

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.,
Petitioner

v.

CLEVELAND MEDICAL DEVICES, INC.,
Patent Owner

Case PGR2024-00012
Patent 11,602,284

PETITIONER'S REQUEST FOR REHEARING
PURSUANT TO 37 C.F.R. §42.71(d)

I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.71(c)-(d), ResMed Corp. (hereinafter “ResMed” or “Petitioner”) requests rehearing of the Decision Denying Institution, entered on June 24, 2024 (Paper 7, the “DDI”), denying ResMed’s request for post-grant review of claims 1-20 (“the challenged claims”) of U.S. Patent No. 11,602,284 (EX1001, “the ‘284 patent”) (“Petition”). The DDI’s determination that the ‘284 patent was not eligible for post-grant review was based on a misapprehension of Federal Circuit law regarding the burden on the parties for an obviousness challenge. Institution of trial is respectfully requested.

After considering Grounds 1 (written description) and 2 (enablement), the DDI determined that the “Petitioner has failed to show that it is more likely than not the pre-AIA priority applications [fn omitted] lack written description support for the claims in the ‘284 patent.” DDI at 12 (citing Prelim. Resp. 8-25). However, the DDI failed to consider Grounds 3-10 (obviousness) of the Petition for which ResMed provided separate and independent bases showing the ‘284 patent is subject to the AIA.

Under Federal Circuit law, Petitioner only has the initial burden of production for obviousness challenges to identify a single limitation not found in earlier priority applications, and to assert prior art that predates the

May 26, 2022 application date of the ‘284 Patent, to demonstrate AIA eligibility. The burden then shifts to the Patent Owner to show entitlement to an earlier asserted priority date—alleged by Patent Owner to be November 4, 2005—necessary to establish the ‘284 Patent as pre-AIA. The DDI explains this pre-AIA entitlement process.¹ Here, for Grounds 3-10 based on obviousness, Petitioner satisfied its burden with a prima facie showing of unpatentability under 35 U.S.C. § 103 with intervening prior art predating the ‘284 patent, and by identifying claim limitations unsupported by the alleged priority applications, thereby showing the ‘284 patent is eligible for post-grant review.

Patent Owner, not Petitioner, failed to make a sufficient counter-showing of entitlement to an earlier priority date as to every claim limitation for any of the challenged claims, merely arguing that the claim term “index of treatment efficacy” was at least **equivalent** to descriptions in the specification of a pre-AIA application. Prel. PO Resp. at 2, 9.

¹ The DDI provides that “[a] **patent claiming the benefit** of priority of an application **filed before March 16, 2013, must have written description support for the claimed invention** in the earlier-filed application in order **to avoid PGR-eligibility**” for a transition application such as the ‘284 patent. DDI at 9 (emphasis added).

This request is allowed without Board authorization. *See* 37 C.F.R. § 42.71(c)-(d).

II. FACTUAL BACKGROUND

The ‘284 patent was filed on May 26, 2022 and contains at least one claim that is not entitled to priority earlier than March 16, 2013. The patent is thus AIA-eligible. Grounds 3-10 are based on prior art dated prior to the application date of the ‘284 patent.

The Petition explained that no priority application of the ‘284 patent discloses certain claim limitations found in claims 1-20, including the “index of treatment efficacy.” Petition at 2-3. The Petition explains that independent claim 1 “lacks written description and enabling support in a priority application filed before March 16, 2013.” Petition at 4. For Grounds 3-10, the claims are unpatentable under 35 U.S.C. § 103. Petition at 7.

Patent Owner argued that “the ‘284 Patent and its priority applications disclose calculating a quantitative ‘level of severity’ of sleep-disorder symptoms while the patient is being treated, **which refers to the claimed ‘index of treatment efficacy’ in different terms.**” Prel. PO Resp. at 8 (emphasis added); *see also id.* at 9 (arguing “the ‘284 Patent describes the concept of ‘an index of treatment efficacy’ in other equivalent terms”). The claims, however, positively recite **both** terms. The Response stated only

that, for Grounds 3-10, “because Petitioner fails to carry its burden to show lack of written description or non-enablement, it failed to establish that the ‘284 Patent is PGR-eligible for and that the references (*e.g.*, Bao, Klee, and Pirzada) are prior art.” Prel. PO Resp. at 30-31. As below, that is not the test.

III. LEGAL STANDARD

The standard of review for rehearing is abuse of discretion. 37 C.F.R. § 42.71(c); *see also* 37 C.F.R. § 42.71(d) (“request must specifically identify all matters the party believes the Board misapprehended or overlooked.”). “An abuse of discretion occurs if the decision (1) is clearly unreasonable, arbitrary, or fanciful; (2) is based on an erroneous conclusion of law; (3) rests on clearly erroneous fact findings; or (4) involves a record that contains no evidence on which the Board could rationally base its decision.” *Redline Detection, LLC v. Star Envirotech, Inc.*, 811 F.3d 435, 442 (Fed. Cir. 2015).

The DDI, contrary to law, collapsed the entire Petition into a single pre-AIA priority question, misapprehending controlling law about priority for grounds based on obviousness. Yet the DDI recognized that the patent owner, seeking to establish an earlier priority date for a challenged claim under 35 U.S.C. §§ 119 or 120, must still substantiate entitlement to an earlier effective date in compliance with § 112(a). DDI at 9 (explaining transition patent to show pre-AIA support to avoid PGR).

IV. ARGUMENT

A. The DDI misapprehended the law in its failure to consider Grounds 3-10 based on obviousness.

In AIA proceedings, the general rule is that “[t]he moving party has the burden of proof to establish that it is entitled to the requested relief.” 37 C.F.R. §42.20(c); *see also* 35 U.S.C. § 326(e) (“In a post-grant review instituted under this chapter, the petitioner shall have the burden of proving a proposition of unpatentability by the preponderance of the evidence.”). Here, the Petition sets forth 10 independent grounds of unpatentability, Grounds 1-10, demonstrating more likely than not that at least one of the challenged claims is unpatentable under post-AIA 35 U.S.C. §§112 and/or 103.

After considering only Grounds 1 (written description) and 2 (enablement) and without addressing Grounds 3-10, the DDI denied institution and concluded that “Petitioner has not satisfied its burden of proving that it is more likely than not that the pre-AIA priority applications failed to provide written description support for and failed to enable the challenged claims.” DDI at 24. Yet, in each of Grounds 3-10, ResMed identified prior art that predates the filing date of the ‘284 patent, May 26, 2022, and presented a prima facie showing of unpatentability, thus providing an independent basis that the ‘284 patent is subject to the first-inventor-to-file provisions of the AIA, i.e., it is a patent “that contains . . . a claimed

invention that has an effective filing date” on or after March 16, 2013. *See* AIA § 3(n)(1); 35 U.S.C. § 100 (note) AIA First Inventor to File Provisions.

Thus, by carrying its burden of production for Grounds 3-10, ResMed showed not only that it is entitled to the unpatentability relief sought, but also that the ‘284 patent is eligible for post-grant review. *See also* 37 C.F.R. § 42.204(a) (requiring only that “petitioner must certify that the patent for which review is sought is available for post-grant review.”). While each of Ground 3-10 demonstrates why institution would be appropriate (*see* Section IV.B below), having presented an independent basis for post-grant review eligibility in each of Grounds 3-10, the DDI’s failure to consider each is legal error for which reconsideration is sought.

B. The Board’s PGR-eligibility decision is based on an erroneous conclusion of law.

The DDI did not follow Federal Circuit law in denying institution on at least Grounds 3-10. *See Dynamic Drinkware v. Nat’l Graphics, Inc.*, 800 F.3d 1375 (Fed. Cir. 2015). In *Drinkware*, the Federal Circuit clarified the two different burdens of proof for an obviousness-based post-grant challenge that a petitioner and a patent owner must satisfy. *Id.* at 1378. First, the petitioner has the burden of persuasion “to prove ‘unpatentability by a preponderance of the evidence,’ 35 U.S.C. § 316(e), and that burden never shifts to the patentee.” *Id.* Second, the petitioner initially has the burden of

production to come forward with invalidating prior art. *Id.* at 1379-80; *Bausch & Lomb, Inc. v. BarnesHind/Hydrocurve, Inc.*, 796 F.2d 443, 449 (Fed. Cir. 1986) (finding that **the only showing a party challenging validity needs to make** is that “the art must have existed as of the date of invention, presumed to be the filing date of the application until an earlier date is proved.”) (internal quotations omitted) (emphasis added). Here, after the Petition made the requisite showing, Patent Owner failed to prove each limitation of any challenged claim of Grounds 3-10 had written description support in an earlier application.

The DDI, for Grounds 3-10, failed to follow prior PTAB decisions. For example, the Director explained in *Penumbra* the requirement for a patent owner to substantiate any assertion of earlier priority, with no exception identified for pre-AIA patent claims:

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*, 800 F.3d at 1379–80 (discussing burdens in *inter partes* review to show entitlement to provisional filing dates). “[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,” which include fulfilling the requirements of § 112. *In re NTP, Inc.*, 654 F.3d 1268, 1276–77 (Fed. Cir. 2011) (citations omitted)); *see also 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). *Penumbra, Inc. v. RapidPulse, Inc.*, IPR2021-01466, Paper 34 at 18 (March 10, 2023) (Precedential) (emphasis added).

For Grounds 3-10, the Petition identified and explained how and where new matter emerged in the ‘284 patent claims. DDI at 9-10; *see* Petition at 26 (referring to non-disclosed limitations in concert with Grounds 3-10). Patent Owner never attempted to show how each limitation for any one claim was entitled to the alleged 2005 priority date to overcome Grounds 3-10 as required by *Penumbra*. *See also, SPTS Techs. v. Plasma-Therm*, IPR2018-00618, Paper 24 at 28 (PTAB Aug. 26, 2019) (requiring PO to show “why the written description in the earlier application supports the claim”); *Maxlite, Inc. v. Jiaxing Super Lighting Electric Appliance Co., Ltd.*, IPR2020-00208, Paper 14 at 6 (PTAB Jun. 1, 2021) (reversing decision denying institution as abuse of discretion on same issue).

The Petition, for at least Grounds 3-10, carried its burden to show

PGR eligibility for the challenged claims based on the precedential *Penumbra* decision. Once ResMed satisfied its initial burden of production by showing a reference as prior art before the application filing date (May 2022), the burden then shifted to the Patent Owner to show that all limitations of any challenged claim benefits from an earlier filing date that predates the prior art. *Dynamic Drinkware* at 1379-80; *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008); *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1305 (Fed. Cir. 2008) (finding that once a defendant satisfied its initial burden of production by coming forward with evidence that [a reference] was anticipatory prior art, “the burden was on [the patent owner] to come forward with evidence to the contrary” and that the “district court therefore correctly placed the burden on [the patent owner] to come forward with evidence to prove entitlement to claim priority to an earlier filing date”). Patent Owner, however, failed to address all claim limitations for any challenged claim.

Regarding the burden on the parties, in a Final Written Decision for PGR, the Board explained that ““we are not aware of any obligation on the part of Petitioner to address . . .’ every limitation of a challenged claim under § 112(a)).” *Inguran, LLC v. Premium Genetics (UK) Ltd.*, PGR2015-00017, Paper 22 at 33 (PTAB Dec. 20, 2016). Expounding on that principle, in

Unified Patents, LLC v Dolby Labs. Licensing Corp., the Final Written

Decision distinguished *Inguran*, but agreed that a Patent Owner must show the presence of every claim limitation for a challenged claim in a priority application:

[T]he Board specifically noted that the **patent owner failed to provide support for all limitations in either the preliminary response or the subsequent briefing**. *Inguran*, Paper 22, 33 (“Patent Owner, however, does not address the remaining limitations of claim 1 and whether the prior applications disclose those remaining limitations in the manner required by § 112(a). *See* PO Resp. 3–6; Prelim. Resp. 7–13.”). **Here, Patent Owner addressed each limitation in its Preliminary Response**. Prelim. Resp. 40–47.

Unified Patents, LLC v Dolby Labs. Licensing Corp., IPR2021-00275, Paper 48 at 31-32 (PTAB, June 15, 2022) (emphasis added). Federal Circuit precedent and Board decisions confirm that pre-AIA eligibility is determined based on burdens of production involving a prior art challenge. It was legal error for the DDI to not consider whether the burdens of production among the parties was met, and to shift the burden to Petitioner for Grounds 3-10.

V. RELIEF REQUESTED

For these reasons, Petitioner respectfully requests that the board reconsider and grant post-grant review of the ‘284 patent based on Grounds 1-10, as explained in the Petition and supporting evidence.

PGR2024-00012

U.S. Patent No. 11,602,284

Date: July 24, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing PETITIONER'S REQUEST FOR REHEARING PURSUANT TO 37 C.F.R. §42.71(d) has been served via electronic mail upon the following:

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