Trials@uspto.gov
571.272.7822

Paper No. 39
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS, LLC,
Petitioner,

v.

PURDUE PHARMA L.P.,
THE P.F. LABORATORIES, INC., and
PURDUE PHARMACEUTICALS L.P.,
Patent Owner.

Case IPR2016-01412
Patent 9,034,376 B2

Before LORA M. GREEN, CHRISTOPHER G. PAULRAJ, and JACQUELINE T. HARLOW, *Administrative Patent Judges*.

PAULRAJ, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

Amneal Pharmaceuticals LLC ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–13 and 16–19 of U.S. Patent No. 9,034,376 B2 (Ex. 1001, "the '376 patent"). Paper 1 ("Pet."). The P.F. Laboratories, Inc., Purdue Pharma L.P., and Purdue Pharmaceuticals L.P. (collectively, "Patent Owner") filed a Preliminary Response to the Petition. Paper 7 ("Prelim. Resp."). We determined that the information presented in the Petition demonstrated that there was a reasonable likelihood that Petitioner would prevail in challenging claims 1–13 and 16–19 as unpatentable under 35 U.S.C. § 103(a). Pursuant to 35 U.S.C. § 314, the Board instituted trial on February 14, 2017, as to those claims of the '376 patent. Paper 9 ("Institution Decision" or "Inst. Dec.").

Following our institution, Patent Owner filed a Response to the Petition (Paper 17, "PO Resp.") and Petitioner filed a Reply to Patent Owner's Response (Paper 21, "Reply"). An oral hearing was held on October 4, 2017. The transcript of the hearing has been entered into the record. Paper 38 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. Based on the record before us, we conclude that Petitioner has demonstrated by a preponderance of the evidence that claims 1–13 and 16–19 of the '376 patent are unpatentable as obvious.

A. Related Proceedings

The '376 Patent is asserted in two civil actions pending in the United States District Court for the District of Delaware captioned *Purdue Pharma L.P. et al. v. Amneal Pharmaceuticals LLC*, 15-831, filed September 17,

2015 (Ex. 1002) and *Purdue Pharma L.P. et al. v. Amneal Pharmaceuticals LLC*, 15-1152, filed December 15, 2015 (Ex.1003). Pet. 1; Paper 5, 1. A related patent, U.S. Patent No. 8,337,888 ("the '888 patent"), was the subject of a district court proceeding in the Southern District of New York captioned Purdue Pharma L.P. et al. v. Amneal Pharmaceuticals LLC, No. 13-3372 ("the SDNY Litigation") (Ex.1005). Pet. 1–2. The Federal Circuit upheld the invalidity of the claims of the '888 patent on April 8, 2016 (Ex. 1006). *Id.*

Additionally, in IPR2016-01413, Petitioner filed a separate Petition challenging the same claims of the '376 patent on other grounds of unpatentability. Pet. 2; Paper 5, 1. Petitioner previously filed petitions in IPR2016-01027 and IPR2016-01028 seeking cancellation for unpatentability of claim 1 of U.S. Patent No. 9,060,976 ("the '976 patent"), which is another member of the same patent family. *Id.* On November 8, 2017, we issued Final Written Decisions in IPR2016-01027 and IPR2016-01028 determining that claim 1 of the '976 patent was shown to be unpatentable. *See* IPR2016-01027, Paper 48; IPR2016-01028, Paper 47.

B. The '376 Patent (Ex. 1001)

The '376 patent issued on May 19, 2015, with Curtis Wright, Benjamin Oshlack, and Christopher Breder as the listed co-inventors. Ex. 1001. The '376 patent is a continuation of application number 13/349,449, which issued as the '888 patent. *Id.*

The '376 patent notes that opioid analgesics may sometimes be subject to abuse. *Id.* at 1:21. According to the '376 patent, the opioid analgesic may be more potent when administered parenterally as compared to the same dose administered orally. *Id.* at 1:22–224. The '376 patent

discloses that "[o]pioid antagonists have been combined with certain opioid agonists in order to deter the parenteral abuse of opioid agonists," but states that there is still a need of opioid dosage forms that are less subject to abuse. *Id.* at 1:36–38, 2:13–15. Thus, the '376 patent discloses "oral dosage forms . . . comprising an opioid analgesic; and an aversive agent or agents as a component(s) of the dosage form helps to prevent injection, inhalation, and/or oral abuse by decreasing the 'attractiveness' of the dosage form to a potential abuser." *Id.* at 2:46–51.

According to the '376 patent:

> In certain embodiments of the present invention, the dosage form comprises an aversive agent such as a gelling agent to discourage an abuser from tampering with the dosage form and thereafter inhaling, injecting, and/or swallowing the tampered dosage form. Preferably, the gelling agent is released when the dosage form is tampered with and provides a gel-like quality to the tampered dosage form which slows the absorption of the opioid analgesic such that an abuser is less likely to obtain a rapid "high". In certain preferred embodiments, when the dosage form is tampered with and exposed to a small amount (e.g., less than about 10 ml) of an aqueous liquid (e.g., water), the dosage form will be unsuitable for injection and/or inhalation. Upon the addition of the aqueous liquid, the tampered dosage form preferably becomes thick and viscous, rendering it unsuitable for injection.

Id. at 3:1–15. Moreover, the '376 patent defines the term "unsuitable for injection" "to mean one would have substantial difficulty injecting the dosage form (e.g., due to pain upon administration or difficulty pushing the dosage form through a syringe) due to the viscosity imparted on the dosage form, thereby reducing the potential for abuse of the opioid analgesics in the dosage form." *Id.* at 3:15–22.

The ’376 patent identifies hydroxypropyl methylcellulose (HPMC) and polyethylene oxide (PEO) among the possible gelling agents that may be employed. *Id.* at 6:46–62. The ’376 patent also teaches that the dosage form employing the aversive agents may be a “controlled release” oral dosage form that “provides effective pain relief for at least 12 hours, or at least about 24 hours when orally administered to a human patient.” *Id.* at 3:44–50.

C. District Court Proceeding Involving the ’888 patent

According to the district court in the SDNY Litigation, the ’888 patent relates to “a controlled release oral dosage form containing oxycodone that forms a gel when dissolved in an aqueous liquid,” wherein the “gelling properties . . . enable it to resist abuse by injection, snorting, and oral ingestion.” Ex. 1005, 1. Claim 1 of the ’888 patent is reproduced below:

> 1. A controlled release oral dosage form comprising:
>
> from about 2.5 mg to about 320 mg oxycodone or a pharmaceutically acceptable salt thereof; and
>
> a gelling agent comprising polyethylene oxide in an effective amount to impart a viscosity of at least about 10 cP when the dosage form is subjected to tampering by dissolution in from about 0.5 to about 10 ml of an aqueous liquid;
>
> the dosage form providing a therapeutic effect for at least about 12 hours when orally administered to a human patient.

Ex. 1004, 40:22–32.

The district court concluded that the ’888 patent was invalid as obvious. Ex. 1005, 40. Specifically, the district court found that the prior art teaches that gelling agents prevent potential abuse (*id.* at 41), and that the prior art teaches that PEO acts both as an agent to control the rate of release in sustained release dosage forms and as a gelling agent (*id.* at 43).

The Court of Appeals for the Federal Circuit, our reviewing court, affirmed the decision of the district court in a short per curium order. Ex. 1006. Specifically, the Federal Circuit held:

> The judgment of the United States District Court for the Southern District of New York is affirmed on the ground that the court did not err in concluding that the asserted claims of U.S. Patent No. 8,337,888 would have been obvious.

Id. at 2.

D. Challenged Claim

Petitioner challenges claims 1–13 and 16–19 of the '376 patent. Independent claim 1 is illustrative, and is reproduced below:

> 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 polyethylene oxide and hydroxypropylmethylcellulose, 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.

Ex. 1001, 40:21–33.

Independent claims 18 and 19 also recite controlled release oral dosage form with the same ingredients recited in claim 1, but require the gelling agent in an effective amount to impart a viscosity either "unsuitable for parenteral administration" (claim 18) or "unsuitable to pull into an insulin syringe" (claim 19) when the dosage form is subject to tampering by dissolution in from 0.5 to 10 ml of an aqueous liquid, and further require that

the oral dosage form "does not comprise a semipermeable wall." *Id.* at 41:23–42:25.

E. Instituted Grounds of Unpatentability

We instituted *inter partes* review based on the following patentability challenges in this proceeding:

References	Basis	Claims challenged
Palermo,[1] Joshi,[2] and the Handbook[3]	§ 103(a)	1–13 and 16–19
Oshlack,[4] Joshi, the Handbook, and Doyon[5]	§ 103(a)	1–13 and 16–19

Petitioner relies on the Declarations of Anthony Palmieri III, Ph.D. (Ex. 1007) and Robert J. Timko, Ph.D. (Ex. 1040) to support its Petition and Reply.

Patent Owner relies on the Declarations of Stephen Byrn, Ph.D. (Ex. 2001; Ex. 2054), Benjamin Oshlack (Ex. 2081), Curtis Wright IV, M.D., M.P.H. (Ex. 2092), Robert J. Paradiso (Ex. 2095), and Clifford M. Davidson (Ex. 2102) to support its Response.

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[1] Palermo, WO 99/32120, published Jul. 1, 1999 (Ex. 1011) ("Palermo").
[2] Joshi et al., Pub. No. US 2002/0187192 A1, published Dec. 12, 2002 (Ex. 1014) ("Joshi").
[3] Kibbe (ed.), HANDBOOK OF PHARMACEUTICAL EXCIPIENTS (3d ed. 2000) (Ex. 1012) ("Handbook").
[4] Oshlack et al., U.S. Patent 5,508,042, issued Apr. 16, 1996 (Ex. 1009) ("Oshlack").
[5] Doyon et al., U.S. Patent 5,283,065, issued Feb. 1, 1994 (Ex. 1046)("Doyon").

II. DISCUSSION

A. Level of Skill in the Art

Petitioner contends that a person of ordinary skill in the art for the '976 patent would have "a degree in one or more fields of medicine, chemical engineering, chemistry, pharmaceutical science, polymer chemistry, pharmaceutics, pharmaceutical technology, pharmacokinetics, and/or pharmacology, and/or a number of years of industry training or experience in one or more of those fields." Pet. 15 (citing Ex.1007 ¶¶ 31–34). Patent Owner agrees with Petitioner's proposed level of skill in the art. PO Resp. 24 (citing Ex. 2001 ¶¶ 74–75). We, therefore, apply that skill level in our analysis, with the understanding that the level of skill is also reflected in the prior art of record. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

B. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. *See* 37 C.F.R. §42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–45 (2016) (upholding the use of the broadest reasonable interpretation standard). Under the broadest reasonable construction standard, claim terms are presumed to have their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

On the present record, we determine that only the following claim term requires explicit construction for purposes of our Final Written

Decision. "[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy.'" Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Matal, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (quoting *Vivid Techs, Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

i. "gelling agent in an effective amount to impart a viscosity . . . "

Claim 1 recites a "gelling agent in an effective amount to impart a viscosity of at least 10cp," claim 18 recites a "gelling agent in an effective amount to impart a viscosity unsuitable for parenteral administration," and claim 19 recites a "gelling agent in an effective amount to impart a viscosity unsuitable to pull into an insulin syringe." Ex. 1001, cls.1, 18, 19. Petitioner contends that "whether defined numerically (cl.1) or functionally (cls.18, 19) all [these limitations] address the same thing in the context of the specification — the amount needed to provide a viscosity that would provide abuse deterrence." Pet. 16–17 (citing (Ex.1007 ¶¶ 36–37). As such, Petitioner asserts that the broadest reasonable interpretation of all these limitations is that the gelling agent imparts a viscosity of at least 10 cP. *Id.* at 17–18.

Patent Owner agrees that a "gelling agent in an effective amount to impart a viscosity" refers to an amount of gelling agent needed to provide the claimed viscosity, which is numerically recited in claim 1 as "at least 10cP." Patent Owner, however, disputes Petitioner's application of the same numerical viscosity requirement for claims 18 and 19, arguing that "[t]he fact that the dosage forms of claim 1, comprising a gelling agent in 'an effective amount to impart a viscosity of at least 10 cP,' are abuse-deterring, does not mean that ***all*** abuse-deterring dosage forms of the '376 patent may

impart a viscosity as low as 10 cP when tampered." PO Resp. 25–26. Patent Owner thus argues that "[c]laims 18 and 19 similarly provide different viscosity requirements from claim 1, using functional limitations instead of a numerical one." *Id.* at 26.

We find Petitioner's proposed construction to be more persuasive based on the '376 patent specification. In particular, the specification defines "unsuitable for injection" "to mean that one would have substantial difficulty injecting the dosage form (e.g., due to pain upon administration or difficulty pushing the dosage form through a syringe) due to the viscosity imparted on the dosage form, thereby reducing the potential for abuse of the opioid analgesic from the dosage form." Ex. 1001, 3:15–20. Additionally, in an example concerning the formation of a gel at different concentrations, the specification characterizes certain solutions as "THICK (10 cP to 60 cP): Although a syringe can be filled with this solution, it was hard to do." *Id.* at 32:8–24, Table 3. Thus, the specification teaches that a viscosity of at least 10 cP is difficult to pull into a syringe or administer parenterally (via injection). Patent Owner does not address these teachings of the specification.

We, therefore, determine that the broadest reasonable interpretation of "unsuitable for parenteral administration" and "unsuitable to pull into an insulin syringe" encompasses a gelling agent that imparts a viscosity of at least 10 cP.

C. Prior Art Relied Upon

Petitioner relies upon the following prior art teachings for its patentability challenge in this proceeding:

i. Overview of Palermo (Ex. 1011)

Palermo teaches a controlled release matrix preventing abuse of sustained release dosage forms of opioids. Ex. 1011, Title, 8:1–2. Oxycodone and its pharmaceutically acceptable salts are among the preferred opioids disclosed. *Id.* at 7:5–6, 13:14–30. Oxycodone can be used in, for example, a range of 2.5 to 800mg. *Id.* at 20:28–30. Palermo specifically exemplified 13.5mg of oxycodone per dose. *Id.* at 14:5 (Table 1). The dosage forms of Palermo preferably provide 12 hours or more of controlled release. *Id.* at 21:18–25, 33:18–20.

Palermo's controlled release matrix employs "[h]ydrophilic and/or hydrophobic materials" such as cellulose ethers and "any pharmaceutically acceptable hydrophobic material or hydrophilic material which is capable of imparting controlled release of the active agent and which melts (or softens to the extent necessary to be extruded)." *Id.* at 28:19–23. Hydroxyalkylcelluloses, and in particular HPMC, are identified as preferred matrix materials and binders. *Id.* at 28:27–30, 30:16–1732:3–4, 30:13–17.

To address the problem of drug abuse, Palermo teaches the combination of an opioid antagonist with the opioid agonist in the dosage form, with the amount of opioid antagonist included in an amount "sufficient to counteract opioid effects if extracted together with the opioid agonist and administered parenterally." *Id.*, Abstract. Palermo additionally teaches that further ingredients, including gelling agents, may be incorporated into the dosage form in order to make separation of the opioid agonist from the opioid antagonist more difficult. *Id.* at 6:29–31, 40:9–10.

ii. Overview of Joshi (Ex. 1014)

Joshi is drawn to a pharmaceutical composition that reduces drug abuse, wherein the composition comprises a central nervous system stimulant and a gel forming polymer. Ex. 1014 ¶ 1. According to Joshi, adding a gel forming polymer to the composition "reduces or eliminates potential drug abuse by swelling in the presence of moisture which is, for example, present in the dermis layer of skin and mucous membrane, and thus, prevents nasal absorption and injectability of the drug." *Id.* ¶ 9.

Joshi teaches that PEO is a preferred gel forming polymer, and that the polymer may have a molecular weight "from about 70,000 to about 2,000,000." *Id.* ¶¶ 21–22. The gel forming polymer is from about 2 to about 40 weight percent of the composition. *Id.* ¶ 23. The tablets are prepared, for example, by forcing the solid ingredients through a mesh, blending the solid ingredients, and compressing them into a tablet. *Id.* ¶ 37. Joshi teaches also that additional agents that are commonly used to prepare oral pharmaceutical dosage forms may also be used, such as enteric coatings. *Id.* ¶ 26.

Joshi references WO 97/33566 in its "Background of the Invention," which teaches an opioid composition that deters abuse, wherein an opioid antagonist is incorporated into the system to reduce the effect of the opioid. *Id.* ¶ 6.

iii. Overview of Handbook (Ex. 1012)

The Handbook of Pharmaceutical Excipients ("Handbook") includes entries for both hydroxypropyl methylcellulose (HPMC) and polyethylene oxide (PEO). Ex. 1012, 252–55, 399–400.

The Handbook teaches that HPMC is available in several grades which vary in viscosity, and that "[g]rades may be distinguished by

appending a number indicative of the apparent viscosity, in mPa s [cP[6]], of a 2% w/w aqueous solution at 20°C." *Id.* at 252; *see also id.* at 253 ("a wide range of viscosity types are commercially available."). HPMC grades with viscosities ranging from 80–120 up to 80,000–120,000 MPa s are identified. *Id.* at 254. The Handbook teaches that "[i]n oral products, [HPMC] is primarily used as a tablet binder, in film-coating, and as an extended-release tablet matrix." *Id.* at 252. "High viscosity grades may be used to retard the release of drugs from a matrix at levels 10-80% w/w in tablets and capsules." *Id.*

With respect to PEO, the Handbook also teaches its use as a "tablet binder," and that "higher molecular weight grades provide delayed drug release via the hydrophilic matrix approach." *Id.* at 399. The Handbook includes a table identifying the viscosity for different grades of PEO at 25°C, ranging from 20–50 to 8,800–17,600 MPa S (5% solution). *Id.*

iv. Overview of Oshlack (Ex. 1009)

Oshlack is directed to controlled release oxycodone compositions. Ex. 1009, Title. The oral dosage form taught by Oshlack "preferably contains between 1 and 500 mg, most especially between 10 and 160 mg, of oxycodone hydrochloride." *Id.* at 5:29–31. Oshlack teaches oral dosage formulations comprising a controlled release matrix, which "may be any matrix that affords in vitro dissolution rates of oxycodone within the narrow ranges required and that releases the oxycodone in a pH independent manner." *Id.* at 5:34–37. Although a controlled release matrix is preferred, "normal release matrices having a coating that controls the release of the

[6] It is undisputed that 1 milli-Pascal second (mPa s) = 1 centipoise (cP). Ex. 1007 ¶ 93 n.5.

drug may [also] be used." *Id.* at 5:37–39. Preferably, the oral dosage form contains between 5–25% of a hydroxyalkyl cellulose as the matrix. *Id.* at 6:3–5. Oshlack teaches that, in the case of oxycodone, the controlled release dosage form gives at least 12 hours of pain relief. *Id.* at 5:11–14.

v. Overview of Doyon (Ex. 1036)

Doyon is generally directed to controlled release pharmaceutical compositions. Ex. 1036, Title. Doyon teaches the use of film coatings for a controlled release dosage form, which can be used to modify properties such as "release rates, disintegration rates, taste, texture, color, physical appearance and the like." *Id.* at 6:11–15. Doyon provides several examples of film coating compositions. *Id.* at 12:1–64.

D. Joshi's Status as Prior Art

Before we turn to the merits of Petitioner's patentability challenges, we must first address Patent Owner's argument, raised for the first time after our Institution Decision, that the Joshi reference does not qualify as prior art to the '376 patent. Joshi is relied upon for both patentability challenges at issue in this proceeding. Joshi was published on December 12, 2002 based on an application filed August 30, 2001 (Ex. 1014), and further claims priority to a provisional application (U.S. 60/287,509) ("the '509 provisional") filed on April 30, 2001 (Ex. 1013). Accordingly, Petitioner asserted in the Petition that Joshi qualifies as prior art under 35 U.S.C. § 102(e). Pet. 21.

In its Patent Owner Response, Patent Owner contends that Joshi does not qualify as § 102(e) prior art for two reasons. First, Patent Owner asserts that the '376 patent is entitled to an earlier filing date based on the provisional application (U.S. 60/310,534 ("the '534 provisional")) filed on

August 6, 2001, whereas Petitioner has not met its burden of showing that Joshi is entitled to the benefit of its own earlier provisional filing date. PO Resp. 13–15. Second, even assuming that Joshi is entitled the provisional filing date of April 30, 2001, Patent Owner alleges an earlier invention date for the '376 patent. *Id.* at 16–19; *see also id.* at 30–31.

Petitioner contends that Patent Owner is collaterally estopped from relitigating Joshi's availability as prior art based on the final judgment in the SDNY Litigation relying upon Joshi to invalidate claims of the related '888 patent. Reply 7–9.[7] Petitioner further asserts that Patent Owner has failed to carry its burden of establishing an earlier conception and diligence in reduction to practice of the claimed invention prior to Joshi. *Id.* at 9–14.

i. Patent Owner is Collaterally Estopped from Challenging Joshi's Prior Art Status

As an initial matter, we determine that Patent Owner is collaterally estopped from disputing the status of Joshi as prior art to the '376 patent based on the SDNY Litigation.

"Under the doctrine of issue preclusion, also called collateral estoppel, a judgment on the merits in a first suit precludes relitigation in a second [proceeding] of issues actually litigated and determined in the first suit." *In re Freeman*, 30 F.3d 1459, 1465 (Fed. Cir. 1994) (citing *Lawlor v. National Screen Serv. Corp.*, 349 U.S. 322, 326 (1955)). The Federal Circuit has

[7] During oral argument, Patent Owner's counsel argued that Petitioner should have raised collateral estoppel in its Petition, and not for the first time in its Reply. *See* Tr. 34:18–35:7. However, because Patent Owner had not previously disputed Joshi's prior art status, Petitioner's first opportunity to raise collateral estoppel was in its Reply and we therefore consider the arguments to be timely raised. Patent Owner never sought to file a sur-reply to address Petitioner's collateral estoppel arguments.

articulated a four-factor test in determining whether collateral estoppel attaches: "(1) the identity of the issues in a prior proceeding; (2) the issues were actually litigated; (3) the determination of the issues was necessary to the resulting judgment; and (4) the party defending against preclusion had a full and fair opportunity to litigate the issues." *Levi Strauss & Co. v. Abercrombie & Fitch Trading Co.*, 719 F.3d 1367, 1371 (Fed. Cir. 2013). Collateral estoppel can attach in proceedings before the Office for identical issues that were addressed with respect to a different patent during prior district court litigation. *See In re Arunachalam*, No. 2016-1607, 2017 WL 4387224, at *2–4 (Fed. Cir. Oct. 3, 2017) ("In light of Dr. Arunachalam's previous opportunity to litigate the validity of the asserted claims of the '500 Patent, which contain the [same] terms . . . , we see no reason to allow her to appeal the patentability of the challenged claims of the '556 Patent, which also contain the same critical terms.").

All four factors for collateral estoppel are met here. With regard to the first factor, the issue of Joshi's status as prior art is identical for both proceedings. The '376 patent is part of the same chain of continuity as the '888 patent, and both patents share the same specification and claim priority to the same non-provisional application filed August 6, 2002 and provisional application filed August 6, 2001. As such, to the extent Joshi qualifies as prior art to the '888 patent, it would also qualify as prior art to the '376 patent.

We recognize that Patent Owner in this proceeding has presented evidence of prior conception and reduction to practice, focusing on the invention claimed in the '376 patent, in an attempt to antedate the Joshi reference. *See* PO Resp. 16–19. However, the claims at issue in both

proceedings are very similar, with the only substantive difference being that the claimed formulation of the '376 patent requires a gelling agent that comprises both PEO and HPMC while the claimed formulation of the '888 patent requires only PEO as the gelling agent. With respect to the claimed gelling agent requirement, Patent Owner relies upon a disclosure in a draft application indicating that thickening agents including "hydroxypropyl methylcellulose, . . . polyethylene oxide . . ., and mixtures thereof" may be employed. Ex. 2054 ¶ 54; Ex. 2091, 5. To the extent that Patent Owner contends that this disclosure shows prior conception of a formulation that includes both HPMC and PEO,[8] Patent Owner could have relied on the same disclosure to argue that the inventors had previously conceived of a formulation that includes PEO in the district court proceedings. Thus, notwithstanding the minor difference in the patent claims, we find Patent Owner's evidence of prior invention would have been relevant in both proceedings. *See Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013) ("Our precedent does not limit collateral estoppel to patent claims that are identical. Rather, it is the identity of the issues that were litigated that determines whether collateral estoppel should apply.").

We also find the second, third, and fourth factors for collateral estoppel to be satisfied. The district court in the SDNY Litigation specifically addressed Joshi's status as prior art as follows:

> Although the parties did not stipulate that the Joshi publication qualifies as prior art to the '888 Patent, Purdue has never argued that it does not. Joshi was filed August 30, 2001 but claims priority to Provisional Application No. 60/287,509, filed April 30, 2001. With respect to the Court's obviousness

[8] As discussed further below, we find Patent Owner's arguments unpersuasive in this regard.

> analysis, the disclosures of the provisional application are identical to those of the non-provisional application. (*Compare* DTX 1497, *with* DTX 2611; *see also* Maurin Tr. 762-63). Therefore, Joshi qualifies as prior art to the '888 Patent. *See* 35 U.S.C. § 102(e) (2006); 35 U.S.C. § 119(e)(1) (2006); *see generally In re Giacomini*, 612 F.3d 1380 (Fed. Cir. 2010).

Ex. 1005, 42 n.11. As noted by the district court, Patent Owner has never previously argued that Joshi did not qualify as prior art. The court's findings on Joshi were necessary to the judgment holding the '888 patent claims invalid, which findings were affirmed by the Federal Circuit. Ex. 1006. Furthermore, Patent Owner had a full and fair opportunity to litigate the issue in the SDNY Litigation but chose not to make the arguments it now seeks to present in this proceeding. Collateral estoppel applies to "issues that were or *could have been raised*" in the prior litigation. *In re Deckler*, 977 F.2d 1449, 1452 (Fed. Cir. 1992) (emphasis added).

Accordingly, we determine that Patent Owner is collaterally estopped from challenging Joshi's prior art status.

ii. Joshi Qualifies as Prior Art

Moreover, even assuming collateral estoppel does not attach to the issue, we determine based on the record that Joshi qualifies as prior art under § 102(e) as of the August 6, 2002 filing date of the '376 patent.

As set forth in *Dynamic Drinkware, LLC. v. National Graphics, Inc.*, once petitioner has satisfied its initial burden of production by arguing that a prior art reference anticipated the claims of the challenged patent, the burden of production then shifts to the patent owner to argue or produce evidence that either that the alleged prior art does not actually anticipate, or that the reference is not in fact prior art because the asserted claims in the challenged patent are entitled to the benefit of an earlier filing date (constructive or

otherwise). 800 F.3d 1375, 1380 (Fed. Cir. 2015); *see also Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008) (holding that patent owner has the "burden of going forward with evidence either that the prior art does not actually anticipate, or, as was attempted in this case, 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"). Thereafter, the burden of production returns to the petitioner "to prove that either the invention was not actually reduced to practice as argued, or that the [alleged] prior art was entitled to the benefit of a filing date prior to the date of [patent owner's] reduction to practice." *Dynamic Drinkware*, 800 F.3d at 1380. Critically, even though the burden of production may shift, "[i]n an *inter partes* review, the burden of persuasion is on the petitioner to prove 'unpatentability by a preponderance of the evidence,' 35 U.S.C. § 316(e), and that burden never shifts to the patentee." *Id.* at 1378.

Accordingly, we apply that framework to our analysis of Joshi's prior art status. Here, Petitioner has satisfied its initial burden of production by asserting that Joshi qualifies as prior art under 35 U.S.C. § 102(e), and that Joshi in combination with other prior art renders the challenged claims obvious. *See* Pet. 21.

Even assuming a filing date of August 30, 2001 for Joshi based on its non-provisional application,[9] the reference would still qualify as prior art

[9] In its Response, Patent Owner argues that Petitioner "has failed to carry its burden of proof that Joshi's effective date is earlier than August 30, 2001." PO Resp. 15. We agree that Petitioner has not shown in this proceeding that Joshi is entitled to an earlier filing date by comparing the claims of Joshi to the '509 provisional. *See* Tr. 16:15–20:4 (Petitioner's counsel acknowledging that Petitioner did not do a "claim mapping" comparing the claims of the Joshi publication to the disclosure in Joshi's provisional

under § 102(e)(1) if the '376 patent is not entitled to a filing date earlier than August 6, 2002 based on its own provisional or an earlier conception date. As noted above, Patent Owner has the burden of production to show an earlier filing date (constructive or otherwise) for the '376 patent.

In this regard, Patent Owner contends that the '376 patent is entitled to claim the benefit of the August 6, 2001 filing date of the '534 provisional, and, as support, relies upon Dr. Byrn's comparison of each element of the '376 patent claims to the disclosures of the '534 provisional. PO Resp. 13; Ex. 1026; Ex. 2054 ¶ 55. Patent Owner additionally relies upon a draft of the patent application dated April 25, 2001 ("April 25th draft application") as corroborating evidence of prior conception. PO Resp. 16; Ex. 2054 ¶ 54; Ex. 2091. Patent Owner asserts that "from the time just prior to the filing of the Joshi provisional (i.e., April 29, 2001) until the filing of the '534 provisional application on August 6, 2001, the inventors exercised reasonable diligence in reducing their inventions to practice." PO Resp. 17. We find that the claims of the '376 patent do not have written description support in either the '534 provisional or the April 25th draft application.

In particular, with respect to the requirement that the claimed formulation includes both PEO and HPMC as gelling agents, Dr. Byrn relies upon the following disclosure in the '534 provisional application:

> 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

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application). Nonetheless, for the reasons explained herein, an earlier date for Joshi is not necessary for it to qualify as prior art to the '376 patent.

> cellulose, sodium caboxymethyl cellulose, methylcellulose, ethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, and *hydroxypropyl methylcellulose*, attapulgites, bentonites, dextrins, alginates, carrageenin, gum tragacanth, gum acacia, guar gum, xanthan gum, pectin, gelatin, kaolin, lecithin, magnesmm aluminum silicate, the carbomers and carbopols, polyvinylpyrrolidone, polyethylene glycol, *polyethylene oxide*, polyvinyl alcohol, silicon dioxide, surfactants, mixed surfactant/wetting agent systems, emulsifiers, other polymeric materials, *and mixtures thereof*, etc.

Ex. 1026, 10; Ex. 2054 ¶ 55. Dr. Byrn relies upon a similar disclosure in the April 25th draft application: "Various agents having thickening properties can be employed including, for example, hydroxypropyl methylcellulose, . . . polyethylene oxide . . ., and mixtures thereof." Ex. 2054 ¶ 54; Ex. 2091, 5.[10]

Although the statements above encompass "mixtures" of HPMC and PEO among a myriad of other possibilities for the gelling agent, we find no basis to conclude that the inventors of the '376 patent were in possession of the specifically claimed formulation from such a broad disclosure.[11] The

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[10] The April 25th draft application is heavily redacted and we thus cannot discern what other materials were specifically contemplated as "thickening agents" by that time. *See* Ex. 2091, 5. However, given the nature and amount of the redactions and Patent Owner's assertion that the draft application ultimately led to the filing of the '534 provisional with the broad disclosure set forth above, we find it reasonable to conclude that additional materials were included in the draft application. Moreover, the draft application was forwarded as part of an email from Patent Owner's attorney, which "[e]nclosed the latest draft of the tamper resistant application." Ex. 2091. As such, there is no evidence to suggest that the list of thickening agents included as part of the draft application originated from the inventors as opposed to patent counsel.

[11] We recognize that the same broad disclosure with a "laundry list" of possible gelling agents is found in the specification of the '376 patent. *See*

Federal Circuit has held that such "laundry list" disclosures are insufficient to satisfy the written description requirement when there is no further guidance ("blazemarks") provided about which species or combination of species included as part of the list may be selected to arrive at the claimed invention. *See Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571 (Fed. Cir. 1996). Not having specifically named or mentioned the combination in any manner, "one is left to select[] from the myriads of possibilities encompassed by the broad disclosure, with no guide indicating or directing that this particular selection should be made rather than any of the many others which could also be made." *In re Ruschig*, 379 F.2d 990, 995 (CCPA 1967); *see also Los Angeles Biomedical Research Inst. at Harbor-UCLA Med. Ctr. v. Eli Lilly & Co.*, 849 F.3d 1049, 1057 (Fed. Cir. 2017) ("To satisfy the written description requirement, the disclosure in each application must 'reasonably convey[ ]' to those skilled in the art that as of the claimed priority date the inventor was in possession of the later claimed subject matter.") (citing *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991)).

Other evidence of record further supports our conclusion 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. In his Declaration, inventor Benjamin Oshlack attests that Patent Owner's laboratory scientists focused on "testing the syringeability of various concentration solutions of pectin, sodium alginate, and sodium acrylate, as well as combinations of pectin and sodium alginate" between January 4 and

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Ex. 1001, 6:46–62. We, however, do not address the issue of written description support for any of the subsequently filed applications.

17, 2001. Ex. 2081 ¶ 22. Additionally, Mr. Oshlack attests that the scientists had evaluated "xanthan gum, carrageenan, and locust bean gum (and combinations thereof) as gelling agents, between April 5 and 12, 2001." *Id.* ¶ 23. None of the laboratory notebook excerpts proffered by Patent Owner mention a combination of HPMC and PEO as gelling agents to be used in an oxycodone formulation. Exs. 2087–2090. Consistent with the testing actually done, the working examples set forth in the '534 provisional (as well as in the '376 patent) focus on xantham gum, pectin, microcrystalline cellulose, and hydroxyethlcellulose as the gelling agents. *See* Ex. 1026, 44– 49 (Examples 1–5). We find, therefore, that the inventors did not particularly consider either PEO or HPMC, let alone both PEO and HPMC in combination, when evaluating possible gelling agents for an abuse-deterrent formulation of oxycodone.

Accordingly, because we find that the '376 patent is not entitled to a filing date earlier than August 6, 2002, we further determine that Joshi qualifies as § 102(e) prior art as of that date. Having determined that Joshi qualifies as prior art, we turn to the merits of Petitioner's patentability challenges.

E. Obviousness over Palmero, Joshi, and Handbook

Petitioner asserts that claims 1–13 and 16–19 are rendered obvious by the combination of Palermo, Joshi, and the Handbook. Pet. 20–34. Petitioner presents a claim chart for each of the challenged claims. *Id.* at 35–43.

With respect to this challenge, Petitioner contends "Palermo discloses dosage forms that include a sustained-release, abuse-deterrent drug matrix, which can be made using HPMC mixed with oxycodone or its salts." *Id.* at 25. Petitioner acknowledges that Palermo does not specifically teach

including PEO with HPMC, but relies upon Palermo's teaching to include "a further ingredient which makes separation of the opioid agonist from the opioid antagonist more difficult. Such further ingredients may include gelling agents." *Id.* (citing Ex. 1011, 6:30–7:1, 40:7–10; Ex. 1007 ¶¶ 48, 86). Petitioner also acknowledges that Palermo discloses the use of an antagonist for abuse deterrence, but asserts that the claims of the '376 Patent do not exclude opioid antagonists or require abuse deterrence be achieved by only one means. *Id.* at 26–27.

Petitioner further relies upon Joshi's teaching that PEO may be used as a gelling agent to provide abuse deterrence. *Id.* at 26 (citing Ex. 1014 ¶¶ 8–9, 21; Ex. 1007 ¶ 87). In particular, Petitioner contends that "Joshi specifies that gelling agents may have a molecular weight ('MW') of 70,000-2,000,000, with a preferred range of 100,000-1,000,000," and that "Joshi's gelling agents are present in an amount of about 2 to 40 weight percent." *Id.* at 28 (citing Ex.1014 ¶¶ 22–23; Ex. 1007 ¶ 92). In view of the properties of PEO disclosed in the Handbook, Petitioner contends that a skilled artisan "would see PEO as being completely consistent with Palermo's teaching and likely to provide the improved abuse deterrence predicted by Palermo, just as it did in Joshi." *Id.* at 26 (citing Ex. 1007 ¶ 87).

Petitioner also asserts, based on the Handbook, that the MW ranges disclosed in Joshi correspond to grades of PEO having a viscosity of 30–50 cP, 400–800 cP, and 2000–4000 cP, which are all greater than the 10 cP viscosity required by claim 1. *Id.* at 28–29 (citing Ex. 1012, 399; Ex. 1014 ¶ 22; Ex. 1007 ¶¶ 92–94). Additionally, Petitioner contends that these viscosities would be unsuitable for parenteral administration (as required by

claim 18) and would be unsuitable to be pulled into an insulin syringe (as required by claim 19). *Id.* at 29 (citing Ex. 1034, F-56; Ex. 1007 ¶ 94). Accordingly, Petitioner contends that a skilled artisan would appreciate that the viscosity of solutions can vary with the amount of PEO and/or HPMC and their MW or grade, and that the adjustment of viscosities to achieve the claim requirements would have been a matter of routine optimization. *Id.* at 28, 30–31 (citing Ex. 1007 ¶¶ 96–97). Petitioner relies upon a similar optimization rationale with respect to the more specific viscosities recited in dependent claims 2–6. *Id.* at 32–33.

Petitioner relies upon Joshi's teaching that 1 ml of water was used for testing to allege the obviousness of dependent claim 8 (specifying that the aqueous liquid is water), dependent claim 9 (specifying dissolution in 1 to 3 ml of aqueous liquid), and dependent claim 12 (specifying tampering by dissolution in the aqueous liquid after crushing). *Id.* at 32 (citing Ex. 1014 ¶¶ 42–43; Ex. 1007 ¶ 101). With respect to claim 13 (specifying tampering by dissolution in the aqueous liquid after heating at greater than 45 °C), Petitioner contends that a skilled artisan "would appreciate that viscosity measurements are dependent on the temperature at which the viscosity is taken," and that the claim is obvious based on the same optimization rationale. *Id.* at 34.

With respect to the ratio of gelling agent to drug recited in dependent claim 7 (40:1 to 1:40), Petitioner asserts that the examples of Joshi fall within this range, thus, rendering it obvious. *Id.* at 33 (citing Ex. 1014 ¶¶ 36, 38, 40; Ex. 107 ¶ 103). With respect to the requirement in dependent claim 10 specifying the salt oxycodone hydrochloride and the further requirement in dependent claim 11 specifying a dosage of 10–80 mg of that

salt, Petitioner relies upon the fact that Palermo specifically teaches an oxycodone does of 13.5 mg, and asserts that the use an oxycodone salt in an equivalent amount would have been obvious. *Id.* at 33 (citing Ex. 1011, 7:6, 14:5; Ex. 1007 ¶ 103).

With respect to the requirement in dependent claim 16 that the dosage form is "without a semipermeable wall" (also recited in independent claims 18 and 19), Petitioner asserts that the skilled artisan would understand this to preclude the dosage form from being an osmotic device. *Id.* at 31 (citing Ex. 1001, 24:37–46; Ex. 1007 ¶ 98). Petitioner contends that none of the references relied upon in the Petition include a semipermeable wall, thereby satisfying this requirement. *Id.*

With respect to the requirement in dependent claim 17 that the dosage form further comprise a film coat, Petitioner asserts that Palermo discusses the use of such a coating, which renders this claim obvious. *Id.* at 34 (citing Ex. 1011, 21:8–11, 27:13–15; Ex. 1007 ¶ 105).

Patent Owner has made several arguments as to why the challenged claims are not proven obvious based on the teachings of Palermo, Joshi, and Handbook. Patent Owner focuses primarily on the limitations recited in independent claims 1, 18, and 19.

Patent Owner contends that Palermo would not lead to the claimed inventions because it is directed toward use of an opioid antagonist for deterring abuse, and does not disclose the use of gelling agent alone to deter abuse. PO Resp. 34. Additionally, Patent Owner contends that Palermo does not teach or suggest anywhere the use of PEO, and Palermo only discusses using HPMC with hydrophobic materials for controlled-release matrices and never mentions any utility as a gelling agent or for deterring

abuse. *Id.* Patent Owner further contends that Palermo does not disclose any examples or *in vitro* or *in vivo* data for extended-release dosage forms. *Id.* at 34–35.

We are unpersuaded by these arguments. The '376 patent claims do not require the use of gelling agent alone to deter abuse, and thus do not preclude the inclusion of an opioid antagonist in the formulation as taught by Palermo. Moreover, Palermo teaches a formulation that includes HPMC as part of the matrix, and further teaches that additional gelling agents may be included in order to make drug extraction more difficult. Ex. 1011, 6:31–7:1, 30:13–17, 40:7–10. Contrary to Patent Owner's argument that Palermo only discloses using HPMC with hydrophobic materials, Palermo teaches that "any pharmaceutically acceptable hydrophobic material or hydrophilic material which is capable of imparting controlled release and which melts (or softens to the extent necessary to be extruded) may be used." *Id.* at 28:20–23. Additionally, Patent Owner's criticism that the prior art does not disclose any drug release data is without merit. Other than a general requirement that the controlled release matrix provides a therapeutic effect for at least 12 hours, the challenged claims of the '376 patent do not require any particular dissolution profile or release rate for the drug. Palermo teaches that formulations disclosed therein can provide up to 24 hours of sustained release of the therapeutically active agent. *Id.* at 21:18–25, 33:18–20

Patent Owner also asserts that the prior art taught away from the claimed inventions. PO Resp. 35–37. In particular, Patent Owner contends that drug release from HPMC matrix formulations is dependent on temperature, the active pharmaceutical ingredient, and interactions between

the HPMC and elements in the product and gastric media. *Id.* at 35 (citing Ex. 2001 ¶¶ 62, 65; Ex. 2013, 2746, 2748; Ex. 2054 ¶¶ 27-33, 99). As to temperature, Patent Owner contends that the prior art taught that the viscosity of HPMC decreased when heated. *Id.* (citing Ex. 2054 ¶¶ 26-27; Ex. 1012, 254). Moreover, Patent Owner argues that HPMC was known to produce unpredictable changes in drug release, which would lead to "dose dumping" and/or failure of drug release. *Id.* at 36–37(citing Ex. 2054 ¶¶ 32-33, 100; Ex. 2067 at 131, Ex. 2055, 143; Ex. 1016, 2570). Patent Owner further contends the prior art touted the use of gelling agents, including HPMC and PEO, in formulations designed to deliver drug through the nasal mucosa, which is the opposite of the claimed invention. *Id.* at 37 (citing Ex. 2054 ¶ 102; Ex. 2079; Ex. 2080).

We do not find that the evidence of record shows that the prior art taught away from the claimed invention. We note that Exhibits 2013 and 2055, relied upon by Patent Owner to allege teaching away, were published *after* the alleged filing date of the '376 patent and thus do not qualify as prior art. And as they are after the filing date, they do not reflect the knowledge of the ordinary artisan at the time of invention. Other prior art references relied upon by Patent Owner and 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. *See, e.g.*, Exs. 2065–2067. However, none of the references suggest that HPMC should not be used in a drug formulation for those reasons. In this regard, we credit Dr. Timko's undisputed testimony that the 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. Ex. 1040 ¶ 60. Furthermore, the fact that some prior art (Exs. 2079 and 2080) taught that HPMC could be used in nasal delivery applications does not suggest that HPMC could not be used in the manner required by the claimed invention. In short, Patent Owner has not identified any prior art teaching that specifically "criticize[d], discredit[ed], or otherwise discourage[d]" the use of HPMC for abuse-deterrent or controlled release formulations. *Galderma Labs.*, 737 F.3d at 738.

Patent Owner relies on Bastin[12] as discouraging the use of gelling agents. PO Resp. 39–40. Patent Owner asserts that Bastin teaches a combination in which only 50% of the drug was released within two hours, and the remaining drug was "trapped in the tablet matrix" with no release after two hours, which would preclude an extended release. *Id.* (citing Ex. 1015, 5:29–36, 28:1–22). As such Patent Owner contends that "Bastin takes a fundamentally opposite approach to the '376 claims, teaching separating the drug and gelling agent and focusing on immediate-release." *Id.* Patent Owner relies also on the CPDD Paper[13] as teaching away from challenged claim 1 because, although it taught the inclusion of antagonists, it did not identify the use of gelling agents to confer abuse deterrence in a drug formulation. *Id.* at 40.

Consistent with the district court determination in the SDNY Litigation, we determine that Bastin does not teach away from claim 1.

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[12] Bastin et al., WO 95/20947, published August 10, 1995 ("Bastin") (Ex. 1015).

[13] James Zacny et al., *College on Problems of Drug Dependence Taskforce on Prescription Opioid Non-Medical Use and Abuse: Position Statement*, 69 DRUG AND ALCOHOL DEPENDENCE 215–232 (2003) (Ex. 2009) ("CPDD Paper").

Specifically, the portions of Bastin relied upon by Patent Owner relate to immediate release formulation, not extended release dosage forms. As stated by the district court:

> 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. And although all of the gelling patents focus primarily on immediate release tablets, Bastin notes that its invention may include a sustained release coating or "materials known in the art intended for the modification of release characteristics of the drug." Although the '888 Patent may be the first patent to disclose in detail controlled release dosage forms that utilize gelling agents to deter abuse, the Court cannot find that the prior art taught away from such formulations.

Ex. 1005, 46–47 (citations and footnote omitted).

The CPDD paper has a publication date of 2003, and, thus, does not qualify as prior art to the '376 patent and Patent Owner has not pointed to any evidence that the CPDD paper reflects the understanding of the ordinary artisan at the time of the invention. Moreover, even if the CPDD paper were considered, we find nothing in its disclosure that would have discouraged the skilled artisan from including a gelling agent at the time of invention. The fact that the CPDD paper taught alternative strategies for tackling the abuse problem is not a teaching away. *See In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004) ("The prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed.").

Patent Owner argues that Joshi and Handbook do not suggest modifying Palermo to practice the claimed inventions, and that Petitioner has not presented evidence of motivation to combine particular portions of the prior art in a way that practices the claimed inventions. PO Resp. 40–47. Patent Owner contends that Joshi relates only to immediate-release formulations and central-nervous-system (CNS) stimulants, and does not mention opioids or oxycodone in its formulations or provide guidance about how to modify the formulations described in Palermo to arrive at the claimed inventions, including its specific combination of PEO and HPMC. *Id.* at 40–41. Patent Owner further contends that the Handbook does not describe any formulation, or any manufacturing technique, that involves the combination of HPMC and PEO. *Id.* at 42. .

We are unpersuaded by these arguments. As discussed above, Palmero teaches the use of an extended release oxycodone formulation that contains HPMC. Ex. 1011, 30:16–17, 32:3–4. Joshi specifically mentions both sustained release formulations and opioid compositions as part of the background of the invention described therein, and thus its teachings regarding the use of gelling agents are not limited to only immediate-release formulations and/or CNS stimulants. Ex. 1014 ¶¶ 4, 6. Joshi, like Palmero, is concerned the oxycodone abuse problem and teaches that PEO is a preferred gelling agent that may be used for an abuse deterrent formulation. Ex. 1014 ¶ 8. Additionally, the Handbook, which is incorporated by reference into Palmero (Ex. 1011, 33:6–8), teaches that high molecular weight grades of PEO provide delayed drug release and, therefore, could be used in sustained release formulations. Ex. 1012, 399. As for motivation to select PEO as opposed to other gelling materials taught in the prior art, the

evidence shows that PEO was among the best-known and most well-understood gelling agents, and that PEO is useful in controlled release formulations. Ex. 1007 ¶ 87; 1040 ¶48. We, therefore, find that a skilled artisan would have been motivated to combine the prior art teachings.

Finally, we are unpersuaded by Patent Owner's contention that the prior art fails to disclose the claimed "viscosity elements." PO Resp. 56–58. As discussed above, we have construed claims 1, 18, and 19 to require a gelling agent that imparts a viscosity of at least 10 cP. Dependent claims 2–6 require a higher viscosity (up to 5000 cP) for the gelling agent. Joshi teaches that the use of gelling agents can prevent "injectability of the drug." Ex. 1014 ¶ 9. The Handbook teaches that HPMC and PEO are available in several grades which vary in viscosity. Ex. 1012, 252, 399. Given that the prior art teaches that HPMC and PEO may be used as gelling agents to deter drug abuse, we likewise find that "it would have required very little effort" for a skilled artisan to determine the appropriate quantitative viscosity at which syringeability and parenteral injection became difficult. 1040 ¶ 41.

For the reasons outlined above, we determine that Petitioner has demonstrated a reasonable expectation of success in arriving at the claimed invention. We are unpersuaded by Patent Owner's arguments to the contrary. PO Resp. 52–56. Patent Owner's arguments are premised on the alleged unpredictable influence of gelling agents on drug release. *Id.* at 54. However, reasonable expectation of success does not require absolute predictability. *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988). As evidence of unpredictability, Patent Owner relies upon a Notice of Allowance in a related patent application in which the examiner indicated that the "prior art states clearly that structure-property relationship of

mixtures comprising gel-forming polymers in solutions/gels are still under scrutiny." PO Resp. 38, 52 (citing Ex. 2007, 9, 12). Patent Owner fails to mention that the same Notice of Allowance was withdrawn and the pending claims of that application were subsequently rejected. Ex. 1050. Regardless, we do not consider an Examiner's statement to be substantive evidence of unpredictability. Furthermore, given the well-known utility of PEO and HPMC in pharmaceutical formulations, we credit Dr. Palmieri's testimony that "[i]t would be routine for a [skilled artisan] to make adjustments to the amount or grade of HMPC and/or the combination of HPMC and PEO, to optimize the viscosity to a degree that will deter abuse and also provide an acceptable controlled release of the active agent when the dosage form is taken properly." Ex. 1007 ¶ 65.

Accordingly, having considered the record as a whole, we determine that a preponderance of the evidence establishes the obviousness of claims 1–13 and 16–19 based on the combination of Palmero, Joshi, and the Handbook.

F. Obviousness over Oshlack, Joshi, Handbook, and Doyon

Petitioner also asserts that claims 1–13 and 16–19 are rendered obvious by the combination of Oshlack, Joshi, the Handbook, and Doyon.[14] Pet. 44–54. Petitioner includes a claim chart for each of the challenged claims. *Id.* at 55–62.

With respect to this challenge, Petitioner relies upon Oshlack's disclosure of a sustained release matrix that includes HPMC mixed with oxycodone hydrochloride. *Id.* at 46 (citing Ex. 1009, 5:34–66). Petitioner

[14] Petitioner only relies upon Doyon for claim 17's requirement of a film coating. *See* Pet. 54, 59.

acknowledges that Oshlack does not teach including PEO and does not discuss abuse deterrence, but asserts that courts recognized there was a publicly known abuse crisis for oxycodone by early 2000, and, thus, a skilled artisan would have been motivated to produce abuse deterrent controlled release formulations. *Id.* at 46–47. Petitioner further relies upon the teachings of Joshi and the Handbook, in the same manner as discussed above, to assert that a skilled artisan would have been motivated to include HPMC and PEO as abuse-deterrent gelling agents in Oshlack's formulation, and that it would have been routine to adjust the amount and grades of PEO and HPMC used so as to optimize the viscosity to deter abuse while also providing acceptable controlled release. *Id.* at 47–50. With respect to claim 17, Petitioner asserts that the skilled artisan would have ample "motivation to film coat the controlled release tablets of Oshlack to modify the taste, texture, color, physical appearance, etc. with a reasonable expectation of success based on the teaching of Doyon." *Id.* at 54.

Patent Owner's arguments for this patentability challenge largely overlap its arguments for the challenge based on Palermo, which we find unpersuasive for the reasons discussed above. PO Resp. 47–52. With respect to this challenge specifically, Patent Owner argues that Oshlack, which disclosed the original OxyContin formulation, would not lead to the claimed inventions because there is no disclosure of PEO or the use of gelling agents in Oshlack, or a suggestion that a combination of PEO and HPMC might solve the problem of abuse. *Id.* at 48. Patent Owner further contends that the "natural solution" would have been to keep the original OxyContin formulation and add abuse deterrence in the form of opioid antagonists. *Id.* at 49–50.

We are unpersuaded by these arguments. Oshlack teaches oral controlled release dosage formulations that can have a therapeutic effect for at least 12 hours, wherein the controlled release matrix can be composed of HPMC and 1-500mg of oxycodone hydrochloride. Ex. 1007 ¶ 106; Ex.1009, at 5:19–67, 15:7–18. Given the known problem of OxyContin abuse, a skilled artisan would have found ample motivation to turn to Joshi's teachings regarding the use of gelling agents, and specifically PEO, to help reduce abuse potential. Ex. 1006 ¶ 109; Ex. 1014 ¶¶ 8, 9, 21. Furthermore, the Handbook confirms that HPMC and PEO are well known excipients that may be used in sustained release formulations. Ex. 1012, 252, 399. Contrary to Patent Owner's arguments, the record evidence does not suggest that the skilled artisan would have *only* considered the use of an opioid antagonist to tackle the abuse problem.

Accordingly, having considered the record as a whole, we determine that a preponderance of the evidence establishes the obviousness of claims 1–13 and 16–19 based on the combination of Oshlack, Joshi, Handbook, and Doyon.

G. Motion to Exclude

Petitioner has filed a Motion to Exclude Exhibits 2009, 2013, 2018, 2019, 2021, 2026, 2051, 2052, 2055, 2061, 2064, 2077, 2081, 2085–2090, 2092–2094, 2096–2100, 2104 and portions of Exhibits 2001 and 2054. Paper 31. Patent Owner filed an Opposition to Petitioner's Motion to Exclude. Paper 32. Petitioner filed a Reply to Patent Owner's Opposition. Paper 34.

Petitioner contends that Exhibit 2009, which is the CPDD paper, is irrelevant insofar as it was published after the priority date for the '376

patent. Paper 31, 3. Petitioner also argues that Exhibits 2013, 2055, 2061, 2093, and 2094 similarly are not prior art and have no probative value as Patent Owners offered no evidence that the authors of the papers qualify as persons of skill in the art. *Id.* As discussed above, we find that the post-filing publication date of any references relied upon by Patent Owner goes to the weight to be accorded rather than admissibility of the evidence. Accordingly, we deny Petitioner's motion to exclude these exhibits or the portions of the Expert Declarations relying upon those exhibits.

Petitioner further contends that Exhibits 2081, 2087, 2088, 2089, 2090, 2092, and 2096 (the "Swear Behind Exhibits") are also irrelevant because "[n]one of these exhibits shows possession of the claimed invention before the provisional filing date of Joshi." *Id.* at 5. Likewise, Petitioner contends that Exhibits 2097–2100, which are certain email communications with Patent Owner's outside counsel, are irrelevant because they do not establish conception of the claimed invention before the Joshi provisional, and as such are also irrelevant to proving diligence. We again find Petitioner's arguments go to the weight rather than admissibility, and accordingly deny Petitioner's motion to exclude these Swear Behind Exhibits and email communications or the portions of the Expert Declarations relying upon those exhibits.

Petitioner contends that Exhibits 2051 and 2077 are irrelevant because they are depositions of its expert Dr. Palmieri from two other proceedings (IPE2016-01027 and IPR2016-01028). *Id.* at 6. However, Exhibit 2077 is Dr. Palmieri's deposition transcript from this proceeding and the companion case IPR2016-01413. Nonetheless, we decline to exclude either Exhibit

2051 or Exhibit 2077 since they may properly serve as evidence of any alleged inconsistency in Dr. Palmieri's testimony.

Petitioner seeks to exclude Exhibits 2085 and 2086 as inadmissible hearsay. *Id.* at 6–8. Patent Owner contends that Petitioner failed to object to Exs. 2085 and 2086 under FRE 802 as inadmissible hearsay and thus is estopped from moving to exclude these exhibits on this ground. Paper 32, 11. Under 37 C.F.R. § 42.64(b)(1), a party must serve objections to evidence served with particularity within five business days of service of the evidence, or the objection is waived. "The objection must identify the grounds for the objection with sufficient particularity to allow correction in the form of supplemental evidence." *Id.* In its Reply to Patent Owner's Opposition to the Motion to Exclude, Petitioner contends that it had "objected to all exhibits under FRE 802 to the extent those exhibits were offered for the truth of the matter asserted." Paper 34, 3 (citing Paper 18, 1). We do not consider Petitioner's "catch-all" objection in Paper 18 to satisfy the particularity requirement for evidentiary objections under Rule 4264(b)(1). On that basis, we deny Petitioner's Motion to Exclude Exhibits 2085 and 2086.

We have not relied upon the other Exhibits sought to be excluded, and therefore dismiss Petitioner's Motion to Exclude those Exhibits as moot.

H. Cross-Examination Observations

Patent Owner filed Observations on the cross-examination testimony of Dr. Timko. Paper 29. Petitioners, in turn, filed a Response. Paper 33. We have considered Patent Owner's observations and Petitioners' responses in rendering this Final Written Decision, and accorded the cross-examination testimony appropriate weight where necessary.

I. Motion to Seal

Patent Owner has filed a motion to seal Exhibits 2086–2091, 2097, and 2101–2102 on the basis that these exhibits contain confidential and non-public information pertaining to research and development efforts. Paper 16. Petitioner does not oppose the motion to seal.[15]

"There is a strong public policy for making all information filed in a quasi-judicial administrative proceeding open to the public, especially in an inter partes review which determines the patentability of claims in an issued patent and therefore affects the rights of the public." *Garmin Int'l v. Cuozzo Speed Techs.*, LLC, IPR2012–00001, slip op. at 1–2 (PTAB Mar. 14, 2013) (Paper 34). For this reason, except as otherwise ordered, the record of an *inter partes* review trial shall be made available to the public. *See* 35 U.S.C. § 316(a)(1); 37 C.F.R. § 42.14. Motions to seal may be granted for good cause; until the motion is decided, documents filed with the motion shall be sealed provisionally. *See* 37 C.F.R. §§ 42.14, 42.54(a). The moving party bears the burden of showing that there is good cause to seal the record. *See* 37 C.F.R. § 42.20(c).

As set forth in the Board's Trial Practice Guide, confidential information that is sealed subject to a protective order ordinarily will become public 45 days after final judgment in a trial. Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,761 (Aug. 14, 2012). A party seeking to maintain confidentiality of information may file a motion to expunge the information before it becomes public; however, if the existence

[15] The parties also filed a Joint Motion for Entry of a Stipulated Protective Order. Paper 7. We grant the motion and enter the parties' Stipulated Protective Order.

of the information is identified in a final written decision following trial, there is an expectation that the information will be made public. *Id.* This rule "balances the needs of the parties to submit confidential information with the public interest in maintaining a complete and understandable file history for public notice purposes." *Id.*

We agree that the exhibits sought to be sealed appear to contain confidential business information insofar as they relate to Patent Owner's research and development efforts as well as attorney communications. Nonetheless, Patent Owner has affirmatively relied upon these exhibits to allege a prior conception date and reduction to practice. *See* PO Resp. 16–19. We have considered and relied upon that evidence in reaching our conclusion with regard to Joshi's prior art status. We specifically discuss Exhibit 2091 (the April 25th draft application) as well as Exhibits 2087–2090 (laboratory notebook excerpts) in this Final Written Decision. Under the Board's procedures, this means that there is an expectation that these exhibits will be made part of the public record. Furthermore, the public's interest in understanding the basis for our decision on patentability means that any good cause alleged in the Motion to Seal must overcome this heightened public interest.

On that basis, we deny Patent Owner's Motion to Seal. The normal consequence of a denial of a motion to seal would be to immediately unseal the documents. However, because the public release of documents would be irreversible, we provide Patent Owner with ten business days to renew its Motion to seal by providing sufficient justification that outweighs the public interest. Any renewed Motion to Seal shall also include proposed redactions for this Final Written Decision as well as narrowly redacted public versions

of the exhibits sought to be sealed. In the absence of any action on the part of Patent Owner, at the expiration of ten days from the date of this Decision, Exhibits 2086–2091, 2097, and 2101–2102 will be made available to the public.

III. CONCLUSION

Based on the evidence and arguments, Petitioner has demonstrated by a preponderance of the evidence that claims 1–13 and 16–19 of the '376 patent are unpatentable under 35 U.S.C. § 103 as obvious over the combination of Palermo, Joshi, and Handbook and the combination of Oshlack, Joshi, Handbook, and Doyon.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–13 and 16–19 of the '376 patent are held to be unpatentable;

FURTHER ORDERED that Petitioner's Motion to Exclude is *denied-in-part* and *dismissed as moot-in-part*;

FURTHER ORDERED that Patent Owner's Motion to Seal is *denied-without-prejudice*;

FURTHER ORDERED that the this Final Written Decision will be made available to the public ten (10) business days after the entry date of this Decision, unless prior to that time, Patent Owner renews its Motion to Seal and provides a proposed redacted versions of the Final Written Decision and any of the exhibits sought to be sealed;

FURTHER ORDERED that Joint Motion for Entry of a Stipulated Protective Order is *granted*;

FURTHER ORDERED that because this is a Final Written Decision,

parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

PETITIONER:

Tedd W. Van Buskirk
Nichole M. Valeyko
LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK, LLP
tvanbuskirk@lernerdavid.com
nvaleyko@lernerdavid.com

PATENT OWNER:

Gasper J. LaRosa
Pablo Hendler
Kelsey I. Nix
Kenneth S. Canfield
Sarah A. Geers
Lisamarie LoGiudice
JONES DAY
gjlarosa@jonesday.com
phendler@jonesday.com
knix@jonesday.com
kcanfield@jonesday.com
sgeers@jonesday.com
lloguidice@jonesday.com