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From: Butler, James [mailto:james.butler@amylin.com]
Sent: Wednesday, May 03, 2006 8:49 PM
To: AB93Comments
Subject: Amylin Pharmaceuticals, Inc. comments on changes to continuation practice

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May 3, 2006

BY ELECTRONIC MAIL TO AB93COMMENTS@USPTO.GOV

Mail Stop Comments – Patents
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attention: Robert W. Bahr

Comments to Notice of Proposed Rulemaking Entitled: *Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims*

Dear Mr. Bahr:

Amylin Pharmaceuticals, Inc. welcomes the opportunity to comment on the proposed rule changes related to the examination of claims in patent applications published in the January 3, 2006 *Federal Register*.

Amylin Pharmaceuticals, Inc. is a biopharmaceutical company located in San Diego, California. Originally founded in 1987, Amylin received approval for two, first-in-class drugs for the treatment of diabetes in 2005. Amylin employs approximately 1200 people and has been issued over 50 United States patents. Amylin is also the assignee or exclusive licensee of numerous additional United States patents. Amylin opposes the proposed rule changes for the reasons that the proposed justification for the changes, decreased pendency, is not supported by objective evidence; the proposed rules will disproportionately have a negative effect on biotechnology and pharmaceutical companies which have legitimate reasons for filing continuing applications; the proposed rules are contrary to statute, case law, and international treaties to which the United States is a signatory; the proposed rules will inhibit innovation, create difficulties in licensing and will diminish the public disclosure function of patents; and the proposed rules will not solve the current problems of patent quality but will simply re-create a backlog at the Board of Patent Appeals.

1. The Patent Office Has Presented No Objective Evidence That the Proposed Rules will Result in Decreased Pendency.

In its Notice of Proposed Rule Making, the Office states that the filing of continuing applications has had a "crippling effect on the Office's ability to examine 'new' applications" and that the new rules will allow it to "reduce the backlog of unexamined applications." These statements, however, are not supported by the Office's own statistics. The Office reports that of the 317,000 non-provisional applications, just under 10,000 or 3% were second or more requests for continued examination. It stretches credibility that a mere 3% of the applications are responsible for the Office's current backlog. Moreover, if the backlog were in fact due to continuing applications one would

expect there to be some correlation between the number of continuing applications filed and pendency in an art unit. No such correlation, however, exists. In the 7 art units for which the Patent Office has made data available, the art unit with the highest percentage of continuing applications, 1600, does not have the longest pendency, but instead is 3rd out of 7. Conversely, Art Unit 2100, which has the longest pendency, shows only an average number of continuing applications. Tellingly, at least one official of the Patent Office in a rare moment of candor has publicly admitted that the new rules will do nothing to decrease pendency. Instead, it appears that the Office finds itself with a solution desperately in search of a problem.

2. The Proposed Rules Would Disproportionately Have a Negative Effect on Biotechnology and Pharmaceutical Companies.

Pharmaceutical and biotechnology companies differ from many industries in the cost to develop a product and the time from initial conception to commercialization. It is not unusual for a new chemical entity to take 10 years and a billion dollars in development costs before ever reaching the market. During that time, new data are obtained, and embodiments of the basic invention originally selected for commercial development may be discarded, while other fully described embodiments may be selected or show new properties or uses. Under the present rules, applicants can use continuing applications for the legitimate purposes of adding additional examples and supporting data, and for claiming the final commercial embodiments or additional indications. Under the proposed rules, companies would be forced to predict years in advance the commercial embodiment of their invention, an impossible task.

Many of the currently pending continuing applications in the biotechnology and pharmaceutical arts are the result of the Office's current restriction practice. Under current practice, examiners have essentially no limitation on the number of restriction groups that they can impose on an applicant. Often inventions that will require completely overlapping art searches are restricted out resulting in a duplication of searches and a self-imposed wasting of Office resources. The number of continuing applications filed could be significantly reduced by simply reforming restriction practice instead of the drastic rule changes proposed. In applications involving nucleic acids and proteins, it is now common for examiners to treat each variant of the basic molecule as a separate invention. Thus, even moderate attempts to gain increased scope will result in an excessive number of restriction groups.

Instead of the present system in which the applicant can file divisional applications as different restriction groups are developed, under the proposed rules divisional applications must all be filed at once or rights will be lost. The result will be that the burden on the examining corps will be increased not decreased. The requirement to file all divisionals at once will especially create a hardship on small entities such as start-up companies and non-profit research institutions. The massive costs and associated risks with preparing and filing multiple divisional applications early in development will simply mean that many important discoveries will never be commercialized. It should be noted that the Small Business Administration has notified the Patent Office that its opinion the proposed rule changes will have a significant impact on small businesses.

Additionally, continuing applications, especially Requests for Continued Examination, often result from the current practice of issuing a final rejection at the

second Office action, even when the second Office action contains a new ground for rejection. The applicant must then either file an appeal with its associated delay and expense, or file a continuing application just to address the newly raised grounds for rejection. This problem is exacerbated by the growing tendency of examiners to refuse to enter minor amendments or even discuss the case with the applicant following a final rejection. This, in turn, is likely due to the Office's current examiner evaluation process that rewards examiners for forcing applicants to file RCEs. Often, once the RCE has been filed and the amendment entered or the interview granted, a Notice of Allowance quickly follows. In these cases, contrary to the arguments put forth by the Office, few Office resources are consumed by the continuing application. In fact Office resources are saved since the need for a pre appeal brief conference and the preparation of an examiner's reply are avoided.

Continuing applications are also filed by applicants in order avoid the time and cost of filing an appeal when confronted with an examiner who simply does not understand or will not apply the proper legal standard in examination. This is shown in Board of Appeals statistics in which for every year between 2000 and 2005 the number of examiner reversals exceeded the number of affirmances. This is been especially true in the field of biotechnology were in many years the number of reversals far outnumbers the number of affirmances. Thus, the filing of continuing applications is not an attempt by applicants to "game" the system, but simply an attempt to obtain a proper examination of the application.

3. The Proposed Rules are Contrary to Current Statutes, Case Law and Treaties.

Under the proposed rules, an applicant would be limited to a single continuing application unless the applicant can satisfy the PTO why any amendment, argument or evidence submitted in the second application could not have been previously submitted. The proposed rules would effectively limit priority claims under 35 U.S.C. 120, 121 and 365(c) and limit the right to request continued examination under 35 U.S.C. 132(b). The language of these statutes is clear. Under 35 U.S.C. 120, 121 and 365(c) an applicant may claim priority to an earlier filed application if certain conditions set forth in the statute are met. There are simply no provisions in the statutes for additional restrictions by the PTO. Likewise, 35 U.S.C. 132(b) provides that the Office shall provide for continued examination at the request of the applicant. Although the statute provides for regulations to accomplish continued examination, the only limit on the applicant's ability to request continued examination provided in the statute is the payment of fees.

The PTO acknowledges the existence of case law suggesting that it has no authority to place absolute limits on the number of continuations that can be filed from an original application. The Office contends that the proposed rules do not violate judicial precedent because the limits are not absolute. The rules, however, provide no guidance as to the granting of petitions to file a second continuing application. Notwithstanding the assertion by the Patent Office, judicial precedent strongly suggests that the PTO has no authority to prohibit the filing of a continuing application on its unfettered discretion.

It is our understanding, based on presentations by the PTO, that the limit on the ability to file continuing applications will apply to divisional applications filed in response to a restriction requirement. For example, if an applicant files a divisional application in response to a restriction requirement and the Office issues a subsequent

requirement for restriction in the second application, the applicant would not be able to file the second divisional by right and would not be allowed to claim priority to the original application. This result is contradictory to the provisions of Article 4G(1) of the Paris Convention which states that when a application is found to contain more than one invention, the applicant may file a divisional application and maintain the applicant's claim to priority.

Also under the proposed rules, the PTO proposes to create a rebuttable presumption of patentably indistinct claims in two or more applications that are: (1) filed on the same date; (2) name at least one common inventor; (3) are owned by the same person; and (4) contain substantially overlapping disclosures. Again the PTO appears to have no authority to promulgate this rule, since under 35 U.S.C. 2(b)(2), the PTO can implement regulations only if they are not inconsistent with law. 35 U.S.C. 131 requires that an examination shall be made of the application. In addition, courts have repeatedly held that burden of showing that claims are patentably indistinct rests with the Patent Office. See, *In re Kaplan*, 789 F.2d 1574 (Fed. Cir. 1986); *In re Longi*, 759 F.2d 887 (Fed. Cir. 1985). The establishment of a rebuttal presumption is nothing less than an attempt by the Patent Office to impermissibly shift the burden from the Patent Office to the applicant.

4. The Proposed Rules Will Inhibit Innovation, Create Difficulties in Licensing, and Diminish Public Disclosure.

Instead of promoting innovation, the proposed rules will hamper it, especially in the areas of pharmaceuticals and biotechnology. As discussed above, innovations in these areas involve long development times and high initial costs. The long timelines and high development costs associated with the biotech and pharma industries require the flexibility that the present continuation practice allows. Currently, applicants can file early on the broad inventive concept in order to attract investors and then, as development continues, use continuing applications to adapt claims to cover the eventual commercial embodiment and file new claims to cover additional embodiments that have been validated during development. Under the new rules, companies would be forced to decide between filing early to attract funding and hope that they correctly predicted what the eventual product will look like, or hold off filing, making funding more difficult. Additionally, the retroactive nature of the rules, especially when combined with the proposed limitations on claim examination, may result in patentable subject matter disclosed in pending applications being dedicated to the public. The end result is that innovation will be stifled by the negative impact of these proposed rule changes.

The proposed limits on continuation practice will make licensing of inventions more difficult, thus limiting the commercialization of inventions and denying the public the benefit of these inventions. Non-profit research institutes and universities do not typically commercialize their inventions, but instead license them to third parties. In the situation where the patent holder has several licensees for different aspects of the basic invention, current practice allows for the filing of continuing applications having claims directed to each licensee. Under the proposed rules this would not be possible. Instead, the patent owner would have to try and prosecute a single application to meet the needs of various licensees, who interests may not be aligned. The end result is that it will be more difficult to license patents. The increased difficulty in licensing will starve

innovators of licensing income to fund further innovation and prevent the commercialization of all aspects of the invention, denying the public of potential benefits.

Additionally, the proposed rules may well have the effect of defeating one of the major benefits of the patent system, namely the early disclosure of new innovations. Due to the limitations on continuation practice and the long timelines associated with drug development, many innovators may opt to withhold filing until the ultimate commercial embodiment has been determined. This will deprive the public of information that can be used for further innovation.

5. The Proposed Rules will not Improve Patent Quality and will Simply Shift the Backlog to the Board of Appeals.

Many of the problems associated with patent quality can be associated with the lack of experience and training of many examiners. This, in turn, can be attributed to the high attrition rate among examiners, especially in the pharmaceutical and biotechnology arts. The proposed rules do nothing to address these problems and the Office has provided no objective evidence of any relationship between the number of continuing applications and patent quality. If the Office is serious about improving patent quality, it should investigate ways to improve examiner training and compensation to increase retention. The Office should also look at ways to reduce or eliminate the current incentives to file continuing applications.

It is also likely that the proposed rule changes will not change overall pendency, but simply shift the delay from examination to the appeals process. The Patent Office has been denying that this will occur noting that the time to decision at the Board of Appeals declined to 4.8 months in fiscal year 2005. The 4.8 month time period, however, ignores the considerable amount of time and resources, both of the applicant and the PTO, that go into an appeal prior to its reaching the Board. Specifically not included is the time and resources devoted to the pre-brief appeal conference, preparation of appeal brief and preparation of an examiner's answer. Taken together, these add considerably to the 4.8 month time period and result in substantial costs to the applicants.

RCE practice, which was instituted only 6 years ago, was promoted as a way that applicants could make additional arguments and amendments after final, thus avoiding the need to file appeals and lessening the backlog at the Board of Appeals. Arguably RCE practice has worked and the appeals backlog has lessened. Under the proposed rules, the number of appeals filed is likely to increase, recreating the backlog problem that was only recently solved. The backlog at the Board of Appeals will potentially be exacerbated by the introduction of a post grant opposition procedure. Under the proposed legislation, oppositions must be disposed of within a year. Appeals, with no statutory time limit, are likely to get pushed back, increasing the delay. An unintended consequence of this will be that patent term will be extended. Under the patent term adjustment rules, any time lost due to a successful appeal is credited to the applicant. If recent history is any guide, more than half of the appeals filed will be successful resulting in longer patent term.

Instead of the proposed rules, the Patent Office could do much to reduce the number of continuing applications filed, by improving examiner training, reforming restriction practice, and removing the current incentives for examiner's to force the filing

of continuing applications. In terms of new initiatives, the Patent Office should consider reforming examination procedure so that an examiner does not issue a final Office action as long a prosecution is advancing, and in particular prohibiting the issuance of a final Office action when a new ground for rejection is raised. Additionally, the Office could provide for escalating filing fees for subsequent continuing examinations and could allow the applicant to control the timing of examination by allowing the applicant to request examination at any time during a set time period.

At least for the reasons stated above, Amylin Pharmaceuticals, Inc. opposes the proposed Changes to Practice for the Examination of Claims in Patent Applications and urges the Patent and Trademark Office not to adopt them.

Respectfully submitted,

AMYLIN PHARMACEUTICALS, INC.
James Butler
Director, Patents