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)

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

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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 Motions for Summary Judgment filed by plaintiffs SmithKline Beecham Corporation, SmithKline Beecham PLC and Glaxo Group Limited (collectively "GSK") and plaintiff Triantafyllos Tafas (collectively "plaintiffs") in the above-captioned case. Like plaintiffs, Elan believes that the rules promulgated by the United States Patent and Trademark Office ("PTO") violate the Patent Act and that they should be overturned. *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"). Elan previously submitted an *amicus* brief in support of GSK's Motion for Preliminary Injunction.

B. Background

Elan is a biotechnology company that is committed to discovering, developing, manufacturing and marketing advanced therapies in neurology, autoimmune diseases, and severe pain. *See* Attachment 1, Declaration of Carl Battle ¶ 1 (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. ¶ 2. 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 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. Battle Decl. ¶ 3. At any given time, Elan has numerous products in various stages of drug development. *Id.* 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. *Id.* 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. ¶ 4. 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. *Id.* 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. *Id.* 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. *Id.* 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"). Battle Decl. ¶ 5.

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"). Battle Decl. ¶ 5. 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. *Id.* 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. *Id.*

Elan's early research led to the development of a product that was accepted by the FDA for clinical testing. Battle Decl. ¶ 6. The product successfully completed Phase I clinical trials, but Phase II clinical trials were discontinued in 2002 when adverse effects were observed. *Id.* 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. *Id.* As this research and development advanced, Elan filed continuing applications to pursue claims specific to various commercial embodiments of the invention. Battle Decl. ¶ 7. Having learned a good deal of information during its analysis of the clinical trial results of the first product and its

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

continued research and development, Elan was then poised to advance products from alternative methodologies into the clinic for testing. *Id.* Elan is now conducting Phase II and Phase III clinical trials for alternative products derived from the subject matter disclosed in the original applications. *Id.* 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. *Id.* To date, of the previously filed continuing applications, 19 have matured into granted United States patents. *Id.* To the extent that any other later refinements in the immunotherapeutic approach prove fruitful, Elan will submit continuation applications on those refinements as well. *Id.*

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. Battle Decl. ¶ 8. Elan would then have been prevented from claiming priority back to the original applications for any of its later refined life-saving drugs. *Id.* 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. Battle Decl. ¶ 9. 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. Battle Decl. ¶ 10. Furthermore, any additional commercial embodiments that have been disclosed but have not yet been

claimed or undergone clinical trials will be ineligible for patent protection. Battle Decl. ¶ 10, 21. 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. Battle Decl. ¶ 10, 21. This would result in fewer new life-saving drugs being discovered and the public health could suffer. Battle Decl. ¶ 10.

As Elan's efforts related to Alzheimer's illustrate, drug development is extremely expensive. Battle Decl. ¶ 11. 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. *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. *Id.* In fact, Elan currently spends about $230 million each year on research and development for new drugs. *Id.*

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. Battle Decl. ¶ 12; *see* Faiz Kermani & Pietro Bonacossa, *Patent Issues and Future Trends in Drug Development Journal of Commercial Biotechnology*, 9 J. Com. Biotech. 332 (2003) (asserting that only about 15 percent of new drugs entering development subsequently reach the market). 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. Battle Decl. ¶ 12. 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. Battle Decl. ¶ 12.

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. ¶ 13. Elan also has no relationship with Tafas. *Id.*

Elan has a common interest with GSK, however – both companies rely on strong patent protection to recoup their significant investments in drug development. *Id.*; *see* Memorandum in Support of GlaxoSmithKline's Motion for Summary Judgment at 8-9 (hereinafter "GSK SJ Memo"). 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. ¶ 13. 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.* Just like GSK and Tafas, Elan believes that the Final Rules are improper, violate the Patent Act and must be overturned. Accordingly, Elan respectfully submits this memorandum in support of plaintiffs' summary judgment motions.

II. ARGUMENT

This Court should grant summary judgment in favor of plaintiffs and against the PTO and hold that the Final Rules violate the Patent Act, 35 U.S.C. § 1 et seq., and are improperly retroactive, and so cannot be implemented.

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

The Final Rules violate the Patent Act in several ways. First, the Final Rules violate Section 120 of the Patent Act. Second, the Final Rules violate 35 U.S.C. § 131 by prematurely shifting the burden of examining a patent from the PTO to the patent applicant. Third, the Final Rules are improperly retroactive. Each of these reasons serves as an independent basis to overturn the Final Rules. We address each issue *in seriatim*.

1. The Final Rules Violate Section 120 of the Patent Act

a. Section 120 Imposes No Limits On the Number of Continuation Applications

Final Rule 1.78 which, absent a special showing, imposes a limitation of no more than two continuation applications exceeds the plain language of Section 120 of the Patent Act. 37 C.F.R. 1.78; 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." 35 U.S.C. § 120 (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, argument, or evidence . . . could not have

been submitted during the prosecution of the [two] prior-filed application[s]." Final Rule 1.78(d)(1)(vi), 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. *See* Final Rule 1.78(d)(1), 72 Fed. Reg. 46838.

The PTO asserts that section 120 does not prevent the PTO from putting reasonable conditions on later filings or require that the PTO allow an unlimited number of continuing applications. Memorandum in Support of Defendants' Motions for Summary Judgment (hereinafter "PTO SJ Memo") at 21-22. Instead, the PTO argues that the use of the word "'shall' [in Section 120] simply expresses that applicants will only benefit from the earlier application's filing date 'if' they comply with the requirements of the statute." PTO SJ Memo at 21. This argument is a red herring as even under the PTO's reading of the statute, an applicant is still entitled to an unlimited number of continuations so long as the continuation is "filed before the patenting or abandonment of or termination of proceedings on the first application." 35 U.S.C. § 120. This language does not provide any support for the PTO's imposition of an arbitrary limit on the number of continuations.

The PTO next asserts that Final Rule 1.78 "merely puts reasonable conditions on when continuation applications may be considered properly 'filed' under that section" and again argues that Final Rule 1.78 falls under the PTO's ability to "govern the conduct of proceedings in the [PTO]." PTO SJ Memo at 22. The PTO claims that Final Rule 1.78 is necessary to prevent patent applicants from unreasonably delaying patent prosecution "until a commercially advantageous time." *Id.* Such statements ignore

reality. Unlike the intentional delaying tactics during patent prosecution that may lead to a finding of prosecution laches, pharmaceutical companies do not wish to delay the procurement of patent protection because any delay during prosecution results in a delay in enforcement of the patentee's exclusive rights. *See Symbol Tech., Inc. v. Lemelson Med., Educ. & Research Found.*, 429 F.3d 1051 (Fed. Cir. 2005)(patentee delaying prosecution in order to claim subsequent technological advances by other parties). Instead, the prosecution of pharmaceutical related patents requires a great deal of give and take with the PTO through continuation practice. In fact, the PTO recognizes the necessity of this give and take and admits that continuation practice assists in this process. PTO SJ Memo at 25-26.

The PTO's assertion that the Final Rules are necessary to prevent the indefinite delay of prosecution simply does not apply to Elan or other pharmaceutical companies. Elan, like other pharmaceutical companies, prosecutes its patent applications as quickly and as diligently as possible and indeed has a strong financial incentive to do so. The PTO's attempt to shoehorn the handful of prosecution laches cases into a justification for Final Rule 1.78 is simply not logical and ignores the true facts. Any delay in the issuance of a patent is not an intentional delay on the part of Elan, it is simply a result of the realities of the drug discovery process and the regulatory framework within which pharmaceutical companies must operate.

Section 120 clearly states that if an applicant files a continuing patent application on an invention that was disclosed in an earlier filed patent application by that same inventor, then the continuing patent application **shall** be entitled to the earlier filing date, so long as the continuing application is filed before the patenting or abandonment of or

termination of proceedings on the first application (or another earlier filed continuing application that claims priority back to the first filed application). 35 U.S.C. § 120. Final Rule 1.78 would turn this unequivocal "*shall*" into a "*may so long as the applicant submits a petition establishing why the amendment, argument, or evidence sought to be included in the continuation application could have been submitted during the prosecution of the earlier filed application.*" *See* Final Rule § 1.78(d)(1)(vi), 72 Fed. Reg. 46838. Such an argument turns statutory construction on its head and the Final Rules must be overturned.

b. The "Could Not Have Been Submitted" Previously Standard Will Be Impossible To Meet

It will be virtually impossible for Elan or other pharmaceutical companies to ever make the special "could not have been submitted" previously showing and the PTO has admitted as much. *See* 72 Fed. Reg. 46767-69 (failing to provide any concrete examples of how this standard could be met). As noted above, Elan normally files a very robust initial patent application with a very detailed disclosure along with numerous claims. Battle Decl. ¶ 14. 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. *Id.* Since the continuing application relies upon the same disclosures made in the initial application, 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. *Id.*; *see also* GSK SJ Memo at 14-15, 22.

Indeed, if Elan were to claim that the later filed continuing application could not have been submitted during the earlier filed application, the PTO could reject the later application as not having adequate support in the initial application to support the claim of priority. The filing of the petition could also implicate the PTO's ethical guidelines since the applicant would in effect be admitting that he did not have a good faith basis to claim priority back to the earlier filed application. This could lead to a finding of inequitable conduct and the unenforceability of the entire patent family. Filing the application without a claim of priority is also not an option since the original application, which has likely been published already, would serve as invalidating prior art. *See* 35 U.S.C. § 102(b). Essentially, the subject matter would have been involuntarily surrendered to the public.

2. The Limitations on the Number of Continuations will Stifle Life-Saving Research and Development

If Final Rule 1.78 is allowed to stand, Elan would be prevented from obtaining patent protection on later developed drugs. 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. Battle Decl. ¶ 14. Since the Final Rule 1.78 threshold has already been met for the original applications, any later refinements and/or commercial embodiments of the original invention disclosed in the original applications could only claim priority to the original applications if Elan submits a declaration that Elan could not have submitted the claims earlier. As noted above, since the new continuation application relies upon the

disclosures made in the original applications for its antecedent basis, this requirement will be virtually impossible to meet.

Absent the ability to claim priority back to the original applications, any later application that relates to the subject matter disclosed in the original applications will be rejected by the PTO as being invalid in light of the original applications and/or any patents or other published patent applications that claim priority to the original applications. *See* 35 U.S.C. § 102(a) and (b). As a result, assuming that Elan's clinical testing is successful for a new therapy or drug, Elan would not be able to obtain patent protection on this drug or therapy since Elan would have already exhausted its ability to claim priority back to the original applications and the original applications would be invalidating prior art.

Absent the ability to obtain patent protection on this revolutionary therapy, Elan would have no incentive to develop these drugs as it would not be able to recoup the hundreds of millions of dollars that it willingly invested in development of life-saving drugs. This is because without such patent protection for its invention, Elan's innovative new therapy would be freely exploited by others. Eventually, this would lead to the abandonment of research and development by pharmaceutical and biotech companies and a reduction in the number of life-saving drugs.

Because the PTO lacks substantive rulemaking power and its proposed Final Rules violate the Patent Act, the PTO cannot arbitrarily limit or condition the number of continuation applications to which an applicant is entitled or deprive an application of the benefit of priority. *See Merck & Co., Inc. 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*

re Henriksen, 399 F.2d 253, 254 (C.C.P.A. 1968) (the PTO has "no statutory basis for fixing an arbitrary limit … provided applicant meets all the other conditions of the statute"). Rather, the PTO must comply with the language of Section 120, which provides for an unlimited number of continuation applications. Final Rule 1.78, as well as Final Rule 1.114 which has the same special showing requirement, must be overturned as violating Section 120 of the Patent Act.

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

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 of the Patent Act 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 the 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 F.2d 1443, 1445 (Fed. Cir. 1992) ("[T]he 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 Final Rule 1.265. 72 Fed. Reg. at 46836-37.

Final 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 list all of the references that the applicant deems most closely related to the subject matter of the claims and for each reference cited, identify all of the limitations of each of the claims that are disclosed by the reference. Final Rule 1.265(2) and (3), 72 Fed. Reg. at 46842. 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. Final Rule 1.265(4) and (5), 72 Fed. Reg. at 46842.

The PTO avers that the ESD "is designed to assist the examiner in determining the patentability of the claimed invention." PTO SJ Memo at 10. To the contrary, the ESD constitutes an applicant's own examination of the application, not a means of assisting the examiner. It requires the applicant to search the world for the most relevant prior art and then explain in detail why the subject matter of the application is patentable over the identified prior art. The applicant must also specifically point out how the application complies with the formalities imposed by the Patent Act. These are exactly the PTO's obligations under sections 102 and 131 of 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.

The PTO's asserts that Section 131 merely requires "the Director to issue a patent if the applicant is entitled to one under the law" and that the section says nothing about whether or not the PTO can impose the ESD requirement. PTO SJ Memo at 29. However, simply because the statue is silent as to an ESD does not mean the PTO can impose obligations on applicants that violate the PTO's clear and unambiguous statutory requirement to "cause an examination to be made" in the first instance. Because an ESD requires an applicant to make the examination, Final Rule 1.265 must be overturned as inconsistent with existing patent law.

4. The Final Rules Are Improperly Applied Retroactively

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. ¶ 18. 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.*

Applying the Final Rules retroactively, including Final Rule 1.78, also violates the Patent Act's covenant that in order to obtain patent protection, an inventor must fully disclose what would otherwise be the inventor's trade secrets. Ever since the first Patent Act in 1790, and as more recently codified in the Patent Act of 1952, inventors have had the choice of maintaining their invention as trade secrets, and risk that others could later independently develop or reverse engineer the invention, or the inventor could fully disclose their invention to the Patent Office and in return receive a patent that gave them the right to exclude others from using their invention during the term of the patent.

The disclosure of the invention as part of the patent application process vitiates any future trade secret protection for the disclosed invention. Fully cognizant of this trade off, many inventors freely disclosed their trade secrets in a patent application in order to gain the right to exclude others from using the invention. Thus, inventors made broad disclosures to the PTO, knowing that they could then file continuation applications from these broad disclosures and would be able to fully protect their invention.

Through the application of Final Rule 1.78, however, an inventor who filed a broad disclosure in a patent application prior to November 1, 2007, risks losing the ability to obtain full protection on all that he disclosed. This is because at the time he originally filed his broad disclosure, he could file an unlimited number of continuation applications and claim all that he disclosed. Under the Final Rules, if he already submitted two previous continuation applications, he could no longer submit claims on his broad disclosures and he will lose the remainder of his invention that could have otherwise been maintained as a trade secret.

The PTO asserts that an applicant can maintain trade secret status of its invention by requesting that the PTO not publish the patent application. PTO SJ Memo at 43. The only way for Elan to do this, however, is by giving up its rights to seek patent protection in any foreign countries. *See id.* In today's global economy where pharmaceuticals are used, and often pirated, in numerous foreign countries, giving up global patent protection is simply not a realistic option. In any event, the fact remains that at the time the disclosure was made, Elan relied upon the benefits of Section 120 in disclosing its trade secrets and now that they have been disclosed, the PTO is attempting to extinguish Elan's rights in its inventions.

The PTO's assertion that the Final Rules are only procedural and only have future effect is simply untrue. *See* PTO SJ Memo at 39-40. To the extent Elan has already fully disclosed its invention in an original application and later is prevented by Final Rule 1.78 from claiming all that was disclosed, Elan's substantive rights will be affected as all of Elan's disclosed but unclaimed inventions will be dedicated to the public. Since there was no way of knowing at the time the disclosure was made that Elan would be limited in the number of continuations it could file, it is simply unfathomable that the PTO could claim that the Final Rules do not have a retroactive effect or that they are simply procedural.

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

The development of pharmaceutical and biotechnology products and related medical treatments requires a tremendous amount of time and money. On average, it costs Elan over $500 million to bring a new drug from concept to the market. Battle

Decl. ¶ 11. Elan currently spends about $230 million each year on research and development for new drugs. *Id.*

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. *See* Battle Decl. ¶ 19. Thus, robust patent protection plays a significant role in encouraging Elan to invest in the discovery and development of new drugs. *Id.*; s*ee also* Henry G. Grabowski & John M. Vernon, *Effective Patent Life In Pharmaceuticals*, 19 Int'l J. Tech. Mgmt. 98 (hereinafter "Grabowski & Vernon") (recognizing that "[p]atents play a key role in encouraging the development of new medicines" and that they "are essential for investments in drug research and development"). 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. Battle Decl. ¶ 20. Indeed, at least one survey found that absent patent protection, 60% of the innovations commercialized in a two year period by pharmaceutical firms would not have been developed. *See* Grabowski & Vernon at 99.

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 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.

The discovery of new drugs is a long, complicated, and expensive process. As a result, Elan, like many other pharmaceutical and biotechnology companies, typically files very robust initial applications on a class of new drug products that was discovered as a result of the drug discovery process. Battle Decl. ¶ 14. These initial applications are filed well before any human clinical trials, and typically include a general yet detailed description of a genus of compositions and/or methodologies, and numerous species of the genus. Battle Decl. ¶ 15. All of the species within the genus may be candidates for drug development, clinical trials, and potential sale. *Id.* 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. *Id.*; *see* GSK SJ Memo at 11-12 (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 treatment, dosing regimes and methods of administering used during clinical trials. Battle Decl. ¶ 15.

In practice, the PTO tends to reject initial applications directed to biotechnology or pharmaceutical inventions for various reasons. Battle Decl. ¶ 16. 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. *Id.* 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. Battle Decl. ¶ 17. 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.*

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. ¶ 21. 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. ¶ 22. The proximate effect of the implementation of the Final Rules is that life-saving drugs will become unavailable, unobtainable and unaffordable to consumers.

III. CONCLUSION

Because the Final Rules violate the express language of the Patent Act, they must be overturned, and summary judgment in favor of the plaintiffs should be granted.

Dated: December 27, 2007

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of December 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 PLAINTIFFS' MOTIONS FOR SUMMARY JUDGMENT**" using the CM/ECF system and that service was thereby accomplished on:

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