### 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,	) Civil Action
d/b/a/ GLAXOSMITHKLINE,	)
	)
Plaintiffs,	)
	)
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	)
	)
UNITED STATES PATENT AND	)
TRADEMARK OFFICE,	)
	)
Defendants.	)
	)

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

# DEFENDANTS' OPPOSITION TO AIPLA'S MOTION FOR LEAVE TO FILE A BRIEF IN SUPPORT OF THE "GSK" 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" or the "Office"),

respectfully submit this brief in opposition to the Motion of Proposed Amicus Curiae American

Intellectual Property Law Association ("AIPLA") for Leave to File Its Brief in Support of the

Motion for a Temporary Restraining Order and Preliminary Injunction ("Plaintiffs' Motion") filed

by Plaintiffs SmithKline Beecham Corp., d/b/a GlaxoSmithKline, SmithKline Beecham PLC, and

Glaxo Group Limited, d/b/a GlaxoSmithKline (collectively "Plaintiffs" or "GSK").

#### **INTRODUCTION**

Ostensibly dissatisfied with the extensive briefing and supporting affidavits already submitted by GSK, AIPLA now seeks to enter the fray – raising some entirely new arguments – <u>mere days</u> before this Court's October 31 hearing on GSK's motion for a preliminary injunction. This Court should deny AIPLA's motion for at least two reasons. First, requiring the USPTO to prepare, at this very late date, substantive responses to the several arguments raised in AIPLA's proposed <u>amicus</u> brief, as well as the numerous factual assertions contained in the four attached declarations, is unduly prejudicial. Second, the injection of these new arguments into the litigation (particularly just days before the scheduled preliminary injunction hearing) is an entirely inappropriate use of <u>amicus</u> briefing. Indeed, it is well settled that although an <u>amicus</u> may offer assistance in resolving issues properly before the court, it may not raise <u>additional</u> issues or arguments not raised by the parties. In sum, this Court should not countenance AIPLA's belated, improperly-filed motion, particularly in light of the substantial prejudice to the USPTO.

#### ARGUMENT

#### I. <u>AIPLA'S MOTION IS UNTIMELY</u>

The decision whether to allow amicus participation and how to structure that participation if granted rests within the discretion of the district court. <u>See Hoptowit v. Ray</u>, 682 F.2d 1237, 1260 (9th Cir. 1982); <u>United States v. Ahmed</u>, 788 F. Supp. 196, 198 n.1 (S.D.N.Y. 1992) ("District courts have broad discretion to permit or deny the appearance of amici curiae in a given case."), <u>aff'd</u>, 980 F.2d 161 (2nd Cir. 1992). In exercising that discretion, district courts demand that motions for amicus participation be filed timely. See generally Cmty. Ass'n for Restor. v. <u>DeRuyter Bros. Dairy</u>, 54 F. Supp. 2d 974, 975 (E.D. Wash. 1999) ("The privilege of being heard amicus rests in the discretion of the court which may grant or refuse leave according as it deems the proffered information <u>timely</u>, useful, or otherwise") (emphasis added); <u>Waste Mgm't of Penn.</u> <u>v. City of York</u>, 162 F.R.D. 34, 36 (M.D. Pa. 1995) (requiring prospective amici to demonstrate that the information proffered is "timely and useful"); <u>Leigh v. Engle</u>, 535 F. Supp. 418, 420 (N.D. Ill. 1982). District courts should deny motions for leave to file amicus briefs where the delay in filing was avoidable or when it is prejudicial to the parties. <u>See e.g., Centeno-Bernuy v.</u> <u>Perry</u>, 302 F. Supp. 2d 128, 131 n.1 (W.D.N.Y. 2003) (providing untimeliness as a reason to deny permission to file an amicus brief); <u>O Centro Espirita Beneficiente Uniao Do Vegetal v. Ashcroft</u>, 282 F. Supp.2d 1271 (D.N.M. 2002) (denying motion to enter as amici where the motion was not timely or particularly helpful).

This Court should deny AIPLA's motion because it is untimely. AIPLA's decision to file this motion a mere <u>three</u> business days before the preliminary injunction hearing deprives the USPTO of a meaningful opportunity to prepare a full and adequate substantive response. AIPLA's brief and accompanying declarations – submitted under the guise of merely discussing the alleged irreparable harm to which the public would be exposed – contain <u>multiple</u> legal conclusions and fact-intensive assertions regarding the legal consequences of the implementation of the Final Rules. These assertions call for extensive factual and legal research, as well as the preparation of counter-declarations. Because the USPTO lacks an opportunity to undertake such efforts before October 31, the Court must deny the motion as untimely.<sup>1</sup> <u>See DeRuyter Bros.</u>

<sup>&</sup>lt;sup>1</sup> Notably, some of AIPLA's assertions are so vague that the USPTO could not fairly respond to them even if it had the time to do so. For example, the declaration of Samson Helfgott refers only to various unnamed "clients," Helfgott Decl.  $\P\P$  9, 10, whose applications the

Dairy, 54 F. Supp. 2d at 975; Waste Mgm't of Penn., 162 F.R.D. at 36; Leigh v. Engle, 535 F. Supp. at 420.

Furthermore, there is absolutely no justification for AIPLA's exceedingly late filing. The USPTO published its notice of final rules in the <u>Federal Register</u> back on August 21, 2007. <u>See</u> 72 Fed. Reg. 46716 (Aug. 21, 2007) ("Final Rules"). The notice provided that the effective date of the Final Rules is November 1, 2007, <u>see id.</u> at 46716, with some provisions not requiring compliance until February 1, 2008, <u>see e.g., id.</u> at 46717. As a 17,000-member national association in existence for over 100 years, <u>see</u> Proposed Amicus Br. at 1, AIPLA was undoubtedly aware of such a significant rules package as of August 21, 2007 (it did, after all, submit public comments in 2006).

AIPLA, which is primarily comprised of intellectual property "attorneys employed in private practice and by corporations, universities and government," <u>id.</u>, has failed to articulate why a reasonable investigation would not have disclosed the existence of two civil actions challenging the final rules package, both of which requested preliminary injunctions. <u>Cf.</u> <u>Norgaard v. DePuy Orthopaedics, Inc.</u>, 121 F.3d 1074, 1075 (7th Cir. 1997) (noting that ignorance of other court's docket "is nothing but negligence, which does not justify untimely action"). Indeed, in <u>Tafas v. Dudas, et al.</u> Civil Action No. 1:07cv846 (JCC/TRJ) (consolidated with this action), the plaintiff filed a motion seeking a preliminary injunction back on August 22, 2007 – the day after USPTO published its final rules. (Dkt. No. 3). The <u>Tafas</u> case has been pending in

USPTO has no way of identifying.

this Court for more than two months.<sup>2</sup>

Moreover, it is clear from their declarations that the four declarants – all patent lawyers – have long been well aware of these rules. Even if AIPLA itself may not have weighed in with an amicus brief, these lawyers certainly could have filed lawsuits or timely amicus briefs on behalf of the clients whose interests they now – quite oddly – seek to represent through the association to which they personally belong. In view of the size of these client entities, there is no reason why the clients, through their counsel, could not have timely come to Court to represent their own interests. <u>See, e.g.</u> Kappos Decl. (representing IBM); Magen & Hetz Decls. (representing SanDisk Corp.).

In any event, AIPLA's lack of advance knowledge of GSK's motion – as well as the alleged, unidentified difficulties that apparently have precluded this "large volunteer organization" from acting timely – are irrelevant. Whatever reasons AIPLA may belatedly articulate for filing its motion on the eve of the hearing, they do not serve to mitigate the prejudice to the USPTO. Indeed, as set forth above, AIPLA's late filing has simply left defendants with virtually no time to respond meaningfully to the arguments posed in its brief and, even more prejudicially, the detailed declarations. As this Court is aware, USPTO counsel is still rapidly preparing its response to GSK's substantial and late-filed motion for a preliminary injunction, while also preparing for oral argument on October 31, 2007, and anticipating receipt of the opposition to its partial motion to dismiss in <u>Tafas</u> today. This Court should reject AIPLA's excuse and deny its attempt to sandbag the USPTO. If it wishes to be heard, AIPLA will have ample opportunity to timely provide the

<sup>&</sup>lt;sup>2</sup> The plaintiff in <u>Tafas</u> withdrew his motion for preliminary injunction on September 9, 2007. <u>See</u> (Dkt. No. 15). There has, however, been briefing in the <u>Tafas</u> case since plaintiff withdrew his preliminary injunction motion.

Court its views at the summary judgment stage.

### II. AIPLA'S PROPOSED AMICUS BRIEF IMPROPERLY CONTAINS NEW ARGUMENTS

Historically, an amicus curiae has been a non-partisan provider of legal perspective or information to the court. Ryan v. Commodity Futures Trading Comm'n, 125 F.3d 1062, 1063 (7th Cir. 2006) (Posner, J.). Its purpose was to provide impartial information on matters of law about which there was doubt, especially in matters of public interest. Miller-Wohl Co. v. Comm'r of Labor & Indus., 694 F.2d 203, 204 (9th Cir. 1982). "The orthodox view of amicus was, and is, that of an impartial friend of the court - not an adversary party in interest in the litigation." United States v. Michigan, 940 F.2d 143, 164-165 (6th Cir. 1991). In that vein, courts have routinely restricted amicus curie from raising additional legal issues or arguments not already addressed by the parties. See, e.g., Russian River Watershed Protection Comm. v. Santa Rosa, 142 F.3d 1136, 1141 n.1 (9th Cir. 1998) (refusing to consider issue raised only by an amicus); Cellnet Comm'ns, Inc. v. F.C.C., 149 F.3d 429, 443 (6th Cir. 1998) ("While an amicus may offer assistance in resolving issues properly before a court, it may not raise additional issues or arguments not raised by the parties."); United States v. Sturm, Ruger & Co., Inc., 84 F.3d 1, 6 (1st Cir. 1996) ("While amicus briefs are helpful in assessing litigants' positions, an amicus cannot introduce a new argument into a case."); Wyatt By And Through Rawlins v. Hanan, 868 F. Supp. 1356, 1358-59 (M.D.Ala. 1994) ("The named parties should always remain in control with the amicus merely responding to the issues presented by the parties. An amicus cannot initiate, create, extend, or enlarge issues.").

Here, although not mentioned in the amicus brief itself, all four declarations attack certain provisions of the Final Rules that are not the subject of plaintiffs' preliminary injunction motion,

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and therefore, are entirely new legal arguments to which defendants must respond. <u>See</u> Kappos, Magen, Hetz Decls.(criticizing the implementation of 37 C.F.R. § 1.78(f)<sup>3</sup>); Helfgott Decl. (discussing the Rules' effect on the international Patent Cooperation Treaty ("PCT") filing and examination processes). Specifically, through the submissions of the Kappos, Magen, and Hetz declarations, AIPLA challenges 37 C.F.R. § 1.78(f) – a provision of the Final Rules designed to prevent the duplicate examination of the same invention – asserting that compliance with the new rule will result in unrecoverable expenses, and therefore, irreparable harm.<sup>4</sup> Leaving aside the dubious proposition that such compliance costs constitute "irreparable harm," any analysis of the propriety of § 1.78(f) and its putative detrimental impact is completely absent from GSK's brief, and therefore, it is not currently before the Court. AIPLA's blatant attempt to dramatically expand the scope of the already numerous and complex issues pending in GSK's preliminary injunction motion should be summarily rejected as improperly exceeding the bounds of the amicus curiae role. <u>See Cellnet Communications, Inc.</u>, 149 F.3d 429 at 443; <u>cf. Artichoke Joe's Cal. Grand</u>

<sup>&</sup>lt;sup>3</sup> AIPLA's implicit contention that the implementation of 37 CFR 1.78(f) on November 1, 2007 would expose the public to irreparable harm is specious at best. <u>See</u> Kappos Declaration. It is undisputed that the Final Rule does not require applicants to comply with the requirements of 37 CFR 1.78(f) until February 1, 2008. <u>See</u> 72 Fed. Reg. at 46717.

<sup>&</sup>lt;sup>4</sup> The Rules require that an applicant identify for each application any other commonly-owned applications or patents that have a common inventor and that have a filing or priority date within two months of the filing or priority date of the application. See 72 Fed. Reg. 46721; 37 C.F.R. § 1.78(f)(1). As explained in the memorandum supporting the USPTO's motion to dismiss filed in Tafas, p. 10, the Final Rules set forth a rebuttable presumption that an application and any identified commonly-owned applications or patents contain at least one "patentably indistinct claim (<u>i.e.</u>, a claim that does not patentably differ from the claims in a previously filed patent application) if the identified applications or patents have (i) an inventor in common with the application, (ii) the same filing or priority date as the application, and (iii) substantial overlapping disclosure with the application. 72 Fed. Reg. 46722; 37 C.F.R. § 1.78(f)(2).

<u>Casino v. Norton</u>, 353 F.3d 712, 719 n.10 (9th Cir. 2003) (recognizing that courts generally "do not address issues raised only in an amicus brief"); <u>Universal City Studios, Inc. v. Corley</u>, 273 F.3d 429, 445 (2d Cir. 2001) (noting that the amicus brief is "normally not a method for injecting new issues into an appeal").

#### **CONCLUSION**

For these reasons, the Court should deny AIPLA's motion for leave to file an <u>amicus</u> brief. In the alterative, and at a minimum, the USPTO respectfully requests that the Court strike the four declarations. A proposed Order is attached for the convenience of the Court.

/s/

Respectfully submitted,

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# **CERTIFICATE OF SERVICE**

I hereby certify that on October 26, 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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