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From: Butler, James [mailto:james.butler@amylin.com]
Sent: Wednesday, May 03, 2006 8:46 PM
To: AB94Comments
Subject: Amylin Pharmaceuticals, Inc. comments on Changes to Examination of Claims

May 3, 2006

BY ELECTRONIC MAIL TO AB94COMMENTS@USPTO.GOV

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

Attention: Robert A. Clarke

Comments to Notice of Proposed Rulemaking Entitled: *Changes to Practice for the Examination of Claims in Patent Applications*

Dear Mr. Clarke:

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 they disproportionately have a negative effect on biotechnology and pharmaceutical companies; are contrary to statute and case law; are contrary to international treaties to which the United States is a signatory; will create a substantial financial burden, especially on the biopharmaceutical industry and small entities; will create greater uncertainty and increased litigation; and will not substantially improve patent quality.

1. The Proposed Rule Disproportionately Have a Negative Effect on Biotechnology and Pharmaceutical Companies.

The very nature of pharmaceutical and biotechnology inventions dictates a number of useful embodiments. For example, a pharmaceutical composition may be useful to treat several indications, be formulated for different modes of administration, have different dosing regimes, and alternative means of manufacture. Likewise, a biopharmaceutical innovation may encompass numerous variants each with its own set useful properties. In its Notice of Proposed Rule Making, the Patent Office provides data to support its allegation that the proposed rule changes will affect only a limited number of applications. The use of these numbers by the Patent Office is disingenuous. The Office reports that only 1.2 percent of applications contain more than 10 independent claims. This number would be meaningful if the proposed rules restricted examination to 10 independent claims, but the proposed rules are much more limiting. The proposed

rules allow examination of not more than 10 independent claims, and that if fewer than 10 independent claims are present, the applicant may select additional dependent claims so that the total of all claims to be examined is 10. If the applicant wants more than 10 claims examined, the rules require the applicant to justify such examination. Thus, the appropriate statistic to measure the scope of applications affected is the number of applications having greater than 10 claims. A random sample of 50 U.S. patent applications related to pharmaceutical compositions and methods of treatment published on April 20, 2006, revealed that all but five had greater than 10 claims. Thus the proposed rule changes will affect that vast majority of biotechnology and pharmaceutical applications. The comparison to the use of representative claims before the Board of Appeals is also misplaced. In the appeals process, the application has undergone examination so that the issues have often been narrowed to relatively few. In the present situation, no examination has taken place so there has been no narrowing of the issues. In addition, the Board of Appeals has no per se limit on the number of representative claims as do the present proposed rules.

2. The Proposed Rules are Contrary to Statute and Case Law.

The proposal to limit initial examination to representative claims is contrary to existing statutes. Under 35 U.S.C. 131, the "Director shall cause an examination to be made...of the alleged new invention." (emphasis added) It is axiomatic that the alleged new invention is defined by the claims and that the applicant is entitled to define the alleged new invention as narrowly or as broadly as the applicant sees fit. There is no provision in the statute for the examination of a representative portion or embodiment of the alleged new invention or for the Director to impose additional burdens on the applicant who wishes the full extent of the alleged new invention to be examined. The Patent and Trademark Office has no "inherent authority" to do less than the statute commands it to do.

If an applicant wished more than 10 claims initially examined, the new rules require that the applicant, in the words of the Patent Office, "share the burden of examination by submitting an examination support document." In this examination support document, among other things, the applicant is required to explain how each of the claims is patentable over the prior art, the utility of the invention embodied by the claims, and to show that the claims are supported as required by 35 U.S.C. 112. The proposed rules are in direct conflict with well-established case law that the Patent Office has the initial burden of determining patentability and that the Patent Office may not shift this burden to the applicant. Section 102 states that "[a] person shall be entitled to a patent unless -." (emphasis added). Courts have repeatedly interpreted this language as placing the initial burden of determining patentability over the prior art solely with the Patent Office. *See, e.g., In re Warner*, 379 F.2d 1011 (C.C.P.A. 1967); *In re Oetiker*, 977 F.2d 1443 (Fed. Cir. 1992). These same courts have held that the burden is also on the Patent Office regarding the patentabilty of the claims over the prior art under 35 U.S.C. 103. *Id.* Likewise, the initial burden of showing lack of utility or failure to meet the requirements of 35 U.S.C. 112 rests solely with the Patent Office. *See, e.g., In re Langer*, 503 F2d 1380 (C.C.P.A. 1974) (utility); *Ex parte Sorenson*, 3 U.S.P.Q. 2d 1462 (B.P.A.I. 1987) citing, *In re Wertheim*, 541 F.2d 257 (C.C.P.A. 1976) (written description). The

Patent Office simply has no authority, inherent or otherwise, to shift to applicants a burden placed upon it by statute and the courts.

3. The Proposed Rules are Contrary to International Treaties

Under Article 17 of the Patent Cooperation Treaty (PCT), the United States Patent Office as a Receiving Office is required to search all claims not excluded from searching by the treaty or its implementing regulations. Likewise under Article 31 PCT, the Patent Office must prepare a preliminary examination report on the searched claims when requested by the applicant. Upon entry into the national phase, the Patent Office cannot impose a limitation that is contrary to the provisions of the treaty. *See Caterpillar Tractor Co. v. Commissioner for Patents*, 650 F. Supp. 218 (E.D. Va. 1986). Thus, the result of the proposed rules may be that applicants will simply shift to entering the United States through national phase PCT filings rather than filing applications directly in the USPTO. In this case, under the proposed rules, the USPTO would be making the questionable argument that efficiency is increased by not examining claims that under the requirements of the PCT it would have already searched and issued a preliminary opinion on patentablity.

4. The Proposed Rules Will Create a Substantial Financial Burden.

If put into effect, the retroactive nature of the rule changes will impose a substantial deadweight loss on the economy. This loss will be especially felt by the pharmaceutical/biotechnology industry and small entities. The retroactive nature of the rules would require applicants to select 10 representative claims for each application that has not yet received an Office action or risk having important aspects of their invention go unexamined. This risk is exacerbated by the Patent Office's proposed limits on continuation practice. The Patent Office's statistics show over 600,000 applications awaiting action. Assuming only half of these contain more the 10 claims, that leaves 300,000 applications which applicants must review and select 10 representative claims. Conservatively, such an analysis of the file and filing of an amended claim set would take 2 hours at a cost of $300.00 per hour based on the current billing rates of patent attorneys. This would represent a loss of $180,000,000 to the economy. This value grossly underestimates the true cost, since it does not account for the substantial cost associated with the production of an examination support document should the applicant wish more than 10 claims examined. As noted above, since the vast majority of applications in the pharmaceutical and biotechnology industries contain greater than 10 claims, these industries will be disproportionately affected. Small entities and non-profit research institutions, such as universities, with limited resources will find this financial burden especially difficult. This cost shifting from the government to the private sector will only serve to limit resources available for innovation.

5. The Proposed Rules Will Create Greater Uncertainty and Increased Litigation.

One result of the proposed rules, especially when combined with the proposed limits on continuation practice, is that Applicants will file limited applications in order to avoid the potential problems associated with filing an examination report document discussed below. Such applications containing only 10 claims can be expected to contain

a narrow disclosure to support only those claims. Thus, the new rules will serve to defeat one of the major benefits to the public of the patent system, namely the early disclosure of information. Under the current system, applicants can file an application covering the full scope of the invention. Upon publication, the application gives notice to the public of the full extent of the invention and the information provided can be used by the public to spur further improvements or new, competing products by way of design arounds. With the narrow disclosure that the proposed rules will encourage, uncertainty will be created about the full scope of the invention and the knowledge flow to the public will be diminished. Much of the difficulty associated with the examination of applications in the business methods and software arts can be attributed to the lack of public disclosure in these areas. This lack of disclosure can, in turn, be attributed to the past unavailability of patent protection in these areas which discouraged the disclosure of new innovations. The proposed rules will simply serve to spread the problems associated with non-disclosure in the business methods area across the patent system.

The proposed examination support document will provide fertile ground for future litigation. The requirement that the applicant opine as to the patentablilty of the claims over the prior art will provide an entirely new basis for attacking patents, thus increasing the already high cost of litigation. Many of the problems associated with this proposal were pointed out in the public comments regarding the Patent Office's previous proposal to privatize searching. Apparently not having learned from its previous mistake, the Patent Office is now proposing a system guaranteed to impose even a greater litigation cost on the economy.

6. The Proposed Rules Will Not Substantially Improve Patent Quality.

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. Moreover, nowhere has the Patent Office shown any relationship between the number of claims and patent quality or lack thereof. The Patent Office and the nation as a whole would be better served by the Patent Office devoting more resources to the training and compensation of patent examiners, and by doing away with the current point system that mandates resolution of examination during an arbitrary time period regardless of the complexity of the invention.

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