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 CURIÆ ELAN PHARMACEUTICALS, INC. IN SUPPORT OF PLAINTIFFS' MOTIONS FOR SUMMARY JUDGMENT

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

1. Elan is a biotechnology company that is committed to discovering, developing, manufacturing and marketing advanced therapies in neurology, autoimmune diseases, and severe pain.

2. 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.

3. Elan relies upon strong patent protection and the ability to file multiple continuation applications when it decides to invest enormous sums of money on the research and development of new drugs. At any given time, Elan has numerous products in various stages of drug development. For example, two of its products for the treatment of Alzheimer's disease are now into Phase II clinical testing to determine preliminary efficacy, dosage, and expanded evidence of safety and a third has just entered Phase III testing. 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.

4. 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, since the 1980's, Elan has been conducting scientific research with the goal of developing products for the treatment of Alzheimer's disease. Much of Elan's research and development of Alzheimer's therapies is premised on the hypothesis that beta amyloid causes the disruption of thinking and pathology that is the hallmark of Alzheimer's disease. This hypothesis is currently the leading approach in the

development of therapeutic treatments that scientists hope may fundamentally alter the progression of the disease, and evidence suggests that clearance of beta amyloid may lead to improved cognitive function in Alzheimer's patients.

5. Over the years, Elan's scientists have investigated various traditional therapeutic approaches, including inhibiting enzymes that produce beta amyloid as well as a novel approach of using the body's immune system to clear existing beta amyloid (the "immunotherapeutic approach"). In the late 1990's, Elan filed several patent applications relating to its core invention of an immunotherapeutic approach to the treatment of Alzheimer's disease (hereinafter referred to as the "original applications"). These original applications, as well as later filed continuation applications[1] that claimed priority back to the original applications, disclosed a multitude of pharmaceutical compositions and methodologies for implementing the immunotherapeutic approach based on Elan's research. When Elan's original applications published, Elan's scientific breakthrough became an instant sensation in the scientific community and the field of Alzheimer's immunotherapy was born.

6. Elan's early research led to the development of a product that was accepted by the FDA for clinical testing. The product successfully completed Phase I clinical trials, but Phase II clinical trials were discontinued in 2002 when adverse effects were observed. While the clinical testing of the original product was in progress, Elan was also investing significant financial and human resources in the continued research and development of various other aspects of the immunotherapeutic invention embodied in its earlier filed original applications.

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[1] The terms "continuation application" or "continuing applications" refer collectively to continuation applications, continuation-in-part applications and requests for continuing examinations.

7. As this research and development advanced, Elan filed continuing applications to pursue claims specific to various commercial embodiments of the invention. Having learned a good deal of information during its analysis of the clinical trial results of the first product and its continued research and development, Elan was then poised to advance products from alternative methodologies into the clinic for testing. Elan is now conducting Phase II and Phase III clinical trials for alternative products derived from the subject matter disclosed in the original applications. These and other alternative methodologies and products were disclosed and claimed in a significant number of continuation applications, most of which claimed priority back to the original applications. To date, of the previously filed continuing applications, 19 have matured into granted United States patents. To the extent that any other later refinements in the immunotherapeutic approach prove fruitful, Elan will submit continuation applications on those refinements as well.

8. If Final Rule 1.78 was in existence at the time Elan filed its original applications on this immunotherapy, it is likely that Elan would have expended all of its continuations by right on early embodiments of the invention that did not prove to be commercially viable. Elan would then have been prevented from claiming priority back to the original applications for any of its later refined life-saving drugs.

9. If Elan's continuation applications are not accorded their rightful claim to priority under 35 U.S.C. § 120, Elan's published original applications could then be cited as prior art against these continuation applications and Elan would be unable to claim patent protection on the later commercial embodiments of the potentially life saving invention.

10. Should the Final Rules become effective, with their inherent retroactive effect, the Final Rules will effectively preclude Elan from obtaining patent protection commensurate in scope with its disclosure to the public. Without the potential for later patent protection, Elan would have far less incentive to invest in extensive research and development in its search for new and beneficial drugs and therapies. This would result in fewer new life-saving drugs being discovered and the public health could suffer.

11. As Elan's efforts related to Alzheimer's illustrate, drug development is a long, complicated and expensive process. 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. On average, it costs Elan over $500 million to bring a new drug from concept to the market. In fact, Elan currently spends about $230 million each year on research and development for new drugs. Only a small percentage of the drug therapies initially discovered and explored by pharmaceutical companies ever make it to drug store shelves.

12. Because drug development is extremely expensive, can take many years, and has a low success rate, companies engaged in such activities 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. In this regard, Elan is no exception. Elan's

competitive position depends, in part, on its ability to obtain patents on the life-saving technologies and products that it has developed.

13. 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. Elan also has no relationship with Tafas. 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 biotechnology companies involved in drug discovery and development.

14. Elan normally files a very robust initial patent application with a very detailed disclosure along with numerous claims. Elan makes this detailed disclosure with the understanding that as further research on the disclosed invention is conducted, Elan will then submit additional continuing applications that rely upon the specification and disclosure of the first filed patent. Since the continuing application relies upon the same disclosures made in the initial application and does not interject new matter, it would be virtually impossible to make a showing that the information claimed in a later filed continuing application could not have been submitted during the prosecution of the originally filed application. For example, though Elan has already submitted more than two continuing applications that claim priority back to its original immunotherapy patent

applications, there is no guarantee that the drugs currently in the clinic will actually be the drug approved for the treatment of Alzheimer's disease.

15. The initial robust applications are typically filed well before any human clinical trials, and usually include a general yet detailed description of a genus of compositions and/or methodologies, and numerous species of the genus. All of the species within the genus may be candidates for drug development, clinical trials, and potential sale. Accordingly, for many of its portfolios, Elan, just like GSK, typically files such an initial application with the understanding that it will prosecute additional patent claims in continuing applications based on further progress in research, development and 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 treatment, dosing regimes and methods of administering used during clinical trials.

16. In practice, the PTO tends to reject initial applications directed to biotechnology or pharmaceutical inventions for various reasons. In response, Elan tends to file continuation applications to provide the examiners with additional information to help them better understand the complex inventions through the natural discourse facilitated by prosecution and/or to narrow Elan's initial claims and focus on covering particular species currently under a fairly advanced stage of research and development.

17. 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 and to focus on additional species as they advance through the product pipeline. 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.

18. 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. 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.

19. In addition to its overarching desire to develop drugs that cure life-threatening diseases, Elan is willing to spend this much money every year on research and development for new drugs because it knows that it will able to recoup some or all of its investment once it discovers the next life-saving drug. Thus, robust patent protection plays a significant role in encouraging Elan to invest in the discovery and development of new drugs.

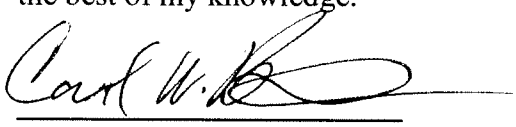
20. Absent the ability to exclude competition through patent protection, Elan will have less ability to recoup its investments made in drug discovery and development and, ultimately, less money to invest in innovation.

21. 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.

22. 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.

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



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Date