NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

IN RE: DEPOMED, INC.,
Appellant

2016-1378

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2014-00652.

Decided: February 21, 2017

ARLENE L. CHOW, Hogan Lovells US LLP, New York, NY, argued for appellant. Also represented by ERIC J. LOBENFELD, THOMAS SCHMIDT; JESSICA LYNN ELLSWORTH, Washington, DC.

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

Before DYK, REYNA, and STOLL, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* STOLL.

Concurring opinion filed by *Circuit Judge* REYNA.

STOLL, *Circuit Judge*.

Endo Pharmaceuticals, Inc. filed a petition for inter partes review with the Patent Trial and Appeal Board to review the patentability of Depomed, Inc.'s U.S. Patent No. 6,723,340. The Board instituted an IPR proceeding on a subset of the grounds in the petition and ultimately determined that two instituted grounds collectively rendered claims 1, 3–5, and 10–13 unpatentable as obvious. Depomed appeals from the Board's final written decision, challenging the Board's patentability determination. We affirm.

BACKGROUND

I.

Depomed is the assignee of the '340 patent, which is generally directed to vehicles for drug delivery. Specifically, the '340 patent discloses "[u]nit dosage form tablets for the delivery of pharmaceuticals [that] are formed of the pharmaceutical dispersed in a solid unitary matrix that is formed of a combination of poly(ethylene oxide) and hydroxypropyl methylcellulose." '340 patent Abstract. The patent explains that many drugs have their greatest therapeutic effect when they are released in the stomach in a prolonged, continuous manner because such delivery presents fewer side effects and reduces the need for repeated or frequent dosing.

Gastric retention, where the particles in a drug are retained in the stomach for a prolonged duration, can be achieved by using drug formulation particles small enough to be swallowed comfortably but that swell to a larger size upon contact with gastric fluids. "One means of achieving a swellable particle is to disperse the drug in a solid matrix formed of a substance that absorbs the gastric fluid and swells as a result of the absorbed fluid." *Id.* at col. 2 ll. 28–31. These polymer matrices also pro-

vide a controlled release of a drug over a prolonged period of time.

Poly(ethylene oxide) ("PEO") is a matrix material that possesses both swelling and controlled release properties but raises toxicology concerns when used in the amounts required for high drug dosages. Hydroxypropyl methylcellulose ("HPMC") is another matrix material that swells to a lesser degree than PEO but offers "the benefit of a more even and generally faster erosion in the gastric environment so that the dosage forms can clear the GI tract more predictably after a few hours of drug release." *Id.* at col. 3 ll. 20–23. The patent asserts that HPMC can be disadvantageous, however, because it causes a high initial burst of drug release and a lower degree of control over the drug release rate during the initial course of the drug release.

The '340 patent purports to improve on the prior art by combining PEO and HPMC in a matrix "for a swellable, sustained-release tablet [that] provides unexpectedly beneficial performance, avoiding or substantially reducing the problems enumerated above and offering improved control and reliability while retaining both the ability to swell for gastric retention and to control release." *Id.* at col. 3 ll. 35–40. Claim 1 is illustrative of the challenged claims and is reproduced below:

> 1. A controlled-release tablet for releasing a drug into at least a portion of a region defined by the stomach and the upper gastrointestinal tract, said tablet comprising a solid monolithic matrix with said drug dispersed therein, said matrix comprising a combination of poly(ethylene oxide) and hydroxypropyl methylcellulose at a weight ratio that causes said matrix to swell upon contact with gastric fluid to a size large enough to provide gastric retention, wherein;

> said drug has a solubility in water that exceeds one part of said drug per ten parts of water, by weight, and wherein;
>
> said poly(ethylene oxide) has a viscosity average molecular weight from about 2,000,000 to about 10,000,000, and wherein
>
> said hydroxypropyl methylcellulose has a viscosity of from about 4,000 centipose to about 200,000 centipose, measured as a 2% solution in water.

'340 patent col. 11 l. 60 – col. 12 l. 9.

II.

Endo petitioned for IPR of the '340 patent, alleging that claims 1–5 and 10–13 were unpatentable as obvious under 35 U.S.C. § 103 in view of five different prior art grounds.[1] The Board instituted an IPR on claims 1, 3–5, and 10–13 on the obviousness grounds of (1) PCT Application No. WO 98/55107, titled "Gastric-Retentive Oral Drug Dosage Forms for Controlled Release of Highly Soluble Drugs" ("Shell 1998"); (2) Shell 1998 in combination with a 1993 article entitled "Swelling Studies on Mixtures of Two Hydrophilic Excipients" ("Papadimitriou"); and (3) Papadimitriou in combination with U.S. Patent No. 4,871,548. The Board did not institute on two other grounds in Endo's petition, calling them redundant of the instituted grounds. In addition, the Board did not institute review of claim 2.

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[1] Given the effective filing date of the claims of the '340 patent, the version of 35 U.S.C. § 103 that applies here is that in force preceding the changes made by the America Invents Act. *See* Leahy–Smith America Invents Act, Pub. L. No. 112-29, § 3(n), 125 Stat. 284, 293 (2011).

The Board's final written decision concluded that claims 1, 3–5, and 11–13 are unpatentable as obvious in view of Shell 1998. *Endo Pharm., Inc. v. Depomed, Inc.*, IPR2014-00652, 2015 WL 5470293, at *6 (P.T.A.B. Sept. 16, 2015) (*Final Written Decision*). The Board additionally found that claims 1, 3–5, and 10–13 are unpatentable as obvious in view of Shell 1998 in combination with Papadimitriou. *Id.* at *11.

Depomed timely appealed to this court, and shortly thereafter, Endo withdrew as a party to this appeal. Following Endo's withdrawal, the Director of the United States Patent and Trademark Office intervened pursuant to 35 U.S.C. § 143, filing a brief and participating in oral argument. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A) and 35 U.S.C. § 141(c) to review the Board's final written decision.

DISCUSSION

On appeal, Depomed argues that the Board erred in failing to account for the unexpected results of combining PEO and HPMC. Depomed also argues that the Board's obviousness conclusion improperly relied on hindsight bias. Finally, Depomed argues that the Board applied an incorrect legal standard to assess long-felt, but unmet, need. We address each argument in turn.

I.

We first consider Depomed's argument that the Board erred in its obviousness conclusion by failing to account for the unexpected results of combining PEO and HPMC.

A patent claim is unpatentable as obvious "if 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." 35 U.S.C. § 103. Obviousness under § 103 is a mixed question of law and fact. We review the Board's

ultimate obviousness determination de novo and underlying factual findings for substantial evidence. *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016). Substantial evidence "means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Consol. Edison Co. v. NLRB,* 305 U.S. 197, 217 (1938). Factual considerations underlying the obviousness inquiry include the scope and content of the prior art, the differences between the prior art and the claimed invention, the level of ordinary skill in the art, and relevant secondary considerations. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966)). Relevant secondary considerations include commercial success, long-felt but unmet need, failure of others, and unexpected results. *Id.*

Citing column 3, lines 33–65 of the specification, Depomed argues that the Board failed to account for the alleged unexpected properties of the patented invention, namely, that the combination of HPMC and PEO yielded better controlled-release properties compared to using HPMC or PEO alone. Column 3 of the specification states that combining HPMC and PEO as a matrix for a swellable, sustained-release tablet provides "unexpectedly beneficial performance, avoiding or substantially reducing the problems" with using either HPMC or PEO alone. '340 patent col. 3 ll. 33–40.

The Board considered Depomed's argument and determined that, to the contrary, Depomed's evidence of unexpected results was entitled to "little weight" and did not overcome the petitioner's showing of obviousness. *Final Written Decision*, 2015 WL 5470293, at *23. The Board separately explained that one of ordinary skill would have expected that combining HPMC and PEO would provide a solid matrix for controlled drug release because Shell 1998 discloses a finite number of identified, predictable polymers that could be used individually or in

combination, of which HPMC and PEO are "particularly preferred" polymers. *See* J.A. 415. Though Shell 1998 does not explicitly disclose the combination of HPMC and PEO, it suggests the desirability of such a combination by stating that "[c]ertain combinations will often provide a more controlled release of the drug than their components when used individually." *Id.* at 416. The Board held that these facts support a conclusion "that the combination of PEO and HPMC, identified by the Shell 1998 Publication as particularly preferred polymers, would have been obvious to one of ordinary skill in the art at the time of the '340 patent." *Final Written Decision*, 2015 WL 5470293, at *9.

On this record, we conclude that substantial evidence supports the Board's finding that Depomed's evidence of unexpected results is weak and entitled to little weight. "To be particularly probative, evidence of unexpected results must establish that there is a difference between the results obtained and those of the closest prior art, and that the difference would not have been expected by one of ordinary skill in the art at the time of the invention." *Bristol-Myers Squibb Co. v. Teva Pharm. USA, Inc.*, 752 F.3d 967, 977 (Fed. Cir. 2014). Here, Shell 1998 discloses (1) a finite number of matrix polymers, of which HPMC and PEO are preferred; (2) that matrix polymers "can be used individually or in combination"; and (3) that "[c]ertain combinations will often provide a more controlled release of the drug than their components when used individually." J.A. 416. The express disclosure that combinations of polymers will often yield better results than when used alone undermines Depomed's suggestion that the difference between using HPMC and PEO individually and using them in combination would not have been expected.

At bottom, we discern no error in the Board's ultimate conclusion of obviousness. Even after giving Depomed's unexpected results evidence the weight afforded by the

Board, we agree with the Board's ultimate conclusion that the claims are obvious in view of Shell 1998.[2]

II.

Depomed also argues that the Board's analysis of the prior art was erroneous "because it analyzed the prior art through the distorted lens of hindsight bias." Appellant Br. 30. Specifically, Depomed argues that Shell 1998 discloses polymer combinations solely for the purpose of overcoming deficiencies in the controlled release properties of certain polymers in their individual capacities. Because HPMC and PEO did not exhibit these deficiencies in their individual capacities, Depomed argues that a person of ordinary skill in the art would have had no motivation to combine HPMC and PEO, and thus, the Board's obviousness conclusion was the result of hindsight bias. We disagree.

As explained above, Shell 1998 does not explicitly disclose the combination of HPMC and PEO. Shell 1998, nevertheless, discloses combinations including, xanthan gum combined with hydroxyethyl cellulose, hydroxypropyl cellulose, or PEO. We agree, however, with the Board's finding that Shell 1998 "does not limit which polymers could be combined or suggest that certain polymers would not function properly in a combination matrix." *Final Written Decision*, 2015 WL 5470293, at *9. Accordingly, we conclude that substantial evidence supports the

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[2] The concurrence contends that we "appear to accept" an allegedly improper two-step framework in the Board's obviousness analysis. Concurrence 1. We do not suggest a two-step framework. Rather, we simply find substantial evidence supports the Board's factual findings underlying its conclusion of obviousness and agree with its ultimate legal conclusion that the claims are invalid as obvious.

Board's interpretation of Shell 1998 and see no error in the Board's ultimate conclusion of obviousness.

III.

Finally, Depomed argues that the Board incorrectly required evidence demonstrating a failure of others to establish a long-felt but unmet need. We agree.

Though we have held that long-felt but unmet need is closely related to the failure of others, they are distinct considerations. *See, e.g.*, *Graham*, 383 U.S. at 18 (listing long-felt but unsolved need and failure by others as separate secondary considerations); *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litigation*, 676 F.3d 1063, 1081–83 (Fed. Cir. 2012) (noting that "[l]ongfelt need is closely related to the failure of others" but separately analyzing evidence of both in discrete sections). While "[e]vidence is particularly probative of obviousness when it demonstrates both that a demand existed for the patented invention, and that others tried but failed to satisfy that demand," a patent owner may establish a long-felt but unmet need without presenting evidence of failure of others. *In re Cyclobenzaprine*, 676 F.3d at 1082.

In its analysis of Depomed's evidence of long-felt but unmet need, the Board incorrectly stated that evidence demonstrating a failure of others is necessary to show a long-felt but unmet need. At oral argument, however, counsel for the Director correctly acknowledged that evidence of a failure of others is not required to demonstrate long-felt but unmet need. *See* Oral Arg. at 14:40–58, 15:14–24, http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2016-1378.mp3.

Even though the Board misstated the law, it accorded some weight to Depomed's long-felt but unmet need evidence. Depomed's evidence consisted of conclusory inventor testimony that "there was a long-felt need in the

field for a once-daily, gastric-retentive, controlled-release dosage forms to deliver highly soluble drugs slowly, evenly and reproducibly." J.A. 758. Without citing any evidentiary support, the inventor identified problems associated with immediate release dosage forms of metformin and gabapentin and explained that these problems were ameliorated by later dosage forms of these drugs that practiced the '340 patent.

We conclude that, despite the Board's misstatement of the law, substantial evidence supports its assignment of little weight to Depomed's evidence of long-felt but unmet need. We also agree with the Board's ultimate conclusion that the claims are obvious in view of Shell 1998.

CONCLUSION

We have considered Depomed's remaining arguments regarding secondary considerations but discern no errors in the Board's analysis.[3] Because we find that the Board did not err in holding claims 1, 3–5, and 10–13 of the '340 patent unpatentable, we affirm.

AFFIRMED

COSTS

No costs.

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[3] Depomed additionally raises a separate issue challenging the constitutionality of IPR proceedings. We have previously held that such proceedings do not violate Article III or the Seventh Amendment. *MCM Portfolio LLC v. Hewlett-Packard Co.*, 812 F.3d 1284, 1291–93 (Fed. Cir. 2015), *cert. denied*, 137 S. Ct. 292 (2016). "We are bound by prior Federal Circuit precedent 'unless relieved of that obligation by an en banc order of the court or a decision of the Supreme Court.'" *Id.* (quoting *Deckers Corp. v. United States*, 752 F.3d 949, 959 (Fed. Cir. 2014)).

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REYNA, *Circuit Judge*, concurring.

I agree that the asserted claims in this case would have been obvious to a person of ordinary skill in the art at the time of the invention. I write separately to express two concerns.

I.

I am troubled that the Board improperly employed a two-step approach in its obviousness analysis. It first made initial conclusions of obviousness and only later considered Depomed's objective indicia of non-obviousness. By failing to correct the Board's mistake and instead discussing only its ultimate conclusion of obviousness, the majority appears to accept such a two-step framework.

The Board's approach is inconsistent with our precedent. We repeatedly have stated that objective indicia of non-obviousness are vital to an obviousness determina-

tion, not evidence to be ignored or mentioned as a mere afterthought.[1] Such evidence is an important safeguard against hindsight bias,[2] and "may often be the most probative and cogent evidence in the record." *Stratoflex*, 713 F.2d at 1538; *see also* MUELLER ON PATENT LAW

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[1] *See, e.g.*, *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1052 (Fed. Cir. 2016) (en banc) (relying on industry praise, copying, commercial success, and long-felt need to determine that certain claims would not have been obvious); *Leo Pharm. Prods., Ltd. v. Rea*, 726 F.3d 1346, 1357 (Fed. Cir. 2013) ("Whether before the Board or a court, this court has emphasized that consideration of the objective indicia is part of the whole obviousness analysis, not just an afterthought."); *In re Kao*, 639 F.3d 1057, 1067 (Fed. Cir. 2011) ("[W]hen secondary considerations are present, though they are not always dispositive, it is error not to consider them."); *Stratoflex v. Aeroquip Corp.*, 713 F.2d 1520, 1538 (Fed. Cir. 1983) (Markey, C.J.) ("[E]vidence rising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness.").

[2] *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007) ("A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning."); *Graham v. John Deere Co.*, 383 U.S. 1, 36 (1966) (objective indicia "may also serve to 'guard against slipping into use of hindsight,' and to resist the temptation to read into the prior art the teachings of the invention in issue") (citation omitted); *Apple*, 839 F.3d at 1052 (recognizing that objective indicia guard against hindsight bias); *In re Cyclobenzaprine*, 676 F.3d 1063, 1079 (Fed. Cir. 2012) ("The objective considerations, when considered with the balance of the obviousness evidence in the record, guard as a check against hindsight bias.").

§ 9.02[C][2][b] (2012) (noting that the four *Graham* factors, including objective indicia, "have come to be essential to every nonobviousness analysis").

Of particular concern is the establishment of a prima facie standard in the obviousness analysis, whether actual or constructive. In an IPR, the law does not contemplate a burden-shifting test in the treatment of objective evidence of non-obviousness. But in this case, the Board employed just such a test. First, it made prima facie determinations of obviousness. *See* J.A. 17 ("[W]e hold that Petitioner has shown by a preponderance of the evidence that independent claim 1 is unpatentable under 35 U.S.C. § 103(a) for obviousness in view of the Shell 1998 Publication."); J.A. 28 ("[W]e hold that Petitioner has shown by a preponderance of the evidence that dependent claims 3–5 and 10–13 are unpatentable under 35 U.S.C. § 103(a) for obviousness in view of the Shell 1998 Publication."). Only later—in a different section under a different heading—did it consider Depomed's objective indicia of non-obviousness.[3] *See* J.A. 34. Deferring consideration of objective indicia until after deciding a claim would have been obvious allows hindsight bias to creep into step one (the prima facie showing) and limits the meaningfulness of step two. The Board then compounded its error by failing to address all of Depomed's objective indicia. For instance, it labeled one section, "Undue Experimentation and Unexpected Results." J.A. 39. But under that heading, the Board wholly failed to discuss unexpected results. *See* J.A. 39–40. This was error.

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[3] Lest there be doubt, counsel for the PTO admitted at oral argument that the Board employed a two-step process. Oral Arg. at 18:40–19:16, http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2016-1378.mp3.

We have held that district courts may not employ a two-step burden-shifting scheme in an obviousness analysis. *Cyclobenzaprine*, 676 F.3d at 1075. In *Cyclobenzaprine*, the district court erred by making an obviousness determination before considering the patentee's objective indicia of non-obviousness. We noted that a fact finder must "consider all evidence relating to obviousness before finding a patent invalid on those grounds." *Id.* Failure to do so results in an impermissible burden-shifting scheme for which there is "no practical need." *Id.* at 1080 n.7.

As we explained in *Cyclobenzaprine*, the prohibition against burden-shifting does not apply to *ex parte* patent prosecution proceedings, and for good reason. "During prosecution, a patent applicant, as a practical matter, may not have the opportunity to present objective evidence unless and until an examiner reviews the application and issues an obviousness rejection." *Id.* In other words, objective indicia may not be available until well after the examiner first considers the prior art, so it makes sense for the examiner to make a prima facie determination of obviousness and later consider any objective indicia of non-obviousness. *Id.* An IPR, on the other hand, is in many ways unlike *ex parte* prosecution.

For purposes of evaluating whether claims would have been obvious, particularly in light of the practical considerations discussed in *Cyclobenzaprine*, an IPR proceeding is more akin to litigation. As in litigation, "validity, rather than patentability, is the issue." *Id.* And in both forums, "all evidence is presented to the fact finder in a single proceeding." *Id.* Just as a jury hears evidence of both prior art and objective indicia before making its obviousness finding, so too the Board should hear all relevant evidence before determining whether asserted claims would be been obvious. For these rea-

sons, I believe *Cyclobenzaprine*'s prohibition on a burden-shifting scheme for obviousness should apply in the IPR context.[4] And indeed it does.

Recently, we held that burden-shifting "does not apply in the adjudicatory context of an IPR." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1375 (Fed. Cir. 2016). We stated:

> Where, as here, the only question presented is whether due consideration of the four *Graham* factors renders a claim or claims obvious, no burden shifts from the patent challenger to the patentee. This is especially true where the only issues to be considered are what the prior art discloses, whether there would have been a motivation to combine the prior art, and whether that combination would render the patented claims obvious.

Id. at 1376. One of the four *Graham* factors is objective indicia of non-obviousness. As such, in an IPR, the Board should not first make an obviousness determination only later to consider the patentee's objective indicia of non-obviousness. Doing so risks succumbing to the very hindsight bias that objective indicia are intended to ameliorate. *See KSR*, 550 U.S. at 421; *Graham*, 383 U.S. at 36; *Cyclobenzaprine*, 676 F.3d at 1079. In light of *Magnum Oil*, the Board erred by considering Depomed's

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[4] To be sure, IPR proceedings are not identical to district court litigation. *See Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2143–44 (2016). But as we explained in *Cyclobenzaprine* and later in *Magnum Oil*, the similarities most salient to an obviousness analysis discourage burden-shifting.

objective indicia only after determining that certain claims would have been obvious.

II.

My second concern involves assigning "weight" to certain evidence. The majority accepts the Board's finding that it gave "little weight" to Depomed's evidence of unexpected results. *See* Maj. Op. 7.

The Board's assignment of "weight" to this evidence is wrong for two reasons. First, results are either unexpected or they are not. Our case law does not ask whether results are "really unexpected" or just a "little unexpected." We ask only whether the results are unexpected. As such, it is incorrect to assign a particular weight to that evidence.

Second, assigning weight to objective indicia of nonobviousness imposes the very danger of burden-shifting that *Magnum Oil* forecloses. The Board must decide a binary issue: either the challenged claims would have been obvious or they would not have been obvious. It should make this determination only after considering all evidence—both supporting and detracting from a finding of obviousness. For us to assign "weight" to each piece of evidence implies a new, incorrect standard of review. Our review is not, for example, whether evidence of unexpected results "outweighs" the similarity between the challenged claims and the prior art. Our review is whether the challenged claims would have been obvious.[5]

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[5] By analogy, a district court often considers motions to dismiss for failure to state a claim pursuant to Fed. R. Civ. P. 12(b)(6). A court denies a 12(b)(6) motion when the plaintiff alleges sufficient facts that, if true, constitute a cause of action. Denial of a 12(b)(6) motion is

Despite my reservations with both the Board's and majority's analyses, I do not believe remand is necessary here. Depomed's objective indicia, even if analyzed under the proper framework, do not compel a conclusion of non-obviousness in view of Shell and Papadimitriou. I therefore concur in affirming the Board's ultimate obviousness determination.

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not a conclusion that the plaintiff will prevail—rather, the court then turns to the defendant's evidence. Only after considering the totality of the evidence from both sides does the court ultimately decide the case.