

**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 TRIANTAYLLOS TAFAS’S REPLY TO DEFENDANTS’
MEMORANDUM IN OPPOSITION AND IN FURTHER SUPPORT
OF ENTRY OF PRELIMINARY INJUNCTION**

The Plaintiff, Dr. Triantafyllos Tafas (“Plaintiff” or “Dr. Tafas”), through his counsel, Kelley Drye & Warren LLP, submits this Reply to Defendants’ Memorandum In Opposition to Motion for Preliminary Injunction dated October 28, 2007 (the “Preliminary Injunction Opposition”)(Docket No. 46), and in further support of the entry of an Order of preliminary injunction.

As discussed below, the purpose of this brief reply is to clarify several points recently made by Defendants in the court record. Absent such a clarification, Dr. Tafas is concerned that the Court may be left with the false impression that he opposes the entry of a temporary restraining order and preliminary injunction. Additionally, Dr. Tafas' objects to Defendants' request in its Preliminary Injunction Opposition that the Court modify the expedited summary judgment briefing schedule negotiated between Dr. Tafas and the USPTO as a condition precedent to permitting Glaxo to submit its own summary judgment papers on the same schedule.

DR. TAFAS STRONGLY SUPPORTS THE ISSUANCE OF A PRELIMINARY INJUNCTION

First, Defendants stated and/or implied in several recent court filings that Dr. Tafas does not support or the entry of preliminary injunctive relief. For example, Defendants represented in their Emergency Motion to Continue Hearing on Preliminary Injunction Motion dated October 16, 2007 (Docket No. 17) that Dr. Tafas "agreed" that a preliminary injunction was "unnecessary":

By contrast, Triantafyllos Tafas, the plaintiff in another civil action in this Court who is challenging the same Final Rules on substantially the same grounds, filed a complaint challenging the Final Rules on August 22, 2007 and ultimately agreed that a preliminary injunction was unnecessary. See Tafas v. Dudas, Civil Action No. 1:07cv846 (JCC/TRJ)(Dkt. No. 16, p.1).

Emergency Motion, p. 3, ¶ 4 (Emphasis Added) . Similarly, Defendants later implied in their Preliminary Injunction Opposition that Dr. Tafas does not support the issuance of a preliminary injunction -- apparently reasoning that because Dr. Tafas negotiated an expedited briefing schedule on the merits in lieu of proceeding on a preliminary injunction that this constitutes an admission that there is no threatened irreparable harm:

First, Plaintiff will not be irreparably harmed during the pendency of this litigation.

* * * *

[fn 1] The USPTO does not expect prolonged litigation of this case. At present, the USPTO has agreed to an expedited briefing schedule in Tafas v. Dudas, 1:07cv846 (JCC/TRJ), *in lieu* of Dr. Tafas seeking a preliminary injunction....

Preliminary Injunction Memorandum, p. 1 and fn. 1 (footnote citation omitted).

Nothing could be further from the truth as Dr. Tafas strongly supports the issuance of a preliminary injunction here. In fact, Dr. Tafas filed his own preliminary injunction motion at the outset of the case in August 2007 and a hearing was initially set for September 7, 2007. (See Docket Nos. 1-6). The original hearing date were later extended until September 21, 2007 at the USPTO's request. Dr. Tafas' later decision to withdraw his motion for preliminary injunction had nothing to do with the underlying merits of the motion as Defendants seem to be implying.

First, after amending and substantially expanding his complaint, Dr. Tafas decided not to renew his own motion for preliminary injunction only after learning that other major U.S. companies, trade associations and/or business interests (after having had the opportunity to carefully study the legal blueprint set forth in Dr. Tafas' highly publicized law suit for almost a month) were finally starting to get sufficiently up to speed to enable them to mount their own legal challenges to the Revised Rules.

Dr. Tafas reasonably concluded that these larger "players" would likely be in a far better position than himself -- both financially (in terms of their ability to fund the litigation, hire experts, etc.) and due to the sheer scale and breadth of their patent related business operations -- to most effectively illustrate to the Court in a preliminary injunction context the enormous scope, quantum and gravity of immediate irreparable harm that will flow from implementation of the

Revised Rules on November 1, 2007. Since the entire patent community (including Dr. Tafas) would necessarily benefit from the issuance of a preliminary injunction, Dr. Tafas felt it important not to race forward with his own preliminary injunction and, in the process, potentially foreclose others who might be better situated than Dr. Tafas to prosecute this part of the fight from later bringing their own motions should they be so inclined.

While Dr. Tafas continues to strongly believe that he is faced with immediate irreparable harm¹ if the new Revised Rules are not preliminarily enjoined, Dr. Tafas concluded that a larger entity-plaintiff -- with potentially hundreds if not thousands of pending patent applications -- is likely better positioned than Dr. Tafas to establish the kind of factual record that would best illustrate the scope, breadth and types of irreparable harm. In other words, in addition to litigation cost considerations, Dr. Tafas did not renew his own preliminary motion because it was apparent that others with a far greater financial interests at stake were prepared to “pick up the baton” and might be better able to create a factual record that would present the most persuasive case as to the need for a preliminary injunction (particularly as to the balance of hardship and public interest prongs of the preliminary injunction test), were now ready to enter the fray.

In light of all the foregoing, Dr. Tafas decided he could best advance his objective of invalidating the Revised Rules by negotiating a scheduling order that was designed -- regardless of whether anyone actually subsequently came forward to seek a preliminary injunction and/or the outcome of same -- to permit the core legal issues in the case to be

¹ Dr. Tafas filed his Memorandum in Opposition to Defendant’s Partial Motion to Dismiss and a supporting Declaration on October 26, 2007 in which Dr. Tafas reiterates and expands on the immediate irreparable harm caused to him and, *inter alia*, emerging companies, small businesses, research intensive companies and independent inventors by implementation of the Revised Rules. (See Docket No. 31). Dr. Tafas invites the Court to take judicial notice of these matters in further support of the motion for preliminary injunction and/or treat them as *amicus* submissions.

submitted to the Court for a decision on the merits far earlier than would normally be the case under the Federal Rules of Civil Procedure.

Because it was in the interests of all sides to obtain a ruling on the pure legal question as to whether the USPTO's Revised Rules were *ultra vires* as quickly as possible, Dr. Tafas successfully negotiated a highly advantageous scheduling order with the USPTO that provides for : (i) substantially expedited pleading schedule; (ii) substantially expedited production by the USPTO of the administrative record; and (iii) substantially expedited summary judgment briefing schedule with a final hearing on the merits scheduled for December 21, 2007. (See Stipulation and Consent Order was submitted to and approved by the Court on September 21, 2007, as amended (Docket Nos. 16, 23 and 28)(the "Tafas Expedited Scheduling Order").

THE MERITS OF THE CASES SHOULD BE HEARD AT THE SAME TIME

The Tafas Expedited Scheduling Order predated the Court's Order dated October 17, 2007 (Docket No.25)(the "Consolidation Order") consolidating the *Glaxo Smithkline* case into the *Tafas* case. In the Consolidation Order, the Court ruled that the cases are "inextricably interwoven." Since the primary issues for ultimate resolution are the same legal questions, it makes no sense that Glaxo Smithkline ("Glaxo") should be denied the ability to avail itself of the advantageous Tafas Expedited Scheduling Order (as Glaxo requested in its preliminary injunction papers). See Glaxo Proposed Injunction Order, pp. 4-5; Preliminary Injunction Opposition, p. 1 n.1.

Defendants argue that they are prepared to proceed on the merits expeditiously and imply that there is no immediate irreparable harm because the expedited briefing schedule on the merits entered into with Dr. Tafas precludes any possibility of "prolonged litigation" concerning the ultimate merits. (See Preliminary Injunction Opposition, p. 1-2, n.1).

Incongruously, however, Defendants suggest in the very same breath that Glaxo should nonetheless not be permitted to avail itself of the expedited Tafas schedule.

As the Court itself recognized in its *sua sponte* Consolidation Order, the *Tafas* and *Glaxo* cases are “inextricably interwoven.” With the very narrow exception of Dr. Tafas’ claim predicated on the Regulatory Flexibility Act (RFA) and some minor differences in structure and linguistics, for the most part Glaxo’s newly filed claims essentially parrot all the same basic legal theories as set forth in Dr. Tafas’ earlier filed complaints (*i.e.*, that the USPTO’s enactment of the Revised Rules was *ultra vires* and in contravention of the Patent Act, the U.S. Constitution and the APA’s notice and comment provisions). As just one important example, Glaxo’s central argument that the Revised Rules violate Section 120 of the Patent Act (as interpreted in In re Hogan and In re Hendricksen) was extensively briefed in Dr. Tafas’ original preliminary injunction papers filed back in August 2007.

Again, there are no surprises in Glaxo’s complaint or any meaningful expansion in the type or scope of claims that would make it unfair to require the USPTO to litigate the two (2) mirror image cases together on the same expedited track. Defendants may not reasonably claim unfair surprise or any unreasonable prejudice from Glaxo being permitted to submit its summary judgment papers on the same schedule as Dr. Tafas. As previously noted, Dr. Tafas had already asserted all of these claims and the USPTO has been well aware since the filing of Dr. Tafas lawsuit on August 22, 2007 that it would ultimately need to brief all of these legal points. The mere fact that Glaxo has now asserted the same claims and legal theories as Dr. Tafas does not materially increase Defendant’s workload. Moreover, Defendants’ suggestion that a hearing on the merits of the case could somehow be sensibly bifurcated and that the *Glaxo* and *Tafas* cases should be decided sequentially at different times makes no sense at all given that

the primary over-arching legal issues are substantively identical. In effect, Defendants are really asking the Court to nullify the Consolidation Order as a *de facto* matter, but they have entirely failed to present any persuasive explanation as to how it could possibly make sense to separately decide two (2) already consolidated cases that present the exact same core legal questions. Of course, there is none. These two (2) cases need to be heard on the merits at the same time and the inevitability that these mirror image cases would be consolidated was or should have been obvious to Defendants from the first day Glaxo filed its action.

In all events, Dr. Tafas objects to Defendants' suggestion that it should be permitted to renege on the expedited schedule Defendants agreed to with Dr. Tafas nor should the Court condition Glaxo's ability to equally participate with Dr. Tafas in a final hearing on the merits in the consolidated case on negating Dr. Tafas' rights.

Finally, the fact that there is a reasonable expedited schedule already in place that will permit the Court to entertain the reach the merits as early as December 2007 strongly militates in favor of the Court determining that the balance of hardships tilts in favor of issuing a preliminary injunction. As has been set forth exhaustively in the Glaxo papers and the various *amicus* submissions, the implementation of these rules will cause extreme hardship, if not chaos, on November 1, 2007. In light of the fact that the Court would be able to start making a ruling on the final merits of this case in less than 60 days, the USPTO really has no persuasive argument at all that waiting another 60 to 90 days to implement the Revised Rules while the Court considers the summary judgment papers would impose any substantial hardship on Defendants. Such an approach is seemingly far preferable to the other alternative, which is allowing the Revised Rules to become effective and then, if Dr. Tafas and Glaxo prevail on summary judgment, potentially invalidating them as part of summary judgment proceedings in

the next 60 to 90 days -- after the country's entire patent community have changed their positions complying with the Revised Rules.

Thus, for all the foregoing reasons, Dr. Tafas strongly supports the motion for preliminary injunction; continues to believe he is faced with immediate irreparable harm; and, that the balance of hardships and public interests weighs heavily in favor of the Court preliminarily restraining implementation of the Revised Rules so as to maintain the *status quo ante* until the Court is able to consider the case on the merits when it is finally submitted for decision in December 2007.

CONCLUSION

WHEREFORE, Plaintiff respectfully requests that the Court enter an Order of Preliminary Injunction, along with such, other, further and different relief as the Court deems just, equitable and proper.

Dated: October 30, 2007

Respectfully submitted,

s/ Joseph D. Wilson
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