

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
(Alexandria Division)

TRIANTAFYLLOS TAFAS,
Plaintiff,
v.
JON W. DUDAS et al.,
Defendants.

No. 1:07cv846-JCC-TRJ

SMITHKLINE BEECHAM
CORPORATION et al.,
Plaintiffs,
v.
JON W. DUDAS et al.,
Defendants.

No. 1:07cv1008-JCC-TRJ

MEMORANDUM IN SUPPORT OF MOTION
OF PHARMACEUTICAL RESEARCH AND MANUFACTURERS
OF AMERICA FOR LEAVE TO FILE AN AMICUS CURIAE BRIEF

The Pharmaceutical Research and Manufacturers of America ("PhRMA") has moved for leave to file a brief as amicus curiae in support of anticipated motions for summary judgment by plaintiffs in these consolidated cases challenging newly issued Patent and Trademark Office ("PTO") rules governing important aspects of patent prosecution practice. Plaintiffs do not oppose this motion, and Defendants take no position on this motion. Participation by an amicus curiae is appropriate where the proposed amicus has "an important interest" in the case and

would provide “a valuable perspective that is helpful to the Court.” *United States v. Boeing Co.*, 73 F. Supp. 2d 897, 900 (S.D. Ohio 1999). PhRMA clearly meets that standard.

As an initial matter, PhRMA has a significant interest in the newly promulgated PTO rules governing patent prosecution. PhRMA is a non-profit corporation whose members are the country’s leading research-based pharmaceutical and biotechnology companies. These companies are devoted to discovering and developing new medications that allow people to live longer, healthier, and more productive lives. Together, PhRMA’s members account for over 60% of the sales of prescription drugs in the United States. Many of the prescription drugs discovered and developed by PhRMA members are covered by patents. Patent protection provides incentives necessary to spur innovation in this area, and it permits pharmaceutical and biotechnology companies to recoup research and development expenditures needed to develop new life-saving drugs for unmet medical needs. The PTO rules, if allowed to take effect, would impermissibly undercut long-held rights relating to the filing of patent applications that are important to pharmaceutical and biotechnology companies seeking patent protection for complex inventions that can take years to develop.

The breadth of PhRMA’s membership gives PhRMA an important interest and a unique perspective on this litigation. PhRMA’s members span the pharmaceutical and biotechnology industries, and include large and small companies, domestic and international companies, and public and private companies. Its members make hundreds of different kinds of drugs and every year file thousands of patent applications. PhRMA thus is uniquely qualified to comment upon the impact of these new rules on an entire industry.

PhRMA is committed to ensuring that its participation is productive rather than burdensome. Although PhRMA supports the motion for a temporary restraining order and a

preliminary injunction filed by the GlaxoSmithKline plaintiffs (“GSK”), in light of the fast-approaching November 1, 2007 effective date of the PTO regulations and the need for expedited resolution of GSK’s motion, PhRMA is not seeking to file an amicus brief in connection with that motion. Rather, PhRMA seeks only to participate as an amicus in connection with the upcoming summary judgment motions.

In order to eliminate any potential redundancy but ensure that the PTO has an opportunity to respond to PhRMA’s arguments, PhRMA is seeking leave to file its amicus brief one week after the plaintiffs file their motions for summary judgment. Under a recently submitted stipulation in the Tafas case, Mr. Tafas’s motion for summary judgment is due on November 7, 2007, and the PTO’s cross-motion and opposition are due on December 4, 2007. If that schedule remains in place and governs both motions by Mr. Tafas and GSK, then PhRMA seeks leave to file its amicus brief on November 14, 2007. If that schedule changes or a different schedule is imposed for a motion for summary judgment by GSK, PhRMA requests that its brief be due one week after GSK’s summary judgment motion is due.

Date: October 26, 2007

Respectfully submitted,

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CERTIFICATE OF SERVICE

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

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