Nos. 18-1710, 18-1711

United States Court of Appeals for the Federal Circuit

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

Appellants,

v.

ANDREI IANCU, *Director, U.S. Patent and Trademark Office,*

Intervenor.

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR 2016-01412 and IPR 2016-01413

APPELLANTS' COMBINED PETITION FOR PANEL REHEARING AND REHEARING EN BANC

JOHN J. NORMILE
GASPER J. LAROSA
JONES DAY
250 Vesey Street
New York, NY 10281
(212) 326-3939
jjnormile@jonesday.com

GREGORY A. CASTANIAS
JENNIFER L. SWIZE
ROBERT STANDER
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001
(202) 879-3939
gcastanias@jonesday.com

Counsel for Appellants

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Purdue Pharma L.P. et al. v. Iancu

Case Nos. 18-1710; -1711

CERTIFICATE OF INTEREST

Counsel for the:
☐ (petitioner) ☒ (appellants) ☐ (respondent) ☐ (appellee) ☐ (amicus) ☐ (name of party)

Purdue Pharma L.P.; The P.F. Laboratories, Inc.; and Purdue Pharmaceuticals L.P. certifies the following:

1. Full Name of Party Represented by me	2. Name of party in interest represented by me is:	3. Parent corporations and publicly held companies that own 10% or more of stock in the party
Purdue Pharma L.P.	Purdue Pharma L.P.	None
The P.F. Laboratories, Inc.	The P.F. Laboratories, Inc.	None
Purdue Pharmaceuticals L.P.	Purdue Pharmaceuticals L.P.	None

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court (and who have not or will not enter an appearance in this case) are:

JONES DAY: Pablo D. Hendler; Kelsey I. Nix; Kenneth S. Canfield; Sarah A. Geers; Lisamarie LoGiudice

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. *See* Fed. Cir. R. 47.4(a)(5) and 47.5(b).

None.

July 18, 2019
Date

/s/ Gregory A. Castanias
Signature of counsel

Gregory A. Castanias
Printed name of counsel

cc: Counsel of record via CM/ECF

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STATEMENT OF COUNSEL

Based on my professional judgment, I believe the panel decision conflicts with this Court's precedent on priority disputes, *see Dynamic Drinkware, LLC v. National Graphics, Inc.*, 800 F.3d 1375 (Fed. Cir. 2015); *Technology Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316 (Fed. Cir. 2008), and with 35 U.S.C. § 112 and written-description precedent, *e.g.*, *Snitzer v. Etzel*, 465 F.2d 899 (C.C.P.A. 1972).

Based on my professional judgment, I believe this appeal requires an answer to a precedent-setting question of exceptional importance: Where a patent challenger does not dispute that the patent is entitled to a particular priority date, does the patentee nonetheless bear the burden to affirmatively prove entitlement to that date?

/s/ Jennifer L. Swize, Counsel for Appellants

INTRODUCTION

Appellants (collectively "Purdue") request rehearing, whether by the panel or en banc, on important issues regarding priority dates of challenged patents pursuant to 35 U.S.C. § 119 (and its counterpart in § 120).

I. Under longstanding law that places the burden of unpatentability/invalidity on the patent challenger, a patentee bears no burden—of production or persuasion—to prove its patent's entitlement to a priority date that

the challenger does not dispute. The panel erroneously concluded otherwise, misapplying this Court's precedent in *Dynamic Drinkware* and *Technology Licensing*.

In *Dynamic Drinkware* and *Technology Licensing*, each patent challenger asserted art that, in the challenger's view, was prior to the claims-at-issue, and each patentee disagreed, claiming entitlement to an earlier priority date that would pre-date the asserted art. In that scenario—*i.e.*, where the patentee raises an earlier date for its patent than the challenger does—the Court held that the patentee bears a burden of production; it must come forward with evidence supporting entitlement to its claimed earlier priority date.

Dynamic Drinkware and *Technology Licensing* do not place an affirmative burden on the patentee to prove entitlement to the later, uncontested priority date. The burden of production shifts to the patentee only as to those issues put in dispute by the challenger, or new issues that the patentee seeks to raise in defense to the challenger's arguments. The burden cannot "shift" if the date is not in dispute.

Yet, the panel held that "*Purdue* never met *its* burden" regarding entitlement to the *uncontested* date. (Op.11 (emphasis added).) That misapprehends *Dynamic Drinkware* and *Technology Licensing*, and warrants clarification. The burden-

shifting framework of those cases is inapplicable in circumstances like here, and the panel's upending of the burden violates fundamental notions of patent law.

II. Purdue is, in fact, entitled to the uncontested date—the filing date of its provisional application. The panel's contrary conclusion contradicts § 112 and this Court's precedent on "laundry lists" and "blaze marks." Accordingly, even if Purdue does bear a burden to prove entitlement to the uncontested date, rehearing is warranted on the written-description issue.

BACKGROUND

Amneal's petitions. In July 2016, Amneal filed two petitions for IPR review of claims 1-13 and 16-19 ("the claims") of U.S. Patent No. 9,034,376 ("the '376 patent"), asserting three grounds of obviousness. (Appx91, Appx5405.) The claims are directed to extended-release, abuse-deterrent oxycodone formulations that achieve abuse deterrence through the combination of two gelling agents: HPMC and PEO (hydroxypropylmethylcellulose and polyethylene oxide). (Appx176(3:1-39, 40:20-33).) Purdue's patent is a continuation of an application filed August 6, 2002, and claims priority to a provisional application filed August 6, 2001 ("the '534" or "Purdue's" provisional application). (Appx171, Appx998.) The provisional application lists both gelling agents by name, both in the context of about three dozen other gelling agents and by repeatedly calling out HPMC and

PEO as "preferred" or even "especially" preferred. (Appx1019-1020, Appx1031-1033; Purdue Brief "PBr." 37-38.)

Purdue's undisputed August 6, 2001 priority date. In its petitions, and throughout the proceedings, Amneal did not dispute Purdue's entitlement to the benefit of the August 6, 2001 filing date, *i.e.*, Amneal did not dispute that the provisional application sufficiently describes the challenged claims. (Appx118, Appx5227(16:5-6).) Likewise, at Amneal's direction, its expert applied that date. (PBr.39; Appx4332.) Intervenor PTO agrees that Amneal never challenged the August 6, 2001 date. (Oral Arg. at 19:35-20:00 & 27:40-55 ("entitlement of the '376 to the provisional date was not raised" by Amneal).)

Joshi. One prior art reference—Joshi (US 2002/0187192)—was essential to all three grounds. (Appx7, Appx49; *see also* PBr.25; Intervenor's Br. "IBr." 11 (PTO agreeing that "each of the three combinations of prior art" that Amneal asserted and the Board analyzed "includes Joshi").) But Joshi was filed August 30, 2001, *after* the August 6, 2001 filing date of Purdue's provisional application. (Appx509.) To nonetheless use Joshi as prior art, Amneal asserted that Joshi was entitled to the benefit of its own provisional application, filed April 30, 2001. (Appx118, Appx5226.) Purdue disputed Amneal's showing in this regard; Purdue also presented evidence and argument that, in any event, it conceived and reduced

to practice the '376 invention by April 25, 2001, before Joshi's provisional application was filed. (Appx2718-2722.)

The Board's determinations. The Board concluded that Joshi was prior art as of its *August 20, 2001* date, based on a new theory that Amneal had never raised: that the '376 patent was *not* entitled to the August 6, 2001 priority date of its provisional application. (Appx18-23, Appx61-66.) Specifically, the Board concluded that the provisional application does not adequately describe the '376 invention, as required by 35 U.S.C. §§ 119(e) and 112 (pre-AIA).[1] (Appx20-22, Appx62-65.) Using Joshi for all three grounds, the Board held the claims unpatentable. (Appx40, Appx83.)

Appeal. Joshi's status as prior art was the central issue on appeal. The panel upheld the Board's determination to evaluate whether the '376 patent is entitled to the benefit of the August 6, 2001 filing date of its provisional application. (Op.9-12.) In response to Purdue's argument that Amneal had never challenged that date or the sufficiency of the provisional application in describing the claims, the panel

[1] The Board also applied issue preclusion against Purdue, but the panel (correctly) overturned the Board on that issue. (Op.6-8.)

As for the dates that were actually in dispute—*i.e.*, Amneal's argument that Joshi was entitled to the benefit of its provisional application's April 30, 2001 filing date, and Purdue's argument that it was entitled to an April 25, 2001 conception date—the Board rejected both, and they are not at issue in this petition. (Appx19 n.9, Appx22-23.)

erroneously flipped the burden from Amneal to Purdue. The panel stated that "Purdue never met its burden to show that the '376 patent is entitled to claim the benefit of the '534 application's filing date," and "[i]t was therefore not necessary for Amneal to offer expert evidence to the contrary." (Op.11.) The panel further concluded that "Purdue waived its arguments relying on the additional disclosures of the '534 application" by not presenting those disclosures to the Board. (Op.12.) The panel did not explain why Purdue bore the burden of presenting additional disclosures when Amneal had not contested the August 6, 2001 priority date. (*Id.*)

The panel also upheld the Board's determination that the patent lacked written-description support in the provisional application. According to the panel, Purdue's provisional application lists HPMC and PEO as "merely two of many undifferentiated compounds that fall within the genus of gelling agents," and "[s]uch 'laundry list' disclosures do not provide adequate specificity." (Op.10-11.) The panel also stated that the "additional references to PEO and HPMC throughout the provisional application do not constitute 'blaze marks'" sufficient to describe the combination of HPMC and PEO (Op.12), but the panel offered no reasoning.

With Joshi as prior art, the panel affirmed the Board's obviousness determinations. (Op.13-17.)

Purdue appealed. Amneal declined to participate, and the PTO intervened.

ARGUMENT

I. Rehearing is warranted because the panel misapplied *Dynamic Drinkware* and *Technology Licensing*. That precedent does not shift any burden to the patentee for a priority date that the patent challenger never disputes. The panel opinion upends the burden on patent challengers, and invites needless evidence and briefing about undisputed issues.

II. Rehearing is also warranted because the panel misapplied the written-description requirement. The provisional application's disclosures of the claimed HPMC-PEO combination, and repeatedly calling out those ingredients as particularly important, provide sufficient written-description support. The panel opinion's dismissal of a purported "laundry list," and its demand for even more "blaze marks," do not comport with § 112 or precedent.

I. THE PANEL OPINION CONFLICTS WITH PRECEDENT ON THE BURDEN-SHIFTING FRAMEWORK FOR PRIORITY DISPUTES

A. *Dynamic Drinkware* And *Technology Licensing* Are Limited To A Patent's Priority Dates *In Dispute*

For patent challenges under §§ 102 and 103, this Court has articulated a burden-shifting framework for resolving priority disputes between a patent and an asserted prior-art reference. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375 (Fed. Cir. 2015); *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316 (Fed. Cir. 2006)). The patent challenger always bears the initial burden of *production* and the ultimate burden of *persuasion*. *Dynamic Drinkware*, 800 F.3d

at 1378. To meet its burden of production, the challenger must "introduce[] sufficient evidence to put at issue whether there is prior art … dated earlier than the apparent effective date" of the challenged patent. *Tech. Licensing*, 545 F.3d at 1329. The patentee must then respond, bearing the burden to move forward with argument or evidence that the prior art does not render the claims anticipated or obvious, or that the asserted art is not, in fact, prior art. *Dynamic Drinkware*, 800 F.3d at 1380. Finally, the burden shifts back to the challenger, to ultimately "prove" that the asserted references have priority over the challenged patent and render the patent unpatentable/invalid. *Id.*

The burden of production does not shift to the patentee for all conceivable priority issues. The burden shifts only for (1) questions the challenger affirmatively puts "at issue" by satisfying its burden of production, *Tech. Licensing*, 545 F.3d at 1329, and (2) new issues the patentee seeks to introduce, "effectively [as] an affirmative defense." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1376 (Fed. Cir. 2016). For example, the burden would shift to the patentee to prove an earlier date of conception, or to prove entitlement to a provisional filing date *before the date adopted by the challenger* (for instance, if the challenger relies on the filing date of the patent itself). "In such a case, the shifting of the burden of production is warranted because the patentee affirmatively seeks to establish a proposition not relied on by the patent challenger and not a

necessary predicate for the unpatentability claim asserted—effectively an affirmative defense." *Id.*

The burden does *not* shift to establish entitlement to a provisional application, however, when the challenger does not dispute the applicability of that priority date. In that circumstance, burden-shifting is unjustified because the challenger has not put the provisional application's filing date "at issue," *Tech. Licensing*, 545 F.3d at 1329, and the patentee is not introducing the provisional application "effectively [as] an affirmative defense," *Magnum Oil*, 829 F.3d at 1376; *accord Dynamic Drinkware*, 800 F.3d at 1381 (patentee does "not have the burden of producing evidence" on an issue "*until after*" the challenger has specifically placed that issue in dispute) (emphasis added)). In other words, when there is no dispute between the parties as to whether the challenged patent is entitled to the benefit of a provisional application, the shifting burden of production is simply inapplicable.

B. The Panel Misapplied *Dynamic Drinkware* And *Technology Licensing*

Contrary to these premises and precedent, the panel placed a burden on Purdue to affirmatively prove entitlement to its August 6, 2001 priority date, even though that date was not in dispute. The panel's error permeates its decision.

The panel began by stating that it was "important to determine whether the '376 patent is entitled to" the August 6, 2001 date, and held that "Purdue never

met its burden" on that issue. (Op.9, 11.) In reaching that conclusion, the panel repeatedly demanded evidence and argument from Purdue, and excused Amneal from any burden. (Op.9-11 (examining what "*Purdue* argue[d]," what "*Purdue's* expert" offered, what "*Purdue* contend[ed]," and what "*Purdue* highlight[ed]"; finding it "not necessary for Amneal to offer" contrary evidence (emphasis added).) The panel further held that "Purdue waived its arguments relying on the additional disclosures of the '534 application" that were not detailed before the Board (because Amneal had not raised the issue). (Op.12.)

There is, however, nothing "important" about an issue that is not contested, nor was there any basis for placing a burden on Purdue to affirmatively prove up an uncontested issue, or for finding "waiver" of an uncontested issue. One cannot "waive" or forfeit a non-existent right or obligation. It was, instead, *Amneal* that waived the issue. In short, because Amneal never "put at issue" the August 6, 2001 priority date, *Tech. Licensing*, 545 F.3d at 1329, Purdue had no need (or notice) to use the provisional application's filing date as an "affirmative defense," *Magnum Oil*, 829 F.3d at 1376, and the panel should not have shifted the burden to Purdue as to that issue.

To be clear, the burden did shift to Purdue to prove an earlier date of conception, because in that instance Purdue sought priority to April 25, 2001—*before* the August 6, 2001 date Amneal used. (Appx2719-2722.) The burden also

shifted to Purdue to refute Amneal's arguments regarding whether the prior-art combinations rendered the claims obvious. But because Amneal's chosen baseline for its unpatentability arguments was an August 6, 2001 priority date, the burden did not shift to Purdue to affirmatively prove entitlement to that date.

C. Imposing An Affirmative Obligation To Establish An Undisputed Priority Date Also Contradicts Basic Principles Of Patent Law And Fair Process

The panel's contrary rule distorts the burden-shifting framework and conflicts with patent law more broadly.

First, the panel's ruling effectively creates a presumption that a patent is not entitled to the benefit of its provisional application. That places on the patentee an initial burden to prove entitlement. This conflicts with, *e.g.*, *Dynamic Drinkware*'s holding that the patent challenger—not the patentee—bears both the initial burden of production *and* the ultimate burden of persuasion. 800 F.3d at 1378.

Second, the panel's rule would also improperly shift the burden of *persuasion* to the patentee. Consider the sequence of events here. Although Amneal bore the initial burden of production and the ultimate burden of persuasion, Amneal never disputed the August 6, 2001 date, and certainly presented no contrary evidence. Meanwhile, the panel (and the Board) faulted *Purdue* for having "never met its burden to show that the '376 patent is entitled to" that date. (Op.11.) Thus, the only party on whom the Board imposed any burden

was Purdue—contrary to the bedrock principle (observed in *Dynamic Drinkware* and *Technology Licensing*) that the patent challenger always bears the ultimate burden of persuasion.

Third, this Court—like first-instance courts and agencies—generally does not reach issues for which there is no dispute between the parties, including in IPRs where "the petitioner's contentions, not the Director's discretion, define the scope of the litigation." *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1355 (2018); *see also, e.g.*, *Arctic Cat*, *Inc. v. GEP Power Prods., Inc.*, 919 F.3d 1320, 1332 (Fed. Cir. 2019) ("There being no dispute about conception before April 2002," the Court did not address that issue.); *Magnum Oil*, 829 F.3d at 1381 (IPRs are "still a system … in which the petitioner bears the burden of proof"; the Board cannot rely on theories "never presented by the petitioner and not supported by record evidence."). Here, the Board reached an issue that Amneal never disputed, and that Purdue therefore never had an opportunity to address. The panel then improperly used that same undisputed issue as the basis for ruling against Purdue.

Third, impracticalities alone render the panel's rule unworkable, forcing parties to flood the Board and district courts with needless evidence supporting every conceivable priority issue—even entirely undisputed issues. Patent owners relying on the filing date of an earlier patent application would be compelled to present full arguments and claim charts demonstrating written-description support.

So too for enablement, which must also be met to invoke §§ 119 or 120. *New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1294 (Fed. Cir. 2002).

* * *

Whether the panel misapprehended the limits of *Dynamic Drinkware* and *Technology Licensing*, or whether that precedent requires further clarification, the panel decision is incorrect, and rehearing is warranted. Under the correct view, the burden of production shifts only when the challenger places a patent's priority date "at issue," *Tech. Licensing*, 545 F.3d at 1329, thereby requiring the patentee to present evidence and argument in support of its preferred date, "effectively [as] an affirmative defense," *Magnum Oil*, 829 F.3d at 1376.

II. THE PANEL OPINION CONFLICTS WITH THE WRITTEN-DESCRIPTION REQUIREMENT

This petition presents a second issue: Even if the patent's entitlement to its provisional application filing date is considered (and regardless of whether Purdue bore any burden on that issue), the panel misapplied the written-description requirement. *See Dynamic Drinkware*, 800 F.3d at 1378 ("to claim priority" from a "provisional application," the application "must contain a written description of the invention"). The only issue here is whether Purdue's provisional sufficiently describes the combination of HPMC and PEO as gelling agents. It does.

The panel reached a contrary conclusion through multiple errors. At the outset, the panel never should have engaged with an issue that the petitioner

waived during the IPR. *See* Part I, above. Worse, after ignoring Amneal's waiver, the panel erroneously concluded that *Purdue* "waived" arguments showing written-description support by not raising them to the Board. (Op.12.) Given that Amneal never raised the issue—and it was Amneal's burden to do so, *see* Part I, above—it is not surprising that Purdue did not present the full panoply of evidentiary support to the Board.

Compounding these procedural errors, the panel got the merits wrong by misapplying two concepts in written-description law.

A. The Panel Misapplied This Court's Precedent On "Laundry Lists"

Purdue's provisional application lists both "hydroxypropyl methylcellulose" and "polyethylene oxide" "and mixtures thereof" as useful gelling agents. (Appx1007.) That alone is sufficient to describe the invention because it literally discloses the combination. Nonetheless, the panel stated that "PEO and HPMC are merely two of many undifferentiated compounds that fall within the genus of gelling agents," and "'laundry list' disclosures do not provide adequate specificity." (Op.10-11.)

The panel offered no citation for its rule that "laundry list" disclosures are insufficient. Nor is there any logical basis for such a rule, as there is nothing inherently problematic about listing alternative ingredients or structures. *See Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1377 (Fed. Cir. 2005) ("That

specific disclosure, even in a list, makes this case different from cases involving disclosure of a broad genus without reference to the potentially anticipating species."); *In re Driscoll*, 562 F.2d 1245, 1249 (C.C.P.A. 1977) (listing claimed combination among several possibilities was sufficient).

The panel apparently relied on dicta from *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571 (Fed. Cir. 1996), that a "'laundry list' disclosure of every possible moiety for every possible position" is insufficient to describe every species in a genus of chemical compounds. The panel erred in turning stray language from one case into a fixed rule against lists of alternative ingredients.

Even if there is some limit to "laundry list" disclosures, there is no bright-line test, and the '534 specification is not even arguably close to such categorization. Where a "laundry list" disclosure would not provide adequate description for a specific claimed embodiment, the embodiment has had multiple parameters, each with nearly limitless possible options. Thus, in *Fujikawa*, the disclosure of "every possible moiety for every possible position" would require an artisan to sift through every permutation of moieties at seven different positions on a carbon ring to understand that the inventor had possession of the claimed species. 93 F.3d at 1570-71.

Purdue's short list of gelling agents is nothing like *Fujikawa*'s essentially limitless lists and permutations. Purdue's specification lists HPMC and PEO

among a relatively short list of gelling agents that can be used as "mixtures thereof." (Appx1007.)

Moreover, as in *Driscoll* and unlike *Fujikawa*, the specification specifies that each listed agent performs the same function, so "regardless of which of the alternatives is substituted …, the compound as a whole will exhibit the disclosed utility." *Driscoll*, 562 F.2d at 1249. The list of the same type of ingredient—all gelling agents—would reasonably inform an artisan that each gelling agent or combinations thereof could be used to practice the invention. It is impractical to require recitation of every possible combination of similarly-functioning ingredients in order to express that understanding.

B. The Panel Misapplied This Court's Precedent on "Blaze Marks"

Besides, the specification discloses more; it repeatedly identifies both HPMC and PEO as "preferred" or "especially" preferred. (Appx1019-1020, Appx1031-1033; *see* PBr.38; ReplyBr.12, 14.) Nonetheless, the panel stated, in one sentence, that all 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." (Op.10, 12 (citing *Fujikawa*, 93 F.3d at 1571, and *In re Ruschig*, 379 F.2d 990 (C.C.P.A. 1967).) This misapprehends *Fujikawa* and *Ruschig*.

The additional references to PEO and HPMC are sufficient to meet the "blaze marks" requirement. Those references easily allow an artisan to "visualize" the invention and "recognize what is claimed." *Univ. of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 923 (Fed. Cir. 2004). As Purdue's expert testified, "each element" of the claims "can be found in the '534 provisional application." (Appx2907.) The panel failed to provide any reason why a dozen references to HPMC and PEO—including identifying them as preferred or especially preferred—are insufficient. Nor did it cite any case with facts anywhere close to this.

In applying *Ruschig* and *Fujikawa* as it did, the panel appears to have improperly applied a "blaze marks" inquiry that pertains to, unlike here, species claims that are not in fact disclosed in the specification. As this Court recently described *Ruschig*, the specification there "disclosed only a generic structure," so considerable "blaze marks" were required. *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1346 (Fed. Cir. 2013). Likewise in *Fujikawa*, the Court required blaze marks because there was no disclosure specific to the claim. 93 F.3d at 1571.

But where the specification discloses a "literal description" of the invention, that is enough; no further "blaze marks" are needed. *Novozymes*, 723 F.3d at 1347; *accord In re Wako Pure Chem. Indus. Ltd.*, 4 F. App'x 853, 857 (Fed. Cir. 2001)

(sufficient description "where the exact subgenus claimed is clearly discernible in the generalized formula"). Thus, in *Snitzer v. Etzel*, 465 F.2d 899, 902 (C.C.P.A. 1972), the specification adequately described the claimed "laser-active" ytterbium ion, because that ion was listed, albeit with fourteen other possible ions; "the literal description of a species provide[d] the requisite legal foundation for claiming that species."

This case is akin to *Snitzer*, not *Ruschig* or *Fujikawa*. The specification discloses the tree: HPMC and PEO, including "mixtures thereof." (Appx1007.) No further "blaze marks" are needed.

CONCLUSION

Purdue respectfully submits that the panel's opinion warrants panel or en banc reconsideration. And because Purdue is entitled to its August 6, 2001 priority date to pre-date Joshi, the Board's judgments, which all rely on Joshi, should be reversed.

July 18, 2019

Respectfully submitted,

/s/ Gregory A. Castanias

GREGORY A. CASTANIAS
JENNIFER L. SWIZE
ROBERT N. STANDER
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001
(202) 879-3939
gcastanias@jonesday.com

JOHN J. NORMILE
GASPER J. LAROSA
JONES DAY
250 Vesey Street
New York, NY 10281
(212) 326-3939
jjnormile@jonesday.com

Counsel for Appellants

ADDENDUM

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

CERTIFICATE OF COMPLIANCE

1. This petition complies with the type-volume limitation of Federal Rule of Appellate Procedure 35(b)(2)(A): This petition contains 3,891 words, excluding the exempted parts of the petition.

2. This petition complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6): This petition has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman.

Dated: July 18, 2019

/s/ Robert Stander

ROBERT STANDER
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001-2113
(202) 879-7628
rstander@jonesday.com

Counsel for Appellants

CERTIFICATE OF SERVICE

I certify that on July 18, 2019, I served a copy of the foregoing on all counsel of record by CM/ECF.

/s/ Robert Stander

ROBERT STANDER
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001-2113
(202) 879-7628
rstander@jonesday.com

Counsel for Appellants