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Paper 14
Date: March 1, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIQUIDIA TECHNOLOGIES, INC.,
Petitioner,

v.

UNITED THERAPEUTICS CORPORATION,
Patent Owner.

IPR2020-00770
Patent 9,604,901 B2

Before ERICA A. FRANKLIN, ZHENYU YANG, and JOHN E. SCHNEIDER, *Administrative Patent Judges.*

YANG, *Administrative Patent Judge*.

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

INTRODUCTION

Liquidia Technologies, Inc. ("Petitioner") filed a Petition (Paper 1 ("Pet.")), seeking an *inter partes* review of claims 1–9 of U.S. Patent No. 9,604,901 B2 (Ex. 1001, "the '901 patent"). We granted the Petition and instituted *inter partes* review on all challenges to all claims. Paper 7 ("Decision" or "Dec."). United Therapeutics Corporation ("Patent Owner") filed a Request for Rehearing of the Decision. Paper 9 ("Req. Reh'g").

For the reasons expressed below, the Request for Rehearing is denied. As a result, *inter partes* review shall continue on all grounds challenging all claims addressed in the Petition.

STANDARD OF REVIEW

The party challenging a decision in a request for rehearing bears the burden of showing the decision should be modified. 37 C.F.R. § 42.71(d) (2019). A request for rehearing "must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed." *Id.* When rehearing a decision on institution, the Board reviews the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). It is not an abuse of discretion to have made an analysis or conclusion with which a party disagrees. Instead, an abuse of discretion occurs if a decision is based on an erroneous interpretation of law, if a factual finding is not supported by substantial evidence, or if the decision represents an unreasonable judgment in weighing relevant factors. *Arnold P'ship v. Dudas*, 362 F.3d 1338, 1340 (Fed. Cir. 2004).

ANALYSIS

In our Decision, we determined that Petitioner demonstrated a reasonable likelihood of success in showing that the challenged claims

would have been obvious over the asserted combination of Moriarty and Phares. *See* Dec. 22–28. In its Request for Rehearing, Patent Owner contends that our determination to institute *inter partes* review is improper for three reasons. First, Patent Owner argues that we misapprehended the differences between the prior art and the claims at issue. Reh'g Req. 2–5. Second, Patent Owner argues that we misapprehended the standard for inherency. *Id.* at 5–7. Third, Patent Owner argues that we overlooked objective indicia of nonobviousness. *Id.* at 7–10.

Because we did not expressly address Patent Owner's arguments with respect to objective indicia of nonobviousness (*see* Paper 6 ("Prelim. Resp.") 69–71), we address those arguments now. For the reasons explained below, however, we deny the Request for Rehearing because none of Patent Owner's arguments persuade us of an abuse of discretion in instituting review in this proceeding.

Differences between the Prior Art and Claim 1

Patent Owner contends that "the Decision mistakenly finds that 'the combination of Moriarty and Phares teaches the same process steps as challenged claim 1.'" Reh'g Req. 4 (citing Dec. 27). Patent Owner contends that claim 1's recited steps do not involve isolating the treprostinil intermediate. *Id.* at 2–3. Patent Owner contends that claim 1 differs from Phares and Moriarty because each reference separately describes isolating the treprostinil intermediate. *Id.* at 3. Patent Owner contends that Petitioner relies on the ordinarily skilled artisan being motivated to modify the prior art by removing the isolating step from the Moriarty and Phares processes. *Id.* at 2–3. Because of this modification, Patent Owner contends that "Moriarty

and Phares do not teach the same process steps" resulting in the claimed product. *See id.* at 4. We are not persuaded by Patent Owner's argument.

As an initial matter, to the extent that Patent Owner attacks the references individually, we emphasize that we consider the combination of the prior art as a whole. *See In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) ("Non-obviousness cannot be established by attacking references individually where the [challenge] is based upon the teachings of a combination of references.").

In the Decision, we explained that Phares explicitly describes the Moriarty process in teaching the synthesis of (-)-treprostinil, the enantiomer of (+)-treprostinil. Dec. 25 (citing Ex. 1008, 40). Thus, on the record before us at that time, we "agree[d] with Petitioner that an ordinarily skilled artisan would have combined the process of Moriarty with the step of adding diethanolamine to treprostinil as taught by Phares." *Id.* The resulting combination of Moriarty and Phares would not involve isolating the treprostinil intermediate and accordingly, teaches the same process steps as challenged claim 1. Having reconsidered the pre-institution record, we continue to find persuasive Petitioner's argument that a skilled artisan would have found it obvious to add diethanolamine to a treprostinil solution without isolating treprostinil when combining Moriarty with Phares. *See* Pet. 61–62 (citing Ex. 1008, 40; Ex. 1002 ¶¶ 177–178).

Our analysis is consistent with the Board's previous finding in a related proceeding involving U.S. Patent No. 8,497,393 ("the '393 patent"), which is a parent of the '901 patent. *See* Ex. 1001, code (63). The Board previously held that claims of the '393 patent are unpatentable. Dec. 3 (citing IPR2016-00006, Paper 82 (PTAB Mar. 31, 2017) ("the '393

Decision" or "the '393 Dec.")). In doing so, the Board found that "an ordinarily skilled artisan would have modified the process of Moriarty to incorporate the step of adding and dissolving diethanolamine to treprostinil as taught by Phares to eliminate the requirement for intermediate purification, thus, improving synthetic efficiency and reducing cost." The '393 Dec. 47. The Federal Circuit has affirmed that decision. *United Therapeutics Corp. v. SteadyMed Ltd.*, 702 F. App'x. 990 (Fed. Cir. 2017). As we did in the Decision, we continue to "encourage the parties here to discuss whether issue preclusion applies in this proceeding such that Patent Owner cannot reargue this point." Dec. 25 n.7.

In sum, we are not persuaded that we misapprehended the differences between the prior art and claim 1.

Inherency of the Claimed Product

Patent Owner contends that "[b]ecause the recited steps are different from those disclosed in Moriarty and Phares (no isolation of treprostinil after alkylation and hydrolysis steps before forming a salt), then the resulting products cannot be assumed to be the same." Reh'g Req. 5. Patent Owner contends that given the different process steps, Petitioner cannot argue "identical impurities" and "effectively conceded that the resulting impurities may not necessarily be the same as recited in the claims." *Id.* at 6. On the current record, we are not persuaded by Patent Owner's argument.

As discussed above, at this stage of the proceeding, we remain persuaded by Petitioner's argument that the combination of Moriarty and Phares teaches the same process steps, including adding a base to treprostinil solution without isolating treprostinil. Accordingly, we remain persuaded

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