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Paper No. 13
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PHARMACOSMOS A/S,
Petitioner,

v.

AMERICAN REGENT, INC.,
Patent Owner.

PGR2020-00009
Patent 10,478,450 B2

Before ERICA A. FRANKLIN, JON B. TORNQUIST, and JAMIE T. WISZ, *Administrative Patent Judges*.

WISZ, *Administrative Patent Judge*.

ORDER
Conduct of the Proceeding
Supplemental Briefing on 35 U.S.C. § 325(d)
37 C.F.R. § 42.5(a)

I. INTRODUCTION

Petitioner, Pharmacosmos A/S ("Petitioner"), filed a Petition on January 6, 2020, challenging claims of U.S. Patent No. 10,478,450 B2 ("the '450 patent"). Paper 1. American Regent, Inc. ("Patent Owner"), filed a Preliminary Response on May 18, 2020. Paper 12. In its Preliminary Response, Patent Owner argues that the Board should apply its discretion under 35 U.S.C. § 325(d) to deny institution of the requested proceeding because "Petitioner presents the same or substantially the same arguments previously presented during prosecution and related post-grant proceedings." *Id.* at 68–70 (arguing that "the Petition is premised on (1) claim construction arguments regarding the term 'iron polyisomaltose' that the examiner and the Board have repeatedly rejected, and (2) § 112 arguments that the examiner squarely addressed during prosecution.").

In view of *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020) (precedential), we determine that it would be helpful for the parties to provide additional briefing on the applicability of § 325(d) to this case. In particular, the parties should address the framework for analyzing such applicability of § 325(d) set forth in that decision. As explained in the decision, the framework involves considering,

> (1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of the first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.

Advanced Bionics, Paper 6 at 8. Under the first part of the framework, the same art or arguments "must have been previously presented to the Office during proceedings pertaining to the challenged patent." *Id.* at 7. Under the second part of the framework, it must be demonstrated that the Office erred in a material manner, which "may include an error of law, such as misconstruing a claim term, where the construction impacts patentability of the challenged claims." *Id.* at 8–9 n.9. And "[i]f reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability." *Id.* at 9.

Advanced Bionics also acknowledges that the *Becton, Dickinson* factors "provide useful insight into how to apply the framework under . . . § 325(d)." *Id.* at 9 & n.10 (detailing the *Becton, Dickinson* factors). So we also encourage the parties to discuss any *Becton, Dickinson* factors relevant to the facts of this case. The parties may submit additional evidence from the prosecution history of the challenged patent to support any facts asserted in the supplemental briefing regarding the applicability of § 325(d).

II. ORDER

Accordingly, it is

ORDERED that Petitioner is authorized to file a reply to the Preliminary Response, of no more than seven (7) pages and limited to addressing the issue of discretionary denial under 35 U.S.C. § 325(d), by June 9, 2020; and it is

FURTHER ORDERED that Patent Owner is authorized to file a sur-reply to Petitioner's reply, of no more than seven (7) pages and limited to the issue of discretionary denial under 35 U.S.C. § 325(d), by June 16, 2020.

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