Tafas v. Dudas et al Doc. 39 Att. 2

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

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

CONSOLIDATED WITH

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

BRIEF FOR AMICUS CURIÆ ELAN PHARMACEUTICALS, INC. IN SUPPORT OF THE MOTION FOR A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION BY THE "GSK" PLAINTIFFS

Rebecca M. Carr (VSB # 70874)
PILLSBURY WINTHROP
SHAW PITTMAN, LLP
2300 N Street, N.W.
Washington, D.C. 20037
Tel: 202-663-8000
Fax: 202-663-8007
e-mail: rebecca.carr@pillsburylaw.com

Dockets.Justia.com

Scott J. Pivnick (VSB # 48022)
PILLSBURY WINTHROP
SHAW PITTMAN, LLP
1650 Tysons Boulevard
McLean, Virginia 22102-4856
Tel: 703-770-7900
Fax: 703-770-7901
e-mail: scott.pivnick@pillsburylaw.com

Of Counsel
Vincent J. Napoleon
PILLSBURY WINTHROP
SHAW PITTMAN, LLP
2300 N Street, N.W.
Washington, D.C. 20037

ATTORNEYS FOR *AMICUS CURIÆ*
ELAN PHARMACEUTICALS, INC.

I. ELAN HAS AN INTEREST IN MAINTAINING STRONG PATENT PROTECTION

A. Introduction

Elan Pharmaceuticals, Inc., on behalf of itself and its parent and affiliates (herein collectively referred to as "Elan"), submits this brief in support of the Motion for Temporary Restraining Order and Preliminary Injunction filed by Plaintiff GlaxoSmithKline ("GSK") in the above-captioned case. Like GSK, Elan believes that the new rules promulgated by the United States Patent and Trademark Office ("PTO") violate the Patent Act. *See* "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"). Like GSK, Elan will suffer irreparable harm by having to relinquish valuable patent rights if the Final Rules take effect on November 1, 2007. As a result, this Court should grant GSK's motion for a preliminary injunction.

B. Background

Elan is a biotechnology company that is focused on discovering, developing, manufacturing and marketing advanced therapies in neurology, autoimmune diseases, and severe pain. *See* Attachment 1, Declaration of Carl Battle, ¶ 5 (hereinafter "Battle

Decl.”). Elan’s discovery research efforts in neurology are focused on the area of neuropathology-related disorders, such as Alzheimer’s disease, and other neurodegenerative diseases, such as Parkinson’s disease. Battle Decl. ¶ 6. In autoimmune diseases, Elan’s primary emphasis is studying cell trafficking to discover ways to provide disease-modifying therapies for diseases such as rheumatoid arthritis, multiple sclerosis and inflammatory bowel disease. *Id.* In the area of severe pain, Elan’s research efforts focus on inflammatory and neuropathic pain. *Id.*

Elan has numerous products in various stages of drug development. *See* Battle Decl. ¶ 7-13. For example, one of its products for the treatment of Alzheimer’s disease is now into Phase II clinical testing to determine preliminary efficacy, dosage, and expanded evidence of safety. Battle Decl. ¶ 13. In contrast, Elan’s products for the treatment of Parkinson’s disease are only in the early discovery stage where scientific research is being conducted with the aim of developing a drug for the treatment of that medical condition. *Id.*

For Elan, and as is typical with all drug discovery companies, the drug development pipeline is a long period typically spanning many years, if not decades. Battle Decl. ¶ 14. For example, the scientific research that forms the basis of Elan’s current pipeline of products for the treatment of Alzheimer’s disease began in 1986. *Id.* However, Phase I clinical testing of a product for the treatment of Alzheimer’s was not initiated until 2001. *Id.* Although Elan is conducting Phase II clinical testing for a certain product for this indication, Elan still does not have a marketable product for the treatment of Alzheimer’s disease. *Id.*

Drug development is also extremely expensive. Battle Decl. ¶ 15. All aspects of scientific research for drug development are costly, particularly the equipment, materials and repeated experimentation. *Id.* A product must also undergo extensive clinical trials before it can be approved for marketing. *Id.* These trials are primarily concerned with the safety, efficacy and quality of new drugs and are very expensive to undertake. *Id.* As a result of the discovery and testing required, on average, it costs Elan over $500 million to bring a new drug from concept to the market. Battle Decl. ¶ 16. In fact, Elan currently spends about $230 million each year on research and development for new drugs. *Id.*

Because drug development is extremely expensive and can take many years, companies engaged in drug development are heavily dependent upon patent protection. Battle Decl. ¶ 17. These companies, including both traditional pharmaceutical companies and biotechnology companies, rely heavily on the patent system to attempt to secure market exclusivity on any inventions so as to enable those companies to recover their investments in drug development. *Id.*

In this regard, Elan is no exception. Elan's competitive position depends, in part, on its ability to obtain patents on the technologies and products that it has developed. Battle Decl. ¶ 18. For example, one of Elan's most recent products is TYSABRI®, a monotherapy treatment for relapsing forms of multiple sclerosis (MS) that slows the progression of disability and reduces the frequency of clinical relapses. *Id.* TYSABRI® is covered by a number of pending patent applications and issued patents in the United States and many other countries. *Id.* Elan has a basic patent in this country for TYSABRI® covering a humanized antibody and its use to treat MS. *Id.* That basic patent is set to expire in 2017, due to a patent term extension. *Id.* Elan also has numerous

continuation patents and patent applications related to later discovered uses of the invention initially covered by the basic TYSABRI® patent. *Id.* These continuation patents allow Elan to maintain patent protection over its discoveries as the drugs continue to be developed and refined and approved. *Id.* If Elan were to lose its basic patent coverage or be forced to give up the protections afforded by the continuation practice, this would likely give competitors the ability to make, use or sell their own versions of TYSABRI®, which would materially and adversely affect Elan and its ability to develop future groundbreaking drugs like TYSABRI®. *Id.*

In addition, Elan has copied and is currently considering the possibility of copying claims from other published applications or issued patents filed by competitors in order to provoke interferences to determine whether Elan would be entitled to those patents and pending applications because its employees were the first to invent the subject matter at issue, not the competitors who filed the other applications. Battle Decl., ¶ 21; s*ee* 35 U.S.C. § 135 (providing for "interference" proceedings in PTO for applications having claims covering "substantially the same subject matter" as issued patents or other published applications).

C. Elan's Interest in this Case

Elan has no financial interest in GSK and does not currently cooperate with GSK in connection with the development of any of Elan's products on the market or in its drug development pipeline. Battle Decl., ¶ 22.

However, Elan has a common interest with GSK – both companies rely on strong patent protection to recoup their significant investments in drug development. Battle Decl., ¶ 23; see Memorandum in Support of Plaintiff's Motion for a Temporary Restraining Order and Preliminary Injunction (hereinafter "GSK Brief"), at 4-5. Just like

GSK, without patent protection, or with inadequate patent protection, Elan would not be in a position to undertake the huge investment in research and development necessary to bring drugs to the marketplace. Battle Decl. ¶ 23. Just like GSK, Elan believes that the PTO's Final Rules will ultimately result in weakened, if not inadequate, patent protection for pharmaceutical and biotechnology companies involved in drug discovery and development. *Id.* Accordingly, Elan respectfully submits this memorandum in support of GSK's position in this matter.

II. ARGUMENT

The PTO should be preliminarily enjoined from implementing its Final Rules. For the reasons asserted in the GSK Brief, and because the PTO's Final Rules improperly shift the burden of examination onto applicants, implementing the Final Rules will cause irreparable harm to the pharmaceutical and biotechnology industries and negatively impact the public interest in innovation in pharmaceutical products.

A. GSK is Likely To Prevail On the Merits

1. The PTO's Final Rules Violate the Patent Act

For the reasons mentioned in the GSK Brief, Elan respectfully submits that GSK is likely to prevail on the merits of its claim. GSK Brief, at 15-27. Elan believes that the Final Rules are *ultra vires* because the PTO lacks substantive rulemaking power and because they retroactively change the legal consequences of applications that have already been filed based on the current laws. *See Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996) (expressly recognizing the limit to the PTO's power to issue substantive rules). In particular, it is clear that the new Rule 1.78 exceeds the plain language of Section 120 of the Patent Act. 35 U.S.C. § 120.

Section 120 of the Patent Act permits patent applicants to file an unlimited number of continuation applications that will relate back to the filing date of the original application. *Id.* In this regard, the statute expressly states that an "application for patent for an invention disclosed … in an application previously filed in the United States … *shall have the same effect*, as to such invention, as though filed on the date of the prior application …." *Id.* (emphasis added). There is nothing in the language of that statute that gives the PTO the discretion to limit the number of continuation applications or deprive applicants the right of priority granted to such applications under Section 120.

Despite this, in amending Rule 1.78 in the Final Rules, the PTO restricts applicants to only *two* continuation applications without the need for filing a petition and making a special showing that the amendment, arguments, or evidence could not have been submitted during the prosecution of the two prior-filed applications. 72 Fed. Reg. 46839. If this special showing cannot be satisfied, then the subsequent application will lose the benefit of priority that it otherwise would have been entitled to under Section 120 of the Patent Act.

Because the PTO lacks substantive rulemaking power, it simply does not have the power to arbitrarily limit or condition the number of continuation applications to which an applicant is entitled or to deprive an application of the benefit of priority. *See Merck*, 80 F.3d at 1549-50 (expressly recognizing the limit to the PTO's power to issue substantive rules); *In re Henriksen*, 399 F.2d 253, 254 (C.C.P.A. 1968) (stating that the PTO has "no statutory basis for fixing an arbitrary limit to the number of prior applications through which a chain of copendency may be traced to obtain the benefit of the filing date of the earliest of a chain of copending applications, provided applicant

meets all the other conditions of the statute"). Rather, the PTO must comply with the language of the statute, which provides for an unlimited number of continuation applications.

2. The PTO's Final Rules Violate the Patent Act by Shifting the Burden of Evaluating Patentability to the Applicant

One argument not emphasized by GSK and which is worthy of this Court's attention is the impact of the Final Rules on an applicant's entitlement to a patent unless the PTO proves otherwise. In short, contrary to the Patent Act and established case law, the Final Rules will improperly and unfairly shift the burden onto patent applicants to evaluate patentability in the first instance in many cases.

Section 102 of the Patent Act provides that "[a] person shall be entitled to a patent unless" certain conditions for patentability are not satisfied. 35 U.S.C. § 102. Furthermore, Section 131 provides that the "Director shall cause an examination to be made of the application and the alleged new invention; and if on such examination it appears that the applicant is entitled to a patent under law, the Director shall issue a patent therefor." 35 U.S.C. § 131.

In view of these statutory sections, it has been repeatedly held that the PTO carries the burden of proving in the first instance that an application should not issue. Only where the PTO meets that burden does it then shift to the applicant to overcome the *prima facie* case of unpatentability. *See, e.g., In re Oetiker*, 977 F2d 1443, 1444 (Fed. Cir. 1992) ("the examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant."); *In re Piasecki*, 745 F.2d 1468, 1472 (Fed.Cir. 1984) (same).

Despite this statutory language and well-developed case law, the PTO's Final Rules shift this burden by requiring the applicant to perform a search and examination in the first instance in some cases. The Final Rules restrict an applicant to five independent claims and a total number of twenty-five claims before requiring an applicant to file an Examination Support Document ("ESD") in compliance with new Rule 1.265. 72 Fed. Reg. at 46836-37. New Rule 1.265 requires that the applicant conduct a preexamination search of United States patents, patent application publications, foreign patent documents and non-patent literature. *Id.* The ESD must also include a detailed explanation particularly pointing out how each of the independent claims is patentable over the prior art references and a showing where each limitation of each of the claims finds support in the written description of the specification. *Id*.

There can be no doubt that an ESD constitutes an applicant's own examination of the application. It requires both a search and evaluation of the patentability of the claimed invention in view of the formalities imposed by the Patent Act and over the prior art uncovered during the search. That is exactly the PTO's obligations under section 102 and 131 under the Patent Act.

It does not matter that an ESD is only required after the applicant has filed an application containing more than five independent claims and twenty-five total claims. There is simply no statutory basis to require the applicant to evaluate patentability in the first instance in any situation. Compounding the problem is the fact that the Final Rules apply the ESD requirements retroactively, applying them to any pending application that has not yet received a first Office action from the PTO on the merits. 72 Fed. Reg. at 46716. Thus, not only is the PTO violating the Patent Act in future applications, but also

in connection with those that are already pending and which were filed by applicants who had the expectation that they were entitled to an examination *by the PTO* of their applications regardless of the number of independent claims and total number of claims.

Elan currently has numerous applications on file with the PTO that have more than five independent claims and more than twenty-five total claims, and many of those applications have not yet been examined by the PTO in a first Office action. Battle Decl., ¶ 24. Thus, under the Final Rules, Elan will be forced to either do the PTO's job of examination or lose application claims, thereby possibly surrendering valuable patent rights. *Id.*

Because requiring a preexamination search and patentability evaluation simply transfers the PTO's statutory responsibilities onto applicants, and because there is absolutely no statutory basis for such a transfer, the PTO's Final Rules violate the Patent Act.

B. The PTO's Final Rules Will Cause Irreparable Harm to the Pharmaceutical and Biotech Industries and the Public Interest

1. Pharmaceutical and Biotech Companies, Like GSK and Elan, will have to Surrender Claims and Lose Entire Patent Applications

The PTO's Final Rules will drastically harm pharmaceutical and biotechnology companies, such as GSK and Elan, by forcing them to surrender currently pending claims and abandon or lose entire applications. GSK Brief, at 27-28.

For example, the Final Rules restrict applicants to no more than *two* non-provisional continuation applications before requiring a petition showing that the amendment, arguments or evidence could not have been submitted during the prosecution of the prior-filed application. 72 Fed. Reg. at 46839. As a result, if applicants cannot

satisfy this "could not have been submitted" standard, they will lose the benefit of priority which the statute otherwise provides. 35 U.S.C. § 120. Such a loss of priority will allow additional art to be used to invalidate the claims, including an applicant's own earlier-filed application, and entire patent applications may be lost as a result.

Elan has a large number of pending patent applications, including numerous continuation applications, and many of these applications have already had at least two continuations filed. Battle Decl., ¶ 25. For these applications, Elan may be forced to abandon patent rights on what was previously considered patentable subject matter prior to the implementation of the Final Rules. *Id.* While Elan may be able to argue in some cases that the claims in the later-filed continuation applications are patentably distinct or could not have been filed earlier, such an argument will be virtually impossible to make successfully in the pharmaceutical and biotechnology arts because of the broad disclosures typically provided in first filed applications. *Id.* Thus, Elan will be irreparably harmed by implementation of the Final Rules.

The Final Rules also restrict an applicant to five independent claims and a total number of twenty-five claims before requiring the applicant to file an ESD. If an applicant chooses not to file an ESD for whatever reason, then the claims beyond the limit will be forever dedicated to the public domain.

Elan has a large number of patent applications on file with the PTO that have not yet had a first Office action, and many of these applications undoubtedly exceed the limit on the number of claims provided in the Final Rules. Battle Decl., ¶ 24. Because the Final Rules have retroactive effect, Elan is being forced to spend time and money evaluating all of these applications to assess whether an ESD can or should be filed in

connection with each previously-filed application. If Elan does not timely file an ESD in any of its applications, it could risk suspension of the application by the PTO or loss of any excessive claims. *Id.* Of course, the loss of any excessive claims would be irreparable because those potentially valuable patent rights would be dedicated to the public. In addition, if a patent application is suspended pending the filing of an ESD, this could potentially result in a loss of patent term since a patent is only effective twenty years from the date of filing. 35 U.S.C. § 154 (a)(2) (patent term ends 20 years from the date on which the application for patent was filed in the United States).

There is also a strong likelihood that Elan will be involved in a patent interference within the next two years. *See* Battle Decl. ¶ 21. An interference is a proceeding to determine which of two competing inventors is entitled to a patent – a question which turns on priority of invention and which inventor was the first to file an application. *See* 35 U.S.C. § 102(g) (priority of invention governed by respective dates of conception, reduction to practice, and reasonable diligence). Under the Patent Act, subject to certain time restrictions, an interference may be declared by the PTO for application claims which are the same or substantially the same as a patent issued or published application. 35 U.S.C. § 135 (setting forth parameters for an interference). Typically, in order to provoke such a proceeding, the claims of the prior publication or issued patent are copied. *See id* (indicating that claims in interference must be "the same as, or for the same or substantially the same subject matter"). However, if implemented, the Final Rules may preclude applicants such as Elan from copying more than 25 claims from an issued patent or published application given the limit on the number of claims contained in an application under those Final Rules. As a result, even if Elan were successful in getting

the PTO to declare an interference, the Final Rules may prevent Elan from obtaining the entirety of the subject matter to which it is entitled. Thus, in violation of section 102(g) of the Patent Act, the prior patentee or applicant may be able to escape with claimed subject matter simply because it was the first to file an application – *not* because it was not first inventor. In short, the Final Rules threaten to do what the United States Congress has not – change the patent system from first to invent to first to file for some claimed inventions.

Because the Final Rules will force pharmaceutical and biotechnology companies like Elan to surrender claims and lose entire applications, those companies will be irreparably harmed.

2. Surrendering Claims and Entire Applications Will Reduce the Incentive for Innovation in the Pharmaceutical and Biotechnology Industries in this Country

As described above, development of pharmaceutical and biotechnology products and related medical treatments requires a tremendous amount of time and money. As a result of the discovery and testing required, on average, it costs Elan over $500 million to bring a new drug from concept to the market. Battle Decl., ¶ 16. Elan currently spends about $230 million each year on research and development for new drugs. *Id.*

The reason that Elan is willing to spend this much money every year on research and development for new drugs is the potential economic reward for that investment in innovation. *See* Battle Decl. ¶ 18. Of course, robust patent protection plays a significant role in encouraging Elan to invest in the discovery and development of new drugs. *Id.* Robust patent protection for patents brought to market ultimately allows Elan to exclude competition from selling the very drug products that Elan spent so much money to discover and develop. *Id.* Absent the ability to exclude competition through robust

patent protection, Elan will have less ability to recoup its investments made in drug discovery and development and, ultimately, less money to invest in innovation. *Id.*

Because the PTO's Final Rules will force applicants to surrender claims and lose entire patent applications, those rules threaten the robust patent protection a pharmaceutical or biotechnology company needs to recoup investments in research and to continue to invest in innovation. The Final Rules will be particularly harmful to pharmaceutical and biotechnology companies because of the predominant patenting strategy used by such companies as a result of the very nature of drug discovery.

Elan, like many other pharmaceutical and biotechnology companies, typically files very broad initial applications on a class of new drug products that was discovered as a result of the drug discovery process. Battle Decl. ¶ 19. These initial applications are filed well before any human clinical trials, and typically cover a genus of compounds with numerous, structurally-related species of those compounds. *Id.* All of these species may be candidates for drug development, clinical trials, and potential sale. *Id.* Accordingly, Elan, just like GSK, typically files a first application with a broad disclosure and numerous, broad claims with the understanding that it will prosecute additional patent claims in continuation applications based on further research and data collected from human clinical trials. *Id.*; *see* GSK Brief, at 5-6 describing this same claiming strategy. The possible subject matter for these additional claims may include the molecular entities, pharmaceutical compositions, formulations, and methods of making, as well as methods of treatments and methods of administering used during clinical trials. Battle Decl., ¶ 19.

In practice, the PTO tends to reject Elan's broad initial applications for various reasons under Section 112 of the Patent Act, including violation of the enablement and written description requirements under paragraph 1 of that statute. 35 U.S.C. § 112, ¶ 1. In response, Elan tends to narrow its initial claims and as the drug development process continues and more data is developed to support broader claims, Elan files continuation applications to seek broader protection commensurate with the scope of its broad initial application disclosure. Battle Decl. ¶ 20. This process may go on for numerous years and several iterations so long as the drug development process continues to result in further data supporting further continuation applications. *Id.* Thus, under the current rules and because of the nature of the drug industry and federally-mandated drug approval process, it is not unusual to file multiple continuation applications to refine the claims for which the applicant is entitled to a patent. *Id.*

Because of the manner in which pharmaceutical and biotechnology companies protect their new drug developments, if Elan is prohibited from filing more than two continuation applications that claim priority back to the original discovery, there will be significantly reduced economic incentive to pursue breakthrough medicines or therapies. Battle Decl. ¶ 26. By the time the clinical effectiveness of a drug is realized, all patent rights will be waived either because a competitor will have used the earlier published applications to develop their own drug or because the earlier filed patent applications filed by Elan will be used as invalidating prior art on Elan's later discovered refinement of the original drug. *Id.*

It is worth emphasizing that Elan cannot maintain these later advances and refinements as trade secrets because the underlying data related to the new drug must be

disclosed to the Food and Drug Administration as part of the drug approval process. Battle Decl., ¶ 27.

Because the PTO's Final Rules will deter, if not completely prohibit, the very patenting strategy that is dictated by the demands of drug discovery and development, important pharmaceutical inventions will be dedicated to the public domain in the form of abandoned claims and lost continuation applications. Battle Decl. ¶ 28. This information will not benefit the public, however, because without further refinement the information will not allow for the creation of a helpful drug, and without the promise of patent protection, there will be no incentive for a company to undertake the very expensive research that is required. *Id.* Such a loss ultimately will depress Elan's incentive and ability to invest in drug discovery in the first place and cause irreparable harm to the pharmaceutical and biotechnology industries. *Id*.

3. Ultimately, Consumers Will Pay More Money for Fewer Choices of Pharmaceutical Products

Ultimately, consumers will bear the brunt of the PTO's Final Rules. Battle Decl., ¶ 29. Because there will be less incentive to invest in drug discovery in the long run, there will be fewer and fewer innovations in drug discovery. *Id.* In real terms, this means fewer products on the market and increased prices for consumers. *Id.* Certainly, Elan and others will be forced to raise prices to try to recoup their investments in research and development. *Id.*

There are serious emerging public health threats in this country and the world, including Avian Flu, antibiotic resistant strains of certain bacteria, and SARS just to mention a few. Battle Decl. ¶ 30. It is in the public interest to support a robust patent system that provides the foundation for encouraging investment to combat these and

other public health threats. *Id.* Certainly, given these threats, now is not the time to decrease incentive to innovate in the pharmaceutical and biotechnology industries. Because the current system provides for robust patent protection and encourages investment in innovation, implementation of the PTO's Final Rules should be preliminarily enjoined and the *status quo* should be maintained.

III. CONCLUSION

Because the Final Rules violate the language of the Patent Act, and because companies like Elan and ultimately consumers will be irreparably harmed absent a preliminary injunction against implementation of the PTO's Final Rules, GSK's motion should be granted.

Dated: October 29, 2007

Respectfully submitted,

By: /s/

Rebecca M. Carr (VSB # 70874)
PILLSBURY WINTHROP
SHAW PITTMAN, LLP
2300 N Street, N.W.
Washington, D.C. 20037
Tel: 202-663-8000
Fax: 202-663-8007
e-mail: rebecca.carr@pillsburylaw.com

Scott J. Pivnick (VSB # 48022)
PILLSBURY WINTHROP
SHAW PITTMAN, LLP
1650 Tysons Boulevard
McLean, Virginia 22102-4856
Tel: 703-770-7900
Fax: 703-770-7901
e-mail: scott.pivnick@pillsburylaw.com

ATTORNEYS FOR *AMICUS CURIÆ*
ELAN PHARMACEUTICALS, INC.

Of Counsel
Vincent J. Napoleon
PILLSBURY WINTHROP
SHAW PITTMAN, LLP
2300 N Street, N.W.
Washington, D.C. 20037

CERTIFICATE OF SERVICE

I hereby certify that on this 29th day of October 2007, I electronically filed in Case Nos. 1:07cv1008 and 1:07cv846 (JCC/TRJ) the foregoing "Brief for *Amicus Curiæ* Elan Pharmaceuticals, Inc. in Support of the Motion for a Temporary Restraining Order and Preliminary Injunction by the 'GSK' Plaintiffs" using the CM/ECF system and that service was thereby accomplished on:

Elizabeth M. Locke, Esq.
KIRKLAND & ELLIS LLP
655 15th Street, NW – Suite 1200
Washington, DC 20005
e-mail: elocke@kirkland.com

and

Craig C. Reilly, Esq.
RICHARD MCGETTIGAN REILLY & WEST PC
1725 Duke Street, Suite 600
Alexandria, VA 22314
e-mail: craig.reilly@rmrwlaw.com

Attorneys for Plaintiffs in Civil Action No. 1:07cv1008 (JCC/TRJ)

and

Lauren A. Wetzler, Esq.
United States Attorney's Office
2100 Jamison Ave.
Alexandria, VA 22314
e-mail: lauren.wetzler@usdoj.gov

Attorney for Defendants in Civil Action Nos. 1:07cv1008 (JCC/TRJ) and 1:07cv846 (JCC/TRJ)

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

Joseph Dale Wilson, III, Esq.
KELLEY DRYE & WARREN LLP
Washington Harbour
3050 K Street NW, Suite 400
Washington, DC 2007
E-mail: jwilson@kelleydrye.com

Counsel for Plaintiff in Civil Action No. 1:07cv846 (JCC/TRJ)

/s/
Rebecca M. Carr (VSB # 70874)
PILLSBURY WINTHROP
SHAW PITTMAN, LLP
2300 N Street, N.W.
Washington, D.C. 20037
Tel: 202-663-8000
Fax: 202-663-8007
e-mail: rebecca.carr@pillsburylaw.com