

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE OFFICE OF THE UNDER SECRETARY OF COMMERCE
FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE
UNITED STATES PATENT AND TRADEMARK OFFICE

BOEHRINGER INGELHEIM ANIMAL HEALTH USA INC.,
Petitioner,

v.

KANSAS STATE UNIVERSITY RESEARCH FOUNDATION,
Patent Owner.

PGR2022-00021
Patent 10,954,274 B2

Before KATHERINE K. VIDAL, *Under Secretary of Commerce for
Intellectual Property and Director of the United States Patent and
Trademark Office.*

DECISION

Vacating the Decision Denying Institution and Remanding to the Patent
Trial and Appeal Board for Further Proceedings

I. INTRODUCTION

On December 22, 2021, Boehringer Ingelheim Animal Health USA Inc. (“Petitioner”) filed a Petition requesting a post-grant review of claims 1–27 of U.S. Patent No. 10,954,274 B2 (Ex. 1001, “the ’274 patent”). Paper 2 (“Pet.”). Kansas State University Research Foundation (“Patent Owner”) did not file a Preliminary Response. On July 15, 2022, the Patent Trial and Appeal Board (“Board”) issued a Decision denying institution of post-grant review. Paper 9 (“Decision” or “Dec.”). I initiated *sua sponte* Director review of the Board’s Decision on August 12, 2022. Paper 10.

Based on the analysis set forth below, I am vacating the Board’s Decision Denying Institution of Post Grant Review, only to the extent the Board, in exercising discretion under 35 U.S.C. § 325(d) to deny the Petition, did not explain the basis for its finding that the Petitioner’s enablement challenge constituted, under *Advanced Bionics*,¹ the same or substantially the same arguments previously presented to the Office on written description. As I explain in more detail below, as a matter of principle and law, the mere finding of adequate written description by an examiner can never on its own and without more constitute “the same or substantially the same arguments” under *Advanced Bionics* as a challenge for lack of enablement. *See Ariad Pharms., Inc. v. Eli Lilly & Co.*, 589 F.3d 1336 (Fed. Cir. 2010) (en banc). While “written description and enablement often rise and fall together,” *see Ariad*, 598 F.3d at 1352, the written description and enablement requirements involve different considerations and an argument made regarding one requirement does not necessarily

¹ *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020) (precedential).

equate to an argument made regarding the other. To the extent the Board found that Petitioner's enablement challenge constituted the same or substantially the same arguments previously presented to the Office on written description, the Board must set forth its rationale in sufficient detail to inform the parties and the public and allow for review.

I remand to the Board for further proceedings consistent with this Decision.

II. BACKGROUND

Petitioner challenged claims 1–27 of the '274 patent under 35 U.S.C. § 112(a) as unpatentable for lacking written description and enablement, and under 35 U.S.C. § 103 as obvious in view of prior art. *See* Pet. 29–80. Petitioner specifically argued that the '274 patent specification does not provide written description support for the full scope of the claimed genus. *See id.* at 29–54. Separately, Petitioner argued that the '274 patent specification does not enable the full scope of the claims to be practiced without undue experimentation. *See id.* at 54–67.

Under the first part of the *Advanced Bionics* framework, the Board found that the Office previously considered Petitioner's argument that the claims lack written description support during examination. Dec. 15–17. Under the second part of the *Advanced Bionics* framework, the Board also found that Petitioner did not demonstrate that the Office materially erred in its previous written description analysis. *See id.* at 17–19. Although the Examiner expressly distinguished written description from enablement

during examination,² the Board found that “Petitioner’s enablement challenge is largely redundant to the Examiner’s rejection based on lack of adequate written description or otherwise focuses on certain functional characteristics disclosed in the Specification that are not recited in the challenged claims.” *Id.* at 19. Accordingly, as to both written description and enablement the Board exercised discretion under 35 U.S.C. § 325(d) to deny institution. *Id.* at 20. As to the obviousness challenges under 35 U.S.C. § 103, the Board did not reach the merits of certain grounds that were predicated on the 35 U.S.C. § 112 written description challenge (Grounds 3–5) and also found that Petitioner did not demonstrate that the challenged claims were more likely than not unpatentable for certain grounds that were predicated on a 2015 or 2016 priority date (Ground 6). *Id.* at 20–26.

As noted above, I initiated Director review of the Board’s Decision denying Institution. Paper 10.

III. DISCUSSION

As explained in *Advanced Bionics*, the Board addresses § 325(d) by applying a “two-part framework.” In the first part of the framework, the Board asks whether the same or substantially the same prior art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office. *Advanced Bionics* at 8.

Here, in applying *Advanced Bionics* to Ground 2, the Board found that “Petitioner’s enablement challenge is largely redundant to the Examiner’s

² See Ex. 1002, 159 (“Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision.”) (citing *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991)).

rejection based on lack of adequate written description or otherwise focuses on certain functional characteristics disclosed in the Specification that are not recited in the challenged claims.” Dec. 19. As to the “functional characteristics” referenced by the Board, the Board contrasted this PGR with that challenging U.S. Patent No. 10,450,351 B2 (“the ’351 patent”), of which the challenged ’274 patent is a divisional. *See Boehringer Ingelheim Animal Health USA Inc. v. Kansas State Univ. Res. Found.*, PGR2020-00076, Paper 42 (PTAB Jan. 31, 2022) (finding all claims unpatentable based on a lack of written description in a final written decision). The Board observed that “in contrast to the claims set forth in the related ’351 patent, this is not the case where the claims use functional language to define a composition.” Dec. 19. The Board further noted that

unlike in the claims of the ’351 patent, the products claimed in the ’274 patent recite structural limitations—there is no requirement that the protein be capable of inducing an immunological response, for example. *See* Pet. 66 (Petitioner concluding that the Specification provides insufficient guidance to practice the full scope of the claims without undue experimentation because of the work “left to a POSITA, who would need to synthesize and screen numerous of candidate nucleic and amino acid sequences for immunological activity to identify operative embodiments of the claims.”).

Id. The Board was correct to focus on whether the claims themselves were enabled and to find inapposite Petitioner’s arguments as to whether functional language — appearing only in the specification — was enabled.

I now turn to the more difficult issue — whether the Board’s finding that “Petitioner’s enablement challenge is largely redundant to the Examiner’s rejection based on lack of adequate written description” supports denial of institution under § 325(d). I start, as a matter of principle and law,

by concluding that the mere finding of adequate written description by an examiner can never on its own and without more constitute “the same or substantially the same arguments” under *Advanced Bionics* as a challenge for lack of enablement. *See Ariad*, 589 F.3d 1336.

As an initial matter, the tests for written description and enablement differ. The written description inquiry is a question of fact and is sufficient when it “reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Id.* at 1351; *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1335 (Fed. Cir. 2021). Separately, the enablement inquiry is a question of law and “requires that the specification teach those in the art to make and use the invention without undue experimentation.” *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988); *see also Amgen Inc. v. Sanofi, Aventisub LLC*, 987 F.3d 1080, 1084 (Fed. Cir. 2021), cert. granted in part, 2022 WL 16703751, No. 21-757 (U.S. Nov. 4, 2022). While “written description and enablement often rise and fall together,” *see Ariad*, 598 F.3d at 1352, the written description and enablement requirements involve different considerations and an argument made regarding one requirement does not necessarily equate to an argument made regarding the other.

That said, I can envision a scenario in which a party might premise an enablement challenge on a factual issue that has already been resolved by an examiner during examination. In such a circumstance, patent owners, investors, and the public are entitled to rely on that factual determination, absent material error. To the extent the Board found such a factual issue or otherwise had a rationale for finding that the Petitioner’s enablement challenge constituted the same or substantially the same arguments

previously presented to the Office on written description, the Board must set forth its rationale in sufficient detail to inform the parties and the public and allow for review.

Accordingly, I vacate the Board's Decision and remand to the Board to, within one month, issue a new decision on institution. Specifically, the panel should issue a decision providing its rationale (affirmative or negative) regarding whether § 325(d) applies to Ground 2 (enablement) based upon the written description arguments presented during original prosecution. If the panel determines that § 325(d) applies to Ground 2, the rationale should include express findings explaining how the enablement argument here is the "same or substantially the same" as the written description argument previously presented to the Office under *Advanced Bionics* prong one. If the panel determines that § 325(d) should not apply to Ground 2, the panel should then evaluate whether Petitioner carried its burden to show that it is more likely than not that at least one of the claims challenged in the Petition is unpatentable based on lack of enablement (Ground 2). If the Board determines that § 325(d) should apply to Ground 2 or, if § 325(d) does not apply and the Board determines that Petitioner has not met its burden on the enablement ground, the Board shall deny the Petition, consistent with the Board's earlier determination that denial is proper for all other grounds. *See* Dec. 20, 26. If the Board ultimately determines that Petitioner has met its burden on the enablement ground, the Board will further evaluate:

- (1) whether § 325(d) is sufficiently implicated that its statutory purpose would be undermined by instituting review on all challenges presented in the

Petition,³ and (2) whether instituting a trial with respect to all challenged grounds is an efficient use of the Board's time and resources under 35 U.S.C. § 314(a) as established in the informative decisions in *Chevron* and *Deeper*.⁴

IV. ORDER

Accordingly, based on the foregoing, it is:

ORDERED that the Decision Denying Institution is *vacated*;

FURTHER ORDERED that the case is remanded to the Board to issue, within one month, a decision on institution consistent with my instructions above.

³ See *SAS Q&As* Question D1, available at www.uspto.gov/sites/default/files/documents/sas_qas_20180605.pdf.

⁴ See *Chevron Oronite Co., LLC v. Infineum USA L.P.*, IPR2018-00923, Paper 9 (PTAB Nov. 7, 2019) (informative); *Deeper, UAB v. Vexilar, Inc.*, IPR2018-01310, Paper 7 (January 24, 2019) (informative).

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