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

TRIANTAFYLLOS TAFAS,	:	
Plaintiff,	:	
v.	:	**1:07cv846 (JCC/TRJ)**
JON W. DUDAS, et al.,	:	
Defendants.	:	

CONSOLIDATED WITH

SMITHKLINE BEECHAM CORPORATION, d/b/a GLAXOSMITHKLINE, et al.,	:	
Plaintiffs,	:	
v.	:	**1:07cv1008 (JCC/TRJ)**
JON W. DUDAS, et al.,	:	
Defendants.	:	

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

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INTRODUCTION

Plaintiffs, SmithKline Beecham plc, SmithKline Beecham Corporation d/b/a GlaxoSmithKline, and Glaxo Group Limited d/b/a GlaxoSmithKline (collectively referred to as "GSK"), filed a motion for a temporary restraining order ("TRO") and preliminary injunction to temporarily and preliminarily enjoin the Defendant, 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 Defendant United States Patent and Trademark Office ("PTO") from implementing the new PTO rules ("Final Rules") that were published on August 21, 2007, and are scheduled to go into effect on November 1, 2007. In support of that motion, GSK filed the Declaration of Harry F. Manbeck, Jr., former Commissioner of Patents and Trademarks of the United States and Assistant Secretary of Commerce ("Manbeck declaration").[1] In response to GSK's motion, Defendants filed a motion to strike the Manbeck declaration.

The Defendants' motion to strike should be denied. It is nothing more than a red herring designed to misdirect the Court into a fruitless ancillary evidentiary dispute away from the merits of GSK's motion for preliminary injunctive relief and a TRO. The evidentiary dispute is fruitless because the Manbeck declaration is admissible based on two well-known exceptions to the doctrine of record review (supporting preliminary injunctive relief and explaining complex and technical matters), and buttressed by a long line of patent-specific cases where expert testimony—including testimony from former Commissioner Manbeck—is readily admitted on patent law, patent prosecution, and the PTO.

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[1] That position was equivalent to the position now held by Defendant Jon W. Dudas. *See* Patent and Trademark Efficiency Act, Pub. L. No. 106-113, § 4732 (1999); *see also* 5 U.S.C.A § 3 (West 1991).

BACKGROUND

I. The Final Rules Implicate Extremely Complex Issues Of Patent Prosecution.

This Administrative Procedure Act ("APA") action involves the highly specialized and technical field of patent prosecution. In January 2006, the Defendants issued Proposed Rules setting forth changes to the practice of examining claims in patent applications and to the practice for continuing applications, requests for continued examination, and applications containing patentably indistinct claims. (A00001-A00023.) These Proposed Rules represent an abrupt about-face in patent prosecution procedures, and thus drew over 500 comments (overwhelmingly negative) totaling more than 2,500 pages in length. (A00591-A03199.) The comments emphasized, among other things, that the Defendants lacked authority to promulgate the Proposed Rules, that the Proposed Rules violated the express language of the controlling patent laws, and that the retroactive application of the Proposed Rules would be illegal. (*Id.*)

In response to the widespread and sustained criticism of the Proposed Rules, the Defendants took over eighteen months to revamp the rules. On August 21, 2007, the PTO published the Final Rules. *See* "Changes To Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications," 72 Fed. Reg. 46,716, 46,716-843 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1). (A09390-A09518.) The Final Rules and the explanations thereof occupy 128 pages of the *Federal Register*. The *Federal Register* entry discusses the current system of patent prosecution and how the Final Rules are purportedly necessary to increase the administrative efficiency of the PTO. The Final Rules also differ substantially from the Proposed Rules in ways that the commentators could not have anticipated. (*See, e.g.*, Verified Am. Compl. (D.I. 5) ¶¶ 134-38 (pleading that the PTO's final 5/25 claim rule is not a logical outgrowth of the proposed ten "representative" claims rule).)

The size of the Final Rules is exceeded only by the complexity of the new system that those rules embody. For example, the publication of the Final Rules prompted the PTO also to publish "Highlights of the Changes in this Final Rule" (2 pages), "Changes Relative to the Rules Originally Proposed in January of 2006" (3 pages), "Transitional Practice for Continuation and Continuation-in-part Applications" (1 page), "Commonly Owned Applications and Applications Containing Patentably Indistinct Claims" (2 pages), "Section-By-Section Summary of the Changes in this Final Rule" (10 pages), "Questions and Answers [Regarding the] Claims and Continuations Final Rule" (63 pages), and a presentation slide set regarding the "Claims and Continuations Final Rule" (111 slides). (Exs. 1-7.) In light of the vagueness and complexity of new rule 37 C.F.R. § 1.265, which sets forth the requirements of the PTO's new onerous examination support document ("ESD"), the PTO, on September 6, 2007, issued a 16-page memorandum providing "Guidelines for Examination Support Document (ESD) Under 37 CFR 1.265." (Ex. 8.) Then, on October 10, 2007, in a purported attempt to clarify the harsh retroactive impact the Final Rules will have on certain pending applications, the PTO issued a five-page memorandum entitled "Clarification of the Transitional Provisions Relating to Continuing Applications and Applications Containing Patentably Indistinct Claims." (Ex. 9.) In sum, since the PTO published the Final Rules on August 21, 2007, it has issued over 200 pages of material providing guidance—directed largely to practitioners and companies who are already familiar with patent prosecution—as to how the Final Rules will affect patent prosecution. GSK is aware of no other situation in which the ink was barely dry on a set of final rules, and indeed the rules had not yet even gone into effect, where the issuing agency engaged in a furiously paced effort to issue guidance documents "clarifying" what it had purported to finalize only days or weeks before.

Further highlighting the complexity of the Final Rules is the fact that the PTO itself cannot seem to abide by them. On October 11, 2007, the PTO announced internally that it would begin applying the new ESD requirement "on or about October 15, 2007" despite the Final Rules' effective date of November 1, 2007. (Ex. 10.) In fact, the PTO's early implementation of the 5/25 rule resulted in at least five of GSK's pending applications as being marked "Flagged for 5/25" (*i.e.*, GSK's applications were flagged for violating new 37 C.F.R. § 1.75(b), which requires an applicant to file an ESD if the application contains more than five independent or twenty-five total claims). (Exs. 11-15.) Two days after GSK filed its motion for a TRO and preliminary injunction, which established that the Final Rules would immediately and irreparably harm GSK, Defendants withdrew their "Flagged for 5/25" entries. (*Id.*) Then, on October 19, 2007, the PTO issued a memorandum to its examiners in which it rescinded its earlier October 11, 2007 memorandum, belatedly recognizing that applications should not be examined under the Final Rules until at least November 1, 2007, the effective date of the Final Rules. (Ex. 16.)

II. The Manbeck Declaration Aids In Explaining The Extremely Complex Issues Of Patent Prosecution.

Defendants do not dispute that former Commissioner Manbeck is qualified to aid the Court in understanding these "extremely complex issues of patent prosecution."[2] (Defs.' Mem. in Supp. of Mot. to Strike Manbeck Decl. (D.I. 27) ("Defs.' Br.") at 3, ¶ 5.) As the Commissioner, Mr. Manbeck, among other things, was responsible for all aspects of the patent-

[2] Defendants' motion to strike is the second instance in which Defendants have failed to acknowledge that Harry F. Manbeck, Jr. served as the Commissioner of Patents and Trademarks of the United States. (Defs.' Br. at 2 (referring to former Commissioner Manbeck as "a lawyer, who has experience in patent and trademark law"); Defs.' Emergency Mot. to Continue Preliminary Injunction Hearing (D.I. 17) ("Defs.' Continuance Mot.") at 3 n.2 (referring to former Commissioner Manbeck as "an attorney from a law firm").)

granting process for the United States. Moreover, he has had a distinguished career as a member of the private bar, including holding the position of Chief Patent Counsel for General Electric Company for about 20 years. These experiences provide Mr. Manbeck with a unique perspective and understanding of patent law and patent prosecution before the PTO.

Mr. Manbeck's declaration aids in providing context to the Final Rules and assists in explaining the "extremely complex" material involved in GSK's request for injunctive relief—a matter that the PTO did not and could not have made findings about in its agency record. (*See, e.g.*, Manbeck Decl. ¶ 17 (explaining nuances of continuation applications and other concepts in "the lexicon of patent practitioners"); ¶ 19 (explaining importance of priority date).) The declaration also helps to explain the current, well-established system of patent prosecution and how the Final Rules fundamentally alter that system. (*See id.* ¶ 38 (explaining various reasons an applicant may file a continuation application); ¶ 40 (discussing "normal, customary, sanctioned and accepted reasons for filing continuations prior to the Final Rules").) And the Manbeck declaration helps the Court understand GSK's irreparable injury by explaining how the new Final Rules alter the regulatory status quo, and how the Final Rules upset GSK's settled expectations, as well as the expectations of similarly-situated pharmaceutical and technology-based firms. (*See id.* ¶¶ 45-47 (explaining the ethical dilemma presented by Final Rules and near impossible evidentiary burden of Final Rules in comparison to existing rules).)

ARGUMENT

I. The Manbeck Declaration Is Admissible And Proper Under Federal Rule Of Evidence 702.

The Defendants object to the Manbeck declaration, arguing that it "compete[s] with the judge by rendering legal conclusions" in violation of Federal Rule of Evidence 702. (Defs.' Br. at 4.) That argument is misguided.

It is well-established and routinely accepted that expert testimony may be provided to explain the specialized and technical aspects of patent prosecution. *See, e.g., Chamberlain Group, Inc. v. Interlogix, Inc.*, No. 01 C 6157, 2002 WL 653893, at *1 (N.D. Ill. Apr. 19, 2002) (rejecting plaintiff's argument that expert report must be stricken because it consisted "solely of legal conclusions disguised as expert testimony"; explaining that expert testimony on "the operation of the Patent and Trademark Office" can be helpful to the court in understanding patent issues); *Revlon Consumer Prods. Corp. v. L'Oreal S.A.*, No. 96-192, 1997 WL 158281, at *3 (D. Del. Mar. 26, 1997) (holding that defendants' expert would be allowed to testify "as to matters of PTO practice and procedure"); *Cameco Indus., Inc. v. La. Cane Mfg., Inc.*, No. 92-3158, 1995 WL 468234, at *4 (E.D. La. July 27, 1995) (permitting expert to testify "about the patent application process, the operations and functions of the patent and trademark office, and the materiality of relevant prior art"); *Swift Agric. Chems. Corp. v. Miss. Chem. Corp.*, No. J78-0149(R), 1986 WL 11610, at *7-8, 11 (S.D. Miss. June 2, 1986) (relying on expert testimony of former Commissioner of the PTO to understand complexities of patent prosecution procedures).

Indeed, many district courts have recognized former Commissioner Manbeck as an expert on patent law, patent prosecution, and the PTO—the very topics at issue in this case—and have allowed him to testify on those topics. *See, e.g., Armament Sys. & Procedures, Inc. v. IQ Hong Kong Ltd.*, No. 00-C-1257, 2007 WL 1267877, at *1 (E.D. Wis. Apr. 24, 2007) (denying motion

to exclude expert testimony of former Commissioner Manbeck because he is an "undoubted expert not only in patent law but in the workings of the Patent and Trademark Office, [who] would be able to provide some *factual* context" for the court) (emphasis in original); *Sanitec Indus. Inc. v. Micro-Waste Corp.*, No. H-04-3066, 2006 WL 1544529, at *3 (S.D. Tex. June 2, 2006) (denying motion to exclude expert testimony of former Commissioner Manbeck and permitting him to testify "about patent procedures and patent law concepts . . . to provide factual or background testimony in areas in which he has extensive experience and expertise"); *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 68 F. Supp. 2d 508, 525 (D.N.J. 1999) (discussing at-length the expert testimony of former Commissioner Manbeck, who testified as "an expert in patent law, the United States Patent Office and its procedures").

The case law cited by Defendants is inapposite. None of Defendants' cases involve an expert declaration submitted to explain the complexities of patent prosecution—never mind how extensive rule changes at the PTO of the magnitude involved here will affect patent prosecution. Indeed, none of their cases even involve patents or patent law. As such, they do not address the fact that many district courts have recognized and allowed experts, such as former Commissioner Manbeck, to testify on patent law and PTO procedures.

GSK does not expect the Court to cite former Commissioner Manbeck's declaration as legal authority for the impropriety of the Defendants' actions. (*Cf.* Defs.' Br. at 3 n.2 (incorrectly predicting that GSK will argue that their legal challenges rest exclusively on evidence from the Manbeck declaration).) Instead, GSK has provided ample statutory and case law support to establish the impropriety of the Final Rules (as discussed below). Rather, the Manbeck declaration serves the legitimate purpose of helping the Court, as fact finder, understand an "extremely complex" area of patent practice. As such, the Manbeck declaration is

appropriate under Rule 702 and this Court has broad discretion to allow it. *See Salem v. U.S. Lines Co.*, 370 U.S. 31, 35 (1962) ("[T]he trial judge has broad discretion in the matter of the admission or exclusion of expert evidence.").

Finally, it is important to note that GSK nowhere urges this Court to defer to the Manbeck declaration—that is not the purpose of the declaration. Hence, accusations by the Defendants that GSK seeks to introduce that declaration to "usurp" (Defs.' Br. at 3) the Court's powers are far-fetched, to say the least.

II. The Manbeck Declaration Helps To Explain The Complex Material Implicated By The Final Rules.

The Defendants also object to the Manbeck declaration on the grounds that it introduces material beyond the administrative record. Affidavits, however, may be introduced to place in context and explain complex material in an agency record. *See, e.g., Acumenics Research & Tech. v. U.S. Dep't of Justice*, 843 F.2d 800, 806 n.7 (4th Cir. 1988). Indeed, Defendants' very own cited authority supports this proposition:

> [I]t is both unrealistic and unwise to 'straightjacket' the reviewing court with the administrative record. It will often be impossible, especially when ***highly technical matters are involved***, for the court to determine whether the agency took into consideration all relevant factors unless it looks outside the record to determine what matters the agency should have considered but did not.

Asarco, Inc. v. Envtl. Protection Agency, 616 F.2d 1153, 1160 (9th Cir. 1980) (emphasis added) (recognizing that affidavits may supplement the administrative record by providing background information); *see also Envtl. Def. Fund, Inc. v. Costle*, 657 F.2d 275, 286 (D.C. Cir. 1981) (same); *IMS, P.C. v. Alvarez*, 129 F.3d 618, 624 (D.C. Cir. 1997) (stating that there are "accepted exceptions to the principle that the court cannot consider information that falls outside the agency record").

In fact, in another case Defendants cite to support their argument, this Court recognized that affidavits may be used to "explain or clarify technical terms ***or other difficult subject matter included in the record***."[3] *Am. Canoe Ass'n, Inc. v. Envtl. Protection Agency*, 46 F. Supp. 2d 473, 477 (E.D. Va. 1999) (Ellis, J.) (emphasis added) (citing *Pub. Power Council v. Johnson*, 674 F.2d 791, 793 (9th Cir. 1982) (Kennedy, J.)). Indeed, there is a parallel right for regulated parties to introduce evidence outside the administrative record where it is necessary to provide context for courts deciding unfamiliar issues. *See Pub. Power Council*, 674 F.2d at 794 ("There are also cases in which supplementation of the record through discovery is necessary to permit explanation or clarification of technical terms or subject matter involved in the agency action under review.").

That parallel right is important given the Defendants' concession that the record here involves "extremely complex issues of patent prosecution procedure" (Defs.' Continuance Mot. at 3, ¶ 5), and that Defendants submitted a similar declaration in the *Tafas* case to clarify certain aspects of that process (*see* Decl. of Karen M. Young ¶¶ 30-36). Unless the purpose of the Defendants' motion to strike is to perpetuate this acknowledged complexity, their efforts to prohibit litigants like GSK from dispelling that confusion, in part, through the testimony of a former Commissioner of Patents, is inexplicable. Going further, the Defendants have also attempted to functionally supplement the record through various hastily-assembled guidance documents prepared outside of the APA and *Federal Register* processes and issued in the brief period since it announced the Final Rules. Nowhere do the Defendants explain why their own efforts to dispel confusion through both the Young declaration submitted in *Tafas* and their

[3] The Defendants' discussion of the scope of judicial review omitted the emphasized text without noting the omission by ellipsis or otherwise. (Defs.' Br. at 6-7.)

newly-minted guidance documents is proper, but that the efforts of a regulated industry to cut through complexity and support its claims of irreparable injury are not. *Cf. Clifford v. Pena*, 77 F.3d 1414, 1418 (D.C. Cir. 1996) (rejecting argument that extra-record affidavit submitted by the "Director of Maritime Administration's Office of Subsidy and Insurance . . . to provide the court with background information about the subsidy program and the current state of the American shipping industry" was improper).

In short, because the Manbeck declaration provides background information regarding issues related to patent prosecution that the Defendants concede are "extremely complex," and provides context as to how the regulatory status quo has been altered, it falls within one of the well-recognized exceptions of judicial review of an administrative record, and may be considered by the Court.

III. The Manbeck Declaration Is Admissible Because It Supports A Request For Immediate Injunctive Relief And Complies With The Local Rules.

The Defendants also object to former Commissioner Manbeck's declaration, arguing that it cannot be considered because it is a legal brief disguised as a declaration to avoid the page limits of the Local Rules. The Defendants' argument is a straw man. GSK did not submit a declaration from former Commissioner Manbeck to circumvent the page limits in briefing. Nor does GSK expect the Court to cite the declaration as proof that the Defendants have acted contrary to the Patent Act.

Instead, Mr. Manbeck's declaration supports GSK's request for immediate injunctive relief to preserve the status quo by, for example, explaining how the Final Rules fundamentally alter the longstanding system of patent prosecution. Doing so is entirely permissible as a matter of administrative law. *See, e.g.*, *Esch v. Yeutter*, 876 F.2d 976, 991 & n.166 (D.C. Cir. 1989) ("Not surprisingly then, the courts have developed a number of exceptions countenancing use of

extra-record evidence . . . (4) when a case is so complex that a court needs more evidence to enable it to understand the issues clearly . . . and (8) in cases where relief is at issue, especially at the preliminary injunction stage.").

In the administrative record, the Defendants did not make any findings regarding the certain irreparable harm to GSK, nor could they have done so. In such a situation, evidence beyond the administrative record may be considered to support a request for preliminary relief. *See, e.g., Shalala v. Ill. Council on Long Term Care*, 529 U.S. 1, 23-24 (2000) ("[A] court reviewing an agency determination under [a typical judicial review provision] has adequate authority to resolve any statutory or constitutional contention that the agency does not, or cannot, decide, including, where necessary, the authority to develop an evidentiary record." (internal citations omitted).)

The Manbeck declaration clarifies the Defendants' alteration of the regulatory status quo and their trampling of existing rights in doing so. The Manbeck declaration does not raise any new arguments or cite to any new authority. Rather, as the Defendants concede, the declaration provides an appropriate explanation of some of the patent prosecution concepts at issue in this case.[4] Indeed, many of those concepts were similarly discussed in an affidavit that Defendants

[4] (*See* Defs.' Br. at 7 n.4 (conceding that the Manbeck declaration defines "some technical terms").) The fact that Defendants believe their motion to dismiss memorandum in the *Tafas* case "provides a far more exhaustive explanation of the patent concepts at issue" than the Manbeck declaration is irrelevant. This amounts to an argument that the government is free to explain background principles, but that regulated parties may not. As explained above, the law recognizes parallel rights in the government and in litigants challenging agency action to explain, from their own respective standpoints, complex material in extra-record submissions.

submitted in the *Tafas* case to support their motion to dismiss.[5] (*See* Decl. of Karen M. Young, ¶¶ 31-36.) Thus, the Manbeck declaration is admissible and complies with the Local Rules' page limitation.

IV. The Final Rules Are *Ultra Vires*, Contrary To Statutory Authority, Impermissibly Retroactive, Arbitrary And Capricious, And Should Be Enjoined Immediately.

In footnote two of their motion to strike, Defendants assert that the Plaintiffs "lack any competent" authority to support the legal assertions in the motion for TRO and preliminary injunction if the Manbeck declaration is disregarded. (Defs.' Br. at 3 n.2.) Defendants are mistaken.

GSK has amply supported its request for emergency relief with authority demonstrating that the Defendants lack any authority to engage in substantive rulemaking; that Defendants lack authority to engage in retroactive rulemaking; and that the Final Rules are contrary to the express language of the patent laws, arbitrary and capricious, and vague. (*See* Pls.' Mem. Supp. Mot. TRO and Prelim. Inj. at 7-11, 15-27 (Defendants lack substantive rulemaking authority, citing *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996) and *Eli Lilly & Co. v. Bd. of Regents of Univ. of Wash.*, 334 F.3d 1264, 1269 n.1 (Fed. Cir. 2003); Defendants lack authority to promulgate retroactive rules, citing *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988), *Landgraf v. USI Film Prods.*, 511 U.S. 244, 272-73 (1994), and *Leland v. Fed. Ins. Admin.*, 934 F.2d 524, 527 (4th Cir. 1991); Defendants lack authority to restrict the number of

[5] It is worth noting that, in the *Tafas* case, Defendants submitted a thirty-page motion to dismiss supported by an eight-page declaration, which discussed patent prosecution concepts such as requests for continued examination, divisional applications, continuing applications, reissue applications, claims, and patentable subject matter. (*See* Decl. of Karen M. Young ¶¶ 31-36.) Thus, under Defendants' theory regarding page limits, Defendants themselves violated the Local Rules in the *Tafas* case, further showing that Defendants' position lacks merit.

continuing patent applications, citing 35 U.S.C. § 120, *Godfrey v. Eames*, 68 U.S. 317, 325-26 (1863), *In re Henriksen*, 399 F.2d 253, 254 (C.C.P.A. 1968), *Ex parte Hull*, 191 U.S.P.Q. 157, 159 (Pat. & Tr. Office Bd. App. 1975), 37 C.F.R. § 10.85(a)(5)).) That authority is further buttressed by the authority cited in GSK's 52-page Verified Amended Complaint. Quite simply, for Defendants to assert that Plaintiffs "lack any competent authority" belies both credibility and reality.

Hence, the focus at the oral argument to be held on October 31, 2007 should remain firmly fixed on the question of the PTO's authority to issue the Final Rules, the likelihood of GSK's prevailing on the merits, and on the other factors in the four-part balancing test routinely applied by courts sitting in equity—not on fruitless evidentiary disputes.

CONCLUSION

For the foregoing reasons, the Defendants' motion to strike the Manbeck declaration should be denied.

Date: October 26, 2007

Respectfully submitted,

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

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