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

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

CONSOLIDATED WITH

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

DECLARATION OF CARL BATTLE IN SUPPORT OF BRIEF FOR AMICUS CURIAE ELAN PHARMACEUTICALS IN SUPPORT OF THE "GSK" PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

I, Carl Battle, hereby declare under the penalty of perjury that:

1. I am the Senior Vice President & Chief Intellectual Property Counsel of Elan Pharmaceuticals, Inc., an amicus curiae in this matter.

2. I direct the global legal functions for intellectual property and provide legal counsel for related litigation, licensing and business development activities for Elan Pharmaceuticals, Inc. and its parent and affiliates (collectively referred to as "Elan"). I am

responsible for establishing and implementing corporate patent, trademark, and product exclusivity strategies, and providing effective counsel to senior management to achieve corporate business objectives. I held previous positions as Vice President, Global Intellectual Property at Pharmacia Corp., Vice President-Patents at Schering-Plough Corp., Senior Director-Patent & Trademark Affairs at Novartis Corp., and corporate patent counsel for Warner-Lambert Co. and Rohm and Haas Co. I began my legal career in Akron, Ohio as a corporate patent attorney for B.F. Goodrich Co. and an adjunct law professor at the University of Akron School of Law. I attended Dartmouth College and graduated with a bachelor's degree in chemistry/economics in 1976. I received a Juris Doctorate degree (with honors) in 1982 from the Delaware Law School of Widener University in Wilmington, Delaware. I currently reside in Half Moon Bay, California.

3. I am admitted to practice in New Jersey, Pennsylvania, Ohio, U.S. Courts of Appeals for the Federal Circuit and Third Circuit, U.S. District Courts in New Jersey and Eastern District of Pennsylvania, and before the United States Patent and Trademark Office ("PTO").

4. As Senior Vice President and Chief Intellectual Property Counsel at Elan, I am intimately familiar with the research, development, documentation and protection of Elan's cutting edge pharmaceuticals. As the Chief Intellectual Property Counsel, I oversee 4 in house attorneys and numerous outside counsels who prepare and file patent applications on Elan's behalf. As a result, I am very familiar with the U.S. patent system and the laws, rules, and regulations that govern the patent application and prosecution process. I have reviewed the PTO's "Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, Examination of Claims in Patent Applications," 72 Fed. Reg. 161 at p. 46716 (August 21, 2007)(to be codified at 37 C.F.R. pt. 1)(the "Final Rules"). I believe

implementation of the Final Rules will adversely affect not only GSK's but also Elan's and other similarly situated biotech and pharma organizations' ability to protect their continuing research efforts, will hamper innovation, and will minimize capital investment in new drug technologies.

5. Elan is a biotechnology company that is focused on discovering, developing, manufacturing and marketing advanced therapies in neurology, autoimmune diseases, and severe pain. Elan has approximately 2000 employees worldwide.

6. 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. 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. In the area of severe pain, Elan's research efforts focus on inflammatory and neuropathic pain.

7. In neurology, Elan is focused on building upon its breakthrough research and extensive experience in the area of neuropathology-related disorders such as Alzheimer's disease, where the company's efforts include programs focused on small molecule inhibitors of beta secretase and gamma secretase, enzymes whose actions are thought to affect the accumulation of the amyloid plaques found in the brains of patients with Alzheimer's disease. Elan is also studying other neurodegenerative diseases, such as Parkinson's disease.

8. Elan in collaboration with Wyeth is continuing to pursue beta amyloid immunotherapy for mild to moderate Alzheimer's disease in a Phase II study of a humanized monoclonal antibody, AAB-001. This therapeutic antibody, which binds to and clears beta amyloid peptide, is designed to provide antibodies to beta amyloid directly to the patient, rather

than requiring the patient to mount their own individual response. It is believed that this approach may eliminate the need for the patient to mount an immune response to beta amyloid.

9. Elan and Wyeth are also developing ACC-001, a novel beta amyloid-related active immunization approach now in Phase I clinical trials. This approach is intended to induce a highly specific antibody response to beta amyloid. The goal is to clear beta amyloid while minimizing side effects such as inflammation of the central nervous system.

10. Beta and gamma secretases are proteases (enzymes that break down other proteins) that appear to clip the amyloid precursor protein (APP), resulting in the formation of beta amyloid. This is significant because if the "clipping" of APP could be prevented, the pathology of Alzheimer's disease may be changed. As a result of these discoveries, Elan has developed and is pursuing advanced discovery programs focused on identifying and developing small molecule inhibitors of beta and gamma secretases. Elan has been at the forefront of research in this area.

11. Beta secretase is believed to initiate the first step in the formation of beta amyloid, the precursor to plaque development in the brain. Elan has been an industry leader in beta secretase research for more than 10 years. Our finding published in Nature in 1999 concerning the role beta secretase plays in beta amyloid production is considered a landmark discovery. Today, Elan continues to be at the center of understanding the complexities of beta secretase and advancing potential disease-modifying agents that inhibit its role in Alzheimer's disease pathology. This program is in the preclinical discovery phase.

12. Gamma Secretase is an unusual multi-protein complex that is thought to play a significant role in the formation of beta amyloid. Elan has played a critical leadership role in the increased awareness of how gamma secretase may affect AD pathology. Elan's finding,

published in 2001, that functional gamma secretase inhibitors appear to reduce beta amyloid levels in the brain was an important step in this area of AD research. Elan's gamma secretase research is currently in the preclinical discovery phase.

13. Thus, Elan has numerous products in various stages of drug development. As noted above, 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. 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.

14. 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. 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. However, Phase I clinical testing of a product for the treatment of Alzheimer's was not initiated until 2001. 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.

15. Drug development is extremely expensive. All aspects of scientific research for drug development are costly, particularly the equipment, materials and repeated experimentation. A product must also undergo extensive clinical trials before it can be approved for marketing. These trials are primarily concerned with the safety, efficacy and quality of new drugs and are very expensive to undertake.

16. Elan currently spends approximately $230 million per year on research and development. On average, it costs over $500 million to bring a new drug from concept to the market.

17. Because drug development is extremely expensive and can take many years, companies engaged in drug development are heavily dependent upon patent protection. 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.

18. 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. 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. TYSABRI® is covered by a number of pending patent applications and issued patents in the United States and many other countries. Elan has a basic patent in this country for TYSABRI® covering a humanized antibody and its use to treat MS. That basic patent is set to expire in 2017, due to a patent term extension. Elan also has numerous continuation patents and patent applications related to later discovered uses of the invention initially covered by the basic TYSABRI® patent. These continuation patents allow Elan to maintain patent protection over its discoveries as the drugs continue to be developed, refined and approved. 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®.

19. 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. 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. All of these species may be candidates for drug development, clinical trials, and potential sale. 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. 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.

20. 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. 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. 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.

21. 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 competitor who filed the other applications.

22. 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.

23. However, Elan has a common interest with GSK – both companies rely on strong patent protection to recoup their significant investments in drug development. 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. Just like GSK, Elan believes that the PTO's Final Rules will ultimately result in weakened, if not inadequate, patent protection for pharmaceutical and biotech companies involved in drug discovery and development.

24. 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. If Elan does not timely file an ESD in any of these applications, it could risk suspension of the application by the PTO or loss of any excessive claims. 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.

25. Elan also has a large number of pending patent applications that are continuation applications, and many of these continuation applications have already had at least two previous continuations filed. 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. 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.

26. 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. 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.

27. 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.

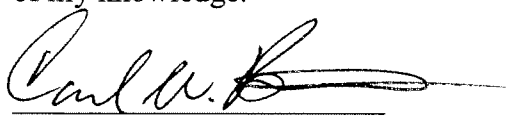
28. Because the PTO's Final Rules will deter, if not completely prohibit, the very patenting strategy that is dictated by the demands of drug discovery and development, important pharmaceutical inventions will be dedicated to the public domain in the form of abandoned claims and lost continuation applications. 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. 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.

29. Ultimately, consumers will bear the brunt of the PTO's Final Rules. 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. In real terms, this means fewer products on the market and increased prices for consumers. Certainly, Elan and others will be forced to raise prices to try to recoup their investments in research and development.

30. 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. 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.

31. I declare under penalty of perjury that the foregoing is true and correct, to the best of my knowledge.



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Date