United States Court of Appeals for the Federal Circuit

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Appellant

v.

MYLAN PHARMACEUTICALS INC.,
Appellee

2021-1981

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2019-01657.

Decided: May 9, 2023

KENNETH WAYNE DARBY, Fish & Richardson PC, Austin, TX, argued for appellant. Also represented by MATT COLVIN, Dallas, TX; LAUREN ANN DEGNAN, WALTER KARL RENNER, Washington, DC; JOHN STEPHEN GOETZ, New York, NY.

DOUGLAS H. CARSTEN, McDermott Will & Emery, Irvine, CA, argued for appellee. Also represented by WENDY L. DEVINE, Wilson, Sonsini, Goodrich & Rosati, PC, San Francisco, CA; ELHAM FIROUZI STEINER, San Diego, CA; TASHA THOMAS, RICHARD TORCZON, Washington, DC.

Before REYNA, MAYER, and CUNNINGHAM, *Circuit Judges*.

CUNNINGHAM, *Circuit Judge*.

Sanofi-Aventis Deutschland GmbH owns U.S. Patent No. RE47,614 ("the '614 patent"). Mylan Pharmaceuticals Inc. petitioned the Patent Trial and Appeal Board ("Board") for inter partes review of claims 1–18 of the '614 patent. In its final written decision, the Board found all challenged claims unpatentable as obvious over prior art. *Mylan Pharms. Inc. v. Sanofi-Aventis Deutschland GmbH*, IPR2019-01657, Paper 39, 2021 WL 1158193 (P.T.A.B. Mar. 26, 2021) ("*Decision*"). Sanofi argues on appeal that Mylan failed to argue that U.S. Patent No. 4,144,957 ("de Gennes") constitutes analogous art to the '614 patent and instead compared de Gennes to another prior art reference. We agree with Sanofi. Because Mylan argued that de Gennes is analogous to another prior art reference and not the challenged patent, Mylan did not meet its burden to establish obviousness premised on de Gennes and the Board's factual findings regarding analogousness are not supported by substantial evidence. We reverse.

I. BACKGROUND

A. The Challenged Patents

The '614 patent is entitled "Drug Delivery Device and Method of Manufacturing a Drug Delivery Device." The '614 patent's stated invention relates to a "drug delivery device" that can be "configured to allow setting of different dose sizes." '614 patent col. 1 ll. 26–32.

The '614 patent seeks to provide a drug delivery device to improve "operability with respect to dosage control and/or improved reproducibility of the dosage in connection with different cartridges." *Id.* col. 1 ll. 51–55. It purportedly achieves this objective using a "spring washer" that can "exert a force on the cartridge and secure the cartridge against movement" and is "secured to the housing so as to prevent relative axial movement between [the] spring

washer and housing." *Id.* col. 1 ll. 59–67, col. 2 ll. 31–35. The '614 patent explains that spring washers are advantageous because spring washers can secure the cartridge "without requiring much space," allowing for "a very compact drug delivery device." *Id.* col. 2 ll. 15–17.

The '614 patent has 18 claims, all of which require a "spring washer" secured by "at least two fixing elements." *Id.* col. 8 l. 1 to col. 10 l. 18. As an example, claim 1 recites:

> 1. A drug delivery device comprising:
>
> a housing with a proximal end and a distal end,
>
> a cartridge adapted to accommodate a drug,
>
> a cartridge retaining member adapted to retain the cartridge, the cartridge retaining member releasably secured to the housing, and
>
> a *spring washer* arranged within the housing so as to exert a force on the cartridge and to secure the cartridge against movement with respect to the cartridge retaining member,
>
> wherein the *spring washer has at least two fixing elements* configured to axially and rotationally fix the spring washer relative to the housing.

Id. col. 8 ll. 2–14 (emphases added).

B. IPR Proceedings

Mylan petitioned the Board to institute IPR proceedings on the ground that all claims of the '614 patent are obvious based on a combination of three prior art references: (1) U.S. Patent Application No. 2007/0021718 ("Burren"); (2) U.S. Patent No. 2,882,901 ("Venezia"); and (3) de Gennes. J.A. 92. Mylan relied on Burren—cited as prior art within the '614 patent—to teach the use of springs within a drug-delivery device. J.A. 107–09. Mylan sought to combine Burren with Venezia to teach the use of spring

washers within drug-delivery devices and de Gennes to add "snap-fit engagement grips" to secure the spring washer. J.A. 109–11. In its petition, Mylan argued that "De Gennes, while concerned with a clutch bearing [in automobiles], addresses a problem analogous to that addressed in *Burren* (axially [sic] fixation and support of two components relative to one another)." J.A. 111 (emphasis added). Mylan's expert reiterated the same point, stating that "although De Gennes is concerned with a clutch bearing, it addresses a problem analogous to that addressed in *Burren*." J.A. 1507 (emphasis added).

In its patent owner response, Sanofi argued that de Gennes is not analogous art to the '614 patent. J.A. 2309. Sanofi argued that de Gennes relates to cars and not drug delivery devices or medical devices, such that a person of ordinary skill in the art "would not have considered a clutch bearing to be within the same field of endeavor." J.A. 2310. Sanofi further argued that de Gennes is not "reasonably pertinent" to the '614 patent's problem, J.A. 2312, which it asserted is "secur[ing] a cartridge against movement within a housing." J.A. 2313; *accord* J.A. 2415 (Sanofi's expert).

Mylan responded by repeating its Burren-centric arguments. J.A. 3153–55; *accord* J.A. 3372–78 (Mylan's expert). In its petitioner reply, Mylan argued that Sanofi's analogousness arguments relied on a "faulty understanding of controlling law." J.A. 3136. Mylan criticized Sanofi as "tr[ying] to change the pertinent problem by importing extraneous goals from" the '614 patent, asserting that "Burren's suggestion . . . provides the pertinent problem in this case," and that a skilled artisan "reading Burren (rather than reading the goals of [the '614 patent] with hindsight) would have considered" de Gennes highly relevant. J.A. 3154–55. When asked during oral argument before the Board as to which "problem" should be examined for the analogous art test, Mylan's counsel stated "[i]t doesn't really matter" and that "the problem to be solved . . . is

really identical[ly] presented between Burren and [the '614 patent]. They're both interested in solving the same issue and that is on the Burren side accommodating various cartridge lengths and on the [the '614 patent] side identifying the cartridges." J.A. 3705.

In its final written decision, the Board determined that Burren in combination with Venezia does not render the challenged claims of the '614 patent unpatentable. *Decision* at *15. However, the Board found that Burren in combination with Venezia and de Gennes does render the challenged claims unpatentable because, among other things, the "snap-fit connection" of de Gennes taught the "fixing elements" of the '614 patent. *Id.* at *15–18, *25.

In reaching its conclusion, the Board found de Gennes constituted analogous art to the '614 patent. *Id.* at *7–9. Because all parties agreed the '614 patent and de Gennes belong to distinct fields of endeavor, the Board focused on whether de Gennes was "reasonably pertinent" to a problem faced by the inventor of the '614 patent. *Id.* at *7–8. The Board rejected Sanofi's definition of the "problem" as too narrow and adopted Mylan's definition: "axially fixing two components relative towards each other." *Id.* at *8–9. In a footnote, the Board agreed Mylan "refer[red] to Burren when identifying a problem," stating that Burren's "defined problem is also relevant to the '614 patent, especially given that the '614 patent acknowledges that Burren's spring performs the same function (that is, solves a same problem) as the '614 patent." *Id.* at *8 n.4. The Board found de Gennes "analogous to the '614 patent" because it "is reasonably pertinent to axially fixing two components relative towards each other, a problem addressed by the inventors of the '614 patent." *Id.* at *9.

Sanofi timely appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

II. DISCUSSION

A. Standard of Review

"We review the [Board's] factual findings for substantial evidence and its legal conclusions de novo." *Donner Tech., LLC v. Pro Stage Gear, LLC*, 979 F.3d 1353, 1358 (Fed. Cir. 2020) (alteration in original) (quoting *Redline Detection, LLC v. Star Envirotech, Inc.*, 811 F.3d 435, 449 (Fed. Cir. 2015)). "Obviousness is a question of law based on underlying facts." *Id.* at 1359 (citing *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357, 1372 (Fed. Cir. 2017)). "Whether a reference is analogous art is an issue of fact." *Id.* (citing *In re ICON Health & Fitness, Inc.*, 496 F.3d 1374, 1378 (Fed. Cir. 2007)).

B. Analogous Art Arguments

Sanofi argues that the Board "altered and extended Mylan's deficient showing" by analyzing whether de Gennes constitutes analogous art to the '614 patent when Mylan, the petitioner, only presented its arguments with respect to Burren. Appellant's Br. 25–26. Sanofi cites our decision in *In re Magnum Oil Tools International, Ltd.* to argue that the Board cannot "raise, address, and decide unpatentability theories never presented by the petitioner and not supported by record evidence." *Id.* at 28 (quoting 829 F.3d 1364, 1381 (Fed. Cir. 2016)). Sanofi argues the Board improperly shifted the burden of persuasion from Mylan—to prove the claims of the '614 patent are unpatentable—to Sanofi—to defend the claims of the '614 patent as patentable. *Id.* at 26–27. Sanofi argues the Board "adopted Mylan's problem statement derived from Burren and then worked backward to relate that problem to the '614 patent," which led the Board to a "legally erroneous conclusion that lacks substantial evidence." *Id.* at 26.

Mylan argues its petition permitted the Board to evaluate de Gennes as analogous art because there is no functional difference between the problem of Burren and the

problem of the '614 patent. Appellee's Br. 25. Mylan also argues Sanofi raises a distinction without a difference because "[t]he evidence and arguments underlying the Board's findings—whether linked to Burren or [the '614 patent]—remained the same." *Id.* at 27. Mylan argues the Board "relied on substantial evidence to find Mylan's definition of the 'problem' more appropriately defined the scope of analogous art." *Id.* at 28.

We agree with Sanofi that Mylan did not carry its burden to argue that de Gennes is analogous to the '614 patent. Moreover, the Board's factual findings regarding analogousness are not supported by substantial evidence. *See Magnum Oil*, 829 F.3d at 1381. Because the Board found that Burren and Venezia alone do not render all the challenged claims unpatentable without the benefit of de Gennes, the Board's finding that de Gennes constitutes analogous art is dispositive to its conclusion. *Decision* at *15–21. Accordingly, we reverse.

We first examine the framework a fact finder must use to evaluate whether a reference constitutes analogous art. Next, we examine whether Mylan supported its arguments properly under this framework.

1. Analogous Art Test

"Two separate tests define the scope of analogous prior art: (1) whether the art is from the same field of endeavor, regardless of the problem addressed and, (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved." *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004) (citations omitted); *see also In re Clay*, 966 F.2d 656, 658–59 (Fed. Cir. 1992); *In re Wood*, 599 F.2d 1032, 1036 (CCPA 1979). The "problem" being examined must not be defined so narrowly as to collapse these inquiries and only consider art within the inventor's field of endeavor. *Donner Tech.*, 979 F.3d at 1360 ("Such a PHOSITA—resigned to considering

art outside her field of endeavor—would thus not identify the problems so narrowly so as to rule out all such art."); *ICON Health*, 496 F.3d at 1380 (refusing to limit problem to treadmills and instead focusing on problems of "supporting the weight" of folding mechanism and "providing a stable resting position").

Mylan argues we should reject Sanofi's "rigid and legally improper analogous-art test" that would set aside the Board's findings "simply because the petition allegedly analyzed the 'problem' to be solved in terms of the prior art instead of [the '614 patent]." Appellee's Br. 34. We disagree.

In evaluating whether a reference is analogous, we have consistently held that a patent challenger must compare the reference to the challenged patent. *Donner Tech.*, 979 F.3d at 1359 (examining whether reference is "reasonably pertinent to one or more of the particular problems to which *the* [*challenged*] *patent* relates" (emphasis added)); *Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995, 1001 (Fed. Cir. 2016) ("If a reference disclosure and *the claimed invention* have a same purpose, the reference relates to the same problem." (emphasis added)); *Bigio*, 381 F.3d at 1325 (examining whether prior art is "reasonably pertinent to the *particular problem with which the inventor is involved*" (emphasis added)). This conclusion is reinforced by the purpose of the analogous art test, which is to examine whether a reference can be considered as prior art to the challenged patent in the first place. *Chemours Co. FC, LLC v. Daikin Indus., Ltd.*, 4 F.4th 1370, 1376 (Fed. Cir. 2021) (analogous art test defines "scope of the relevant prior art"); *Donner Tech.*, 979 F.3d at 1359 ("The scope of the prior art includes all analogous art."); *Cir. Check Inc. v. QXQ Inc.*, 795 F.3d 1331, 1335 (Fed. Cir. 2015) ("To be considered within the prior art for purposes of the obviousness analysis, a reference must be analogous.").

At most, the cases cited by Mylan confirm that an adjudicator must consider the "purposes of both the invention and the prior art"—*Clay*, 966 F.2d at 659—but the purpose of the "prior art" must be evaluated *with reference to* the inventor's purported invention disclosed within the challenged patent. *Id.* ("If a reference disclosure has the same purpose *as the claimed invention*, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection." (emphasis added)). Mylan cites *Mandel Bros., Inc. v. Wallace*, 335 U.S. 291, 295–96 (1948), and *In re Mariani*, 177 F.2d 293, 294–96 (CCPA 1949), to argue it is proper to compare a reference to other references for analogous art purposes. Appellee's Br. 35–36. We disagree with Mylan's interpretation of those cases. In *Mandel Bros.*, the Court held that prior art in the field of chemistry could be considered in examining the patentee's use of urea in the field of cosmetics. 335 U.S. at 296; *id.* at 292 ("The claimed discovery of the patent is in adding to the old acid-salts cosmetics certain types of the reactive amino chemical group, particularly urea."). Thus, the Court's analysis undeniably focused on the problem in the challenged patent. *Id.* As to *Mariani*, that decision declined to "express[] any view upon the question of non-analogous art." 177 F.2d at 296. Even so, Mylan appears to acknowledge that the patentee in *Mariani* sought to challenge that the prior art was "analogous *to the claimed invention*." Appellee's Br. 36 (emphasis added); *see Mariani*, 177 F.2d at 295 ("[T]he gravamen of the allegations of error . . . is that both [prior art] patents are in fields of art not analogous *to the field of appellant's application*." (emphasis added)).

Mylan's arguments would allow a challenger to focus on the problems of alleged prior art references while ignoring the problems of the challenged patent. Even if a reference is analogous to one problem considered in another reference, it does not necessarily follow that the reference would be analogous to the problems of the challenged

patent. Mylan argues that a fact finder must construe the scope of analogous art broadly because "*familiar items may have obvious uses beyond their primary purposes*." Appellee's Br. 35 (emphasis in original) (quoting *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1238 (Fed. Cir. 2010)); *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (2007). We agree. But that conclusion does not allow a fact finder to focus on the problems contained in other prior art references to the exclusion of the problem of the challenged patent.

2. Mylan's Analogous Art Arguments

Next, we turn to whether Mylan properly supported its argument that de Gennes is analogous art to the '614 patent. Because it did not, the Board's conclusion that de Gennes is analogous to the '614 patent is not supported by substantial evidence.

We have routinely held that the petitioner has the burden of proving unpatentability. *Magnum Oil*, 829 F.3d at 1375; *see also Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016) ("It is of the utmost importance that petitioners in the IPR proceedings adhere to the requirement that the initial petition identify 'with particularity' the 'evidence that supports the grounds for the challenge to each claim.'" (quoting 35 U.S.C. § 312(a)(3))). A petitioner has the ultimate burden "to prove 'unpatentability by a preponderance of the evidence.'" *Magnum Oil*, 829 F.3d at 1375 (quoting 35 U.S.C. § 316(e)).

We have reversed the Board's patentability determination where a petitioner did not adequately present a motivation to combine. In *Magnum Oil*, the Petitioner analyzed and asserted a first combination of prior art references and argued that the "same analysis applies" to a second combination of prior art references based on a different primary reference. *Id.* at 1372. The Board instituted the IPR and issued a final written decision in view of the second

combination. *Id.* at 1373. We held that the Board erred because "[n]either the Board nor the petitioner explained why borrowing the rationale for combining the first set of references equally applies to the second set of references." *Id.* at 1378. We reversed because, among other things, the petitioner's conclusory statements could not satisfy the petitioner's burden of demonstrating a motivation to combine and "the Board's factual findings regarding the alleged motivation to combine lacked substantial evidence." *Id.* at 1380–81. Similarly, in *In re IPR Licensing, Inc.*, we reversed a Board decision finding claims unpatentable that relied on draft Universal Mobile Telecommunications System ("UMTS") standards because the petitioner had "not relied on the UMTS standards in its petition" and "pointed to nothing" to support its motivation to combine arguments. 942 F.3d 1363, 1369–70 (Fed. Cir. 2019).

Here, Mylan did not make the analogous art argument on which the Board's obviousness finding relied—that de Gennes is analogous to the '614 patent. *E.g.*, J.A. 111 (IPR Petition) ("Professor Erdman explains how De Gennes, while concerned with a clutch bearing, addresses a problem analogous to that addressed in Burren . . . ."); J.A. 1507 (Expert Declaration) ("[A]lthough De Gennes is concerned with a clutch bearing, it addresses a problem analogous to that addressed in Burren."). As we explain, Mylan's arguments as to Burren are insufficient to carry its burden because they do not address the '614 patent.

Mylan cites several statements in its petition that discuss the purported problem of the '614 patent and the prior art generally to argue that it properly addressed the analogous art issue. *See, e.g.*, Appellee's Br. 23–25. Mylan identified the alleged invention of the '614 patent as "securely holding a cartridge within a drug-delivery device" by incorporating "a spring element—a spring washer—to apply an axially-directed biasing force." J.A. 89. In discussing the level of ordinary skill in the art, Mylan explained that a person of skill in the art "would have been familiar

with elements commonly used to bias and secure components within mechanical devices (*e.g.*, spring elements, fastening structures) and the mechanical principles involved," as "confirmed by [the '614 patent's] specification." J.A. 99. Mylan argued that Burren teaches "injection pens" with "components that perform the same function as those claimed by [the '614 patent]." J.A. 112. Mylan also compared de Gennes to elements of the challenged claims within the '614 patent. J.A. 114–48. None of these passages, however, explain how de Gennes is analogous to the '614 patent.

A petitioner is not required to anticipate and raise analogous art arguments in its petition; instead a petitioner can use its reply to "respond to arguments raised in the corresponding opposition, patent owner preliminary response, patent owner response, or decision on institution." *See* 37 C.F.R. § 42.23. However, Mylan did not use its reply to explain how de Gennes is analogous to the '614 patent. *See* J.A. 3153–56 (Mylan Reply Brief); J.A. 3372–78, 3382 (Mylan's Second Expert Declaration). Instead, Mylan disputed that it needed to frame its arguments as to the '614 patent and accused Sanofi of misunderstanding the law. J.A. 3136 ("Sanofi's analysis of de Gennes' analogousness relies on a faulty understanding of controlling law . . . ."); J.A. 3154 ("Sanofi tries to change the pertinent problem by importing extraneous goals from [the '614 patent] . . . ."); J.A. 3155 ("De Gennes provides these functions, which a POSA reading Burren (rather than reading the goals of [the '614 patent] with hindsight) would have considered highly relevant."). Thus, Mylan's reply also did not argue that de Gennes is analogous to the '614 patent.

In a footnote, Mylan further argues that it carried its burden by arguing at oral argument before the Board that Burren and the '614 patent have the same problem. Appellee's Br. 27 n.2. Although Mylan argued that Burren and the '614 patent address the "same problem," Mylan pointed to a *different problem* than it relied upon to argue that de

Gennes was analogous. *Compare Decision* at *8 ("Petitioner defines the problem as 'axial[ ] fixation and support of two components relative to one another.'"), *with* J.A. 3705 ("They're both interest[ed] in solving the same issue and that is on the Burren side *accommodating various cartridge lengths* and on the ['614 patent] side *identifying the cartridges*." (emphases added)). Recognizing that Mylan raised a new problem, the Board questioned whether de Gennes "address[ed] that problem at all," and Mylan explained that de Gennes "address[es] the holding, the taking up end play in a bearing by applying axial force to hold one component and abut it against another[.]" J.A. 3706. Regardless, Mylan's conclusory statements arguing that Burren and the '614 patent address the "same problem" are insufficient to carry its burden to argue de Gennes is analogous to the '614 patent. *See Magnum* Oil, 829 F.3d at 1380 (holding that conclusory statements that "[t]he same analysis" applied to different prior art did not provide sufficient evidence to base its legal conclusion of obviousness).

We do not interpret the Board's decision as concluding that Mylan argued de Gennes is analogous to the '614 patent. To the contrary, the Board appears to have agreed that "Petitioner and Petitioner's declarant refer to Burren when identifying a problem." *Decision* at *8 n.4. Because Mylan argued that de Gennes is analogous to another prior art reference and not the challenged patent, Mylan did not meet its burden to establish obviousness premised on de Gennes. Thus, the Board's factual finding that de Gennes is analogous to the '614 patent is unsupported by substantial evidence.

III. CONCLUSION

We have considered the parties' other arguments and find them unpersuasive. For the above reasons, we reverse.

REVERSED