

28 September 2007

Via Electronic Mail to: BPAL.Rules@USPTO.gov

Mail Stop Interference
Director of the United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

RE: Ex Parte Appeal Rules

Dear Sir:

Amylin Pharmaceuticals, Inc. appreciates the opportunity to provide comments on the proposed changes to Rules of Practice Before the Board of Patent Appeals and Interferences in Ex Parte Appeals, Notice of proposed rulemaking (the "Notice"), as published in 72 Fed. Reg. 41472 (30 July 2007).

Amylin Pharmaceuticals, Inc. is a biopharmaceutical company headquartered in San Diego, California. Originally founded in 1987, Amylin currently markets two, first-in-class drugs for the treatment of diabetes. Amylin employs approximately 1600 people and holds over 60 United States patents. Amylin is also the exclusive licensee of numerous additional United States patents. Amylin supports the goal of improving patent examination and in particular the goal of making the appeal process more efficient. The proposed rule changes contained in the Notice, however, will decrease efficiency and increase cost by requiring applicants to provide information of little or no relevance in many cases while simultaneously limiting the opportunity of Appellants to fully develop their arguments.

In particular, four of the changes proposed in the Notice with respect to the preparation and submission of an Appeal Brief represent a substantially increased burden on Appellants, without any apparent gain in the efficiency of the appeals process. The proposed new rules of concern would require:

- 1) Appellant to set out the material facts relevant to the rejections on appeal (proposed Bd. R. 41.37(n));
- 2) Where any argument being made to the Board was made in the first instance to the Examiner, Appellant would be required to identify where the argument had been previously presented; and where any argument being made to the Board had not previously been made to the Examiner, Appellant would be required to identify such argument as new in the Brief (proposed Bd. R. 41.37(o));
- 3) A new section, referred to as the "claims support section," comprising an annotated copy of any claim whose patentability is to be argued separately (proposed Bd. R. 41.37(p)); and

- 4) Another new section, referred to as the “drawing analysis section,” comprising an annotated copy of the claims in numerical sequence, indicating in bold face between braces ({ }) after each limitation where, by reference or sequence residue number, each limitation is shown in the drawing or sequence (proposed Bd. R. 41.37(r)).

Each of these proposed rule changes will be addressed separately. With respect to proposed Bd. R. 41.37(n), the requirement for a statement of facts will place a greatly increased burden on every Appellant. The proposal will require Appellants to provide a long and detailed list of every fact necessary to support the Appellant’s position. The listing will further require a reference to a specific page number and, where applicable, a specific line or drawing numeral of the record. This requirement is without apparent limit and without definition, meaning that Appellants would be required to list all possible facts required to support Appellant’s position, even facts that are not in dispute.

There is no reasonable basis for imposing such a requirement on Appellants. Any reference that has been made of record and relied upon to support a rejection will speak for itself. Moreover, it is well established law that references are to be read as a whole and not in isolated fragments. To the extent there may be passages of particular interest to the issues at hand, the goal of increased efficiency makes it equally incumbent on the Office to identify such passages. Unfortunately, the rules do not place a similar burden on the Examiner. The stated goal to increase efficiency and better inform the Board would be more plausible if the rules were to make it clear that an Examiner has the same burden as do Appellants.

Moreover, the vastly over-burdensome nature of this requirement is reflected in the fact that many appeals can essentially be narrowed down to a limited number of contested legal issues and/or a limited number of contested issues of fact. There seems to be no good reason to burden Appellants with a new requirement which could easily double the cost of any appeal, especially where the added information in the record would, in many instances, be of limited, if any, value.

While interference practice currently requires opposing parties to submit a statement of facts—this requirement is reasonable in the context of an *inter partes* format because it permits the reviewing panel to identify the facts upon which the parties agree, as compared to the facts which are in dispute between the parties. This can enable the reviewing panel to focus attention on only those issues and facts that are in dispute between the parties, thereby adding efficiency to the interference process. In contrast, the proposed rules for *ex parte* appeals place no comparable burden on the Examiner to establish the USPTO’s statement of facts. Therefore, requiring only Appellants to provide a statement of facts will not aid the Board in understanding the specific facts that are in dispute. Rather, placing such a burden unilaterally on the Appellant seems designed to simply lay a trap for the unwary, namely provide a basis for the Board to reject an appeal because the Appellant failed to list some fact which the Board may consider to be necessary to support Appellant’s position, even if that fact has never been in dispute and even if the fact is actually established by the record. Such a process clearly exalts form over substance, and is not truly designed to improve the appeal process.

With respect to proposed Bd. R. 41.37(o), which requires an Appellant to identify whether an argument is being made to the Board in the first instance, or if it had previously been made to the Examiner (and if so, where in the record the argument had been previously presented), this is an unnecessary added burden on the Appellant and unnecessarily burdens the Appeal Brief with information of little, if any relevance. If an argument is presented for the first time in the Brief, the Examiner is in the best position to identify this as a new grounds of argument—and would be expected to comment on the merits of any such new argument in the Examiner’s Answer.

While the addition of certain new burdens on Appellants to assist in improving the appeals process may have some merit, the Examiner still has a role in the process, and should properly share the burden of preparing a record ripe for appeal. The added burden introduced by proposed Bd. R. 41.37(o) attempts to improperly shift a burden to Appellants, whereas that burden is properly placed on the Examiner.

Proposed Bd. R. 41.37(n) and Bd. R. 41.37(o) are particularly troublesome given the new requirement in proposed Bd. R. 41.37(v) that appeal briefs be double spaced and in 14 point font. This change from the previously allowed 1.5 spacing and 12 point font will reduce the number of characters available to Appellants by approximately 50%. Given that Appellants will be required to use much of the allowed pages of the brief listing undisputed facts and the location in the record of the first instance of arguments, very little space is left to argue the actual merits of the appeal. Other than a transparent attempt to limit the Appellant’s ability to fully develop arguments on appeal, no rationale is given as to what is unique about *ex parte* appeal briefs among patent documents that they require double spacing and 14 point font.

With respect to proposed Bd. R. 41.37(p), which requires, for each claim argued separately (regardless of the basis on which the claim may have been rejected), an appendix that consists of “an annotated copy of the claim” indicating the page and line where the limitation is described in the specification as filed, this proposed rule is unduly overreaching. It is of note that the requirement is applicable to all claims argued separately, and not just to claims that have been rejected for reasons under 35 U.S.C. 112. While a requirement limited to just those claims that involve an issue of support in the specification would make sense, the proposed rule is substantially more far-reaching as it would apply to any claims argued separately on appeal, regardless of the basis on which those claims have ever been rejected—with reasons relating only to section 112 having any relevance to such a requirement.

Imposition of such an over-reaching new rule will create a substantial new burden on Appellants. No adequate justification has been given as to why such a new burden on Appellants is either necessary or will improve the appeal process.

With respect to proposed Bd. R. 41.37(r), the concerns with respect to this new requirement for inclusion of a “drawing analysis section” are similar to the concerns expressed above with respect to the new requirement for a “claims support section.”

Amylin believes that the added burdens of the proposed rules will dramatically reduce the ability of Appellants who must resort to the appeals process, especially those in the

biopharmaceutical and biotechnology areas, to fully and adequately develop issues on appeal. Improving the quality of the patent system requires not only the elimination of improperly granted patents, but also a fair and balanced process by which Applicants can contest improper denials of patent protection for their innovations. To do otherwise, would go against the goal of promoting science and the useful arts.

Amylin welcomes the opportunity to work with the USPTO to develop a fair set of rules regarding the submission of Appeal Briefs that address USPTO concerns without unduly increasing the costs and risks inherent in the exercise of obtaining patents.

Respectfully submitted,

AMYLIN PHARMACEUTICALS, INC.

James E. Butler

Senior Director, Patents