least three reasons. First, the declaration is improper expert testimony under Federal Rule of Evidence 702, as it does not help "assist the trier of fact to understand the evidence or to determine a fact in issue," but rather usurps the judicial function of deciding questions of law. Second, the Manbeck Declaration improperly seeks to introduce evidence outside the administrative record to challenge the USPTO's actions, even though it is well-established that the Court is generally limited to the administrative record in adjudicating the merits of APA cases. Third, because the Manbeck Declaration is nothing more than an eighteen-page legal brief masquerading as a declaration, it is a blatant attempt to circumvent Local Civil Rule 7(F)(3), which limits briefs to thirty pages. For all of these reasons, the Court should strike Exhibit E from the record and disregard all references to the Manbeck Declaration in Plaintiffs' Memorandum.²

ARGUMENT

I. MANBECK'S EXPERT TESTIMONY IS NOT RELEVANT, HELPFUL, OR NEEDED, AND NO SHOWING HAS BEEN MADE UNDER RULE 702 OF THE FEDERAL RULES OF EVIDENCE.

Rule 702 of the Federal Rules of Evidence permits expert testimony where it "will assist the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702;

² With the Manbeck Declaration properly disregarded, it will become evident that Plaintiffs lack any competent authority for many of their most significant legal assertions. See, e.g., Plaintiffs' Memorandum, p. 7 (citing only declaration to argue that the USPTO lacks authority to regulate continuations); Id., p. 9 (citing only declaration to argue that certain statutes "are the only statutory restrictions on claim presentation"); Id., p. 10 (citing only declaration to support assertions that the ethical rules prevent applicant from filing a petition under the continuation rules).

Persinger v. Norfolk & W. Ry., 920 F.2d 1185, 1188 (4th Cir.1990). Plaintiffs have not demonstrated why this Court requires Mr. Manbeck’s “expert” testimony to make the purely legal determinations of whether the USPTO has exceeded its statutory authority, acted contrary to the Patent Act, or promulgated a vague regulation. It does not. This is an APA case, the merits of which may be decided on cross-motions for summary judgment without the need to develop disputed issues of fact through expert testimony.³ The Manbeck Declaration does nothing more than usurp the function of the Court to decide questions of law.

It is well-settled that an expert is not permitted to compete with the judge by rendering legal conclusions, and that such legal testimony is thus improper under Rule 702. See U.S. Search 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) (finding that the trial court erred in allowing testimony that police officers’ conduct satisfied Fourth Amendment requirements, stating that “[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. It was an abuse of discretion to allow the testimony.”); 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.”); Hygh v. Jacobs, 961 F.2d 359, 364 (2d Cir. 1992) (explaining that Rule 701 and 702 stand ready to exclude opinions phrased in terms of legal criteria and that expert opinions cannot infringe

³ Plaintiffs have conceded the propriety of proceeding on motions for summary judgment in the proposed order filed with Plaintiffs’ Memorandum. (Dkt. No. 12). Although the USPTO objects to the briefing schedule Plaintiffs propose in that order, the USPTO agrees that the merits of the case may be decided on summary judgment motions.

upon the exclusive province of the judge to evaluate the law); Caper v. SMG, 389 F. Supp. 2d 618, 621 n.7 (D.N.J. 2005) (“Expert testimony is not admissible to inform the finder of fact as to the law that will be [applied] to the facts in deciding a case . . . Expert witnesses are also prohibited from drawing legal conclusions This proscription precludes an expert from testifying in the language of statutes, regulations or other legal standards that are at the heart of the case.”).

Indeed, the principle that precludes Mr. Manbeck’s proffered testimony is so well-established as to be virtually textbook law:

The rule regarding legal testimony has been stated as follows: A witness cannot be allowed to give an opinion on a question of law In order to justify having courts resolve disputes between litigants, it must be posited as an a priori assumption that there is one, but only one legal answer for every cognizable dispute. There being only one applicable legal rule for each dispute or issue, it requires only one spokesman of the law, who of course is the judge To allow anyone other than the judge to state the law would violate the basic concept.

Pinal Creek Group v. Newmont Mining Corp., 352 F. Supp. 2d 1037, 1042-43 (D. Ariz. 2005) (citing Specht v. Jensen, 853 F. 2d 805, 807 (10th Cir. 1988)) (citation omitted); see also In re Initial Public Offering Sec. Litigation, 174 F. Supp. 2d 61, 64 (S.D.N.Y. 2001) (“[T]he principle that legal opinion evidence concerning the law is inadmissible is ‘so well established that it is often deemed a basic premise or assumption of evidence law – a kind of axiomatic principle.’”) (quoting Thomas E. Baker, The Impropriety of Expert Witness Testimony on the Law, 40 U. Kan. Law Rev. 325, 352 (1992)).

Because Mr. Manbeck’s personal legal opinions concerning many of the central legal questions in this case are irrelevant and unhelpful under Rule 702, the Court should follow the

lead of countless other courts by striking the Manbeck Declaration and disregarding the numerous references to the declaration in Plaintiffs' Memorandum. It is the role of this Court, not Mr. Manbeck, to decide the legal issues in this case.

II. MANBECK'S EXPERT TESTIMONY ON THE MERITS OF THE FINAL RULES IMPERMISSIBLY AUGMENTS THE ADMINISTRATIVE RECORD IN THIS APA CASE.

Exhibit E of Plaintiffs' Memorandum should also be stricken because it impermissibly introduces into the administrative record—for purposes of disputing the merits of the Final Rules—material that was not before the USPTO when it enacted the Final Rules. It is well-established that in an APA case, “the focal point for judicial review should be the administrative record already in existence, not some new record initially made in the reviewing court.” Camp v. Pitts, 411 U.S. 138, 142 (1973); see also IMS, P.C. v. Alvarez, 129 F.3d 618, 623 (D.C. Cir. 1997) (“It is a widely accepted principle of administrative law that the courts base their review of an agency's actions on the materials that were before the agency at the time its decision was made.”). As this Court has itself said, “in general, judicial review of agency action pursuant to the APA is confined to the agency’s administrative record.” Am. Canoe Ass’n, Inc. v. U.S. Envtl. Prot. Agency, 46 F. Supp. 2d 473, 474 (E.D. Va. 1999) (Ellis, J.) (citing Camp, 411 U.S. at 142).

This Court has recognized three narrow circumstances where the administrative record may be supplemented in an APA case. See Am. Canoe Ass’n., 46 F. Supp. 2d at 473. However, Plaintiffs offer no basis for supplementing the record, and none of the recognized exceptions apply. The Manbeck Declaration does not cure a “failure in the record to explain administrative action;” the USPTO does not intend to introduce evidence outside the administrative record that renders comparable legal conclusions; and Plaintiffs do not seek to supplement the record simply

to “explain or clarify technical terms.”⁴ Id. Accordingly, the Manbeck Declaration is impermissible. See IMS, P.C., 129 F.3d at 624 (“To allow the affidavits to be considered now would be to permit ex post supplementation of the record, which is not consistent with the prevailing standards of agency review.”).

Further, it is clear that the purpose of the Manbeck Declaration, along with its conclusory legal assertions, is to cast doubt on the correctness of the USPTO’s Final Rules. The administrative record may not be supplemented for this reason. See Env’tl. Def. Fund, Inc. v. Costle, 657 F. 2d 275, 286 (D.C. Cir. 1981) (supplementation of administrative record with affidavits challenging the propriety of the agency action not permissible); Asarco, Inc., v. U.S. E.P.A., 616 F.2d 1153, 1160 (9th Cir. 1980) (holding that consideration of outside materials “to determine the correctness or wisdom of the agency’s decision is not permitted”). Allowing the proffered declaration would frustrate the purpose of judicial review under the APA by permitting Plaintiffs to introduce new evidence not presented to the USPTO at the administrative level in order to challenge the merits of the Final Rules. Accordingly, it should be stricken from the record.

III. INTRODUCTION OF EXHIBIT E CIRCUMVENTS THE COURT-IMPOSED PAGE LIMITATIONS UNDER LOCAL RULE 7(F)(3).

Finally, the Court should strike Exhibit E of Plaintiffs’ Memorandum because it is a blatant attempt to circumvent the Court-imposed thirty-page limit on opening and responsive

⁴ Although Mr. Manbeck does define some technical terms, see Plaintiffs’ Memorandum, Ex. E, Part II, the vast majority of his declaration is dedicated to a discussion of his views on the Patent Act and the Final Rules. Moreover, Mr. Manbeck’s effort to define a few technical terms is unnecessary because Plaintiffs have already incorporated into their Verified Amended Complaint a portion of the USPTO’s motion to dismiss memorandum in the companion case, Tafas v. Dudas, 1:07cv846, which provides a far more exhaustive explanation of the patent concepts at issue. See Verified Amended Complaint, p. 14 n. 1 & Ex. A.

briefs. Local Rule 7(F)(3) provides that opening briefs shall not “exceed thirty (30) 8-1/2 inch x 11 inch pages double-spaced.” This rule clearly contemplates that all legal arguments and conclusions must be contained in the thirty-page brief, not in an additional exhibit attached thereto, as attempted by Plaintiffs. Indeed, allowing parties to introduce substantive portions of their briefs and legal arguments as an exhibit renders the Court-imposed page limits meaningless. Such a practice would alleviate parties of their obligation to present the Court with a concise and cogent discussion of the facts and law in their brief itself. With the inclusion of Exhibit E, Plaintiffs have essentially filed a forty-eight-page brief in this case, which exceeds the Court’s page limitation by eighteen pages. The Court should reject the Plaintiffs’ attempt to circumvent the local rules by submitting a legal brief masquerading as a declaration.

CONCLUSION

For all of the foregoing reasons, the Court should strike Exhibit E of Plaintiffs’ Memorandum.

Respectfully submitted,

CHUCK ROSENBERG
UNITED STATES ATTORNEY

By: _____/s/_____
Lauren A. Wetzler
R. Joseph Sher
Ralph Andrew Price Jr.
Assistant United States Attorneys
Justin W. Williams United States 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

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 October 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 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

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

_____/s/_____

Lauren A. Wetzler

Assistant United States Attorney

Justin W. Williams United States 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