

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AQUESTIVE THERAPEUTICS, INC.,
Petitioner,

v.

NEURELIS, INC.,
Patent Owner.

Case IPR2019-00451
Patent 9,763,876 B2

Before ZHENYU YANG, JON B. TORNQUIST, and JAMIE T. WISZ,
Administrative Patent Judges.

WISZ, *Administrative Patent Judge.*

DECISION

Denying Patent Owner's Request on Rehearing of Decision on Institution
37 C.F.R. § 42.71(d)

I. INTRODUCTION

Neurelis, Inc. (“Patent Owner”) requests rehearing of the Board’s Decision (Paper 8) (“Decision”) instituting *inter partes* review of claims 1–36 of U.S. Patent No. 9,763,876 B2 (Ex. 1001, “the ’876 patent”). Paper 10 (“Request for Rehearing” or “Req. Reh’g”). For the reasons that follow, Patent Owner’s Request for Rehearing is *denied*.

II. ANALYSIS

Pursuant to 37 C.F.R. § 42.71(d):

A party dissatisfied with a decision may file a single request for rehearing without prior authorization from the Board. The burden of showing a decision should be modified lies with the party challenging the decision. The request must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply.

When reconsidering a decision on institution, we review the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of discretion exists where a “decision [i]s based on an erroneous conclusion of law or clearly erroneous factual findings, or . . . a clear error of judgment.” *PPG Indus. Inc. v. Celanese Polymer Specialties Co.*, 840 F.2d 1565, 1567 (Fed. Cir. 1988).

Patent Owner contends that we (1) misapprehended the statutory requirements for claiming priority, (2) misapprehended the scope and applicability of 37 C.F.R. § 1.57, and (3) overlooked the due-process requirements of 37 C.F.R. § 1.57. Req. Reh’g 1. We need only address the first argument below for purposes of this Decision.

Patent Owner asserts that we misapprehended the statutory requirements for claiming priority because, rather than addressing the statutory written description requirement, we *sua sponte* applied 37 C.F.R. § 1.57. *Id.* at 3. In making this argument, Patent Owner contends that “the merits of the priority claim are unchallenged” and the Petition does not even suggest that “a person of ordinary skill in the art would have failed to understand the provisional specification . . . or appreciate from the specification what the inventors had invented.” *Id.* at 1, 3. As discussed below, we are not persuaded by this argument.

First, Petitioner did challenge the ’876 patent priority claim in contending that “the presence of any alkyl glycosides (either generally or particularly) – regardless of amount – was not disclosed, described, or enabled by [the] ’558 Provisional.” Petition 20. Furthermore, with supporting testimony from Dr. Nicholas A. Peppas, Petitioner further asserted that the ’558 provisional’s “generic disclosure of ‘surface active agents (especially non-ionic materials)’ . . . does not disclose, describe, and/or enable alkyl glycosides in general (or dodecyl maltoside in particular).” *Id.* (citing Ex. 1008 ¶ 152; Ex. 1041 ¶ 68).

Second, Patent Owner’s argument appears to misapprehend the burden of showing entitlement to priority. Although the petitioner has the ultimate burden of persuasion to prove unpatentability, a patent owner must demonstrate entitlement to a priority date when the patent owner relies on that priority date to overcome an anticipation or obviousness argument. *See Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1379–80

(Fed. Cir. 2015) (discussing burdens in *inter partes* review to show entitlement to provisional filing dates and relying on infringement cases involving continuation-in-part applications); *In re NTP, Inc.*, 654 F.3d 1268, 1276 (Fed. Cir. 2011) (“[A] patent’s claims are not entitled to an earlier priority date because the patentee claims priority. Rather, for a patent’s claims to be entitled to an earlier priority date, the patentee must demonstrate that the claims meet the requirements of 35 U.S.C. § 120.” (citations omitted)); *Research Corp. Techs., Inc. v. Microsoft Corp.*, 627 F.3d 859, 870–71 (Fed. Cir. 2010); *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327–29 (Fed. Cir. 2008); *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1305–06 (Fed. Cir. 2008).

As explained in *Dynamic Drinkware*, a petitioner has the initial burden of going forward to show that there is invalidating prior art. *Dynamic Drinkware*, 800 F.3d at 1379. As discussed in our Decision, Petitioner satisfied its initial burden of production on the issue of whether Gwozdz is prior art by establishing that Gwozdz is entitled to the effective filing date of the Gwozdz provisional. Decision 7. Therefore, Gwozdz is prior art to the ’876 patent under 35 U.S.C. § 102(e)(1) unless Patent Owner can show that the ’876 patent is entitled to the effective filing date of its provisional application (“the ’558 provisional”). *Id.* Thus, the burden of production shifts to Patent Owner, who must show not only the existence of earlier applications, but also how the written description in the earlier applications supports the challenged claims. *Dynamic Drinkware*, 800 F.3d at 1379–80. “[T]o gain the benefit of the filing date of an earlier application

under 35 U.S.C. § 120, each application in the chain leading back to the earlier application must comply with the written description requirement of 35 U.S.C. § 112.” *Zenon Env'tl., Inc. v. U.S. Filter Corp.*, 506 F.3d 1370, 1378 (Fed. Cir. 2007) (quoting *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571 (Fed. Cir. 1997)); *see also In re Hogan*, 559 F.2d 595, 609 (CCPA 1977) (“[T]here has to be a continuous chain of copending applications each of which satisfies the requirements of § 112 with respect to the subject matter presently claimed.” (alteration in original) (quoting *In re Schneider*, 481 F.2d 1350, 1356 (CCPA 1973))). Thus, as discussed in our Decision, Patent Owner must show that each application in the priority chain¹ makes the requisite disclosure of subject matter; otherwise, the ’876 patent is not entitled to the benefit of the filing date of the ’558 provisional. Decision 7 n.6.

On this record, Patent Owner fails to satisfy its burden of production to show entitlement to an earlier filing date. All of Patent Owner’s arguments are focused on the alleged deficiencies with Petitioner’s contentions regarding the disclosure of alkyl glycosides in the ’558 provisional. Prelim. Resp. 24–27. Patent Owner offers no analysis demonstrating that every patent application along the priority chain conveys with reasonable clarity to those skilled in the art that the inventors were in possession of each limitation of each of the challenged claims, as well as the

¹ In this case, the priority chain for the ’876 patent includes a provisional application and a continuation-in-part application. Decision 6.

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