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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:

BIOCOM 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).

BIOCOM is a regional advocacy organization representing more than 500 dues paying life science companies and service providers in Southern California. Strong intellectual property protection is important to attract the substantial investment required to bring new life-saving therapeutics to the market. Toward that end, BIOCOM and its member companies have a keen interest in potential changes to the patent examination and appeal process which may increase the cost of obtaining patents, increase the risk of challenge to the resulting patents, and consequently reduce the ability of small companies which do so much of the innovative research in this country to raise the capital necessary to pursue their goals.

BIOCOM supports the goal of improving patent examination by the United States Patent and Trademark Office (USPTO), especially the goals of making the decision-making process more efficient, thereby minimizing the pendency of appeals before the Office. However, the proposed changes contained in the Notice warrant a closer look and some fine tuning.

While many of the changes proposed in the Notice are more procedural in nature, several of the changes proposed in the Notice with respect to the preparation and submission of an Appeal Brief represent a substantial increased burden on Appellants, and a decreased ability to fully develop the record for appeal, without any apparent gain in the efficiency of the appeals process. The proposed new rules of particular concern would require:

- 1) Appellant to set out in an objective and non-argumentative manner 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));
  - 4) Another new section, referred to as the “drawing analysis section,” comprising an annotated copy of the claim 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); and
  - 5) Defined formatting of Appeal Briefs as to line spacing, font size and page limits. These requirements, especially when considered in view of the increased amount of mandatory discussion (see points (1)-(4) above) serve to dramatically reduce an Appellants’ ability to fully develop arguments on appeal with respect to the real issues in the case (proposed Bd. R. 41.37(v)).

Each of these proposed rules place substantial additional burden on the Appellant. Let us consider the propriety, and possible impact, of each of these proposed new rules. With respect to point (1), for example, 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. That listing will further be required to include 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.

As a preliminary matter, 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. It says what it says. To the extent there may be passages of particular interest to the issues at hand, it is equally incumbent on the Office to identify such passages. Unfortunately, the rules do not place a similar burden on the Examiner. As least if the rules were to make it clear that an Examiner has the same burden as do Appellants, there would be basis to take the Examiner to task if he/she did not meet that burden.

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 interferences currently require 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 which are in agreement between the parties 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 which are in dispute between the parties, thereby adding efficiency to the interference process.

In contrast, in *ex parte* appeals, the subject of the current rules proposals, no comparable burden has been placed on the Examiner to establish the USPTO's statement of facts. Therefore, requiring Appellants to provide a statement of facts will not at all aide 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 point (2), 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.

With respect to point (3), 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.

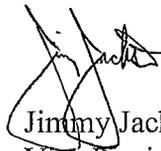
With respect to point (4), the concerns with respect to this new requirement for inclusion of a "drawing analysis section" are similar to the concerns expressed above with respect to the new requirement for a "claims support section."

With respect to point (5), the new requirement that appeal briefs be double spaced and in a font equivalent to 14 point Times New Roman (relative to the currently allowable 1.5 spacing and 12 point font) will substantially reduce the number of characters available to Appellants (i.e., by approximately 50%). These requirements, taken together with a 25 page limit, substantially reduce an Appellants' ability to fully develop the issues for the record. Given that Appellants will be required to use much of the allowed pages of the brief reciting undisputed facts and identifying 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 an Appellants' ability to fully develop arguments on appeal, no rationale is given as to what is unique about ex parte appeal briefs among all patent documents that they require greater line spacing, larger fonts and page limits.

BIOCOM believes that the disproportionate added burdens of the proposed rules on life science companies will dramatically reduce the ability of smaller companies (who make up the majority of BIOCOM's membership) to file and successfully prosecute patent applications to allowance and grant. Moreover, the additional disclosure requirements imposed on those who must resort to the appeals process in order to obtain allowance of their patent filings will subject the patent portfolios of BIOCOM members to added scrutiny, with the potential to significantly reduce the ability of BIOCOM members to raise the capital necessary to pursue their goals.

BIOCOM appreciates the opportunity to comment on the proposed changes and to suggest alternative approaches to addressing USPTO concerns. BIOCOM 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,



Jimmy Jackson  
Vice President of Public Policy  
BIOCOM