

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

_____	)	
TRIANTAFYLLOS TAFAS,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 1:07cv846 (JCC/TRJ)
	)	
JON W. DUDAS, et al.	)	
	)	
Defendants.	)	
_____	)	

CONSOLIDATED WITH

_____	)	
SMITHKLINE BEECHAM	)	
CORPORATION, et al.	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No. 1:07cv1008 (JCC/TRJ)
	)	
JON W. DUDAS, et al.	)	
	)	
Defendants.	)	
_____	)	

**MEMORANDUM IN SUPPORT OF *AMICUS CURIAE* ELAN PHARMACEUTICAL CORPORATION’S MOTION FOR LEAVE TO FILE ITS BRIEF IN SUPPORT OF THE “GSK” PLAINTIFFS’ MOTION FOR A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION**

Elan Pharmaceuticals, Inc., on behalf of itself and its parent and affiliates (herein collectively referred to as “Elan”) submits this memorandum in support of its Motion for leave to file its brief as *amicus curiae* in support of SmithKline Beecham Corporation, SmithKline Beecham PLC and Glaxo Group Limited’s Motion for a Temporary Restraining Order and Preliminary Injunction (“Brief”).

Elan is a biotechnology company that is focused on discovering, developing, manufacturing and marketing advanced therapies in neurology, autoimmune diseases, and severe pain. Elan wishes to submit its *amicus* Brief addressing the likelihood of success on the merits, irreparable harm, and public interest prongs of the pending Motion for Temporary Restraining Order and Preliminary Injunction.

Allowing a non-party to file an *amicus curiae* brief is within the discretion of the Court. *DeJulio v. Georgia*, 127 F. Supp. 2d 1274, 1284 (N.D. Ga. 2001). The filing of an *amicus* brief should be allowed where the *amicus curiae* can “offer insights not available from the parties” or can provide “unique information or perspective that can help the court beyond the help that the lawyers for the parties are able to provide.” *Citizens Against Casino Gambling in Erie County v. Kempthorne*, 471 F. Supp. 2d 295, 311 (W.D.N.Y. 2007). Here, while Elan concurs with GSK’s assertion that the “Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications,” 72 Fed. Reg. 46716 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1) (hereinafter “Final Rules”) are *ultra vires*, Elan’s Brief expands on GSK’s position that the Final Rules improperly shift the burden of examining a patent application from the U.S. Patent and Trademark Office (“PTO”) to the applicant. This burden shifting is contrary to law and serves as a basis to overturn the Final Rules.

Similarly, Elan’s Brief supports the irreparable harm prong and provides additional insight into how Elan and other patent applicants would suffer irreparable harm through the implementation of the Final Rules. Some of this harm would result from Elan and other pharmaceutical companies’ reluctance to invest heavily in research and development of new drugs since the patent protection on drugs will not be as effective and will not allow Elan to



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**CERTIFICATE OF SERVICE**

I hereby certify that on this 29<sup>th</sup> day of October 2007, I electronically filed in Case Nos. 1:07cv1008 and 1:07cv846 (JCC/TRJ) the foregoing “**MEMORANDUM IN SUPPORT OF AMICUS CURIAE ELAN PHARMACEUTICAL CORPORATION’S MOTION FOR LEAVE TO FILE ITS BRIEF IN SUPPORT OF THE ‘GSK’ PLAINTIFFS’ MOTION FOR A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION**” using the CM/ECF system and that service was thereby accomplished on:

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I further certify that on this 29<sup>th</sup> day of October 2007, I caused a copy of the foregoing to be served by U.S. Mail, postage prepaid, upon:

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