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VIA ELECTRONIC MAIL
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The Honorable David Kappos
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Mail Stop Interference
P.O. Box 1450
Alexandria, VA 22313-1450

Attn: Linda Horner, BPAI Rules

RE: Comments on Proposed Rule: "Rules of Practice Before the Board of Patent Appeals and Interferences in Ex Parte Appeals"
74 Federal Register 67987 (December 27, 2009)

Dear Under Secretary Kappos:

Eli Lilly and Company appreciates the opportunity to offer comments regarding the rules proposed by the U.S. Patent and Trademark Office (PTO) regarding "Rules of Practice before the Board of Patent Appeals and Interferences in Ex Parte Appeals."

The proposed changes to the Rules of Practice before the Board of Patent Appeals and Interferences can dramatically influence the patent protection afforded pharmaceutical products. As a researched-based pharmaceutical company, our business depends on strong patent protection, with appropriate patent term adjustment, to assure funding for innovation and advances in the pharmaceutical arts. We offer the following suggestions and comments that we submit may lead to stronger patents with fair and appropriate patent term.

We wish to focus our comments and suggestions on 1) the presumption that the examiner's findings or conclusions are correct unless addressed by the appellant; 2) the applicant's response options in the event that a new piece of art is cited by the examiner; 3) the statement of related cases; and 4) the claim analysis requirement. We submit that each of

these rules will unnecessarily adversely impact all patents, and particularly, pharmaceutical and biotechnology patents.

1) Proposed §41.37(o) Presumption regarding Examiner's Findings

The proposed rule would require that 1) the appellant "shall explain why the examiner erred as to each ground of rejection" and "address all points made by the examiner with which the appellant disagrees;" and 2) "that any finding made or conclusion reached by the examiner that is not challenged will be presumed to be correct." We submit that the wording is unnecessarily vague and ambiguous. Specifically, the terms "ground," "points," "finding,, and "conclusion" in proposed Bd.R. §41.37(o) are particularly unclear and may adversely affect any granted patents relating to the appeal procedure.

"Any finding made or conclusion reached by the examiner that is not challenged will be presumed to be correct (emphasis added)." Further, the rule is silent as to an unchallenged "ground" or "point." An appellant may believe they properly explained why the examiner erred as to each ground of rejection to be reviewed, challenged all "conclusions," and addressed all "points" made by the examiner, but the Board may be of the opinion that a particular "finding" by the examiner was not challenged by the appellant. In such case, the "finding," which may be incorrect, would still be presumed correct under Bd.R.41.37(o). Further, the position of the examiner may shift subtly or significantly from one Office Action to the next, leaving the appellant uncertain if a new finding or conclusion has been set forth. Moreover, Office Actions often contain findings of fact or conclusions that are unclear, incorrect, or seemingly irrelevant. We submit that the proposed requirement to challenge each finding or conclusion that appellant does not wish to accept as correct will needlessly lead to appeal briefs cluttered with challenges that may not be relevant to the argument presented and challenges to conclusions that have previously been traversed but overcome by amendment in the interest of furthering prosecution.

Finally, the duration and scope of the presumption is unclear. It is not clear from the proposed wording if the presumption is solely for purposes of deciding the rejections in the appeal or if the presumption will carry through on subsequent prosecution or actions relating to any patents resulting from the patent family.

We respectfully request that 1) the wording of the proposed rule is clarified to define "ground," "point," "conclusion" and "finding;" 2) that the presumption extends solely to findings or conclusions that are the subject of the appeal; and 3) that the wording is clarified to indicate that the presumption is limited to the appeal proceeding. We respectfully propose that the issue could be resolved by rewording §41.37(o) to read, "Argument. The "argument" shall explain why the examiner erred as to each ground of rejection to be reviewed. Each ground of rejection shall be separately argued under a separate heading."

2) Proposed §41.39 (a)(2) applicant's options in the event of new art.

We appreciate that the examiner may introduce new art to ensure the vigor of the patent resulting from the examination process; however, we are concerned that new art characterized by the examiner as exemplary or cumulative may require the applicant to submit a request for continued examination. It is unclear when a particular reference constitutes a new ground of rejection. In addition, there appears to be no recourse for the applicant finding a need to submit arguments, evidence, or amendment in response to new art that the examiner chooses not to characterize as forming the basis for a new ground of rejection. It appears the Office is advocating essentially a *de facto* presumption that citation of a new reference in an examiner's answer would not be a new ground of rejection. A recent decision by the Board, *Ex parte* ATSUHISA NAKASHIMA, Appeal 2009-001280, (US Patent and Trademark Office, before the Board of Patent Appeals and Interferences, January 7, 2010) (Decision on Appeal), illustrates the challenge facing appellants, wherein the Board declined to consider reply brief arguments that could reasonably be characterized as new nuances. As a result, appellants, who themselves are severely restricted by the Rules with regard to evidence submission after the notice of appeal is filed, may be compelled to file a continuation application in order to submit evidence so as to properly address the new reference which was not considered a new rejection by the Office. If appellants do not file a continuation, they would be unable to file new evidence to properly rebut the newly cited reference. We suggest that the proposed Rule unnecessarily puts appellants' patent term restoration at risk. It is consistent with the Office's stated objective to efficiently grant valid patents when the appellant has the option to file a request to reopen prosecution or at least submit amendments, arguments, and perhaps even evidence in response to newly cited art.

The pharmaceutical industry is particularly vulnerable to the consequences of shortened patent life, and requiring applicants to terminate the "B" portion of the patent term adjustment simply to ensure that a valid patent may grant seems to unnecessarily force requests for continued prosecution under somewhat arbitrary circumstances, leading to an inefficient and unfair result. *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010). We strenuously support citation, entry, and consideration of all pertinent art; however, we request that the appellant is provided with viable alternatives to respond to newly cited art in all instances, whether the examiner construes the art as forming the basis for a new ground of rejection or not. We believe that the matter could be addressed by expanding 41.39 (b) to apply to any new art that is cited or any art that could not earlier have been cited, enabling the Appellant to timely file a request to reopen prosecution for purposes of fully addressing newly cited art.

3) Proposed § 41.37 (t) and 41.37(g)/(u). Evidence and Statement of related cases.

The proposed rules 41.37(t) and 41.37(g)/(u) unnecessarily impose additional costs and appellant responsibility in preparing an appeal brief. The proposed § 41.37 (t) requires appellant to reproduce evidence filed prior to the notice of appeal, as well as any other evidence before the examiner filed before the notice of appeal. Further, proposed § 41.37(g)/(u) requires the appellant to file a "statement of related cases" that must "…identify by application, patent, appeal, interference, or court docket number, all prior to

or pending appeals interferences or judicial proceedings known to any inventors, any attorneys…that are related to…, or have a bearing on the Board's decision in the appeal. A related case includes any continuing application of the application on appeal. Appellant is under a continuing obligation to update this item during the pendency of the appeal." These documents and references are papers that are readily available to the examiner and the BPAI via the USPTO's Information File Wrapper (IFW). It is unclear why appellants should bear the additional costs and provide copies of information that is already of record in the IFW system.

Similarly, it appears that the USPTO should be in a position to readily identify any related cases and receive notice of any updates to the applications pending in the USPTO. The proposed rule unnecessarily encourages inequitable conduct challenges to any resulting patents when the information alleged to be withheld is readily available to the BPAI in the IFW system. As recognized in various cases, inequitable conduct charges have become an absolute plague. As the Court aptly stated in *Burlington Industries*,, "the habit of charging **inequitable conduct** in almost every major patent case has become an absolute **plague.**" *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988).

We request that the proposed rule be modified to clarify that only related US court actions and US court decisions must be cited to the BPAI, and that the BPAI may search the PTO IFW system to identify related cases. Additionally, we request that the rules specify either that the USPTO provide access to the evidence of record or that the rules specify that the appellant supply a listing to identify where the documents are found in the IFW. The USPTO could readily assemble an appendix referring to the evidence and any related cases, and in any format that the BPAI finds useful as it considers the appeal. We submit that this would provide stronger patents that are less vulnerable to charges of inequitable conduct and provide the desired efficiency at minimal additional cost to the Office.

4) Proposed Bd. R. § 41.37(r) Claim annotation

We respectfully submit that the proposed requirement for additional sections of the appeal brief describing claims support, drawing analysis and means/step plus function analysis should be limited to disclosures on which the appellant wishes to rely in arguing the case on appeal. Requiring these analyses for elements of the claim that are not being argued or disputed on appeal burdens appellants for no reason, particularly where a claim is lengthy and complex (as are many pharmaceutical claims), or where many claims are argued separately. We acknowledge the USPTO's intention to clarify the current summary of the claimed subject matter section; however, we believe that this could be clarified by example or education without requiring attorney statements that will necessarily be cited in any patent litigation.

We submit that Proposed Bd.R. § 41.37(r) addressing the claim support and drawing analysis section of the appeal brief is an unnecessary requirement when there are no outstanding 35 U.S.C § 112, first paragraph, rejections on appeal. Bd.R. § 41.37(r) requires, that, for each independent claim involved in the appeal and each dependent claim argued separately,

the appellant must provide an annotated copy of the claim indicating by page and line number, in bold face between braces after every limitation, where the limitation is described in the specification as filed. The Office discussion noted that a significant objective of this claim support requirement is to provide the examiner and the Board with the appellant's perspective on where language of the claims finds support in the specification. The Office's discussion further noted that the claim support requirement will help the Board interpret the scope of claims, or the meaning of words in a claim, before applying the prior art.

This requirement is unnecessarily burdensome on the appellant and appears simply superfluous when there are no outstanding 35 U.S.C § 112, first paragraph rejections on appeal. Moreover, even if a Section 112, first paragraph, rejection is pending, if the rejection relates to fewer than all elements of the rejected claim, as it often is, this requirement is superfluous and unnecessarily. Present Rule § 41.37(c)(1)(v), "Summary of Claimed Subject Matter," requires a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, which shall refer to the specification by page and line number, and to the drawing, if any, by reference characters. This section does not require an element-by-element analysis of the claims. Rather, it provides an easy reference to guide the examiner and the Board to the relevant sections of the specification. It is submitted that the present rule, in the absence of a Section 112, first paragraph, rejection, should provide sufficient guidance to the Board for interpreting the scope of the claims, or meaning of words within a claim before applying the prior art. Furthermore, if there is a Section 112, first paragraph, rejection on appeal, the appellant will necessarily provide specific reference to the specification where the claim elements at issue find support in the specification as filed.

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.

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 and appellants can contest improper denials of patent protection for their innovations. To do otherwise undermines the goal of promoting science and the useful arts.

We appreciate the opportunity to provide comments in response to the Notice and would be pleased to discuss any questions or comments.

Respectfully Submitted,
On behalf of ELI LILLY AND COMPANY

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