

NOTE: This disposition is nonprecedential.

**United States Court of Appeals
for the Federal Circuit**

UNITED THERAPEUTICS CORPORATION,
Appellant

v.

LIQUIDIA TECHNOLOGIES, INC.,
Appellee

**KATHERINE K. VIDAL, UNDER SECRETARY OF
COMMERCE FOR INTELLECTUAL PROPERTY
AND DIRECTOR OF THE UNITED STATES
PATENT AND TRADEMARK OFFICE,**
Intervenor

2022-2133

Appeal from the United States Patent and Trademark
Office, Patent Trial and Appeal Board in No. IPR2020-
00770.

Decided: June 27, 2024

WILLIAM M. JAY, Goodwin Procter LLP, Washington,
DC, argued for appellant. Also represented by WILLIAM
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SANYA SUKDUANG, Cooley LLP, Washington, DC, argued for appellee. Also represented by JONATHAN DAVIES.

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Before HUGHES, STOLL, and CUNNINGHAM, *Circuit Judges*.
STOLL, *Circuit Judge*.

This is the case of a missing oath and purportedly missing claim limitation. United Therapeutics Corporation (UTC) appeals the Patent Trial and Appeal Board's final written decision denying UTC's motion to exclude the declaration of Dr. Jeffrey D. Winkler for failure to include an oath. UTC also appeals the Board's final written decision holding certain claims of U.S. Patent No. 9,604,901 unpatentable as obvious. We affirm the Board's denial of UTC's motion to exclude and its obviousness determination.

BACKGROUND

The '901 patent includes "an improved process to convert benzindene triol to treprostinil via salts of treprostinil and to purify treprostinil." '901 patent, Abstract. Treprostinil is the active ingredient in UTC's drug Remodulin®, *id.* at col. 1 ll. 27–32, which is used to treat pulmonary arterial hypertension, i.e., high blood pressure in the arteries that go from the heart to the lungs. According to the '901 patent, because treprostinil is "of great importance from a medicinal point of view, a need exists for an efficient

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process to synthesize th[is] compound[] on a large scale suitable for commercial production.” *Id.* at col. 1 l. 66–col. 2 l. 3. The ’901 patent discloses “a process for the preparation of [treprostinil], or a hydrate, solvate, or pharmaceutically acceptable salt thereof.” *Id.* at col. 8 ll. 44–46. Claim 1 is the only independent claim and is reproduced below:

1. A pharmaceutical batch consisting of treprostinil or a salt thereof and impurities resulting from (a) alkylating a benzindene triol, (b) hydrolyzing the product of step (a) to form a solution comprising treprostinil, (c) contacting the solution comprising treprostinil from step (b) with a base to form a salt of treprostinil, (d) isolating the salt of treprostinil, and (e) optionally reacting the salt of treprostinil with an acid to form treprostinil, and wherein the pharmaceutical batch contains at least 2.9 g of treprostinil or its salt.

’901 patent, col. 17 l. 24–col. 18 l. 2.

Liquidia’s petition for inter partes review (IPR) asserts that the ’901 patent is rendered obvious by Moriarty¹ in view of Phares². Prior art references Moriarty and Phares describe preparation methods of treprostinil. As relevant to this appeal, Moriarty discloses synthesizing treprostinil “via the stereoselective intramolecular Pauson-Khand cyclization,” which is a known way of producing treprostinil. *J.A.* 1471–78. And Phares teaches various compounds, including treprostinil and its derivatives. Phares states that

¹ Moriarty et al., *The Intramolecular Asymmetric Pauson-Khand Cyclization as a Novel and General Stereoselective Route to Benzindene Prostacyclins: Synthesis of UT-15 (Treprostinil)*, 69 *J. Organic Chemistry* 1890, 1890–902 (2004).

² PCT Application No. WO 2005/007081 A9.

“[a] preferred embodiment of the present invention is the diethanolamine salt of treprostinil.” J.A. 1359. Phares further teaches that “the enantiomer of the commercial drug (+)-Treprostinil was synthesized using the stereoselective intramolecular Pauson Khand reaction as a key step and Mitsunobu inversion of the side-chain hydroxyl group.” J.A. 1390.

Liquidia’s IPR petition also included the declaration of Dr. Jeffrey D. Winkler. J.A. 91; J.A. 94; J.A. 877. The Winkler Declaration contained a signature but lacked any affirmations of truthfulness or any acknowledgement of the punishment for false statements. Following institution, UTC timely served objections to the Winkler Declaration. UTC objected to the Winkler declaration as, among other things, “lacking authentication and not self-authenticating because it lacks sufficient indicia that the exhibit is what it purports to be.” J.A. 331. While Liquidia later filed a corrected Winkler declaration with an oath, the filing was late and Liquidia did not serve any timely supplemental evidence in response to UTC’s objection to the Winkler declaration. *See* J.A. 54–57; J.A. 589; 37 C.F.R. § 42.64(b)(2).

Prior to filing its Patent Owner response, UTC deposed Dr. Winkler about his declaration. During the deposition, Dr. Winkler confirmed that he would provide truthful and accurate testimony, he had written the declaration, and that the declaration contained his signature.

Prior to the oral argument, UTC timely filed a motion to exclude the Winkler Declaration because it “purports to be a declaration, but without authentication because it lacks the statutorily-required oath or caveat for a declaration.” J.A. 590 (citing 35 U.S.C. § 25 and 37 C.F.R. § 42.2). UTC asserted that statements lacking the required certifications “forgo the guarantee of truthfulness imparted by a declarant’s acknowledgment of the possible

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consequences—fine, imprisonment, or penalty of perjury.” J.A. 590 (internal quotation marks and citation omitted).

Liquidia opposed the motion to exclude and asserted that the deposition and refiled declaration rendered the “inadvertently omitted” affirmations of truthfulness harmless and otherwise cured. J.A. 602–03. UTC replied that Liquidia had never received Board authorization to file belated supplemental evidence.

At oral argument, Liquidia explained that the missing language in the Winkler Declaration was the result of a paragraph being accidentally deleted during drafting and not an intentional omission. Liquidia also emphasized the lack of prejudice to UTC, given that UTC had conducted a several-hour deposition of Dr. Winkler, and Liquidia had filed a corrected declaration with an oath. The Board explained, however, that Liquidia did not follow Board rules requiring parties to seek leave prior to submitting supplemental evidence and thus the corrected declaration would be omitted. When questioned as to whether the ability to depose Dr. Winkler resolved the issue of the missing oath, UTC’s counsel reasonably conceded that he would be “hard pressed to sit here and say, you know, that we suffered a specific cognizable prejudice.” J.A. 759 at 64:05–06.

After the hearing, the Board issued a final written decision finding that Liquidia had established by a preponderance of evidence that claims 1–5, 8, and 9 were unpatentable but had not demonstrated the unpatentability of claims 6 and 7. The Board’s unpatentability decision relied, at least in part, on the Winkler Declaration. The Board also denied UTC’s motion to exclude the Winkler declaration in its final written decision. J.A. 53–58. The Board rejected Liquidia’s arguments of curing via the modified Winkler Declaration but agreed with Liquidia that because UTC deposed Dr. Winkler, UTC suffered no undue prejudice.

UTC timely appealed the Board's decision. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

UTC raises two issues on appeal. First, UTC argues that the Board erred in denying UTC's motion to exclude the Winkler Declaration. Second, UTC argues that the Board erred in determining that the challenged claims are unpatentable. We address each issue in turn.

I

Starting with the Board's denial of UTC's motion to exclude the Winkler Declaration, we hold the Board complied with the Administrative Procedure Act.

We review Board decisions for compliance with the Administrative Procedure Act (APA) and set aside "actions of the Board that are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *In re Sullivan*, 362 F.3d 1324, 1326 (Fed. Cir. 2004); 5 U.S.C. § 706. More specifically, we review the Board's procedural or administrative decisions for an abuse of discretion. *Netflix, Inc. v. DivX, LLC*, 80 F.4th 1352, 1358 (Fed. Cir. 2023); see 5 U.S.C. § 706(2). An abuse of discretion occurs when a decision "(1) is clearly unreasonable, arbitrary, or fanciful; (2) is based on an erroneous conclusion of law; (3) rests on [a] clearly erroneous fact finding; or (4) involves a record that contains no evidence on which the Board could rationally base its decision." *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016) (quoting *Bilstad v. Wakalopulos*, 386 F.3d 1116, 1121 (Fed. Cir. 2004)). And of course, when reviewing agency action, we must take account of the rule of harmless error. 5 U.S.C. § 706; *Shinseki v. Sanders*, 556 U.S. 396, 406 (2009) (holding that § 706 requires application of "the same kind of 'harmless-error' rule that courts ordinarily apply in civil cases").

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UTC argues that “[b]y both statute and regulation, declarations or affidavits must be sworn or contain indicia of trustworthiness in order to be admissible.” Appellant’s Br. 14, 19–20. Declarations or affidavits, in UTC’s view, “must be accompanied by a warning that false statements are punishable by fine or imprisonment, or include a certification that the statements made therein are true and are offered under penalty of perjury.” *Id.* at 14 (citing 35 U.S.C. §§ 23, 25; 28 U.S.C. § 1746; 37 C.F.R. §§ 42.53(a), 42.2, 1.68). UTC concludes that declarations or affidavits lacking such are “not admissible.” *Id.* (quoting 37 C.F.R. § 42.61(a)).

In response, the PTO and Liquidia both agree that an oath or declaration is required by regulation but not by statute. *See* Appellee’s Br. 22–23; Intervenor’s Br. 12–14. Both the PTO and Liquidia also contend that consistent with “its rule-making authority, the PTO maintain[s] the discretion to ‘waive or suspend a [regulatory] requirement of parts 1, 41, and 42,’” Appellee’s Br. 23 (quoting 37 C.F.R. § 42.5(b)), and here the Board exercised that discretion to waive the attestation requirement under 37 C.F.R. §§ 1.68, 42. *See* Appellee’s Br. 22–24; Intervenor’s Br. 12–14.

Whether required by statute or regulation, it is clear any declaration or affidavit submitted in IPR proceedings must contain an oath or declaration. The purpose of the oath or declaration is to provide a guarantee of truthfulness where, as here, the testimonial evidence is in paper form. *See Former Emps. of Barry Callebaut v. Chao*, 357 F.3d 1377, 1383 (Fed. Cir. 2004). Moreover, this guarantee of truthfulness—a single line of language—is easy to satisfy.

Here, Liquidia failed to include such an oath or declaration in the Winkler Declaration. Yet, UTC made the strategic decision to “rigorously” depose Dr. Winkler. J.A. 758 at 63:12–15. UTC questioned Dr. Winkler about his declaration under oath, *see* J.A. 12001, and confirmed

there were no issues concerning the truthfulness of the opinions in the Winkler Declaration. At the beginning of the deposition, Dr. Winkler confirmed that he would “provide truthful, accurate testimony.” J.A. 12004 at 9:06–08. Dr. Winkler confirmed that he wrote the Winkler Declaration. J.A. 12013 at 18:11–13. Dr. Winkler even confirmed his signature on the Winkler Declaration. J.A. 12014 at 19:08–21 (testifying as to his signature on the declaration). These are the hallmark guarantees of truthfulness that supplant the missing oath or declaration. Moreover, it is clear that Dr. Winkler provided sworn testimony about the Winkler Declaration that the Board could rely on. On this record, we see no room to fault the Board’s decision to rely on the Winkler Declaration.

For purposes of this opinion, we assume a statutory requirement of an oath or declaration.³ Even with this assumption, however, we find no harmful error in the Board’s decision to rely on the Winkler Declaration. Under the APA, we will not overturn an agency’s decision unless it produced an error that was genuinely harmful or prejudicial. *See Swagway, LLC v. Int’l Trade Comm’n*, 934 F.3d 1332, 1343 (Fed. Cir. 2019) (“The APA specifies that we must take account of the rule of harmless error.”). UTC fails to demonstrate such prejudice here. Critically, the Board concluded that UTC had suffered no prejudice because UTC was able to rigorously depose Dr. Winkler on his opinions, Dr. Winkler confirmed the truthfulness of his declaration during the deposition, and UTC conceded that it suffered no “specific cognizable prejudice.” J.A. 759 at 64:05–06. We see no error in the Board’s finding of no prejudice under these circumstances.

At argument before this court, UTC stressed that the Board focused on counsel’s statement out of context. *See*

³ Such statutory requirement cannot be waived by the Board under 37 C.F.R. § 42.5.

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Oral Arg. at 3:28–5:00, https://oralarguments.cafc.uscourts.gov/default.aspx?fl=22-2133_02062024.mp3. Read in context, it is UTC’s view that its counsel identified two sources of prejudice to UTC. First, UTC argues it was deprived of the opportunity to oppose a Liquidia motion to supplement the record with a corrected version of the Winkler Declaration because Liquidia failed to follow procedure and supplemented the record on its own. Second, UTC argues that the fact that the Board relied on the unsworn testimony of the Winkler Declaration is itself a source of prejudice. Again, we see no harm.

While UTC did not get the opportunity to oppose a motion to supplement a defective declaration, UTC did file a motion to exclude the defective Winkler Declaration. The Board considered UTC’s motion, acknowledged Liquidia’s improper efforts to supplement the record, and correctly noted that “[UTC] deposed Dr. Winkler on his opinions” in the Winkler Declaration. J.A. 58. As noted above, Dr. Winkler testified under oath. Thus, contrary to UTC’s assertion, the Board did rely on the sworn testimony of Dr. Winkler in reaching its decision. Moreover, when pressed, UTC could not adequately explain how it would have changed its tactics, arguments, or deposition strategy. Oral Arg. at 8:54–9:15, 11:23–13:35, https://oralarguments.cafc.uscourts.gov/default.aspx?fl=22-2133_02062024.mp3. Further, as Liquidia and the PTO note, UTC responded to Dr. Winkler’s opinions in its Preliminary Response, Patent Owner Response, Sur-Reply, and its own expert’s declaration. Appellee’s Br. 25; Intervenor Br. 17–18; *see, e.g.*, J.A. 235, J.A. 368–69, J.A. 393, J.A. 528–29; J.A. 3514–15. Therefore, we conclude that the Board did not abuse its discretion in relying on the Winkler Declaration because UTC had a full and fair opportunity to litigate Dr. Winkler’s sworn opinions and suffered no prejudice.

At bottom, under the facts here, substance beats form. We recognize Liquidia should have included an oath or declaration in the Winkler Declaration or sought leave from

the Board to supplement the Winkler Declaration in a timely manner. Because UTC extensively deposed Dr. Winkler, who confirmed the truthfulness of his testimony, however, there is no prejudice here. Although this might create a perverse incentive for a party to not depose a declarant who failed to include an oath or declaration with her affidavit, we are confident the parties will continue to police one another and exercise caution in preparing declarations in support of IPR petitions. Litigation is a risky business, and careful inclusion of an oath or affidavit can eliminate the risk that both UTC and Liquidia bore here.

II

Now, we address obviousness. “We review the Board’s legal conclusions de novo and its factual findings for substantial evidence.” *Univ. of Strathclyde v. Clear-Vu Lighting LLC*, 17 F.4th 155, 160 (Fed. Cir. 2021). “The substantial evidence standard asks ‘whether a reasonable fact finder could have arrived at the agency’s decision,’ and ‘involves examination of the record as a whole, taking into account evidence that both justifies and detracts from an agency’s decision.’” *OSI Pharms., LLC v. Apotex, Inc.*, 939 F.3d 1375, 1381–82 (Fed. Cir. 2019) (quoting *In re Gartside*, 203 F.3d 1305, 1312 (Fed. Cir. 2000)). UTC argues the Board’s underlying fact findings on scope and content of the prior art and motivation to combine are not supported by substantial evidence because the Board relied on Dr. Winkler’s opinions, which, according to UTC, “cited to no actual evidence of the asserted motivation in the prior art” and instead relied on “common sense” to “take the place of actual evidence showing that a [person of ordinary skill] would have viewed omitting [the] isolation steps as both feasible and cost saving.” Appellant’s Br. 35–36. We disagree with both assertions.

First, the Board’s determination that a person of ordinary skill would have been motivated to combine prior art

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references Moriarty and Phares, without an isolation step, is supported by substantial evidence. In reaching its determination, the Board relied on the prior art references Moriarty and Phares, the Winkler Declaration, the Winkler Reply Declaration, and the testimony of Dr. Pinal. *See* J.A. 35–40.

Starting with the prior art references, the Board reasonably found “that an ordinarily skilled artisan would have had a reason to start with the treprostinil free acid of Moriarty and convert it into the diethanolamine salt,” J.A. 36, because Moriarty and Phares were directed to related problems and both experts recognized that Moriarty teaches “a well-known way to make treprostinil,” J.A. 932, and that “Phares teaches how to take that treprostinil and further modify it to produce other molecular entities,” J.A. 2146 at 135:16–19. These other molecular entities, as found by the Board, include “the diethanolamine salt of treprostinil,” J.A. 16, 37, which Phares identifies as “[a] preferred embodiment.” J.A. 1359. The Board then went a step further with its analysis and found that one of ordinary skill would have had reason to combine Moriarty and Phares because Phares improves the treprostinil taught by Moriarty, as the Phares treprostinil diethanolamine “improves at least the bioavailability[] of” Moriarty’s treprostinil. J.A. 37. Both Phares itself and the Winkler Reply Declaration support this conclusion. Dr. Winkler explains that “as disclosed in Phares and well-known to a [person of ordinary skill], forming [treprostinil diethanolamine] would . . . improve the bioavailability of treprostinil.” J.A. 1973–74 ¶ 97; *see* J.A. 1994–95 ¶ 128 (incorporating analysis from J.A. 1973–75); J.A. 1433. Last, the Board reasonably found “that [one of ordinary skill] would have had a reason to eliminate the intermediate isolation step” taught by Moriarty. J.A. 39. The Winkler Declaration makes clear that “instead of isolating the neutral carboxylic acid at this step by removal of the methanol, one could instead add diethanolamine (i.e., a base) to the treprostinil

solution so that removal of the methanol would instead leave a salt, specifically, treprostinil diethanolamine salt.” J.A. 942 ¶ 177 (citing J.A. 1390 (Phares)). As Dr. Winkler elaborated, “a [person of ordinary skill] would understand that an intermediate purification step should be unnecessary because not purifying the intermediate carboxylic acid before addition of a base should not affect salt formation.” J.A. 932–33 ¶ 151. This evidence amply supports each of the Board’s findings that a person of ordinary skill would have had a motivation to combine Moriarty and Phares.⁴

UTC next argues the Board erred because it relied on “common sense” to “fill in a missing limitation.” Appellant’s Br. 40. But UTC’s reliance on *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355 (Fed. Cir. 2016), to limit the use of common sense in an obviousness analysis is misplaced because no claim limitation is missing from the prior art. Here, both Moriarty and Phares disclose treprostinil in

⁴ Contrary to UTC’s contention, Dr. Winkler’s testimony, including his expressed reasons why a person of ordinary skill would have had any motivation to combine, do not need to be expressly lifted from the prior art. See *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406, 415, 418–22 (2007); *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1361 (Fed. Cir. 2006) (“[T]here is no requirement that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art.” (citation omitted)). The Board may properly rely on the knowledge of one of ordinary skill in the art such as Dr. Winkler to help establish a motivation to combine. As the Board correctly notes, this is especially true where the motivation is to enhance commercial viability of a process. See *Dystar*, 464 F.3d at 1367–68.

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solution and Phares further teaches contacting treprostiniol in solution with diethanolamine base to form a salt. *Arendi* limited the application of “common sense” in an obviousness analysis where, unlike here, a claim limitation was *missing* in the prior art.⁵ *Id.* at 1361–63. By contrast, here the Board invoked “common sense” to support, in part, its motivation to combine analysis, *not* to conclude that a claim limitation is satisfied by Petitioner’s combination. *See* J.A. 38. In fact, the *Arendi* court acknowledged this use of common sense was proper and, indeed, typical. “[C]ommon sense is typically invoked to provide a known motivation to combine, not to supply a missing claim limitation.” *Arendi*, 832 F.3d at 1361.

Still, UTC posits that “common sense is being used to fill in a missing limitation—the exclusion of intervening isolation steps.” Appellant’s Br. 39. But the Board relied on more than common sense. Dr. Winkler’s Reply Declaration explains “that an ordinarily skilled artisan would have had a reason to eliminate the intermediate isolation step, ‘thereby increasing synthetic efficiency and lowering production costs for treprostiniol diethanolamine salt.’” J.A. 39 (citing J.A. 2001–03 ¶¶ 140–44); *see also* J.A. 1976–78 ¶¶ 101–03. At bottom, the “Board’s invocation of common sense was properly accompanied by reasoned analysis and evidentiary support” in the form of multiple “pages of

⁵ The Board concluded “that treprostiniol is not isolated from the solution formed in step (b) before forming a salt in step (c)” because claim 1 is *consisting of* the recited steps and itself “dictates that the solution formed in step (b), and not treprostiniol isolated from step (b), is the starting material for forming a salt in step (c).” J.A. 27–28 (Claim Construction Section II.C.3). “Thus, Petitioner must show . . . that the combined teachings of Moriarty and Phares suggest to an ordinarily skilled artisan to skip the intermediate isolation step.” J.A. 34 n.15.

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analysis” on the limitation and reliance on “detailed expert testimony.” *B/E Aerospace, Inc. v. C&D Zodiac, Inc.*, 962 F.3d 1373, 1380 (Fed. Cir. 2020).

CONCLUSION

We have considered UTC’s remaining arguments but do not find them persuasive. For the reasons above, we affirm the Board’s final written decision and its denial of UTC’s motion to exclude the Winkler Declaration.

AFFIRMED