United States Court of Appeals for the Federal Circuit

NOVARTIS AG, LTS LOHMANN THERAPIE-SYSTEME AG,
Appellants

v.

NOVEN PHARMACEUTICALS INC.,
Appellee

2016-1678, 2016-1679

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2014-00549, IPR2014-00550, IPR2015-00265, IPR2015-00268.

Decided: April 4, 2017

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FRANCES LYNCH, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, argued for intervenor Michelle K. Lee. Also represented by NATHAN K. KELLEY, KAKOLI CAPRIHAN, SCOTT WEIDENFELLER.

Before PROST, *Chief Judge,* WALLACH and STOLL, *Circuit Judges.*

WALLACH, *Circuit Judge.*

The instant appeals concern inter partes reviews of U.S. Patent Nos. 6,316,023 ("the '023 patent") and 6,335,031 ("the '031 patent") (together, "the Patents-in-Suit"). In two separate final written decisions, the U.S. Patent and Trademark Office's ("USPTO") Patent Trial and Appeal Board ("PTAB") found that various claims of the Patents-in-Suit ("the Asserted Claims")[1] would have been obvious over the prior art. *See Noven Pharm., Inc. v. Novartis AG* (*Noven I*), No. IPR2014-00549, 2015 WL 5782080, at *23 (P.T.A.B. Sept. 28, 2015) (finding the disputed claims of the '023 patent unpatentable as obvious); *Noven Pharm., Inc. v. Novartis AG* (*Noven II*), No. IPR2014-00550, 2015 WL 5782081, at *23 (P.T.A.B. Sept. 28, 2015) (finding the disputed claims of the '031 patent unpatentable as obvious). The PTAB maintained its findings when asked to reconsider them. *See Noven Pharm., Inc. v. Novartis AG* (*Noven III*), No. IPR2014-00549, 2015 WL 9599194, at *8 (P.T.A.B. Nov. 30, 2015) (denying request to reconsider *Noven I*); *Noven Pharm., Inc. v. Novartis AG* (*Noven IV*), No. IPR2014-00550, 2015 WL 9599195, at *8 (P.T.A.B. Nov. 30, 2015) (denying request to reconsider *Noven II*). Appellants Novartis AG and LTS Lohmann Therapie-Systeme AG (together,

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[1] The Asserted Claims include claims 1–2, 4–5, and 7–8 of the '023 patent and claims 1–3, 7, 15–16, and 18 of the '031 patent.

"Novartis") contest numerous aspects of the Final Written Decisions, including the PTAB's conclusion that prior judicial opinions did not control its inquiry and the PTAB's factual findings in support of its obviousness conclusion. We affirm.

DISCUSSION

I. Subject Matter Jurisdiction and Standard of Review

We possess subject matter jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A) (2012). "We review the PTAB's factual findings for substantial evidence and its legal conclusions de novo." *Redline Detection, LLC v. Star Envirotech, Inc.*, 811 F.3d 435, 449 (Fed. Cir. 2015) (citation omitted). "Substantial evidence is something less than the weight of the evidence but more than a mere scintilla of evidence," meaning that "[i]t is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *In re NuVasive, Inc.*, 842 F.3d 1376, 1379–80 (Fed. Cir. 2016) (internal quotation marks and citations omitted).

II. The PTAB Properly Concluded that the Asserted Claims of the Patents-in-Suit Would Have Been Obvious

A patent claim is unpatentable when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art [('PHOSITA')] to which said subject matter pertains." 35 U.S.C. § 103(a) (2006).[2] Obviousness "is a question of law

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[2] Congress amended § 103 when it passed the Leahy-Smith America Invents Act ("AIA"). Pub. L. No. 112-29, § 3(c), 125 Stat. 284, 287 (2011). However, because the applications that led to the Patents-in-Suit have never contained (1) a claim having an effective filing date

based on underlying findings of fact." *In re Gartside*, 203 F.3d 1305, 1316 (Fed. Cir. 2000) (citation omitted). The underlying factual findings include (1) "the scope and content of the prior art," (2) "differences between the prior art and the claims at issue," (3) "the level of ordinary skill in the pertinent art," and (4) the presence of secondary considerations of nonobviousness such "as commercial success, long felt but unsolved needs, failure of others," and unexpected results. *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 17 (1966); *see United States v. Adams*, 383 U.S. 39, 50–52 (1966).

The PTAB found that the Asserted Claims of the Patents-in-Suit would have been obvious over several different combinations of prior art references. *See Noven I*, 2015 WL 5782080, at *23; *Noven II*, 2015 WL 5782081, at *23. The PTAB found that claims 1–2, 4–5, and 7 of the '023 patent would have been obvious over a combination of two prior art references—United Kingdom Patent Application GB 2,203,040 ("Enz") (J.A. 588–610) and Japanese Patent Application 59-184121 ("Sasaki") (J.A. 634–37)—and that claim 8 would have been obvious over a combination of Enz, Sasaki, and two other references.[3] *See Noven I*, 2015 WL 5782080, at *23. The PTAB also found that claims 1–3, 7, 15–16, and 18 of the '031 patent would have been obvious over Enz and Sasaki. *See Noven II*, 2015 WL 5782081, at *23.

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on or after March 16, 2013 or (2) a reference under 35 U.S.C. §§ 120, 121, or 365(c) to any patent or application that ever contained such a claim, the pre-AIA § 103 applies. *See id.* § 3(n)(1), 125 Stat. at 293.

[3] The PTAB found that Novartis did not separately argue the patentability of claim 8 of the '023 patent, *see Noven I*, 2015 WL 5782080, at *14, and Novartis does not contest that finding here, *see generally* Appellants' Br.

Instead of raising arguments on the basis of a specific claim, patent, or Final Written Decision, Novartis raises broad legal and factual arguments with application to both of the Final Written Decisions. *See* Appellants' Br. 6 n.1 (stating that the appealed decisions "are substantively nearly the same" and that it will refer only to *Noven II* throughout its brief), 35–65 (presenting arguments); *see also* Appellee's Br. 1 n.1 (agreeing to follow Novartis's convention and cite only to *Noven II*). After providing a brief description of the Patents-in-Suit, we address Novartis's arguments in turn.

A. The Patents-in-Suit

The Patents-in-Suit belong to the same patent family, with the '023 patent having issued from a continuation of the application that led to the '031 patent.[4] Entitled "TTS Containing an Antioxidant," the Patents-in-Suit generally disclose a "[p]harmaceutical composition comprising" a compound commonly known as rivastigmine "in free base or acid addition salt form and an antioxidant." '023 patent, Abstract; '031 patent, Abstract. The rivastigmine in the Patents-in-Suit "is useful . . . for the treatment of Alzheimer's disease." '023 patent col. 1 ll. 15–17; '031 patent col. 1. ll. 14–16.

B. Prior Judicial Opinions Did Not Bind the PTAB

Novartis alleges that a fundamental legal error pervades the PTAB's Final Written Decisions: the PTAB

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[4] "A continuing patent application is an application filed subsequently to another application, while the prior application is pending, disclosing all or a substantial part of the subject-matter of the prior application and containing claims to subject-matter common to both applications . . . ." *U.S. Water Servs., Inc. v. Novozymes A/S*, 843 F.3d 1345, 1348 n.1 (Fed. Cir. 2016) (internal quotation marks and citation omitted).

unlawfully reached different conclusions than our court and the U.S. District Court for the District of Delaware ("Delaware District Court"), which addressed the "same" arguments and the "same" evidence and found the Asserted Claims nonobvious in two prior opinions. Appellants' Br. 29; *see id.* at 35–39, 46–47, 52–56, 60–62 (discussing *Novartis Pharm. Corp. v. Watson Labs., Inc.*, 611 F. App'x 988 (Fed. Cir. 2015) and *Novartis Pharm. Corp. v. Noven Pharm., Inc.* (*Noven D. Del.*), 125 F. Supp. 3d 474 (D. Del. 2015)). In support of that position, Novartis relies substantially on a single sentence from our decision in *In re Baxter International, Inc. See, e.g., id.* at 30 (discussing 678 F.3d 1357, 1365 (Fed. Cir. 2012)).

Novartis's argument fails on factual and legal grounds. As an initial matter, the record here differed from that in the prior litigation, meaning that Novartis's argument rests on a faulty factual predicate. With respect to *Watson*, the PTAB found that it "does not control here because [Appellee] Noven [Pharmaceuticals Inc. ('Noven')] has presented additional prior art" like Sasaki "and declaratory evidence that was not before the [c]ourt" in that case.[5] *Noven II*, 2015 WL 5782081, at *2. Similarly, as to *Noven D. Del.*, the PTAB found that it did not control because the parties provided additional evidence that was not before the Delaware District Court.[6] *Id.*; *see*

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[5] Mylan Pharmaceuticals Inc. initially joined Noven as an appellee here, but later withdrew.

[6] Noven also argues that the "record additionally includes four confidential Novartis documents that were not of the record in *Noven* [*D. Del*]." Appellee's Br. 11; *see id.* at 11–13 (discussing the contents of the confidential documents). The PTAB did not identify these documents as the basis for not following *Noven D. Del.*, *see Noven II*, 2015 WL 5782081, at *2, and neither will we, *see Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 169

id. at *5 (identifying as new evidence two declarations of Dr. Agis Kydonieus, two declarations of Dr. Christian Schöneich, and one declaration of Dr. Alexander M. Klibanov). Novartis tacitly concedes that the record here is different. *See* Appellants' Reply 7 n.1 ("The USPTO and Noven argue that the parties submitted expert declarations and deposition testimony that was not before the *Noven* [*D. Del.*] Court. But neither disputes that these materials are *substantively the same* as the experts' testimony before the *Noven* [*D. Del.*] Court." (emphasis added) (citations omitted)), 11 ("The [PTAB] sought to explain its rejection of this [c]ourt's *Watson* decision on grounds that Noven presented art and evidence in the [inter partes review] that was not before the *Watson* [c]ourt[]. *While differences in the record could justify a different outcome overall*, under *Baxter*, they do not support the [PTAB]'s contrary conclusions on the specific rivastigmine art and arguments previously adjudicated in *Watson*." (emphasis added) (citation omitted)). It is unsurprising that different records may lead to different findings and conclusions.

Nevertheless, even if the record were the same, Novartis's argument would fail as a matter of law. The PTAB determined that a "petitioner in an inter partes review proves unpatentability by a preponderance of the evidence (*see* 35 U.S.C. § 316(e)) rather than by clear and convincing evidence[] as required in district court litigation," meaning that the PTAB properly may reach a

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(1962) ("A simple but fundamental rule of administrative law is that a reviewing court, in dealing with a determination or judgment which an administrative agency alone is authorized to make, must judge the propriety of such action solely by the grounds invoked by the agency." (internal quotation marks, ellipses, brackets, and citation omitted)).

different conclusion based on the same evidence. *Noven II*, 2015 WL 5782081, at *2 (italics omitted). That position comports with recent Supreme Court precedent, which held that

> [a] district court may find a patent claim to be valid, and the [USPTO] may later cancel that claim in its own review. . . . This possibility, however, has long been present in our patent system, which provides different tracks—one in the [USPTO] and one in the courts—for the review and adjudication of patent claims. As we have explained . . . , inter partes review imposes a different burden of proof on the challenger. These different evidentiary burdens mean that the possibility of inconsistent results is inherent to Congress'[s] regulatory design.

Cuozzo Speed Techs., LLC v. Lee, 136 S. Ct. 2131, 2146 (2016) (citation omitted). Thus, the prior decisions in *Watson* and *Noven D. Del.* did not bind the PTAB.

Finally, *Baxter* does not necessitate a different conclusion. There, we stated that the USPTO "ideally should not arrive at a different conclusion" if it faces the same evidence and argument as a district court. *Baxter*, 678 F.3d at 1365. Novartis treats "ideally" in that passage as a mandate. *See, e.g.*, Appellants' Br. 30 (citing the relevant passage from *Baxter* and arguing that it "is legal error" for the PTAB to reach a different conclusion). However, the context in which that passage appears demonstrates that we used "ideally" to connote aspiration and, in fact, recognized that Congress has provided a separate review mechanism before the USPTO with its own standards. *See Baxter*, 678 F.3d at 1365 ("However, the fact is that Congress has provided for a reexamination system that permits challenges to patents by third parties, even those who have lost in prior judicial proceed-

ings."). We will not imbue *Baxter* with a meaning that the decision itself does not support.

C. Substantial Evidence Supports the PTAB's Underlying Factual Findings

"As part of the obviousness inquiry, we consider whether a PHOSITA would have been motivated to combine the prior art to achieve the claimed invention . . . ." *In re Warsaw Orthopedic, Inc.*, 832 F.3d 1327, 1333 (Fed. Cir. 2016) (internal quotation marks, brackets, and citation omitted). "The answer[] to th[at] question[] require[s] producing factual findings that we review for substantial evidence." *Id.* (citations omitted). Novartis contends that substantial evidence does not support several of the PTAB's factual findings regarding the motivation to combine Enz and Sasaki. *See* Appellants' Br. 39–45, 48–52, 56–60, 62–65. We disagree.

Before we address Novartis's motivation to combine concerns, we first must understand what Enz and Sasaki disclose. The PTAB found that Enz discloses a transdermal patch containing rivastigmine and an acrylic polymer. *See Noven II*, 2015 WL 5782081, at *7–10; *see also* J.A. 588–610. The PTAB also found Sasaki teaches that (1) "the therapeutic effect of a" compound combined with acrylic polymer "tends to be greatly reduced due to the breakdown and dissipation of the drug when . . . stored for a long time"; and (2) if an antioxidant is added to the combination, "the drug will be stably present without breaking down." *Noven II*, 2015 WL 5782081, at *8 (internal quotation marks and citations omitted); *see* J.A. 634–37. Novartis does not challenge these findings. *See generally* Appellants' Br.

Turning to its motivation to combine arguments, Novartis argues that the record contains no evidence that a PHOSITA "would have been motivated to add an antioxidant" to rivastigmine "absent evidence of oxidative degradation." *Id.* at 40. First, Novartis avers that the record

shows a PHOSITA "would only have added an antioxidant when required to address a known oxidative degradation problem" detected during testing. *Id.* Novartis ignores the PTAB's findings as to the PHOSITA's skill in the art. The PTAB found that a PHOSITA would have, inter alia, "had knowledge of organic chemistry and been able to *analyze* and recognize certain characteristics of a compound based on its chemical structure." *Noven II*, 2015 WL 5782081, at *7. The PTAB further found that "the ability to predict reactivity based on functional group properties is a foundation of organic chemistry, and a [PHOSITA] would have understood that the presence of particular functional groups in a molecule has consequences," such as degradation. *Id.* (citations omitted). Ample record evidence from scholarly sources supports the PTAB's findings. *See* Robert T. Morrison & Robert N. Boyd, *Organic Chemistry* 167 (6th ed. 1992) (J.A. 2892) (providing that "[t]he atom or group of atoms that defines the structure of a particular family of organic compounds and, at the same time, determines their properties is called the functional group" (italics and bold omitted)); *see also* J. Guillory & R. Poust, *Chemical Kinetics and Drug Stability*, *in Modern Pharmaceutics* 181 (Gilbert S. Banker & Christopher T. Rhodes eds., 3d ed. 1996) (J.A. 1846) (providing that "it is possible to anticipate the potential mode(s) of degradation that drug molecules will likely undergo" through "the application of functional group chemistry"). The expert testimony of Dr. Schöneich corroborates the content of these sources. *See* J.A. 1350–52. Thus, substantial evidence supports the PTAB's finding that a PHOSITA would not have waited to add an antioxidant until discovering degradation during testing, but would have assessed a compound's structure in advance of testing to determine whether an antioxidant should be added.

Second, Novartis alleges that Sasaki "does not mention rivastigmine" or otherwise disclose that rivastigmine

is susceptible to oxidative degradation and that the PTAB reached the opposite conclusion by failing to read that reference as a whole. Appellants' Br. 48. To support its position, Novartis cites the testimony of its expert, Dr. Klibanov, and contends that the PTAB "wrongly dismissed this evidence of the art . . . ." *Id.* at 49. Novartis's argument fails for two reasons. First, Novartis predicates its argument on the belief that the prior art must expressly disclose a motivation to combine; however, a "motivation to combine the relevant prior art teachings does not have to be found explicitly in the prior art." *In re Kahn*, 441 F.3d 977, 987 (Fed. Cir. 2006) (citation omitted). Second, the PTAB addressed Dr. Klibanov's testimony and found that it was not relevant because it did not address transdermal devices with acrylic polymer. *See Noven II*, 2015 WL 5782081, at *11. Novartis's argument asks us to reweigh the evidence and give greater weight to Dr. Klibanov's testimony than did the PTAB, which we may not do. *See, e.g.*, *Warsaw*, 832 F.3d at 1333 (explaining that the court "may not reweigh . . . evidence on appeal" (citation omitted)).

Finally, Novartis contends that substantial evidence does not support the PTAB's finding that a PHOSITA would have predicted that "rivastigmine has the potential to oxidatively degrade based on its [chemical] structure." Appellants' Br. 60 (capitalization omitted). In support of its position, Novartis again cites the testimony of Dr. Klibanov, who purportedly testified that the chemical structure of a compound cannot alone inform whether that compound is susceptible to oxidative degradation. *See id.* at 64–65. Novartis's final argument fails for the same reasons as its first two arguments: it ignores the PTAB's findings as to the skill in the art possessed by a PHOSITA, and substantial evidence supports the PTAB's finding that a PHOSITA would have predicted that rivastigmine has the potential to oxidatively degrade based on its chemical structure. *See* J.A. 1350–51, 1846, 2892.

Novartis asks us to give greater weight to the testimony of Dr. Klibanov than did the PTAB, which we may not do. *See Warsaw*, 832 F.3d at 1333.

CONCLUSION

The PTAB found the Asserted Claims unpatentable as obvious for additional reasons not discussed above. *See Noven I*, 2015 WL 5782080, at *23; *Noven II*, 2015 WL 5782081, at *23. However, because we affirm the PTAB's conclusions that the Asserted Claims would have been unpatentable as obvious on the grounds discussed, we need not address the alternative grounds of unpatentability. *See In re Gleave*, 560 F.3d 1331, 1338 (Fed. Cir. 2009) (declining to address alternative grounds of unpatentability when the court upholds one such ground). Therefore, for the foregoing reasons, the Final Written Decisions of the U.S. Patent and Trademark Office's Patent Trial and Appeal Board are

AFFIRMED