NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

PURDUE PHARMA L.P.,
Appellant

v.

DEPOMED, INC.,
Appellee

2015-2029, 2015-2030, 2015-2032

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2014-00377, IPR2014-00378, IPR2014-00379.

Decided: March 24, 2016

GREGORY A. CASTANIAS, Jones Day, Washington, DC, argued for appellant. Also represented by JENNIFER LORAINE SWIZE; JOHN JOSEPH NORMILE, JR., GASPER LAROSA, LISAMARIE LOGIUDICE, New York, NY; ISRAEL SASHA MAYERGOYZ, Chicago, IL.

PAUL J. ANDRE, Kramer Levin Naftalis & Frankel LLP, Menlo Park, CA, argued for appellee. Also represented by LISA KOBIALKA, HANNAH YUNKYUNG LEE.

Before PROST, *Chief Judge,* NEWMAN and LOURIE, *Circuit Judges*.

LOURIE, *Circuit Judge*.

Purdue Pharma L.P. ("Purdue") appeals from the final written decisions of the United States Patent and Trademark Office ("PTO") Patent Trial and Appeal Board ("the Board") affirming the patentability of all of the challenged claims of U.S. Patent 6,340,475 ("the '475 patent") and U.S. Patent 6,635,280 ("the '280 patent") in three related *inter partes* review proceedings. *See Purdue Pharma L.P. v. Depomed, Inc.*, No. IPR2014-00377, 2015 WL 4150832 (P.T.A.B. July 8, 2015) ("*Purdue I*"); *Purdue Pharma L.P. v. Depomed, Inc.*, No. IPR2014-00378, 2015 WL 4150833 (P.T.A.B. July 8, 2015) ("*Purdue II*"); *Purdue Pharma L.P. v. Depomed, Inc.*, No. IPR2014-00379, 2015 WL 4150834 (P.T.A.B. July 8, 2015) ("*Purdue III*"). Because the Board did not err in determining that Purdue, the petitioner, failed to prove that the challenged claims are unpatentable as obvious over the cited prior art, we *affirm*.

BACKGROUND

Depomed, Inc. ("Depomed") owns the '475 and '280 patents, which share the same specification in relevant part, and are both directed to a controlled-release oral dosage form of a soluble drug and a method of use thereof. The claimed dosage form comprises a solid matrix of polymers with the drug dispersed therein. After dosing orally, the polymeric matrix swells as a result of imbibition of water to promote its retention in the stomach during the fed state, *viz.*, in the presence of food, and remains substantially intact when the drug is released in the stomach. Accordingly, the claimed dosage form allows a soluble drug to be administered orally in a way that prolongs its release. That prolonged release reduces the risk of transient overdosing and controls the drug dosage to safer and more effective levels over an extended period of time.

In 2013, Depomed sued Purdue in the United States District Court for the District of New Jersey, alleging infringement of the '475 and '280 patents. Purdue then filed three petitions at the PTO requesting *inter partes* review of the asserted claims on grounds that those claims are unpatentable as, *inter alia*, obvious over Baveja *et al.*, *Zero-Order Release Hydrophilic Matrix Tablets of β-Adrenergic Blockers*, 39 Int'l J. Pharmaceutics 39 (1987) ("Baveja"), U.S. Patent 5,582,837 ("Shell"), and other references. In July 2014, the Board instituted three separate proceedings to review the patentability of the following claims: (1) claims 1, 8–10, 13–15, 43, 45, and 46 of the '280 patent; (2) claims 1, 8–10, 13–15, 61, and 62 of the '475 patent; and (3) claims 43, 54, 55, 57, 58, and 66 of the '475 patent. The district court stayed the litigation pending the Board's review.

Claims 1 and 43 of the '475 patent are representative of the challenged claims and read as follows:

> 1. A controlled-release oral drug dosage form for releasing a drug whose solubility in water is greater than one part by weight of said drug in ten parts by weight of water,
>
> said dosage form comprising a solid polymeric matrix with said drug dispersed therein at a weight ratio of drug to polymer of from about 15:85 to about 80:20,
>
> said polymeric matrix being one that swells upon imbibition of water thereby attaining a size large enough to promote retention in the stomach during said fed mode ["the swelling limitation"],
>
> that releases said drug into gastric fluid by the dissolution and diffusion of said drug out of said matrix by said gastric fluid,

that upon immersion in gastric fluid retains at least about 40% of said drug one hour after such immersion and releases substantially all of said drug within about eight hours after such immersion,

and that remains substantially intact until all of said drug is released ["the substantially intact limitation"].

43. A method of administering to a subject a drug that is therapeutic to said subject when absorbed in the stomach where said drug has at least one ionized group in the pH range 5 through 8,

said method comprising orally administering to said subject a dosage form of said drug while said subject is in a fed mode,

said dosage form comprising a solid polymeric matrix with said drug dispersed therein at a weight ratio of drug to polymer of from about 0.01:99.99 to about 80:20,

said polymeric matrix being one that:

(a) swells upon imbibition of gastric fluid to a size large enough to promote retention in the stomach during said fed mode ["the swelling limitation"],

(b) releases said drug into gastric fluid by the dissolving of said drug by said gastric fluid and either erosion of said matrix or diffusion of said dissolved drug out of said matrix,

(c) retains at least about 40% of said drug one hour after such immersion in gastric fluid,

(d) releases substantially all of said drug within about ten hours after such immersion, and

> (e) remains substantially intact until all of said drug is released ["the substantially intact limitation"],
>
> thereby extending the release rate of said drug with time during said fed mode while releasing substantially all of said drug within said stomach where said drug is maintained in an acidic environment.

'475 patent col. 17 ll. 45–59, col. 25 ll. 39–64.

In July 2015, after briefing and a consolidated oral hearing, the Board issued three final written decisions with similar reasoning in relevant part, in which it concluded that Purdue failed to establish by a preponderance of the evidence that the challenged claims would have been obvious over the cited prior art.[1]

The Board found that Baveja discloses most of the limitations of independent claims 1 and 43 of the '475 and '280 patents, except for the "swelling" and "substantially intact" limitations. In so finding, the Board specifically rejected Depomed's argument that Baveja teaches away from the claimed invention. *Purdue I*, 2015 WL 4150832, at *12; *Purdue II*, 2015 WL 4150833, at *11; *Purdue III*, 2015 WL 4150834, at *12. The Board next found that Shell discloses those limitations that are missing from Baveja. However, despite finding that the cited prior art teaches each limitation of claims 1 and 43 of both patents, *Purdue I*, 2015 WL 4150832, at *14, *20; *Purdue II*, 2015 WL 4150833, at *13; *Purdue III*, 2015 WL 4150834, at *14, the Board found that Purdue failed to establish a

---

[1] Among the instituted grounds, the Board also found that Purdue failed to prove that claims 43, 54, 55, 57, 58, and 66 of the '475 patent were anticipated by U.S. Patent 6,120,803. But that finding is not at issue in this appeal.

reason to combine the prior art to achieve the claimed invention with a reasonable expectation of success, *Purdue I*, 2015 WL 4150832, at *16, *20; *Purdue II*, 2015 WL 4150833, at *15; *Purdue III*, 2015 WL 4150834, at *16.

Specifically, the Board found that, although Baveja and Shell may have interrelated teachings, Purdue failed to explain persuasively "how or why" a person of ordinary skill in the art would have combined the "swelling" and "substantially intact" features of the Shell formulation with the Baveja formulation. *Purdue I*, 2015 WL 4150832, at *16; *Purdue II*, 2015 WL 4150833, at *15; *Purdue III*, 2015 WL 4150834, at *16. The Board also found that, to the extent that Purdue relied on the nature of the problem to be solved to supply a reason to combine the prior art, it improperly used hindsight by defining the problem with a recitation of the challenged claims.

Moreover, the Board found that Purdue failed to establish that a skilled artisan would have had a reasonable expectation of success to achieve the claimed invention. *Purdue I*, 2015 WL 4150832, at *17, *20; *Purdue II*, 2015 WL 4150833, at *16; *Purdue III*, 2015 WL 4150834, at *17. The Board considered expert testimony regarding the large number of variables in play when designing a drug formulation, as well as co-inventor Helm's testimony that it took her years of research to develop the claimed dosage form. The Board also noted that Purdue failed to address why one of ordinary skill in the art would have reasonably expected that modifying the Baveja formulation to incorporate the "swelling" and "substantially intact" features would not affect the other desired properties of the Baveja formulation, such as the drug release profile.

The Board therefore concluded that claims 1 and 43 of both patents were not shown to be unpatentable as obvious. For similar reasons, the Board concluded that Purdue failed to prove that the other challenged claims, which depend from either claim 1 or 43, would have been

obvious over the cited prior art, and therefore did not consider Depomed's evidence of secondary considerations.

Purdue timely appealed to this court. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

We review the Board's legal determinations *de novo*, *In re Elsner*, 381 F.3d 1125, 1127 (Fed. Cir. 2004), and the Board's factual findings underlying those determinations for substantial evidence, *In re Gartside*, 203 F.3d 1305, 1316 (Fed. Cir. 2000). A finding is supported by substantial evidence if a reasonable mind might accept the evidence to support the finding. *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938).

A claim is unpatentable as obvious if the differences between the claimed subject matter and the prior art are such that the subject matter as a whole would have been obvious at the time of invention to a person having ordinary skill in the art. 35 U.S.C. § 103(a) (2006).[2] Obviousness is a question of law premised on underlying issues of fact, including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the pertinent art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence, such as commercial success, long-felt need, and the failure of others. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 427 (2007); *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966); *In re Baxter*, 678 F.3d 1357, 1361 (Fed. Cir. 2012). Similarly, the determinations of what a reference teaches and the existence of a reason to combine references are questions of

---

[2] Because the applications leading to the '475 and '280 patents were filed before March 16, 2013, the pre-Leahy-Smith America Invents Act version of § 103 applies in this appeal. *See* Pub. L. No. 112-29, § 3(n)(1), 125 Stat. 284, 293 (2011).

fact. *In re Beattie*, 974 F.2d 1309, 1311 (Fed. Cir. 1992); *In re Hyon*, 679 F.3d 1363, 1365–66 (Fed. Cir. 2012). In an *inter partes* review proceeding, the petitioner bears the burden of proving a proposition of unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e).

Purdue argues that the Board erred by deviating from the Supreme Court's guidance in *KSR* that an obviousness analysis involves an expansive and flexible approach that accounts for the interrelated teachings of the prior art and the nature of the problem to be solved. Applied here, Purdue contends, those principles necessarily demonstrate how and why a skilled artisan would have had a reason to combine the interrelated teachings of Baveja and Shell, as both references teach similar controlled-release profiles of similar formulations with overlapping drug-to-polymer ratios. Purdue also argues that the problem to be solved provides a further reason to combine Baveja and Shell, for those references already solved the problem by teaching the drug release profile and other limitations of the challenged claims. Purdue maintains that its definition of the problem to be solved came directly from Shell, not from the challenged claims.

Depomed responds that the Board applied the correct legal standard in its obviousness analysis, recognizing that this case involves complex and unpredictable formulation technology. According to Depomed, a skilled artisan would not have had a reason to combine Baveja and Shell to make the claimed dosage form. Depomed asserts that Baveja teaches away from the non-zero-order drug release profiles shown in Figures 1 and 2, on which Purdue relies, by characterizing them as a "major disadvantage." J.A. 1805. Depomed contends that Purdue's generic and conclusory statements of interrelated teachings of the prior art are indicative of the fact that Purdue presented no credible evidence on a motivation to combine the prior art. Depomed responds, moreover, that Purdue improperly relied on hindsight to formulate the problem

to be solved, which cannot be derived from Shell because Shell focuses on drugs of limited solubility and only depicts drug release profiles up to seven hours.

Purdue additionally argues that Baveja and Shell demonstrate actual success, far more than a reasonable expectation of success, and that the Board overlooked the evidence that Baveja discloses actual dosage forms having the claimed drug release profiles and that Shell provides clear direction as to which parameters are critical. According to Purdue, the Board improperly relied on the testimony of co-inventor Helm, who admitted that she was not aware of the cited references, as well as the testimony of Depomed's expert Hopfenberg because that testimony was divorced from the explicit teachings of Baveja and Shell.

Depomed responds that Baveja and Shell do not establish a reasonable expectation of success, and that both parties' experts testified that there were numerous variables affecting controlled-release formulations. Depomed argues that changing any one of those variables could significantly affect the drug release profile. Depomed also responds that Helm is more than qualified to offer testimony as one of ordinary skill in the art, and that Hopfenberg's opinion was properly based on his review of the prior art. Depomed emphasizes that the claimed invention was the product of testing different combinations of polymers and drugs through years of research.

We agree with Depomed that the Board applied the correct legal standard in its obviousness analysis and that substantial evidence supports its finding that Purdue failed to establish that a person of ordinary skill in the art would have had a reason to combine Baveja and Shell to pursue the claimed invention with a reasonable expectation of success. As the petitioner before the Board in an *inter partes* review proceeding, Purdue bore the burden of establishing obviousness of the challenged claims by a preponderance of the evidence. 35 U.S.C. § 316(e). The

Board did not err in finding that Purdue failed to satisfy that burden.

The record shows that the Board correctly determined that each limitation of the challenged independent claims was known in the art, as evidenced by the teachings of Baveja and Shell. In particular, the Board correctly found that Baveja teaches almost all of the limitations of claims 1 and 43 of the '475 and '280 patents, and that Shell teaches the "swelling" and "substantially intact" limitations not otherwise disclosed in Baveja.

Moreover, substantial evidence supports the Board's finding that Baveja does not teach away from the claimed dosage form. Although Baveja expresses a preference for oral dosage forms that exhibit a zero-order release profile over those that do not, that preference does not amount to teaching away from dosages forms with a non-zero-order release profile. *See In re Mouttet*, 686 F.3d 1322, 1334 (Fed. Cir. 2012) ("[J]ust because better alternatives exist in the prior art does not mean that an inferior combination is inapt for obviousness purposes.").

Nevertheless, the Board correctly recognized that "a patent . . . is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR*, 550 U.S. at 418. Indeed, it remains "important to identify a *reason* that would have prompted a person of ordinary skill in the relevant field to combine the elements *in the way* the claimed new invention does." *Id.* (emphases added). As the Board correctly recognized, one may look to "interrelated teachings" of multiple references, *id.*, or a "problem known in the field of endeavor," *id.* at 420, to determine whether there was an "apparent reason" to combine the prior art teachings "in the fashion claimed by the patent at issue," *id.* at 418.

Although the obviousness analysis may not be confined by any formalistic test, or by overemphasis on the explicit teachings of prior art publications, a petitioner

must nevertheless make a sufficient showing that is more than "mere conclusory statements," to establish a reason that would have prompted a skilled artisan to combine the prior art teachings in the way of the claimed invention. *Id.* at 418–19. As we have explained, a patent challenger must demonstrate that a skilled artisan would have had reason to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success from doing so. *See PAR Pharm., Inc. v. TWI Pharm., Inc.*, 773 F.3d 1186, 1193 (Fed. Cir. 2014).

Here, the Board found that Purdue failed to sufficiently show that a skilled artisan would have had a reason to combine the teachings of Baveja and Shell to achieve the claimed invention. That determination is supported by substantial evidence, which we must uphold, rather than revisit *de novo*. The record shows that Purdue presented limited evidence of a reason to combine the teachings of Baveja and Shell. *E.g.*, J.A. 1956–62, 1985–86 (¶¶ 127–28, 131–33, 193–94); Appellant's Br. 38–39. Its expert opined generally on the interrelated teachings of those references, but did not explain in sufficient detail how or why a skilled artisan would have been motivated to combine the "swelling" and "substantially intact" features of the Shell formulation with the Baveja formulation to attain the claimed dosage form.

Moreover, to the extent that Purdue relies on the problem to be solved to supply the reason to combine the prior art, it failed to demonstrate to the Board that the problem was known in the art or that Purdue's formulation of the problem was derived directly from the prior art, rather than from the challenged claims. The Board therefore did not err in finding that Purdue improperly relied on hindsight in formulating the problem to be solved. *Insite Vision Inc. v. Sandoz, Inc.*, 783 F.3d 853, 859 (Fed. Cir. 2015) ("Defining the problem in terms of its

solution reveals improper hindsight in the selection of the prior art relevant to obviousness.").

We also conclude that substantial evidence supports the Board's finding that Purdue failed to sufficiently show that a skilled artisan would have had a reasonable expectation of success in combining Baveja and Shell to achieve the claimed dosage form. As the Board noted, both parties' experts testified on the large number of formulation considerations in play when designing a drug formulation. In light of that, Purdue did not sufficiently explain why a skilled artisan would have expected that the Baveja formulation could be modified to incorporate the "swelling" and "substantially intact" features of Shell, without affecting the other desired properties. In other words, Purdue did not address whether adding the "swelling" and "substantially intact" features to the Baveja formulation would have been reasonably expected to lead to a dosage form that satisfies the other limitations of the challenged claims.

Accordingly, we conclude that the Board did not err in finding that Purdue failed to establish a reason to combine the cited prior art to achieve the claimed invention with a reasonable expectation of success. Because the Board did not reach the merits of Depomed's evidence of secondary considerations, we similarly decline to do so in the first instance on appeal.

CONCLUSION

We have considered the remaining arguments, but find them to be unpersuasive. The Board did not err in determining that Purdue failed to make a sufficient showing that the challenged claims of the '475 and '280 patents would have been obvious over the cited prior art. We therefore affirm the Board's decision.

AFFIRMED