2008-1352

United States Court of Appeals
for the
Federal Circuit

TRIANTAFYLLOS TAFAS,

Plaintiff-Appellee,

and

SMITHKLINE BEECHAM CORPORATION (doing business as GlaxoSmithKline),
SMITHKLINE BEECHAM PLC, and
GLAXO GROUP LIMITED (doing business as GlaxoSmithKline),

Plaintiffs-Appellees,

v.

JON DUDAS, Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office,
and UNITED STATES PATENT AND TRADEMARK OFFICE,

Defendants-Appellants.

Appeal from the United States District Court for the Eastern District of Virginia in consolidated case Nos. 1:07-CV-846 and 1:07-CV-1008, Senior Judge James C. Cacheris

BRIEF OF *AMICUS CURIÆ* ELAN PHARMACEUTICALS, INC. IN SUPPORT OF PLAINTIFFS-APPELLEES AND AFFIRMANCE OF THE COURT'S DECISION

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DATED: OCTOBER 2, 2008

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

TAFAS v. DUDAS

No. 2008-1352

CERTIFICATE OF INTEREST

Counsel for the (petitioner) (appellant) (respondent) (appellee) (amicus) (name of party) Elan Pharmaceuticals, Inc. certifies the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:

Elan Pharmaceuticals, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

Elan Pharmaceuticals, Inc.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

Elan Corporation, PLC

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Kevin T. Kramer, Scott J. Pivnick, Vincent J. Napoleon, Stephanie F. Goeller and Rebecca M. Carr of Pillsbury Winthrop Shaw Pittman LLP

10/1/08
Date

Signature of counsel

Kevin T Kramer
Printed name of counsel

Please Note: All questions must be answered

cc: _____

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STATEMENT OF INTEREST OF AMICUS CURIÆ

Elan Pharmaceuticals, Inc. ("Elan") is a biotechnology company that is committed to discovering, developing, manufacturing and marketing advanced therapies in neurology, autoimmune diseases, and severe pain. Elan's research efforts are focused on discovering drugs to treat complex disorders and diseases, such as Alzheimer's, Parkinson's, rheumatoid arthritis, and multiple sclerosis. Elan currently spends about $230 million each year on research and development for new drugs.

Elan has no financial interest in plaintiffs SmithKline Beecham Corporation, SmithKline Beecham PLC and Glaxo Group Limited (collectively "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 plaintiff Triantafyllos Tafas ("Tafas").

Elan does, however, have numerous patent applications pending before the United States Patent and Trademark Office ("PTO"), including several that would be directly affected by the enactment of the rules at issue in this case. *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").

Because of the significant expense incurred in drug discovery and development, Elan has more than an academic interest in the patent laws. In fact, Elan's very existence is dependent upon strong patent protection. With limited ability to claim the benefit of the filing dates of its earlier applications under the Final Rules, Elan will likely be prohibited from obtaining patent protection on its inventions. As a consequence, Elan will not be in a position to recoup its significant investments in drug development. Because of the substantive impact of the Final Rules on Elan's business, Elan writes to explain why it believes that the decision of the district court should be affirmed.

This brief is being filed with the consent of the parties.

ARGUMENT

I. THE FACTUAL PREMISES FOR THE RULES DO NOT JUSTIFY THEM

In an effort to justify the Final Rules, the PTO argues that there is an "excessive use of continuation and continuation-in-part applications," that "unlimited recourse to continuation applications ... has led to misuse and abuse," and that the prior rules "impose a burden on innovation ... by retarding the Office's ability to examine new applications." PTO Br., at 4-6.

However, these arguments lack factual support and ignore the regulatory and technological landscape facing applicants in the pharmaceutical and biotechnology industries.

A. Continuation Applications Must be Judged in Factual Context

The PTO argues that the use of continuation applications is "excessive" because there is a growing backlog of unexamined applications and continuation applications "play a major role in this problem." PTO Br., at 5. The PTO then explains that continuation applications have increased to nearly one-third of all filings as of 2006. *Id.*

Simply because the number of continuation applications has increased as a percentage of the overall amount of applications does not make that number "excessive." The PTO offers no analysis of the context of those applications in order to prove whether they are warranted based on their factual circumstances.

The PTO's argument appears to stem from its self-proclaimed goal of focusing "the limited examining resources on the examination of new applications." A92 (72 Fed. Reg. 46756). However, the PTO offers no proof that new applications are universally more important to the progress of the useful arts than are continuation applications. Instead, the PTO arbitrarily focuses on some industries to the detriment of others. The PTO

explains that "long pendency of patent applications is problematic in *some industries* (e.g., computer software and hardware technologies) where product life cycles are short and new improvements can quickly make the technology obsolete." *Id.* (emphasis added). The PTO says nothing about industries where product life cycles are long, development slow, and new improvements cannot quickly get to market because of regulatory barriers.

In any event, the PTO's distinction between "new applications" and continuations is somewhat of a shell game. As the PTO admits, the Final Rules do "not place any limit on how many filings an applicant can make." PTO Br., at 42. Rather, the Final Rules simply strike priority benefits for certain applications, thus transforming what would be "continuation applications" into "new applications." Regardless of labels, each additional application still contributes to the PTO's backlog.

Moreover, as the PTO admitted during rulemaking, "[a]pplicants could have different reasons for filing continuation applications, continuation-in-part applications and requests for continued examination." A92 (72 Fed. Reg. 46756). The PTO further admitted in its brief that "[w]hen used properly, continuation applications ... can assist applicants in prosecuting applications and obtaining protection for inventions that meet the Act's requirements for patentability." PTO Br., at 4. Despite this

recognition, the PTO completely ignores industries in which the regulatory scheme and the nature of the technology dictate long periods of research and development and make continuation practice a viable strategy for protecting corporate assets.

Pharmaceutical and biotechnology companies, such as Elan, will typically file first applications with broad disclosures and numerous claims with the understanding that they can and will prosecute additional applications based on further research and data collected during clinical trials. *See, e.g.,* A1992-93, ¶¶ 18-20; A2002-04, ¶¶ 14-17. This process may go on for numerous years and several iterations so long as there is continued drug development data supporting further continuation applications. *Id.* Because of the nature of the business, these companies rely heavily on continuation applications and the use of such applications is not "excessive" given the factual circumstances.

B. Biotechnology Companies Have Legitimate Reasons for Filing Continuation Applications

The PTO's arguments about the "misuse and abuse" of continuation practice do not justify the broad changes imposed by the Final Rules. During rulemaking, the PTO admitted that "a *small minority* of applicants have misused continued examination practice with multiple continued examination filings in order to simply delay the conclusion of examination.

A30 (71 Fed. Reg. 49) (emphasis added). In promulgating its Final Rules, the PTO acknowledged that "it appears that *some applicants* and practitioners have used multiple continued examination filings as a strategy to delay the conclusion of examination." A55 (72 Fed. Reg. 46719) (emphasis added). In its brief, the PTO admitted once again that only "some applicants" abuse continuation practice. PTO Br., at 5 and 6. Despite the admittedly limited nature of the problem, the Final Rules impose limits for all applicants and fail to take into consideration the different reasons that applicants might have for filing continuation applications.

In fact, pharmaceutical companies have legitimate reasons for filing multiple continuation applications. Drug development is a complex, lengthy, and expensive endeavor. A1991, ¶¶ 14-15; A2001, ¶ 11. After potential chemical compounds are identified for use as pharmaceutical products, they must then be clinically tested for safety and efficacy, among other things. A2001, ¶ 11. Data from these tests must be submitted to the Food and Drug Administration for evaluation. A1995, ¶ 27. The result is a long and arduous process that spans years, if not decades. *See* Robert Silverman, *Patent Filing Strategies for Pharmaceutical Products: A Simple Cost-Benefit Analysis Based on Filing Costs and Pharmaceutical Sales*, 33

AIPLA Q. J. 153, 155 (2005) ("there is a long development and clinical testing period required for regulatory approval").

All the while, research and development on those products continues and additional proof and data are generated. For example, clinical tests may suggest that alternative compounds be used to treat a specific disease or that the specific compound being tested might be useful to treat other types of diseases than those that were tested. Because this additional proof and data are gathered much later in time, they would typically be used to support continuation applications. A1993, ¶ 20; A2000, ¶¶ 7, 14-17.

For example, Elan, in the late 1990s filed several patent applications relating to its core invention of an immunotherapeutic approach to the treatment of Alzheimer's Disease. A1999, ¶ 5. These original applications disclosed a multitude of pharmaceutical compositions and methodologies for implementing the immunotherapeutic approach based on Elan's research. *Id.* As research and development advanced, Elan filed continuation applications to pursue claims specific to various commercial embodiments of the invention. A2000, ¶ 7. Having learned a good deal of information as a result of its clinical trials and its 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 continuation applications, most of which claimed priority back to Elan's original applications. *Id.* To date, of the previously filed continuation applications, 19 have matured into granted United States patents. *Id.*

In short, companies such as Elan are as diligent as they can be given the technology at issue and the regulatory scheme.

C. The PTO Misstates its Role in Innovation

In an effort to justify the rules, the PTO argues that the current legal scheme imposes a "burden on innovation." PTO Br., at 5. However, the PTO offers no specific proof that its backlog of unexamined applications burdens innovation in any way.

Further, the PTO is putting the chicken before the egg. Innovation does not occur because the PTO promptly examines "new applications." Rather, innovation occurs because people and businesses invest money into research and development. Investment occurs because people expect to make money through the sale of products derived from research and development. The patent system is meant to provide incentive to invest by giving inventors a limited period of exclusivity in exchange for the

disclosure of their inventions. *See* THE ECONOMIC REPORT OF THE PRESIDENT, February 2006, at 211.

In fact, 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. *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); A2001, ¶ 12. Only through periods of market exclusivity provided by patents can pharmaceutical and biotechnology companies recover their massive investments in drug research and development. *Id.* Because many of their inventions are substantiated well after filing their initial applications, these companies are also heavily dependent on continuation practice to obtain the patent protection they need. *See* Elan's 2007 Annual Report, at 26 ("Our competitive position depends on our ability to obtain patents on our technologies and products").

Despite the role of the patent system, the Final Rules threaten to limit the ability of companies to recoup their investments on their inventions. As discussed more fully below, the PTO's Final Rules deny certain patent applications the right to the benefit of the filing date of an earlier

application. As a consequence, an earlier application may invalidate the claims of any later-filed application and bar it from issuing as a patent.

II. RULE 78 VIOLATES THE PATENT ACT

A. The PTO is Not Entitled to *Chevron* Deference for Rule 78

The PTO argues that it is entitled to *Chevron* deference for its Final Rules. PTO Br., at 17-24. However, with respect to Rule 78, the PTO ignores the fact that Congress has spoken directly to the issue that Rule 78 addresses – the benefit of an earlier filing date.

Under *Chevron*, the threshold question is "whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously express intent of Congress." *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984).

1. Congress Has Spoken Directly to the Precise Question at Issue in Rule 78

Section 120 expressly provides that:

> *An application* for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application *shall have the same effect, as to such invention, as though filed on the date of the prior application*, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the

> filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

35 U.S.C. § 120 (emphasis added). Given this statutory language, so long as the subsequent application meets the requirements of Section 112 (and Section 363 for international applications), is co-pending with the earlier-filed application, and contains a reference to that earlier-filed application, then it "shall have the same effect ... as though filed on the date of the prior application." Thus, the conditions under which an application is entitled to the benefit of an earlier filing date are clear and are expressly set forth in the wording of the statute. It makes no difference whether "an application" is the second application or the tenth application in the chain. *See* 1 U.S.C. § 1 ("In determining the meaning of any Act or resolution of Congress ... words importing the singular number may extend and be applied to several persons or things"). In order to receive the benefit of the earlier filing date, the application need only meet the requirements set forth in Section 120.

Despite the language of Section 120, under Rule 78 an applicant may only file "two continuation applications" without justification. A55 (72 Fed. Reg. 46719); A174 (Fed. Reg. 46838) (37 C.F.R. § 1.78(d)(i)(A)). If an applicant wishes to exceed that number, the applicant must demonstrate why a third continuation application should receive the benefit of the filing date

of an earlier application. A55 (72 Fed. Reg. 46719); A175 (Fed. Reg. 46839) (37 C.F.R. § 1.78(d)(1)(vi)). Of course, a "continuation application" is one that receives the benefit of the filing date of an earlier application.

In support of its presumptive limit on the number of such applications, the PTO argues that "Section 120 does not specifically and unambiguously address whether applicants have an affirmative right to file an unlimited number of continuation applications, or whether its enumerated conditions are exclusive or non-exclusive." PTO Br., at 50. However, the PTO ignores the fact that Section 120 expressly applies to "an application" and that such language applies to multiple applications. 35 U.S.C. § 120; 1 U.S.C. § 1. In stark contrast, Rule 78 presumptively limits the number of continuation applications to two. Nowhere in its brief does the PTO even attempt to deal with the language of Section 120.

2. The PTO's Arguments Regarding Case Law, Legislative History, and the Approach of the Patent Act Do Not Overcome Section 120

Instead of explaining why Congress has not spoken directly to the question posed by Rule 78, the PTO argues that the district court's ruling is inconsistent with Federal Circuit precedent on laches, the legislative history of the Patent Act, and the overall approach of the Patent Act. PTO Br., at 44-49. However, none of these arguments overcomes the express language

of Section 120. Moreover, none of these arguments justifies the limits that Rule 78 places on the ability of an application to receive the benefit of the filing date of an earlier-filed application.

a. Equity Should Be Applied on a Case-by-Case Basis

The PTO's reliance on this Court's decision in *In re Bogese*, 303 F.3d 1362 (Fed. Cir. 2002), is unavailing. That case involved an egregious fact pattern that cannot be generalized to all situations, all applications, and all technologies. In that case, Bogese engaged in a "pattern of receiving a final rejection from the PTO, not amending his application or claims, filing a file wrapper continuation application exactly or almost exactly six months later without any amendments, and abandoning his prior application...." *Id.*, at 1364. After filing his first application in 1978 and two appeals to the Federal Circuit, Bogese repeated his pattern of behavior "eight more times between 1989 and 1994". *Id.* As a result of this egregious conduct, this Court held that "the PTO has authority to order forfeiture of rights for *unreasonable* delay." *Id.*, at 1369 (emphasis added).

Unlike *Bogese*, Rule 78 attempts to universally limit the ability of an application to receive the benefit of an earlier filing date regardless of whether the delay is reasonable in the circumstances. It is one thing to apply an equitable doctrine to punish unreasonable delay of one individual

applicant who is clearly abusing the system, but it is quite another to abrogate a statutory benefit in the name of potential abuse without any consideration of the factual circumstances.

In support of the PTO, various law professors argue that it "would be perverse to conclude that the PTO has the power to individually reject each of the appellees' pending applications because they have filed too many applications ... but no power to set general rules that provide guidance and certainty to applicants." Brief for Intellectual Property and Administrative Law Professors as Amici Curiae Supporting Appellants, at 12. However, the *Bogese* decision was not based on the fact that Bogese filed "too many" applications. Rather, it was a matter of "unreasonable delay." Because the question of whether delay is unreasonable must be addressed in the context of the actual facts of a given case, laches is properly addressed on a case-by-case basis. The PTO cannot abrogate the statutory benefits set forth in Section 120 on the grounds that it receives "too many" applications and therefore continuation applications above a certain number should be categorically treated as "unreasonable delay."

b. Legislative History Supports the District Court's Decision

Based on reported case law, the PTO argues that the legislative history of the 1952 Patent Act supports Rule 78 because "chains of continuing

applications were virtually unknown in the years preceding 1952." PTO Br., at 48.

In fact, a review of the PTO's records reveals many patents issued before 1952 from a priority chain of more than two continuation applications. *See, e.g.*, U.S. Patent No. 2,130,948[1];U.S. Patent No. 2,221,377[2]; U.S. Patent No. 2,252,555[3]; U.S. Patent No. 2,327,652[4]; U.S.

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[1] "The present application is a continuation-in-part of my application Serial Number 91,617, filed July 20, 1936, which is a continuation-in-part of application Serial No. 74,811, filed April 16, 1936, which is a continuation-in-part of abandoned application Serial Number 34,477, filed August 2, 1935, which in turn is a continuation-in-part of Application Serial Number 181 [sic], filed January 2, 1935." United States Patent No. 2,130,948, col. 1, lines 5-13.

[2] "My present application is a continuation-in-part of my copending application, Serial No. 174,655, filed November 15, 1937 ... which, in turn is a continuation-in-part of my application Serial No. 627,096, filed July 30, 1932 .... This later application, in turn, is a continuation-in-part of my application Serial No. 481,349, filed September 11, 1930 ... which was based on a still earlier application, Serial No. 475,622, filed August 15, 1930 ...." United States Patent No. 2,221,377, col. 1, lines 7-17.

[3] "The present application is a continuation-in-part of application Serial Number 74,811 ... filed April 16, 1936, which is a continuation-in-part of abandoned application Serial Number 34,477, filed August 2, 1935 which in turn is a continuation-in-part of U.S. Patent 2,130,523, filed January 2, 1935, and U.S. Patent 2,071,250, filed July 31, 1931." United States Patent No. 2,252,555, col. 1, lines 4-11.

[4] "This application is a continuation-in-part of my co-pending application, Serial No. 148,737, filed on June 17, 1937, which has issued as Patent No. 2,205,420, which in turn is a continuation-in-part of my prior applications, Serial Numbers 119,756 and 119,757, filed on January 7, 1937, which have issued as Patents Nos. 2,120,755 and 2,120,756, respectively, both of which are continuous-in-part of my prior applications, Serial No. 618,305,

Patent No. 2,331,696[5]; U.S. Patent No. 2,356,009[6]; U.S. Patent No. 2,382,882[7]; U.S. Patent No. 2,403,423[8]; U.S. Patent No. 2,416,013[9]; U.S.

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filed on June 20, 1932, which has issued as Patent No. 2,073,937, and Serial No. 648,986, filed on December 27, 1932, which has issued as Patent No. 2,073,938." United States Patent No. 2,327,652, col. 1, lines 7-19.

[5] "This application is a continuation in part of my co-pending application Serial No. 256,304 filed Feb. 14, 1939, which in turn is a continuation-in-part of my application Serial No. 150,745, filed June 28, 1937 which in turn is a continuation-in-part of my application Serial No. 130,735, filed March 13, 1937." United States Patent No. 2,331,696, col. 1, lines 6-13.

[6] "This invention forms a continuation in part of my copending application Ser. No. 204,999, filed April 29, 1938, now Patent 2,265,010, which in turn forms a continuation in part of my then copending applications Ser. No. 164,166, filed September 16, 1937, and issued into Patent 2,170,433, and Ser. No. 155,919, filed July 27, 1937, and issued into Patent 2,170,432, and of my copending application Ser. No. 727,781, filed May 26, 1934, which in turn was copending with my application Ser. No. 743,717, filed September 12, 1934, and issued into Patent No. 2,122,157, the latter two applications being continuations in part of my then pending patent application Ser. No. 625,042, filed July 27, 1932, and issued into Patent 2,091,017, which in turn was copending with my Patent applications Ser. No. 656,103, filed February 10, 1933, and issued into Patent 1,959,879, and Ser. No. 452,132, filed May 13; 1930." United States Patent No. 2,356,009, col. 1, lines 12-31.

[7] "This application is a continuation-in-part of our co-pending application Serial #386,111, filed March 31, 1941 which is a continuation-in-part of our co-pending application Serial #328,321, filed April 6, 1940, which has issued as Patent No. 2,353,899, July 18, 1944, and which in turn is a continuation-in-part of our application Serial #238,066, which was filed October 31, 1938." United States Patent No. 2,382,882, col. 1, lines 1-8.

[8] "This application is a continuation-in-part of my co-pending application Serial No. 368,227, filed December 2, 1940, which in turn, is a continuation-in-part of my co-pending applications Serial No. 296,445, filed September 25, 1939, and Serial No. 333,606, filed May 6, 1940, the latter being a continuation-in-part of application Serial No. 175,775, filed

Patent No. 2,417,428[10]; U.S. Patent No. 2,460,301[11]; U.S. Patent No. 2,550,662[12]; U.S. Patent No. 2,575,693[13]; U.S. Patent No. 2,575,694[14]; U.S.

November 22, 1937." United States Patent No. 2,403,423, col. 1, lines 4-11.

[9] "This invention is a continuation-in-part of my copending application, Serial No. 550,447, filed August 211, 1944, which in turn is a continuation-in-part, insofar as any common subject matter is concerned, of my copending applications, Serial Nos. 467,872 (now Patent No. 2,399,368, issued April 30, 1946), 467,873, and 467,874 (now Patent No. 2,387,162, issued October 16, 1945), all of which were filed on December 4, 1942; the last-mentioned application is a continuation-in-part of application Serial No. 395,282, filed May 26, 1941, now Patent No. 2,320,629, issued June 1, 1943." United States Patent No. 2,416,013, col. 1, lines 12-23.

[10] This application is "a continuation-in-part of my copending applications, Serial Nos. 586,028, 586,029 and 586,030, which in turn are continuations-in-part of my prior application, Serial No. 469,894; Serial No. 588,719 which is a continuation-in-part of my prior application Serial No. 473,217; and Serial No. 589,941." United States Patent No. 2,417,428, col. 1, lines 3-9.

[11] "This application is a continuation-in-part of our co-pending application Serial No. 461,128, filed October 7, 1942, now Patent No. 2,380,454 granted July 31, 1945, which is in turn a continuation-in-part of our application, Serial No. 323,959, filed March 14, 1940, now Patent No. 2,302,703 granted November 24, 1942, which is in turn a continuation-in-part of Serial No. 231,362, filed September 23, 1938." United States Patent No. 2,460,301, col. 1, lines 7-16.

[12] "This application is a continuation-in-part of my copending application Serial No. 749,339, filed May 20, 1947, which is in turn a continuation-in-part of application Serial No. 620,408, filed October 4, 1945, now abandoned which is in turn a continuation-in-part of my application Serial No. 575,736, filed February 1, 1945, now abandoned." United States Patent No. 2,550,662, col. 17, lines 28-35.

[13] "This application is a continuation-in-part of my co-pending application Serial No. 779,424, filed October 11, 1947, which in turn is a continuation-in-part of application Serial No. 630,944, filed November 26,

Patent No. 2,600,465[15]; U.S. Patent No. 2,602,738[16]. Thus, there is substantial factual precedent for filing more than two continuation applications.

As the PTO acknowledges, the 1952 Patent Act was meant to codify practice that existed at that time. *See, e.g.*, S. Rep. No. 82-1979 (1952), *reprinted in* U.S.C.A.A.N. 2394, 2400 ("Sections 120 and 121 express in the statute certain matters which exist in the law today but which had not been written into the statute."); A145. The PTO expressly admits that "Section 120 was enacted by Congress simply to provide a statutory basis for

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1945, now abandoned, which in turn is a continuation-in-part of my original application Serial No. 403,073, filed July 18, 1941, now abandoned." United States Patent No. 2,575,693, col. 2, lines 20-27.

[14] "This application is a continuation-in-part of my co-pending application Serial No. 779,424, filed October 11, 1947, which in turn is a continuation-in-part of application Serial No. 630,944, filed November 26, 1945, now abandoned which in turn is a continuation-in-part of my original application Serial No. 403,073, filed July 18, 1941, now abandoned." United States Patent No. 2,575,694, col. 2, lines 18-25.

[15] This application is a continuation-in-part of my application Serial No. 537,969, which in turn is a continuation-in-part of application Serial No. 532,000 (now Patent No. 2,369,771); which in turn is a continuation-in-part of abandoned application Serial No. 421,250 filed December 1, 1941." United States Patent No. 2,600,465, col. 5, lines 7-12.

[16] "This application is a continuation-in-part of my copending application, Serial No. 19,480 filed April 7, 1948 ... which is a continuation-in-part of my copending application, Serial No. 786,976 filed November 19, 1947 ... which in turn is a continuation-in-part of my application, Serial No. 762,863 filed July 23, 1947." United States Patent No. 2,602,738, col. 1, lines 1-8.

continuation practice." PTO Br., at 16. Because there is ample factual precedent in the PTO's own records for filing more than two continuation applications, the legislative history of the 1952 Patent Act supports the district court's decision.

c. Other Sections of the Patent Act do Not Support the PTO's Arguments

The PTO asserts that the district court's decision is "at odds with the overall approach to the Patent Act." PTO Br., at 49. The PTO expressly cites Sections 112, 134 and 251 in support of its argument. However, none of these Sections precludes an application from getting the benefit of the filing date of an earlier application.

Certainly, giving an application the benefit of the filing date of an earlier application in no way overrides an applicant's requirement to distinctly claim its invention under Section 112, ¶ 2. Any application that matures into a patent still must meet the substantive requirements of the Patent Act, such as definiteness. The PTO, however, asserts that Congress meant that an "initial application" must satisfy Section 112, ¶ 2. PTO Br., at 49. Such a construction does not find any support in the language of the Patent Act. Certainly, Section 112 does not say "initial application," and Congress expressly excepted provisional applications, which are meant to be

"initial applications," from the requirements of Section 112, ¶ 2. 35 U.S.C. § 111(b)(2).

The PTO next argues that the district court's decision "undermines the role of the Board under Section 134" but fails to explain how or why. PTO Br., at 49. In fact, under Section 134, an appeal to the Board is permissive, not mandatory. 35 U.S.C. § 134(a) (an applicant "may appeal" to the Board). Thus, avoiding an appeal by filing another continuation application is not in any way inconsistent with the Patent Act.

Finally, the PTO asserts that the district court's decision "allows applicants to broaden their claims long after the two-year limit for seeking a broadening reissue patent under Section 251 has passed." PTO Br., at 49-50. However, giving an application the benefit of the filing date of an earlier application in no way broadens a patent that has already issued.

B. Rule 78 is Unreasonable

Relying on its argument for *Chevron* deference, the PTO argues that Rule 78 is a reasonable exercise of the PTO's rulemaking powers. However, even if the PTO is entitled to *Chevron* deference, the PTO is simply wrong on this point. Rule 78 is unreasonable in light of its adverse substantive impact on applicants. Further, the PTO's attacks on practitioners do not justify the Final Rules.

1. Rule 78 Strikes Priority Claims

Rule 78 is substantive in its impact because it provides for striking an Applicant's priority claim and converting an Applicant's own disclosure into novelty-defeating prior art. Despite the language of Section 120, Rule 78 adversely affects an applicant's ability to claim the benefit of the filing date of an earlier application. The PTO admits that the rule provides for "striking a priority claim" which opens the door for the PTO to rely upon the applicant's own prior pending application as prior art under 35 U.S.C. § 102. PTO Br., at 27 n.4. There is no dispute that what qualifies as prior art under 35 U.S.C. § 102 is a substantive patent issue. In fact, the PTO admits that Section 102 is a substantive issue. PTO Br., at 24-25 ("the substantive requirements for patentability under 35 U.S.C. §§ 101, 102, 103 and 112"). Because the rule would effectively turn an applicant's own disclosure against him during the examination of subsequent applications, Rule 78 is substantive in its impact and adversely affects an applicant's ability to get a patent.

For example, if Elan's continuation applications are not accorded the benefit of the filing date of earlier applications, those earlier applications could then be cited as prior art against its later applications. A1995, ¶ 26; A2000, ¶9; A2004, ¶21. Depending upon the claims of the later

applications, Elan may be unable to obtain patent protection for any inventions claimed in those later applications because they were disclosed in the earlier applications. *Id.* As a result, Elan's life-saving pharmaceutical products would lack patent protection and others would be free to take the fruit of Elan's research and development. A1995-96, ¶¶28-29.

The PTO analogizes to Rule 15 of the Federal Rules of Civil Procedure in an attempt to justify Rule 78. PTO. Br., at 38-39. This analogy fails because the PTO takes an approach opposite that of how the federal courts routinely approach amendments to pleadings. Under Fed. R. Civ. P. 15, leave is freely given when justice so requires except in cases of bad faith, dilatory conduct, or futility. *See, e.g., Foman v. Davis*, 371 U.S. 178, 182 (1962). Thus, under the Federal Rules of Civil Procedure, there is a presumption that leave to file will be given. In sharp contrast, under Rule 78, there is a presumption against filing a continuation application and the applicant must justify a subsequent filing on the grounds that it "could not have been submitted earlier." A107 (72 Fed. Reg. 46771). In fact, the PTO has indicated that it will suspend or waive its Final Rules only "in an extraordinary situation." A105 (72 Fed. Reg. 46769).

The PTO argues that that "the 'putative' right to make an unlimited number of filings is palpably a procedural right rather than a substantive

one." PTO Br., at 36. However, this misses the point. This is not a numbers game. Companies like Elan are not arguing for an unlimited number of filings, but simply the ability to retain the statutory benefits expressly provided in Section 120 for filings that are made.

Because Rule 78 is contrary to the language of the Patent Act and has a substantive impact on what qualifies as prior art against an application, that rule is unreasonable and cannot survive.

2. The PTO's Attacks on Practitioners and Applicants Do Not Justify the Final Rules

The PTO argues that the Rule 78 is reasonable because the Patent Act authorizes the Office to issue regulations that "govern the recognition and conduct of agents, attorneys, or other persons representing applicants before the Office." 35 U.S.C. § 2(b)(2)(D). The PTO explains that by "setting filing and documentation requirements, the rules regulate ... the conduct of attorneys and other representatives ...." PTO Br., at 14. However, the PTO is overreaching.

In support of its position, the PTO blames practitioners for "submitting carelessly prepared applications" and "engaging in deliberate delay." PTO Br., at 26. The PTO asserts that it "considers both practices to be a 'misuse of [the] continued examination practice' and a violation of an applicant's and practitioner's duty under 37 C.F.R. § 10.18(b)(2)(i) not to

submit an application to cause unnecessary delay or needless increase in the cost of prosecution before the Office." PTO Br., at 26.

Despite its attack on members of the patent bar, the PTO admits that applicants and practitioners have simply "taken advantage" of what the law currently allows – "the availability of an unlimited number of filings." PTO Br., at 26. Other than citing the administrative history of its Final Rules, the PTO makes no attempt to explain why taking advantage of what the law allows is "misuse and abuse" of the patent application process. Simply because the PTO now "considers" admittedly legal behavior to constitute "misuse and abuse" does not make it so or provide a rational basis for abrogating a benefit enacted by Congress.

Further, as discussed above, the PTO repeatedly admitted that the perceived misuse and abuse is negligible. *See, e.g.*, A55 (72 Fed. Reg. 46719) ("*some applicants* and practitioners have used multiple continued examination filings as a strategy to delay the conclusion of examination") (emphasis added). Despite the admittedly *de minimis* nature of the problem, the Final Rules universally limit continuation applications and create an additional administrative process to evaluate exceptions to this limit. *See* Rule 78(d)(1)(vi) (requiring a petition and a special showing that the "amendment, argument, or evidence ... could not have been submitted

during the prosecution of the [two] prior-filed application[s]"). Creating more work for itself and applicants to resolve an admittedly negligible problem is unreasonable.

Moreover, the PTO simply misses the point. The issue is *not* the conduct of representatives, but rather the nature of the technology at issue, the significant investments in research and development, and the regulatory scheme. Given the parameters of its industry, Elan normally files a very robust initial patent application with detailed disclosures. A1993, ¶ 19; A2002, ¶ 14. Elan makes its detailed disclosure with the understanding that as further research on the disclosed invention is conducted, Elan will then be able to submit additional continuation applications that rely upon the specification and disclosure of the parent application. *Id.* Elan prosecutes its patent applications as quickly and as diligently as possible. Any delay is not deliberate, but rather a result of the realities of the drug discovery process and the regulatory framework within which pharmaceutical companies must operate. Simply because Elan and others have taken advantage of the provisions of the Patent Act does not mean that they have in any way misused or abused the patent system. To suggest otherwise is unreasonable, ignores reality, and fails to justify the Final Rules.

III. RULES 75 AND 265 VIOLATE THE PATENT ACT

A. Congress Has Spoken Directly to the Precise Question at Issue in Rules 75 and 265

The PTO argues that it is entitled to *Chevron* deference for Final Rules 75 and 265. PTO Br., at 17-23. The PTO is wrong because Congress has spoken directly to the issue of the contents of applications and whose responsibility it is to examine applications.

Final Rule 75 provides that an application that contains more than five independent claims or more than twenty-five total claims must be accompanied by an Examination Support Document ("ESD"). The Rule requires the ESD to be submitted *before* the issuance of a first Office Action on the merits of the application. A57 (72 Fed. Reg. 46721); A172 (72 Fed. Reg. 46836) (37 C.F.R. § 1.75(b)(1)). As the PTO acknowledges, "Rule 265 requires an applicant to conduct a preexamination search and explain how the claimed invention is patentable over the search results." PTO Br., at 10. *See* A178-79 (72 Fed. Reg. 46842-43) (37 C.F.R. § 1.265).

Congress, however, has directly spoken to these specific issues. For example, Section 111 provides that the contents of an "application shall include ... a specification as prescribed by section 112 ... a drawing as prescribed by section 113 ... and ... an oath by the applicant as prescribed by section 115 of this title." 35 U.S.C. § 111. Further, Section 131 provides

that the "Director shall cause an examination to be made of the application and the alleged new invention." 35 U.S.C. § 131. 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 (emphasis added).

Because the Patent Act requires the Director to "cause an examination to be made," the PTO cannot require the applicant to conduct the examination. However, that is exactly what the Final Rules require since an ESD requires the applicant to conduct the examination in the first instance. For example, 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. A178 (72 Fed. Reg. 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. *Id.* There can be no serious dispute that these are the fundamentals of an examination.

Because the Patent Act defines the contents of an application in Section 111, the PTO cannot impose additional requirements. However, that

is exactly what the Final Rules do by withholding substantive examination until the applicant submits an ESD. In fact, pursuant to the Final Rules, the ESD must be submitted *before* the PTO will issue an Office Action. A57 (72 Fed. Reg. 46721); A172 (72 Fed. Reg. 46836) (37 C.F.R. § 1.75(b)(1)).

B. The PTO's Rules are Unreasonable

Even if the statutory language is considered to be ambiguous and the PTO is entitled to *Chevron* deference, Final Rules 75 and 265 are unreasonable in light of the longstanding rule that the PTO has the burden in the first instance to establish unpatentability.

The PTO acknowledges that Sections 102, 103, and 131 of the Patent Act "collectively have been understood to assign the USPTO the burden of examination and the burden of establishing a *prima facie* case of unpatentability." PTO Br., at 56. In fact, under this Court's precedent, 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 Court's precedent on the subject, the Final Rules require an ESD *before* the PTO will issue an Office Action. A57 (72 Fed. Reg. 46721, A (72 Fed. Reg. 46836) (37 C.F.R. § 1.75(b)(1)). Because an ESD requires the applicant to "explain how the claimed invention is patentable over the search results," and because that examination must be submitted before the PTO will even issue an Office Action, the Final Rules shift the burden onto the applicant to first establish a *prima facie* case of patentability before the PTO will even act on the case. PTO Br., at 10.

The PTO belittles the burden imposed by an ESD, suggesting that it simply requires the applicant to "submit information." PTO Br., at 9, 57, 58. The PTO further suggests that an ESD merely requires applicants to "assist the examiner in determining the patentability of the claims." PTO Br., at 9. The PTO vastly understates the requirements and impact of its Final Rules.

Far from the mere submission of information in assistance of the examiner, the ESD constitutes an applicant's own examination of the application. 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. A178-79 (72 Fed. Reg. 46842-83). There is simply no statutory basis to require the applicant to evaluate patentability in the first instance in any situation.

Because an ESD requires an applicant to conduct an examination and establish patentability in the first instance, the district court's decision is correct and Final Rules 75 and 265 should not be enacted.

CONCLUSION

Because the Final Rules violate the express language of the Patent Act, the PTO is owed no deference, and the decision of the district court should be affirmed.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 2nd day of October 2008, one original and 12 copies of the foregoing BRIEF OF AMICUS CURIÆ ELAN PHARMACEUTICALS, INC. IN SUPPORT PLAINTIFFS-APPELLEES AND AFFIRMANCE OF THE COURT'S DECISION was hand filed with the Clerk of Court, U.S. Court of Appeals for the Federal Circuit, 717 Madison Place, NW – Room 401, Washington, DC 20439, and two copies of the foregoing brief were served by Federal Express, overnight delivery, on each of the following counsel of record for the parties:

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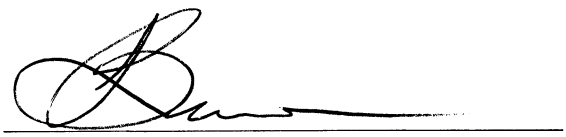

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