NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

PURDUE PHARMA L.P., P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P.,
Appellants

v.

ANDREI IANCU, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,
Intervenor

2018-1710, 2018-1711

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2016-01412, IPR2016-01413.

Decided: April 17, 2019

JENNIFER LORAINE SWIZE, Jones Day, Washington, DC, argued for appellants. Also represented by GREGORY A. CASTANIAS, ROBERT STANDER; GASPER LAROSA, JOHN JOSEPH NORMILE, JR., New York, NY.

MARY L. KELLY, Office of the Solicitor, United States

Patent and Trademark Office, Alexandria, VA, argued for intervenor. Also represented by THOMAS W. KRAUSE, SARAH E. CRAVEN, JOSEPH MATAL.

Before DYK, MAYER, and BRYSON, *Circuit Judges*.

BRYSON, *Circuit Judge*.

Purdue Pharma L.P., P.F. Laboratories, Inc., and Purdue Pharmaceuticals L.P. (collectively, "Purdue") appeal from the decisions of the United States Patent and Trademark Office ("PTO") Patent Trial and Appeal Board in *inter partes* review Nos. IPR2016-01412 and IPR2016-01413. The Board found claims 1–13 and 16–19 of U.S. Patent No. 9,034,376 ("the '376 patent") unpatentable as obvious on three grounds. Because the Board's conclusions are supported by substantial evidence, we affirm.

I

The '376 patent, entitled "Pharmaceutical Formulation Containing Gelling Agent," is directed to abuse-deterrent, extended release formulations of oxycodone, an analgesic. The patent issued on May 19, 2015, and is a continuation of application No. 10/214,412, which was filed on August 6, 2002. The related provisional application No. 60/310,534 ("the '534 application"), was filed on August 6, 2001.

The '376 patent contemplates using two gelling agents, polyethylene oxide ("PEO") and hydroxypropylmethylcellulose ("HPMC") in an oxycodone formulation. When the oxycodone formulation is exposed to an aqueous liquid, those gelling agents impart a viscosity to the formulation that makes it unsuitable for parenteral and nasal administration.

Claims 1, 18, and 19 of the '376 patent are independent claims, and the remainder of the claims are dependent claims. Claim 1 provides as follows:

> 1. A controlled release oral solid dosage form comprising:
>
> a controlled release matrix comprising a mixture of (i) from 2.5 mg to 320 mg oxycodone or a pharmaceutically acceptable salt thereof; and
> (ii) a gelling agent comprising [PEO] and [HPMC], the gelling agent in an effective amount to impart a viscosity of at least 10 cP when the dosage form is subjected to tampering by dissolution in from 0.5 to 10 ml of an aqueous liquid;
> the controlled release matrix providing a therapeutic effect for at least 12 hours when orally administered to a human patient.

Claims 18 and 19 are similar to claim 1, except that both place functional, rather than numerical, limitations on the amount of the gelling agent needed to provide deterrence. Claim 18 requires the gelling agent in an effective amount to impart a viscosity "unsuitable for parenteral administration," and claim 19 requires the gelling agent to be in an amount effective to impart a viscosity "unsuitable to pull into an insulin syringe." '376 patent, claims 18–19.

Amneal Pharmaceuticals LLC ("Amneal") filed two petitions for *inter partes* review of claims 1–13 and 16–19 of the '376 patent. In the first petition, Amneal argued that claims 1–13 and 16–19 were unpatentable for obviousness on two grounds: (1) the combination of WO 99/32120 ("Palermo"), Pub. No. US 2002/0187192 A1 ("Joshi"), and the Handbook of Pharmaceutical Excipients by Kibbe (3d ed. 2000) ("the Handbook"); and (2) the combination of U.S. Patent No. 5,508,042 ("Oshlack"), Joshi, the Handbook, and U.S. Patent No. 5,283,065 ("Doyon"). In the second petition, Amneal argued that claims 1–13 and 16–19 were unpatentable as obvious on a third ground: the combination of U.S. Patent No. 5,273,758 ("Royce"), WO 97/49384 ("McGinity"), U.S. Patent No. 4,070,494 ("Hoffmeister"), Joshi, and the entry for OxyContin in the 1999 edition of

the Physician's Desk Reference ("PDR"). The Board granted the petitions on all three grounds.

Prior to reaching the merits in both proceedings, the Board addressed Joshi's status as prior art. Joshi was published on December 12, 2002, based on an application filed on August 30, 2001; it claims priority to a provisional application filed on April 30, 2001. In the petitions for *inter partes* review, Amneal asserted that Joshi qualifies as prior art under 35 U.S.C. § 102(e). Purdue responded that Joshi does not qualify as 102(e) prior art for two reasons: (1) the '376 patent is entitled to an earlier filing date based on the '534 application, filed on August 6, 2001, whereas Joshi is not entitled to its provisional filing date of April 30, 2001, and (2) even if Joshi is entitled to priority based on its provisional filing date of April 30, 2001, the '376 patent has an earlier invention date.

Amneal contended that Purdue was collaterally estopped from relitigating Joshi's availability as prior art based on the final judgment in a district court case regarding U.S. Patent No. 8,337,888 ("the '888 patent"), which derived from the same provisional application as the '376 patent. In that litigation, the court relied on Joshi to invalidate claims of the '888 patent. In addition, Amneal asserted that Purdue failed to carry its burden of establishing earlier conception and diligence in reducing the claimed invention to practice prior to Joshi's priority date.

The Board held that Purdue was collaterally estopped from challenging Joshi's status as prior art. The Board recognized that Purdue has never previously argued that Joshi did not qualify as prior art. However, the Board concluded that collateral estoppel "applies to 'issues that were or could have been raised,'" J.A. 18, 61, and that Purdue could have challenged Joshi's status as prior art in the district court proceeding regarding the '888 patent, but did not.

The Board further held that, even if collateral estoppel did not apply to the issue of Joshi's priority, Joshi qualifies as prior art under section 102(e) because Purdue failed to satisfy its burden of production to show that the '376 patent is entitled to a filing date earlier than August 6, 2002. The Board explained that the claims of the '376 patent do not have written description support in either the '534 provisional or a draft of the patent application dated April 25, 2001. According to the Board, both the '534 provisional and the draft application merely include "laundry list" disclosures of possible gelling agents, in which "[HPMC] . . . [PEO] . . . and mixtures thereof" are among a large number of other possible gelling agents. *Id.* at 21, 64. Neither document "specifically named or mentioned the combination in any manner." *Id.* at 22, 65. Additionally, the Board found that "the inventors of the '376 patent had not conceived of or reduced to practice the claimed formulation prior to Joshi's August 30, 2001 filing date." *Id.*

The Board also addressed whether Joshi was entitled to the earlier filing date of its provisional application. The Board concluded that Amneal had failed to show "that Joshi is entitled to an earlier filing date by comparing the claims of Joshi to the '509 provisional." *Id.* at 19 n.9, 62 n.8. Yet even without the benefit of the filing date of Joshi's provisional application, the Board found that the August 30, 2001, filing date of Joshi's non-provisional application still pre-dated the '376 patent's August 6, 2002, priority date.

On the merits, the Board found Purdue's arguments—*inter alia*, that the prior art merely discussed PEO and HPMC in laundry list disclosures, and that drug release from HPMC matrix formulations was dependent on temperature, pH, and the active pharmaceutical ingredient—to be unavailing. According to the Board, the prior art taught that HPMC, PEO, and a combination of the two may be used as gelling agents to deter drug abuse, and an experienced formulator would have "taken into account the

factors that could affect drug release from a matrix when formulating an abuse-deterrent, extended release dosage form for oxycodone." *Id.* at 28–29, 75. The Board therefore held that the '376 patent is unpatentable for obviousness on all three instituted grounds.

II

On appeal, Purdue challenges the Board's conclusion that Joshi qualifies as prior art (though not arguing prior inventorship). Purdue contends that the Board improperly invoked collateral estoppel, and that the claims of the '376 patent have written description support in the '534 provisional application. Purdue also challenges the Board's conclusion that claims 1–13 and 16–19 of the '376 patent are unpatentable as obvious. It argues that a person of ordinary skill would have lacked motivation to combine HPMC and PEO in an abuse-deterrent, extended release oxycodone formulation, and would have lacked a reasonable expectation of success in doing so. Amneal did not appear in this court, so the Director of the PTO intervened to defend the Board's decision. The Director supports the Board's rulings on all issues but one: the Director submits that the Board relied on an incorrect reading of *Dynamic Drinkware, LLC v. National Graphics, Inc.*, 800 F.3d 1375 (Fed. Cir. 2015), to hold that Joshi was not entitled to an earlier filing date. In the Director's view, however, that issue does not affect the Board's ultimate conclusion.

A

Purdue challenges the Board's invocation of collateral estoppel on two grounds: that the issue of Joshi's priority was not actually litigated in the district court case involving the '888 patent, and that the priority issues regarding the '888 patent are not identical to the priority issues for the '376 patent. We agree with Purdue that the issue of Joshi's priority was not actually litigated in the district court case involving the '888 patent, and therefore do not

address whether the priority issues regarding the '888 patent are identical to the priority issues for the '376 patent.

The Restatement (Second) of Judgments (1982) has guided this Court's application of the principles of collateral estoppel. *See Voter Verified, Inc. v. Election Sys. & Software LLC*, 887 F.3d 1376, 1383 (Fed. Cir. 2018); *Jackson Jordan, Inc. v. Plasser Am. Corp.*, 747 F.2d 1567, 1575–76 (Fed. Cir. 1984) (citing cases); *see also Arizona v. California*, 530 U.S. 392, 414 (2000). Regarding the determination of whether an issue is actually litigated, comment e of section 27 of the Restatement states that "[a] judgment is not conclusive in a subsequent action as to issues which might have been but were not litigated and determined in the prior action." *See Voter Verified,* 887 F.3d at 1383. The Restatement further explains that

> [a]n issue is not actually litigated if the defendant might have interposed it as an affirmative defense but failed to do so . . . if it is raised by a material allegation of a party's pleading but is admitted (explicitly or by virtue of a failure to deny) in a responsive pleading . . . if it is a stipulation between the parties. . . . In the case of a judgment entered by confession, consent, or default, none of the issues is actually litigated.

Restatement (Second) of Judgments § 27, cmt. e.

The issue of Joshi's priority was not actually litigated in the district court proceeding. The district court stated that "the parties did not stipulate that the Joshi publication qualifies as prior art to the '888 patent." *In re: OxyContin Antitrust Litig.*, No. 04-MD-1603 (SHS), 2015 WL 11217239, at *24 n.11 (S.D.N.Y. Apr. 8, 2015). And the Board acknowledged that Purdue "has never previously argued that Joshi did not qualify as prior art." J.A. 18, 60. The requirement that the issue be actually litigated was therefore not met.

The Board based its collateral estoppel ruling on the notion that "collateral estoppel applies to 'issues that were or *could have been raised*' in the prior litigation." That statement, however, conflates the principles of collateral estoppel and res judicata. *See Allen v. McCurry*, 449 U.S. 90, 94 (1980) ("Under res judicata, a final judgment on the merits of an action precludes the parties or their privies from relitigating issues that were or could have been raised in that action. Under collateral estoppel, once a court has decided an issue of fact or law necessary to its judgment, that decision may preclude relitigation of the issue in a suit on a different cause of action involving a party to the first case.").

The Director makes several arguments in support of the Board's collateral estoppel ruling. First, according to the Director, Purdue did not distinguish between the Joshi provisional and non-provisional applications in its appeal from the district court to the Federal Circuit. Based on that fact, the Director contends that Purdue implicitly admitted that the disclosures in Joshi and its provisional application are interchangeable, and that Joshi is entitled to the benefit of the provisional application's priority date.

The Director also argues that Purdue responded to Amneal's obviousness challenge by submitting evidence and argument about the relevant teachings of Joshi and its provisional application. Therefore, the Director argues, "[t]he fact that Purdue did not directly challenge the sub-issue of Joshi's entitlement to its provisional's filing date does not mean that the issue was not actually litigated – it was an essential part of Amneal's case." Director's Br. 32.

The Director's arguments are unavailing. There is no support for the proposition that failing to distinguish between a provisional and non-provisional application, without more, indicates that Joshi's priority date was actually litigated. Nor does the fact that Joshi's priority date might have been a potentially important question in the earlier

litigation mean that it was actually litigated. The priority date for the Joshi reference therefore cannot be determined based on collateral estoppel.

B

In light of our disposition of the collateral estoppel issue, it is important to determine whether the '376 patent is entitled to priority to the filing date of its provisional application. "For a patent to claim priority from the filing date of its provisional application, it must satisfy 35 U.S.C. § 119(e)(1) (2006)." *Dynamic Drinkware*, 800 F.3d at 1378. Accordingly, we have made clear that under section 119(e)(1),

> the specification of the *provisional* must 'contain a written description of the invention and the manner and process of making and using it, in such full, clear, concise, and exact terms,' 35 U.S.C. § 112 ¶ 1, to enable an ordinarily skilled artisan to practice the invention *claimed* in the *non-provisional* application.

New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co., 298 F.3d 1290, 1294 (Fed. Cir. 2002); *see Dynamic Drinkware*, 800 F.3d at 1378.

Purdue argues that the '534 provisional application satisfies the written description requirement as to the '376 claims. It points to the following disclosure in the '534 provisional as supporting the claimed dosage forms:

> In certain embodiments of the present invention wherein the dosage form includes an aversive agent comprising a gelling agent, various gelling agents can be employed including, for example and without limitation, sugars or sugar derived alcohols, such as mannitol, sorbitol, and the like, starch and starch derivatives, cellulose derivatives, such as microcrystalline cellulose, sodium carboxymethyl cellulose, methylcellulose, ethyl cellulose,

> hydroxyethyl cellulose, hydroxypropyl cellulose, and [HPMC], attapulgites, bentonites, dextrins, alginates, carrageenan, gum tragacanth, gum acacia, guar gum, xanthan gum, pectin, gelatin, kaolin, lecithin, magnesium aluminum silicate, the carbomers and carbopols, polyvinylpyrrolidone, polyethylene glycol, [PEO], polyvinyl alcohol, silicon dioxide, surfactants, mixed surfactant/wetting agent systems, emulsifiers, other polymeric materials, and mixtures thereof, etc. In certain preferred embodiments, the gelling agent is xanthan gum. In other preferred embodiments, the gelling agent of the present invention is pectin.

'534 application, at 10. Purdue's expert, Dr. Stephen Byrn, relied on that disclosure to conclude that the '534 specification discloses the HPMC and PEO gelling agent claim element of the '376 patent. Purdue contends that Dr. Byrn's testimony was entirely unrebutted by Amneal. In addition, Purdue highlights other portions of the '534 application that discuss HPMC and PEO as components in preferred embodiments of the invention, though never in combination.

The Director argues that the disclosure from the '534 application quoted above does not reasonably convey to an ordinary artisan that the inventor had possession of oxycodone dosage forms containing mixtures of PEO and HPMC. Additionally, the Director argues that Purdue never cited the other portions of the '534 application disclosures to the Board, and thus waived reliance on them.

This Court has recognized that "simply describing a large genus of compounds is not sufficient to satisfy the written description requirement as to particular species or sub-genuses." *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571 (Fed. Cir. 1996); *see In re Ruschig*, 379 F.2d 990, 994–95 (CCPA 1967). In the '534 application disclosure, PEO and HPMC are merely two of many undifferentiated

compounds that fall within the genus of gelling agents. Such "laundry list" disclosures do not provide adequate specificity to constitute written description support for Purdue's claim of priority. To be sure, the language "mixtures thereof" suggests the possibility of combining two or more of the listed gelling agents. Without more, however, that language fails to highlight any preference for how many and which gelling agents to combine.

The expert testimony on which Purdue relies does not compel a different conclusion. Purdue's expert, Dr. Byrn, failed to identify any rationale to distinguish PEO and HPMC from the other listed gelling agents. Instead, Dr. Byrn merely stated that "each element of the inventions in claims 1–13 and 16–19 of the '376 patent can be found in the '534 provisional application," and cited the laundry list disclosure quoted above. J.A. 2907–09. That undeveloped, conclusory evidence does not undermine the Board's finding on this issue. *See SkinMedica, Inc. v. Histogen Inc.*, 727 F.3d 1187, 1210 (Fed. Cir. 2013).

As for Purdue's argument that Amneal's expert failed to rebut Dr. Byrn's testimony, Purdue never met its burden to show that the '376 patent is entitled to claim the benefit of the '534 application's filing date. It was therefore not necessary for Amneal to offer expert evidence to the contrary. *See Dynamic Drinkware*, 800 F.3d at 1379 (stating that once the petitioner meets its initial burden of going forward with evidence that there is anticipating prior art, the patent owner has "the burden of going forward with evidence either that the prior art does not actually anticipate, or . . . that it is not prior art because the asserted claim is entitled to the benefit of a filing date prior to the alleged prior art." (quoting *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008))).

Purdue argues that the declaration of Amneal's expert, Dr. Robert J. Timko, affirmatively supports Purdue's position on priority. Dr. Timko acknowledged that the '376

patent "claims priority to its own provisional application filed on August 6, 2001." J.A. 4332. Purdue characterizes that statement as an acknowledgment that the '376 patent has written description support in the '534 provisional. We disagree. Dr. Timko's statement that the patent "claims priority" to its provisional application merely acknowledges that the patent asserts priority as of that date; it does not constitute an agreement or concession that the claimed priority date is accurate.

Finally, we agree with the Director that Purdue waived its arguments relying on the additional disclosures of the '534 application. *See In re Baxter Int'l, Inc.*, 678 F.3d 1357, 1362 (Fed. Cir. 2012) ("Absent exceptional circumstances, we generally do not consider arguments that the applicant failed to present to the Board."). Even if Purdue's arguments were considered, they would not change the result. The additional references to PEO and HPMC throughout the provisional application do not constitute "blaze marks" that indicate or direct that a particular combination should be made "rather than any of the many others which could also be made." *In re Ruschig*, 379 F.2d at 995.

Accordingly, the court finds that substantial evidence supports the Board's conclusion that the claims of the '376 patent do not have written description support in the '534 provisional application.

C

On appeal, Purdue's argument that Joshi does not qualify as prior art is based entirely on its contention that the claims of the '376 patent have written description support in the '534 provisional. Purdue does not challenge the Board's findings that claims of the '376 patent are not supported by the draft of the patent application dated April 25, 2001, or that the inventors of the '376 patent did not conceive of or reduce to practice the claimed formulation prior to Joshi's August 30, 2001, filing date. Therefore, given our conclusion that the claims of the '376 patent do not have

written description support in the '534 provisional, we hold that Joshi qualifies as prior art and that the Board permissibly relied on Joshi in all three grounds of the Board's obviousness analysis.[1]

III

As stated above, the Board found claims 1–13 and 16–19 of the '376 patent unpatentable as obvious on three grounds. We focus on ground 3, and conclude that the Board's finding that the '376 patent would have been obvious over Royce, McGinity, Hoffmeister, Joshi, and the PDR is supported by substantial evidence.

As the Board explained, Royce teaches a sustained release formulation that includes both PEO and HPMC. Royce also suggests that sustained release dosage formulations may be used for analgesics, a category of drug that includes oxycodone. McGinity teaches controlled release dosage forms of analgesics. Hoffmeister and Joshi teach that HPMC and PEO are gelling agents that may be used in an abuse-deterrent formulation. And the PDR teaches extended release oxycodone formulations in doses of 10 mg, 20 mg, 40 mg, and 80 mg. Purdue makes a series of arguments challenging the Board's obviousness determination. The Court finds each argument unconvincing.

First, Purdue challenges the Board's finding of a motivation to combine the cited references. Purdue argues that the Board impermissibly cherry-picked PEO and HPMC from lists of ingredients in prior art. Example 2 in Royce, however, expressly discloses sustained release dosage forms comprising PEO and HPMC. Example 2's disclosure of a combination of PEO and HPMC as gelling agents

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[1] Our decision on this issue renders moot the Director's contention that the Board relied on an incorrect reading of *Dynamic Drinkware* to conclude that Joshi was not entitled to an earlier filing date.

contradicts Purdue's argument that Royce emphasizes sustained release dosage forms using PEO only, and that Royce merely discusses HPMC as an optional component: HMPC is not an optional component in the example 2 formulation. Purdue points out that example 2 of Royce was for a placebo, and that the only example in Royce that shows an extended release profile for a drug product uses PEO alone. While that is true, nothing in Royce suggests that PEO-based tablets, as compared to tablets containing PEO and HPMC, are preferred in sustained release dosage formulations.

Second, Purdue argues that the Board asked whether an artisan *could have* combined HPMC and PEO, rather than whether an artisan *would have* done so. According to Purdue, "[b]y choosing HPMC or PEO from laundry lists of possibly ingredients, without direction from the reference themselves . . . the Board improperly focused on what was possible for an ordinary artisan, and not what an ordinary artisan would have been motivated to choose." Appellants' Br. 47. Because Royce successfully combined HPMC and PEO, however, that argument fails. Nor do we agree with Purdue that the Board used the wrong legal standard for assessing the motivation to combine. Purdue criticizes the Board for stating that a skilled artisan "would have therefore understood that oxycodone hydrochloride could also be included among the possible drugs in the sustained release formulation." J.A. 71. Nothing in that statement, however, reflects a misunderstanding of the proper standard.

Third, Purdue argues that the prior art taught away from using HPMC in an abuse-deterrent, extended release formulation in three ways. According to Purdue, the prior art taught that heating an aqueous solution of HPMC decreases its viscosity, and that HPMC's abuse-deterrent gelling effects would be rendered ineffective by a typical method of drug abuse (i.e., heating the dosage form). Next, Purdue argues that the prior art taught that HPMC improves the absorption of drugs through the nasal tissue,

and thus would not deter nasal abuse. Last, Purdue characterizes the prior art as suggesting that HPMC would not reliably release oxycodone over an extended period of time.

As the Board found, Dr. Timko offered undisputed testimony that refutes Purdue's teaching away arguments.[2] *See id.* at 75. Dr. Timko stated that "[t]he references Purdue cites are publications teaching that HPMC was, in fact, a well-known gelling agent for use in a matrix dosage form and any potential interactions could be easily addressed." *Id.* at 4343. According to Dr. Timko, "[a]n experienced formulator, at the time of the invention, would be aware of all of these things and would formulate their dosage form accordingly." *Id.*

Fourth, Purdue argues that the science of abuse-deterrent extended release oxycodone formulations was so unpredictable that there was no expectation of success for the claimed dosage forms. According to Purdue: (1) the gelling agents were generally unpredictable in extended release pharmaceutical formulations, (2) none of the prior art

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[2] Purdue argues that Dr. Timko's testimony was not undisputed. According to Purdue, the Board ignored Dr. Byrn's declaration, which allegedly contradicted Dr. Timko's conclusions. We disagree. The Board directly addressed Dr. Byrn's declaration, finding that the "prior art references relied on by . . . Dr. Byrn merely discuss how the viscosity, gelling, and drug release properties of HPMC-based formulations may be affected by temperature and other external factors." J.A. 75. Those observations, according to the Board, failed to "suggest that HPMC should not be used in a drug formulation for those reasons." *Id.* Dr. Byrn did not contradict Dr. Timko's testimony that an experienced formulator could easily address the effects of external factors on the HPMC-based formulation. *See id.* at 2929–30. Thus, we conclude that Dr. Timko's testimony on that point was undisputed.

contained relevant data on the rate of drug release from HPMC-PEO formulations, and (3) the Bastin prior art reference (WO 95/20947) reinforced the understanding that gelling agents would lead to unpredictable rates of drug release.

All three of those arguments fail. As to the first argument, Royce demonstrated the success of a mixture of PEO and HPMC in controlled-release oral dosage forms.

As to the second argument, the challenged claims of the '376 patent do not require any particular dissolution profile or release rate for the drug. Therefore, while the prior art does not contain data on the rate of drug release from the HPMC-PEO formulations, the Court finds it sufficient that the prior art suggests a reasonable probability of success based on controlled release formulations using PEO. *See Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007) ("[The] case law is clear that obviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonably probability of success."); *see also* J.A. 838 (Royce depicts a controlled release profile of clemastine fumarate using PEO, over a period of 18 hours).

As to the third argument, the Bastin prior art reference merely suggests that gelling agents would pose a problem for immediate release formulations. *See* J.A. 545 ("[T]he gelling agent in a single layer with the drug substance causes a serious retardation of release"). It does not, however, suggest that gelling agents were unpredictable for sustained release formulations. *See In re: OxyContin Antitrust Litig.*, 2015 WL 11217239, at *26 ("Placed in its proper context, Bastin provides very little support to Purdue. Bastin expressed concern about gelling agents' effect on drug release only with respect to *immediate release* formulations, for which delay poses a serious problem. By drawing an explicit comparison between gelling agents and the swelling properties of rate controlling high molecular

weight polymers, Bastin in fact implies that gelling agents are well-suited to controlled release dosage forms."). The Board's finding that the prior art provided a reasonable expectation of success is thus supported by substantial evidence.

IV

We affirm the Board's determination that claims 1–13 and 16–19 of the '376 patent are unpatentable for obviousness.

Each party shall bear its own costs for these appeals.

AFFIRMED