

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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AMNEAL PHARMACEUTICALS LLC.,  
Petitioner,

v.

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

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Case IPR2016-01412  
Patent 9,034,376 B2

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Before MICHAEL P. TIERNEY, *Vice Chief Administrative Patent Judge*,  
LORA M. GREEN, and CHRISTOPHER G. PAULRAJ, *Administrative  
Patent Judges*.

PAULRAJ, *Administrative Patent Judge*.

DECISION  
Institution of *Inter Partes* Review  
37 C.F.R. § 42.108

I. INTRODUCTION

Amneal Pharmaceuticals LLC (“Petitioner”) filed a Petition (Paper 1, “Pet.”), requesting institution of 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”).

Purdue Pharma L.P., The P.F. Laboratories, Inc., and Purdue Pharmaceuticals L.P.. (collectively, “Patent Owner”) timely filed a Preliminary Response (Paper 8, “Prelim. Resp.”).

We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” Upon consideration of the Petition and the Preliminary Response, and for the reasons explained below, we determine that Petitioner has shown that there is a reasonable likelihood that it would prevail with respect to at least one of the challenged claims. We, thus, institute an *inter partes* review of claims 1–13 and 16–19 of the ‘376 Patent.

*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. U.S. Patent No. 8,337,888 (“the ‘888 patent”), which claims priority to the same earlier-filed application as the ‘376 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

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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. Pet. 2; Paper 5, 1. We instituted *inter partes* review in IPR2016-01413 on January 18, 2017. IPR2016-01413, Paper 9. Also, Petitioner previously filed petitions in IPR2016-01027 and IPR2016-01028 seeking cancellation of claim 1 of U.S. Patent No. 9,060,976, which is another member of the same patent family. Pet. 2; Paper 5, 1.

*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 teaches 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 “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 (the SDNY Litigation)*

According to the district court in the SDNY Litigation, the related '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 only difference between claim 1 of the '888 patent and claim 1 of the '376 Patent is the additional inclusion of HPMC as a gelling agent.

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. Illustrative 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.

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.”

*D. The Asserted Ground of Unpatentability*

Petitioner challenges the patentability of the claims of the ‘376 Patent based on the following grounds:

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

Petitioner further relies upon the declaration of Anthony Palmieri III, Ph.D. (Ex. 1007) (“Palmieri Decl.”).

## II. ANALYSIS

### A. Claim Construction

We interpret claims using the “broadest reasonable construction in light of the specification of the patent in which [they] appear[.]” 37 C.F.R. § 42.100(b); *see also* *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under the broadest reasonable construction standard, claim terms are generally given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). “Absent claim language carrying a narrow meaning, the PTO should only limit the claim based on the specification . . . when [it] expressly disclaim[s] the broader definition.” *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004). “Although an inventor is indeed free to define the specific terms used to

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<sup>1</sup> Palermo, WO 99/32120, published Jul. 1, 1999 (Ex. 1011) (“Palermo”).

<sup>2</sup> Joshi et al., Pub. No. US 2002/0187192 A1, published Dec. 12, 2002 (Ex. 1014) (“Joshi”).

<sup>3</sup> Kibbe (ed.), HANDBOOK OF PHARMACEUTICAL EXCIPIENTS (3d ed. 2000) (Ex. 1012) (“Handbook”).

<sup>4</sup> Oshlack et al., U.S. Patent 5,508,042, issued Apr. 16, 1996 (Ex. 1009) (“Oshlack”).

<sup>5</sup> Doyon et al., U.S. Patent 5,283,065, issued Feb. 1, 1994 (Ex. 1046) (“Doyon”).

describe his or her invention, this must be done with reasonable clarity, deliberateness, and precision.” *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

At this stage of the proceeding, we determine that no explicit construction of any claim term is necessary to determine whether to institute a trial in this case. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (“[C]laim terms need only be construed ‘to the extent necessary to resolve the controversy.’”) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

### *B. Obviousness Analysis*

#### *1. Content of the Prior Art*

Petitioner relies upon the following prior art in its challenges.

##### *a. 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 cellulose ethers. *Id.* at 28:27–30, 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.

*b. 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. Joshi additionally specifies that HPMC may be included as a gel forming polymer. *Id.* ¶ 15. 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.

*c. The 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<sup>6</sup>], 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

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

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.*

*d. Oshlack (Ex. 1009)*

Oshlack teaches oral dosage formulations comprising a controlled release matrix that can be composed of 5–25% of a hydroxyalkylcellulose, which can be HPMC, and 1-500mg of oxycodone hydrochloride. Ex.1009, at 5:19–67, 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.

*e. Doyon (Ex. 1036)*

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.” Ex. 1036, 6:11–15.

*2. Obviousness over Palermo, Joshi, and the 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 that “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).

We have considered the arguments and evidence presented by Patent Owner in its Preliminary Response. As an initial matter, we note that Patent Owner relies heavily upon the Declaration of Stephen Byrn, Ph.D. to support its arguments. Ex. 2001 (“Byrn Decl.”). Although Dr. Byrn disagrees with Petitioner’s Declarant, Dr. Palmieri, on many issues of fact, our rules provide that “a genuine issue of material fact created by such testimonial evidence will be viewed in the light most favorable to the petitioner solely for purposes of deciding whether to institute an *inter partes* review.” 37 C.F.R. 42.108(c). Accordingly, we resolve any disputed factual issues in the parties’ Declarations in Petitioner’s favor at this stage.

Relying upon the Federal Circuit’s decision in *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352 (Fed. Cir. 2011), Patent Owner argues that the

original FDA-approved formulation for OxyContin<sup>®</sup> should be the starting point for the obviousness analysis. Prelim. Resp. 41–43. Based on that starting point, Patent Owner argues that it would not have been obvious to modify original OxyContin<sup>®</sup> to achieve the claimed invention. *Id.* at 43–48. We do not agree that Patent Owner’s analysis is the only correct approach for determining the obviousness of the challenged claims. Although the patent challenger in *Unigene* relied upon a prior FDA-approved drug as the “reference composition,” the Federal Circuit did not suggest that *only* previously approved drugs may be considered as the starting point when alleging obviousness of a pharmaceutical composition. As we noted earlier, “the obviousness analysis is not constrained by starting with the commercially available form of the drug.” IPR2016-01028, Paper No. 12, 30. Rather, under the correct obviousness analysis, “any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.” *KSR, Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (2007); *see also Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 737 (Fed. Cir. 2013) (“Nothing in the statute or our case law requires [the challenger] to prove obviousness by starting with a prior art commercial embodiment and then providing motivation to alter that commercial embodiment.”).

Moreover, the challenged claims are broadly directed to conferring abuse deterrence on sustained release formulations of oxycodone generally, rather than only a specific improvement upon the previously-existing OxyContin<sup>®</sup> formulation. For instance, the other ingredients besides oxycodone HCl included in the original OxyContin formulation are not recited in the claims of the ‘376 Patent. Prelim. Resp. 46 (citing Ex. 1009, Table 7).

As such, contrary to Patent Owner's arguments (Prelim. Resp. 48–51), we determine that the record at this stage supports a conclusion that the skilled artisan would have considered Palermo's teachings, which discusses sustained release oxycodone formulations, as an appropriate starting point for the obviousness analysis.

We are further unpersuaded by Patent Owner's arguments that the skilled artisan would not have referred to Joshi (Prelim. Resp. 51, 55–56), as the use of a gelling agent to address the problem of oxycodone abuse would have been considered relevant regardless of whether the drug was contained in a sustained-release or immediate-release formulation. *See In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004) (a prior art reference may be considered in an obviousness analysis if the “art is from the same field of endeavor, regardless of the problem addressed” or if it “is reasonably pertinent to the particular problem with which the inventor is involved”). Furthermore, although Palermo teaches the use of an opioid antagonist to help prevent drug abuse, there is no basis for us to conclude that Joshi's teachings regarding the use of gelling agents would be inapplicable to compositions in which an antagonist is used. Indeed, Joshi cites specifically to compositions in which an opioid antagonist is used as relevant background art. Ex. 1014 ¶ 6.

Patent Owner argues that Petitioner made no showing of why the skilled artisan would have come up with the specific combination of two gelling agents. Prelim. Resp. 52–56. Patent Owner contends that the use of gelling agents would have an “unpredictable influence” of the drug's release profile and could “trap” the drug, and “[i]t is especially not predictable how a combination of two structurally different polymers would influence

viscosity.” *Id.* at 54–55. We are unpersuaded by this argument on the current record. Petitioner has pointed out that Palermo already teaches a formulation that includes HPMC, and further teaches that additional gelling agents may be included in order to make drug extraction more difficult. Pet. 22 (citing Ex. 1011, 30:13–17); *id.* at 22 (citing Ex. 1011, 6:20–7:1, 40:7–10). Accordingly, we determine that the record at this stage supports a conclusion that the skilled artisan would have had a sufficient reason with a reasonable expectation of success to turn to Joshi’s teachings that HPMC and PEO are appropriate gelling agents that may both be used in combination in a pharmaceutical formulation to prevent drug abuse while also providing controlled release. The Handbook further confirms that both HPMC and PEO are well known gelling agents that may be used in pharmaceutical compositions. Ex. 1012. Thus, at this stage, we credit Dr. Palmieri’s opinion that a skilled artisan would have considered it routine to combine the appropriate grades of HPMC and PEO in order “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. *See KSR*, 550 U.S. at 417 (“[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.”).

We are also unpersuaded on the current record by Patent Owner’s argument that the references cited in the Petition fail to disclose the claimed viscosity elements. Prelim. Resp. 59–61. With respect to claims 1 and 3–6, which recite specific numeric viscosities, Patent Owner argues that the

Handbook's disclosure of "the viscosity of a solution of PEO or an alkylcellulose (or the molecular weight of a substance) is not the viscosity of a tampered dosage form, let alone the claimed dosage forms." *Id.* at 60 (citing Ex. 2001 ¶ 42). With respect to claim 9, which recites that the viscosity is imparted when the dosage form is dissolved in 1 to 3 ml of aqueous liquid, Patent Owner argues that "Joshi does not report viscosities . . . , only molecular weights, and those molecular weights are of PEO, not a tampered oxycodone dosage form. *Id.* at 60–61 (citing Ex. 2001 ¶ 98–99). With respect to claims 18 and 19, which recite the viscosity in functional terms, Patent Owner argues that Petitioner "failed to provide any basis for its assumption that the PEO-only *or* HPMC-only solutions in the cited references have the claimed viscosities for the claimed *dosage forms* using the claimed combination of gelling agents (PEO *and* HPMC)." *Id.* at 61. However, as discussed above, the Handbook teaches that HPMC and PEO are both available in grades that meet the claimed viscosity requirements. Ex. 1012. Furthermore, Joshi teaches that the extractability of drug from water can be inhibited using a gelling agent. Ex. 1014, ¶ 43. As such, the record supports a finding that a skilled artisan would have found it obvious to adjust the molecular weights of the PEO and HPMC polymers used in the formulation in order to obtain a viscosity greater than 10 cP when dissolved in water so as to achieve both optimized sustained release and reduce the potential for abuse of the drug by making it unsuitable for injection. Ex. 1007 ¶ 65.

Additionally, we are unpersuaded on the current record by Patent Owner's argument that the art taught away from using a gelling agent in an extended-release formulation to deter abuse. Prelim. Resp. 56–59. First,

Patent Owner argues that the '376 Examiner recognized that a POSA would have avoided gelling agents based on the fact that the same Examiner allowed claims in a later application in the same family. *Id.* at 56–57. However, we are not bound by the Examiner's findings made in other applications in determining whether to institute an *inter partes* review of the challenged claims of the '376 Patent. Nor do we consider the Examiner's statements made during prosecution of the related applications to be clear evidence that the prior art taught away from using a gelling agent in extended release formulations.

Patent Owner relies on Bastin<sup>7</sup> as discouraging the use of gelling agents. *Id.* at 58–59. Patent Owner asserts that Bastin teaches a combination in which only 50% of the drug was released within two hours, and suggests that the gelling agent should be reduced, but that reduction may result in limiting the abuse resistance potential of the tablet. *Id.* at 58 (citing Ex. 1015, 28:1–22, 5:29–362). We determine, consistent with the district court determination in the SDNY Litigation, that Bastin does not teach away from the challenged claims. 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

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<sup>7</sup> Bastin et al., WO 95/20947, published August 10, 1995 (Ex. 1015) (“Bastin”).

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).

Patent Owner relies also on the CPDD Paper<sup>8</sup> as teaching away from challenged claim 1. Prelim. Resp. 59. Specifically, Patent Owner argues that paper taught the use of extended release formulations, such as original OxyContin<sup>®</sup>, or the inclusion of antagonists, but does not suggest the use of gelling agents. *Id.* However, the CPDD paper has a publication date of 2003. Ex. 2009, 215. The challenged patent claims a priority date as early as August 6, 2001. Ex. 2001, Title Page. Thus, as noted by the district court, the CPDD Paper was not prior art to the ’888 Patent (Ex. 1005, 45 n.13), and is not prior art to the ’376 Patent, which is a continuation of ’888 Patent. Ex. 1001, cover page. Patent Owner, at this stage of the proceeding, does not point us to any evidence that the CPDD paper reflects the understanding of the ordinary artisan at the time of invention. Thus, as the paper was not available until 2003, two years after the time of invention, it could not have discouraged the ordinary artisan from including a gelling agent at the time of invention.

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<sup>8</sup> 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”).

Accordingly, for the foregoing reasons, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing with respect to its obviousness challenge of claims 1–13 and 16–19 based on the combination of Palermo, Joshi, and the Handbook.

*C. Obviousness over Oshlack, Joshi, the 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.<sup>9</sup> 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 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 be 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

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<sup>9</sup> Petitioner only relies upon Doyon for claim 17’s requirement of a film coating. *See* Pet. 54, 59.

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.” Pet. 54.

Patent Owner’s arguments for this patentability challenge largely overlap its arguments for the challenge based on Palermo, which are discussed above. Prelim. Resp. 37–61. For the reasons stated above, we are unpersuaded by Patent Owner’s arguments based on the current record.

Accordingly, for the foregoing reasons, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing with respect to its obviousness challenge of claims 1–13 and 16–19 based on the combination of Oshlack, Joshi, the Handbook, and Doyon.

*D. 35 U.S.C. § 325(d)*

Patent Owner also argues that Petitioner’s challenges should be denied under § 325(d) the same or equivalent references were considered during prosecution. Prelim. Resp. 34–37.<sup>10</sup> Denial of institution under § 325(d) is a matter of discretion. We are not persuaded that denial on that basis is an appropriate exercise of discretion here. The Petition presents additional arguments and evidence beyond what was already considered by the Examiner, including those presented in the Palmieri Declaration (Ex. 1007). Accordingly, we do not find that “the same or substantially the same

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<sup>10</sup> Although the heading in Patent Owner’s Preliminary Reference states “Ground 1 Should Be Denied under § 325(b)” (Prelim. Resp. 36), we understand that to be a typographical error and that Patent Owner intended to refer to § 325(d) as referenced in the arguments under that heading. *Id.* at 37.

prior art or arguments previously were presented to the Office.” 35 U.S.C. § 325(d).

### III. CONCLUSION

We conclude that Petitioner has established a reasonable likelihood of prevailing on its assertion that claims 1–13 and 16–19 of the ‘376 Patent are unpatentable as obvious.

At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claim or the construction of any claim term. Thus, our view with regard to any conclusion reached in the foregoing could change upon consideration of Patent Owner’s merits response and upon completion of the current record.

### IV. ORDER

Accordingly, it is:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted as to claims 1–13 and 16–19 of U.S. Patent No. 9,034,376 B2 based on the following ground of unpatentability:

- A. Claims 1–13 and 16–19 under 35 U.S.C. § 103(a) as obvious over the combination of Palermo, Joshi, and the Handbook;
- B. Claims 1–13 and 16–19 under 35 U.S.C. § 103(a) as obvious over the combination of Oshlack, Joshi, the Handbook, and Doyon.

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the ’376 patent is hereby instituted commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial.

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FURTHER ORDERED that the trial is limited to the grounds of unpatentability listed above, and no other grounds of unpatentability are authorized for *inter partes* review.

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