

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PHARMACOSMOS A/S,
Petitioner,

v.

AMERICAN REGENT, INC.,
Patent Owner.

Case PGR2020-00009
Patent No. 10,478,450

**PATENT OWNER'S SUR-REPLY ON THE ISSUE OF
DISCRETIONARY DENIAL UNDER 35 U.S.C. § 325(d)
(AUTHORIZED BY THE BOARD'S JUNE 2, 2020 ORDER, PAPER NO. 13)**

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The Examiner and Board have repeatedly rejected Petitioner’s incorrect claim construction of “iron polyisomaltose” and its meritless § 112 challenges. Petitioner fails to identify any error in the Office’s previous determinations; in fact, neither the Petition nor Reply provides any substantive analysis of the Office’s previous findings. In *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, the Board exercised its discretion to deny institution because, even though the petitioner raised new art and arguments, it failed to identify error in the Examiner’s previous consideration of similar art and arguments. IPR2019-01469, Paper 6, at 21-22 (PTAB Feb. 13, 2020). “At bottom, this framework reflects a commitment to defer to previous Office evaluations of the evidence of record unless material error is shown.” *Id.* at 9. Similar to *Advanced Bionics*, the Board should defer to the Office’s previous evaluations as Petitioner fails to establish any error by the Office.

I. *Advanced Bionics* Warrants Denial of Institution Under § 325(d)

A. Claim Construction

***Advanced Bionics* Prong 1 (*Becton Dickinson* factors a-d):** The Examiner and the Board have already addressed whether “polyisomaltose” is linear and includes oligoisomaltoses and agreed with Patent Owner on both points. POPR, 20-26, 30-31, 55-57. During prosecution of the ’450 patent and its parent ’549 patent, the Examiner questioned the meaning of “polyisomaltose,” and Patent Owner conclusively defined “iron polyisomaltose” as linear. Ex. 1002, 188, 206-207, 209-

212; Ex. 1007, 99-101, 111. The Examiner then applied this definition and eventually allowed the claims. Ex. 1002, 237. Patent Owner also cited Monofer[®], an iron oligosaccharide complex, stating that “[o]ne example of an iron polyisomaltose complex is an iron isomaltoside (e.g., Monofer[®]), where the carbohydrate component is a pure linear chemical structure of repeating α 1-6 linked glucose units.” Ex. 1007, 99-101, 111. Petitioner concedes that Monofer[®] is an oligoisomaltose. Pet., 3, 18 (citing Ex. 1048). The Examiner found Patent Owner’s arguments “persuasive” and further equated “polyisomaltose” and “isomaltose oligomers,” finding that “one of ordinary skill in the art ... would have been able to practice *the invention for iron polyisomaltose complex* ... [because] one of ordinary skill in the art would have been able to select *isomaltose oligomers* to block anaphylaxis to dextrans.” Ex. 1007, 142. Petitioner’s contention that the Examiner never “formally” considered the linearity and oligomer issues or gave it “ cursory” treatment (Reply, 1-2) is belied by the record. *Becton Dickinson* factor (d) favors denial.

In an IPR challenging the parent ’549 patent, the Board likewise equated “iron polyisomaltose” and oligosaccharides by finding the limitation was met by prior art disclosing “isomaltose *oligosaccharides*.” Ex. 1098, 21. Petitioner argues that Patent Owner “omits critical details”—that this finding was based only on an “alternative” construction offered by Petitioner. Reply, 3-4. But the Board applied

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