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Paper 14
Date: May 6, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AYLA PHARMA LLC,
Petitioner,

v.

NOVARTIS AG,
Patent Owner.

IPR2020-00295
Patent 9,533,053 B2

Before GRACE KARAFFA OBERMANN, CHRISTOPHER M. KAISER, and JAMIE T. WISZ, *Administrative Patent Judges*.

KAISER, *Administrative Patent Judge*.

DECISION
Denying Petitioner's Request on Rehearing of
Decision Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.71(d)

INTRODUCTION

Ayla Pharma LLC ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting an *inter partes* review of claims 1–13 of U.S. Patent No. 9,533,053 B2 (Ex. 1002, "the '053 patent"). Novartis AG ("Patent Owner") filed a Preliminary Response. Paper 7 ("Prelim. Resp."). With our authorization, Petitioner filed a Reply (Paper 10), and Patent Owner filed a Sur-Reply (Paper 11). On August 6, 2020, we denied institution of *inter partes* review because Petitioner had not shown a reasonable likelihood that it would prevail with respect to at least one challenged claim. Paper 12 ("Decision" or "Dec."). Petitioner requests rehearing of the Decision under 37 C.F.R. § 42.71(d)(2). Paper 13 ("Req. Reh'g"). We have considered Petitioner's Request for Rehearing and, for the reasons set forth below, we deny the requested relief.

STANDARD OF REVIEW

A party requesting rehearing bears the burden of showing that a decision should be modified. 37 C.F.R. § 42.71(d). The party must identify all matters it believes the Board misapprehended or overlooked, and the place where each matter was addressed previously in a motion, an opposition, or a reply. *Id.* When rehearing a decision on petition, we review the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of discretion occurs when a "decision was 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) (citations omitted).

DISCUSSION

Petitioner requests rehearing of our denial of institution, arguing that we abused our discretion in three respects. Req. Reh'g 1–15. We consider each of Petitioner's arguments below.

A. Reason to Combine Bhowmick, Castillo, and Yanni

Each of Petitioner's asserted grounds of unpatentability relies on the obviousness of the challenged claims over a combination of prior-art references. Pet. 11–12. The Board explained in the Decision why Petitioner had not "shown sufficiently that a person of ordinary skill in the art would have had a reason to combine the teachings of Bhowmick, Yanni, and Castillo." Dec. 8–11. Petitioner argues that the Board's determination "misapprehends the law and overlooks the facts set forth in the Petition." Req. Reh'g 1–9.

1. Incorporation of Castillo into Bhowmick

Petitioner argues first that we overlooked its argument that Bhowmick incorporates Castillo by reference, making a reason to combine those references unnecessary. *Id.* at 2–5. We find this argument unpersuasive of an abuse of discretion for two reasons.

First, Petitioner argues that it previously presented this argument on page 24 of the Petition, but it made no such argument in that location. *Id.* at 4. On the subject of the incorporation by reference of Castillo into Bhowmick, the indicated portion of the Petition states that "Bhowmick even discusses Castillo and its teachings that PVP improves the stability of olopatadine solutions." Pet. 24. There is no argument that this "discuss[ion]" represents an incorporation by reference or that it otherwise

provides a reason to combine the teachings of the two references.[1] *Id.* Accordingly, Petitioner's argument that Bhowmick incorporates Castillo by reference is new, and we need not address it. 37 C.F.R. § 42.71(d).

Second, even if Petitioner had argued in the Petition that Bhowmick incorporated Castillo by reference, we would not be persuaded that this argument eliminated the need to propose a reason to combine the teachings of the references in a manner that would result in the particular ophthalmic solution that is the subject of the challenged claims. Assuming, for the sake of argument, that Bhowmick incorporated Castillo sufficiently to make Castillo's disclosure part of Bhowmick (turning the combination of Castillo and Bhowmick into something akin to a single reference), that still would not dispense with the need to articulate a reason to combine the disparate teachings of the references. *In re Stepan*, 868 F.3d 1342, 1346 n.1 (Fed. Cir. 2017) (a reason to combine the teachings is needed even in a single-reference obviousness ground). Accordingly, the mere fact that Castillo might be incorporated into Bhowmick does not obviate the need for a reason to combine them.

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[1] Petitioner cites to the declaration of Dr. Paul A. Laskar in IPR2018-01020 and IPR2018-01021 as providing some explanation of the alleged incorporation by reference of Castillo into Bhowmick. Pet. 24 (citing Ex. 1014 ¶ 197). But that testimony does no more than repeat the Petition's statement that "Bhowmick even discusses Castillo and its teachings that PVP improves the stability of olopatadine solutions." *Compare* Pet. 24, *with* Ex. 1014 ¶ 197. Even if Dr. Laskar had argued that Bhowmick's "discuss[ion]" of Castillo amounted to an incorporation of Castillo by reference into Bhowmick, Petitioner's adoption of that argument without discussing it in the Petition would amount to an incorporation into the Petition by reference, in violation of the Board's rules. 37 C.F.R. § 42.6(a)(3).

Where, as here, each ground advanced in the Petition asserted three or more references in combination, we are not persuaded that the Petition articulated, with sufficient particularity, any reason with a rational underpinning why an ordinarily skilled artisan would have been led to combine them in the manner claimed. Thus, we did not abuse our discretion by not concluding that Bhowmick incorporated Castillo by reference.

2. Alleged "Substantial Evidence" in the Petition

Petitioner also argues that the Board "overlooked the substantial evidence establishing [a] motivation to combine" Bhowmick, Castillo, and Yanni. Req. Reh'g 5–9. In making this argument, Petitioner directs us to pages 15, 16, and 18–24 of the Petition as having presented this argument previously. *Id.* None of these pages presents such an argument that we overlooked. Pages 15 and 16 describe the teachings of Bhowmick, Yanni, and Castillo without explaining why those teachings would have led a person of ordinary skill in the art to combine them. Pet. 15–16. Pages 18–21 discuss the reasons for a person of ordinary skill in the art to have combined the teachings only of Bhowmick and Yanni. *Id.* at 18–21. Pages 21–23 discuss the teachings of Castillo, but the only argument offered for why a person of ordinary skill in the art would have combined those teachings with the teachings of Bhowmick and Yanni is the statement on page 23 that the Board discussed in the Decision. *Id.* at 23 ("A POSA would have been motivated to look to Castillo because, like Bhowmick, Castillo taught ophthalmic olopatadine solutions for treatment of allergic disorders comprising similar excipients."); *see* Dec. 10 (discussing this argument). Thus, we disagree with Petitioner's statement in the Rehearing Request that "[t]he Petition also explained that because Castillo teaches using

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