

September 25, 2007

MEMORANDUM

To: Director, U.S. Patent and Trademark Office
From: Alkermes, Inc.
Re: *Ex parte* Appeal Rules

On July 30, 2007, the United States Patent and Trademark Office (“PTO”) issued a Notice of Proposed Rule Making pertaining to the rules of practice before the Board of Patent Appeals and Interferences (“Board”) in *ex parte* appeals. *See* Rules of Practice Before the Board of Patent Appeals and Interferences in Ex Parte Appeals, 72 Fed. Reg. 41,472 (July 30, 2007). These comments are provided in response to the proposed rules.

I. INTRODUCTION

The PTO stated that “changes are needed to permit the Board to handle an increasing number of *ex parte* appeals in a timely manner.” *Id.* at 41,472. In some instances, the proposed rules adopt practices similar to those governing appellate briefs filed with the U.S. Court of Appeals for the Federal Circuit. *Id.* In view of the expectation for over 5,000 *ex parte* appeals in 2008, *id.*, we favor any change to the existing rules that enables the Board to timely adjudicate the increasing number of *ex parte* appeals while maintaining the same fairness that is provided to patent applicants under existing rules.

In that regard, however, the proposed rules are deficient in two respects. First, by requiring an appellant in proposed rule 41.37(o)(7) to specify for each rejection under 35 U.S.C. § 103 the errors in the Examiner’s rejection and the specific limitations in the rejected claims that are not described in the prior art relied upon in support of the rejection, and to explain how those

limitations render the claimed subject matter not obvious over the prior art, the PTO unfairly shifts the burden of proving a *prima facie* case on appeal from the PTO to the patent applicant. Second, the 25-page limitation on the length of an appeal brief under proposed rule 41.37(v)(5) unduly burdens appellants and will delay proceedings before the Board by forcing frequent use of the means by which appellants can request an extension of the page limitation.

To alleviate these concerns while furthering the efficiency of the Board's decision-making process, we respectfully suggest that proposed rule 41.37(o)(7) not be adopted as currently written, and that proposed rule 41.37(v)(5) be modified in one of two ways to promote fairness to the appellant—either (a) increase the proposed 25-page limitation to 50 pages, or (b) increase the proposed 25-page limitation to 30 pages but exclude from it the Statement of Facts and allow appellants to utilize single spacing for lengthy quotations. The proposed rules as amended in this manner will fairly maintain the burden of establishing a *prima facie* case of obviousness squarely with the PTO and will promote efficiency in the briefing process before the Board.

II. PROPOSED RULE 41.37(o)(7) SHOULD NOT BE ADOPTED BECAUSE IT SHIFTS THE *PRIMA FACIE* BURDEN UNDER SECTION 103 TO THE PATENT APPLICANT

Under 35 U.S.C. § 103, the PTO has the burden of establishing a *prima facie* case of obviousness. *See In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988); *Ex Parte Pearson*, 2007 WL 2724457, at *3 (B.P.A.I. Aug. 31, 2007) (“In rejecting claims under 35 U.S.C. § 103, the Examiner bears the initial burden of establishing a *prima facie* case of obviousness.”); *Ex Parte Krehbiel*, 2007 WL 2698505, at *2 (B.P.A.I. Aug. 28, 2007) (“To reach a conclusion of obviousness under § 103, the Examiner bears the burden of producing factual basis supported by teaching in a prior art reference or shown to be common knowledge of unquestionable demonstration. Our reviewing court requires this evidence in order to establish a *prima facie* case.”). The PTO can satisfy its

burden “by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references.” *Fine*, 837 F.2d 1074. Until it does, however, the patent applicant under Federal Circuit jurisprudence need not offer rebuttal evidence—*i.e.*, the *prima facie* burden remains with the PTO until satisfied. *See, e.g., Hyatt v. Dudas*, 492 F.3d 1365, 1368 (Fed. Cir. 2007) (stating that in order to invoke its authority to compel the disclosure of information that the Examiner deems pertinent to patentability, “the PTO must first establish a *prima facie* case for the rejection”).

Only after the *prima facie* case of obviousness has been established does the burden of going forward shift to the patent applicant, who must then rebut the *prima facie* case in order to save patentability. *See In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984). In that instance, rebuttal evidence may include any showing of facts sufficient to support a conclusion opposite that which may be drawn from the *prima facie* case, including evidence of secondary considerations and the like. *Id.* The patent applicant thus has no burden whatsoever until the PTO establishes a *prima facie* case, and even then to rebut the case the patent applicant need not necessarily identify specific limitations absent in the prior art.

Turning this principle on its head, proposed rule 41.37(o)(7) requires for each rejection under 35 U.S.C. § 103 that, if appropriate, the appellant must specify in its brief the errors in the Examiner’s rejection and the specific limitations in the rejected claims that are not described in the prior art relied upon in support of the rejection. The appellant also must explain under the proposed rule how the limitations render the claimed subject matter not obvious over the prior art. While the proposed rule is directed to simplifying the Board’s task on appeal and somewhat ambiguously places requirements on the appellant where “appropriate,” it effectively shifts the

PTO's burden of establishing a *prima facie* case of obviousness to the appellant to show that the claims set forth in the application are not obvious. In this manner, however, the Board's task under existing law cannot be simplified.

To be sure, upon reviewing the Examiner's determination of obviousness on appeal, the Board "must necessarily weigh all of the evidence and argument," including that received from the appellant. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). If examination by the Examiner does not produce a *prima facie* case of unpatentability, however, "then *without more* the applicant is entitled to grant of the patent." *Id.* (emphasis added.) The rules governing *ex parte* appeals thus should not require as a matter of course an appellant's rebuttal by way of a specific limitation-by-limitation analysis or otherwise until the PTO has sufficiently advanced a *prima facie* case to rebut. For this reason, proposed rule 41.37(o)(7) should not be adopted.

III. PROPOSED RULE 41.37(v)(5) SHOULD BE AMENDED (1) TO INCREASE THE 25-PAGE LIMITATION TO 50 PAGES OR (2) TO INCREASE THE 25-PAGE LIMITATION TO 30 PAGES EXCLUDING THE STATEMENT OF FACTS AND TO ALLOW SINGLE SPACING OF LENGTHY QUOTATIONS

As a prudential matter, the PTO should relax the 25-page limitation set forth in proposed rule 41.37(v)(5) since there is no such limitation on the length of an Examiner's rejection or the number of references cited therein. Out of necessity, we have filed appeal briefs in excess of 25 pages in response to an Examiner's rejection based on as many as nine references in final and advisory actions that exceed 25 pages. In every such case, the proposed rule would compel a request for an extension of the 25-page limitation in order to effectively argue patentability. This is particularly true in view of the requirements in proposed rule 41.37(n) that a Statement of Facts, to be included *within* the page limitation, present a line-by-line recital of the prior art references at issue if material and relevant to the rejection on appeal, and, in proposed rule 41.37(o), that any finding made by the Examiner that is not challenged is presumed correct. Examiners are not

constrained by a page limitation in issuing office actions, nor are they limited in the number of rejections they make or the number of documents they cite. As such, it will often be the case that an appellant cannot comply with the Statement of Facts requirements, and ensure that incorrect findings are addressed and not waived, without exceeding the 25-page limitation. Ironically, then, the proposed rule would not promote efficiency before the Board but rather the opposite, creating a very real danger that frequent use of the means by which appellants request an extension of the page limitation would swallow any benefit that the rule itself purports to provide.

As stated by the PTO, the proposed rules in some instances “adopt practices similar to those of the Court of Appeals for the Federal Circuit.” 72 Fed. Reg. at 41,472. However, the rules applicable to briefing before the Federal Circuit are not so strict as those proposed by the PTO. For example, an appellant is allowed under Federal Rule of Appellate Procedure 32(a)(7) to file a brief of 30 pages (or more if nonetheless under 14,000 words) and is allowed under Federal Rule of Appellate Procedure 32(a)(4) to utilize single spacing for quotations of more than two lines long. The relaxed rules are adequate for litigants before the Federal Circuit and allow the court to grant motions by litigants to file an extended brief “only for extraordinary reasons.” *See* Fed. Cir. R. 28(c).

Looking as does the PTO to the rules governing briefing before the Federal Circuit, and taking into account the fact-intensive nature of a typical appeal of an Examiner’s rejection, we request that proposed rule 41.37(v)(5) be amended according to one of the following two alternatives:

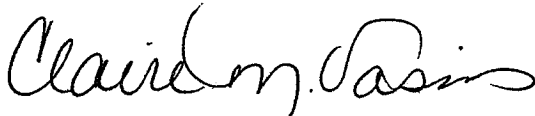
- the 25-page limitation should be increased to 50 pages; or
- the 25-page limitation should be increased to 30 pages excluding the Statement of Facts, and appellants should be allowed to utilize single spacing for lengthy quotations.

We respectfully suggest that proposed rule 41.37(v)(5) amended in this manner would best balance the needs of the appellant and PTO alike.

IV. CONCLUSION

Patent applicants recognize the need for change in anticipation of the expected number of *ex parte* appeals in the coming years. 72 Fed. Reg. at 41,472. With the exceptions identified herein, the proposed changes to the rules of practice before the Board in such appeals are commendable. By not adopting proposed rule 41.37(o)(7) as currently written, and modifying proposed rule 41.37(v)(5) by increasing the proposed 25-page limitation to 50 pages, or to 30 pages but excluding from it the Statement of Facts and allowing appellants to utilize single spacing for lengthy quotations, the PTO will promote both efficiency and fairness in *ex parte* appellate practice before the Board.

Thank you for this opportunity to comment on the proposed rules. We appreciate your consideration.



Claire M. Vasios, Ph.D.
Vice-President, Intellectual Property
Alkermes, Inc.
88 Sidney Street
Cambridge, MA 02139