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Paper 103
Entered: July 22, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS, LLC,
Petitioner,

v.

ENDO PHARMACEUTICALS INC.,
Patent Owner.

Case IPR2014-00360[1]
Patent 8,329,216 B2

Before TONI R. SCHEINER, FRANCISCO C. PRATS, and JACQUELINE WRIGHT BONILLA, *Administrative Patent Judges*.

BONILLA, *Administrative Patent Judge.*

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

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[1] Case IPR2014-01365 has been joined with this proceeding.

I. INTRODUCTION

Amneal Pharmaceuticals, LLC, ("Petitioner") filed a Petition requesting *inter partes* review of claims 1, 2, 6, 12–14, 17, 21–43, 45–51, and 54–82 of U.S. Patent No. 8,329,216 ("the '216 patent"). Paper 1 ("Pet."). Endo Pharmaceuticals Inc. ("Patent Owner") filed a Preliminary Response. Paper 7 ("Prelim. Resp."). As authorized (Paper 9), Petitioner filed a Reply to the Preliminary Response addressing the issue of whether Petitioner was served with a complaint alleging infringement of the '216 patent more than one year before the Petition was filed, and, therefore, subject to a bar under 35 U.S.C. § 315(b). Paper 11. Patent Owner filed a Surreply on this issue. Paper 14. We determined that § 315(b) did not bar institution in this case. Paper 15, 10.

Thereafter, we determined that the information presented in the Petition demonstrated that there was a reasonable likelihood that Petitioner would prevail in challenging claims 1, 2, 6, 12–14, 17, 21–43, 45–51, and 54–71, but not claims 72–82,[2] of the '216 patent as unpatentable. Paper 16 ("Dec. to Inst."), 2, 21–22. Pursuant to 35 U.S.C. § 314, we instituted this proceeding on July 25, 2014, to review whether claims 1, 2, 6, and 12 of the '216 patent would have been obvious under 35 U.S.C. § 103 over Maloney,[3] and also whether claims 1, 2, 6, 12–14, 17,

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[2] Petitioner filed a Request for Reconsideration of our Decision not to review claims 72–82 as obvious over other cited references. Paper 18, 1. We denied that Request (Paper 21, 6).

[3] Maloney, International Pub. No. WO 01/08661 A2, "Opioid Sustained-Released Formulation," filed July 27, 2000, published Feb. 8, 2001 (Ex. 1006).

21–43, 45–51, and 54–71 would have been obvious over Oshlack[4] and the Handbook of Dissolution Testing ("the Handbook").[5] Dec. to Inst. 22.

After institution of trial, Patent Owner filed a Patent Owner Response. Papers 31, 32 ("PO Resp."), and Petitioner filed a Reply to the Response. Papers 49, 50 ("Reply"). Patent Owner also filed a Contingent Motion to Amend (Paper 29, "Motion"), and Petitioner filed an Opposition to the Contingent Motion to Amend (Paper 51, "Opp.").

Meanwhile, Petitioner filed a second Petition requesting *inter partes* review of claims 5, 16, 44, 46, 47, and 72–82 of the '216 patent. IPR2014-01365, Paper 2 ("Second Petition"). On the same day, Petitioner filed a Motion for Joinder, requesting joinder of the Second Petition with the Petition in the instituted proceeding. IPR2014-01365, Paper 3 ("Joinder Motion"), 1–2. We granted Petitioner's Motion for Joinder in relation to the ground that claims 44 and 47 of the '216 patent would have been obvious over Oshlack and the Handbook, but not in relation to any asserted grounds regarding claims 5, 16, 46, and 72–82 in the Second Petition. IPR2014-00360, Paper 64, 2, 15.[6]

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[4] Oshlack et al., U.S. Patent No. 5,958,452, "Extruded Orally Administrable Opioid Formulations," filed Apr. 10, 1997, issued Sept. 28, 1999 (Ex. 1007).
[5] William A. Hanson, HANDBOOK OF DISSOLUTION TESTING, v-xii, 1–13, 26–53, 69–91, 111–23 (2d ed. 1991) (Ex. 1008).
[6] In our Decision granting Petitioner's Motion for Joinder In-Part and Instituting *Inter Partes* Review, we note "[r]egarding claims 46 and 47, as noted by Petitioner, '[d]ue to an unintentional inconsistency in claim numbering in the First Petition, trial was instituted for claims 46 and 47 without Petitioner's specific analysis of these claims in the First Petition.'" Paper 64, 7.

As authorized (*id*. at 15–17), Patent Owner then filed a Supplemental Response to the Second Petition (Paper 66, "Supp. PO Resp."), as well as a Supplemental Motion to Amend claims 44 and 47 (Paper 67, "Supp. Motion"). Petitioner filed a Supplemental Reply to the Supplemental Response (Paper 77, "Supp. Reply"), as well as a Supplemental Opposition to the Supplemental Motion to Amend (Paper 78, "Supp. Opp."). Patent Owner filed a Reply to both of Petitioner's Oppositions to Motions to Amend (Paper 81, "Reply to Opps.").

Patent Owner filed a Motion to Exclude Evidence. Paper 86. Petitioner filed an Opposition (Paper 95), and Patent Owner filed a Reply (Paper 98). Petitioner likewise filed a Motion to Exclude Evidence. Paper 90. Patent Owner filed an Opposition (Paper 93), and Petitioner filed a Reply (Paper 97).

In addition, Patent Owner filed an Unopposed Motion for Entry of Protective Order (Paper 27) and two Motions to Seal certain evidence. Paper 30 ("First Motion to Seal"); Paper 83 ("Second Motion to Seal").

An oral hearing was held on May 27, 2015. A transcript of the hearing has been entered into the record. Paper 102 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6(c). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons that follow, we determine that Petitioner has not shown by a preponderance of the evidence that claims 1, 2, 6, 12–14, 17, 21–51, and 54–71 of the '216 patent are unpatentable. We dismiss Patent Owner's Contingent Motions to Amend, as well as Patent Owner's and Petitioner's Motions to Exclude Evidence. We grant Patent Owner's Motion for Entry of Protective Order, grant-in-part Patent Owner's First Motion to Seal, and grant Patent Owner's Second Motion to Seal.

A. Related Proceedings

Both parties identify, as a district court matter related to the current proceeding, *Endo Pharms. Inc. v. Amneal Pharms., LLC*, C.A. No. 12-CIV-8115 (SDNY) ("the district court matter"). Pet. 3; Prelim. Resp. 4. In addition, the parties identify IPR2014-00361 and IPR2014-00160 as related to the current proceeding. Pet. 3; Paper 5, 1. In IPR2014-00361, involving U.S. Patent No. 8,309,122 ("the '122 patent"), we determined that § 315(b) barred institution of *inter partes* review, as the Petition in that case was filed more than one year after a complaint alleging infringement of the '122 patent was served on Petitioner. IPR2014-00361, Paper 14. In IPR2014-00160, involving U.S. Patent No. 7,851,482, after institution, a different panel granted Patent Owner's request for adverse judgment. IPR2014-00160, Paper 24.

In the current case, both parties discuss *In re Kao*, 639 F.3d 1057 (Fed. Cir. 2011), which previously addressed, on appeal from the Board, rejections of claims in three U.S. patent applications, i.e., Appl. No. 11/680,432 ("the '432 application"), Appl. No. 12/167,859 ("the '859 application"), and Appl. No. 11/766,740, over Maloney (Ex. 1006), cited in this proceeding. *See, e.g.*, *Kao*, 639 F.3d at 1065, 1070; Pet. 8–9, 22; Prelim. Resp. 17–18. The Federal Circuit vacated and remanded the case to the Board, which rendered a decision in *Ex parte Kao*, 2009-013710, 2012 WL 3307358 (BPAI Aug. 9, 2012), reversing rejections at issue by the Examiner.

Petitioner contends that the '432 application is "the parent of '216 patent," and the '859 application is "related" to the '216 patent. Pet. 8–9, 22. These two applications are related to the '216 patent, but all three are continuations of the

same parent application, Appl. No. 10/190,192. Some claim limitations at issue in the Federal Circuit case are similar to limitations recited in challenged claims here.

B. The '216 Patent (Ex. 1001)

The '216 patent relates to oral controlled release pharmaceutical formulations comprising oxymorphone, and methods of using the same for sustained pain relief. Ex. 1001, 2:14–32. The '216 patent describes "methods for alleviating pain for 12 to 24 hours using a single dose of a pharmaceutical composition by producing a blood plasma level of oxymorphone and/or 6-OH oxymorphone of at least a minimum value for at least 12 hours or more." *Id*. at 2:61–65.

The Specification defines certain pharmacokinetic parameters, such as $AUC_{(0\text{-}inf)}$ ("Area under the drug concentration-time curve from time zero to infinity") and C_{max} ("Maximum observed drug concentration"). *Id*. at 11:33–48. The Specification presents pharmacokinetic data obtained in clinical studies investigating controlled release ("CR") and immediate release ("IR") tablet formulations of oxymorphone, such as shown in Figures 6 and 7, presenting graphs of mean blood plasma concentrations of oxymorphone versus time. *See, e.g.*, *id*. at Figs. 6, 7, 2:46–49, 13:58–20:59 (Studies 2 and 3), 23:61–26:25 (Study 5).

C. Claims At Issue

We instituted a trial in relation to challenges of claims 1, 2, 6, 12–14, 17, 21–51, and 54–71 of the '216 patent. Dec. to Inst. 22; Paper 64, 2, 15. Of those, claims 1, 13, 21, 31, 38, 49, 55, and 66 are independent. Claims 1, 13, 31, and 66 are illustrative and reproduced below, with emphases added.

1. An oral controlled release oxymorphone formulation, comprising:

a. *about 5 mg to about 80 mg* of oxymorphone or a pharmaceutically acceptable salt of oxymorphone; and

b. *a hydrophilic material*,

wherein upon oral administration of the formulation to a subject in need of an analgesic effect:

(i) the formulation provides detectable blood plasma levels of 6-OH oxymorphone and oxymorphone;

(ii) the blood plasma levels of 6-OH oxymorphone and oxymorphone peak within about 1 hour to about 8 hours after administration;

(iii) *the blood plasma levels of 6-OH oxymorphone and oxymorphone exhibit a ratio of area under the curve ($AUC_{(0\ to\ inf)}$) of blood plasma level versus time for 6-OH oxymorphone compared to oxymorphone in a range of about 0.5 to about 1.5*;

(iv) the duration of the analgesic effect is through at least about 12 hours after administration; and

(v) *the blood plasma levels of oxymorphone exhibit two or three peaks within about 12 hours after administration.*

13. A pharmaceutical tablet prepared by:

a. mixing oxymorphone or a pharmaceutically acceptable salt of oxymorphone and controlled release granules comprising a hydrophilic material and one or more optional excipients; and

b. directly compressing the mixture of (a) to form the tablet,

wherein upon placement of the tablet in an *in vitro dissolution test comprising USP Paddle Method at 50 rpm in 500 ml media having a pH of 1.2 to 6.8 at 37º C., about 15% to about 50%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 1 hour in the test.*

31. A method for treating pain in a human subject in need of acute or chronic pain relief, comprising the steps of:

(a) Providing a solid oral dosage form of a controlled release oxymorphone formulation with a release rate profile designed to provide adequate blood plasma levels over at least 12 hours to provide sustained pain relief over this same period comprising about 5 mg to about 80 mg oxymorphone or a pharmaceutically acceptable salt thereof wherein oxymorphone is the sole active ingredient, and wherein upon placement of the composition in an *in vitro dissolution test comprising USP Paddle Method at 50 rpm in 500 ml media having a pH of 1.2 to 6.8 at 37º C., about 15% to about 50%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 1 hour in the test*; and

(b) administering a single dose of the dosage form to the subject, wherein the *oxymorphone C_{max} is at least 50% higher when the dosage form is administered to the subject under fed as compared to fasted conditions*.

66. An analgesically effective controlled release pharmaceutical composition for oral delivery, comprising:

a. a controlled release delivery system with a release rate profile designed to provide adequate blood plasma levels over at least 12 hours to provide sustained pain relief over this same period; and

b. about 5 mg to about 80 mg of oxymorphone or a pharmaceutically acceptable salt of oxymorphone,

wherein oxymorphone is the sole active ingredient, wherein upon placement of the composition in an *in vitro dissolution test comprising USP Paddle Method at 50 rpm in 500 ml media having a pH of 1.2 to 6.8 at 37º C., about 15% to about 50%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 1 hour in the test*, and wherein upon oral administration of the composition to a human subject, the blood plasma levels of oxymorphone comprise one or more peaks.

Ex. 1001, 26:35–55, 27:33–45, 28:66–29:19, 32:34–50.

II. ANALYSIS

A. Claim Construction

The Board interprets 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). There is a "heavy presumption" that a claim term carries its ordinary and customary meaning. *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002).

Petitioner offers claim construction of the phrases "controlled release" and "about." Pet. 4–5. Petitioner notes that the '216 patent defines "controlled release" as encompassing formulations that "release no more than about 80% of their active pharmaceutical ingredients within 60 minutes" under the claimed dissolution conditions. *Id*. (citing Ex. 1001, 3:31–33). Petitioner contends that "about" encompasses "at least the standard statistical error" for dissolution testing values. *Id*. at 5. Patent Owner responds that no claim construction is necessary. PO Resp. 7–8. Based on the record before us, we determine that Petitioner's proposed constructions are the broadest reasonable construction of the above-mentioned phrases.

B. Obviousness over Maloney

Petitioner contends that claims 1, 2, 6, and 12 would have been obvious over Maloney, relying on Declarations by Dr. Anthony Palmieri (Ex. 1003), Ms. Vivian Gray (Ex. 1002), and Dr. Mario Gonzalez (Ex. 1031). Pet. 7–26; Reply 2–3, 7–8. Patent Owner contends otherwise, relying on Declarations by Dr. Diane Burgess (Ex. 2070) and Mr. Marv Kelly (Ex. 2053). PO Resp. 14–26, 54–60.

1. Maloney (Ex. 1006)

Maloney describes an opioid sustained release formulation comprising a mixture of a hydrophilic matrix-forming agent, an ionic exchange resin, and one or more opioid compound(s). Ex. 1006, 1, 6–7. The term "opioid" includes an opioid analgesic, such as morphine, codeine, oxycodone, oxymorphone, etc. *Id*. at 8–9, 13. Maloney teaches that a matrix-forming agent may be "any polymer not readily degradable by the body," such as hydroxypropylmethylcellulose ("HPMC") or ethylcellulose, among others. *Id*. at 9–10. In addition, the formulations may include "diluents," such as lactose, starch, sucrose, etc. *Id*. at 10–11.

Maloney discloses that the formulation may comprise "from about 0.1 - 500 mg opioid compound, a matrix-forming polymer from about 10 - 95% w/w, an ion exchange resin from about 0.1 - 50% w/w, a diluent from about 0 - 100% w/w, a glidant from about 0 - 5% w/w and a lubricant from about 0 - 20% w/w." *Id*. at 11. In one embodiment, the formulation may comprise "between about 30 and 65% of a matrix-forming polymer, more preferably between about 50 - 60% matrix-forming polymer, and between 5 and 15% of a[n] ionic exchange resin." *Id*. at 8, 13.

Examples in Maloney present, among other oxycodone formations, Formula 6 comprising, *inter alia*, 30 mg/tablet oxycodone hydrochloride, 14.5% w/w lactose, and 55.0% w/w HPMC, i.e., "Methocel K100M (Premium)." *Id*. at 17 (Formula 6 in Example 2); *see also id*. at 15–24.

2. Analysis

Petitioner contends that a controlled release oxymorphone composition disclosed in Maloney expressly or inherently comprises the different elements

recited in claims 1, 2, 6, and 12, and provides, upon oral administration, the requisite properties recited in those claims. Pet. 12–19, 23. We address certain elements of claim 1, as disputed by the parties to be rendered obvious by Maloney, below.

Unlike other challenged independent claims of the ’216 patent, claim 1 does not require specific release profiles “in an in vitro dissolution test comprising USP Paddle Method at 50 rpm in 500 ml media having a pH of 1.2 to 6.8 at 37º C.” Dec. to Inst. 9–12. Instead, claim 1 requires that, upon administration of the oxymorphone formulation, “blood plasma levels of 6-OH oxymorphone and oxymorphone exhibit a ratio of . . . $AUC_{(0\ to\ inf)}$ . . . for 6-OH oxymorphone compared to oxymorphone in a range of about 0.5 to about 1.5,” and “two or three peaks within about 12 hours after administration.” Ex. 1001, 26:34–55. Petitioner contends that such properties would have been inherent to oxymorphone compositions, regardless of formulation. Pet. 16–19.

Regarding the “two or three peaks” element in claim 1, Petitioner points us to Figures 6 and 7 of the ’216 patent. Pet. 17. Those figures show mean plasma concentration versus time results in relation to subjects administered controlled release (Treatment 2A and 2B in Fig. 6, Treatments 3A and 3B in Fig. 7) or immediate release (Treatment 3C in Fig. 6, Treatments 3C and 3D in Fig. 7) oxymorphone tablets, as described in Studies 2 and 3 in the ’216 patent. Ex. 1001, 13:58–16:66. Based on that data, Petitioner asserts that “the presence of 2 or 3 peaks after administration of any oxymorphone formulation is an inherent property of all oxymorphone compositions.” Pet. 17 (citing Ex. 1003 ¶ 95).

Patent Owner responds that Maloney does not disclose multiple peak plasma levels of oxymorphone, and Petitioner fails to establish that the recited "two or three peaks" limitation is inherent to all oxymorphone compositions. PO Resp. 2–3, 16–22. Specifically, Patent Owner contends that testimony by Dr. Burgess clarifies that the "multiple peaks in the oxymorphone plasma concentration within 12 hours of administration are *not* inherent to all oxymorphone compositions." *Id*. at 17–18 (citing Ex. 2070 ¶¶ 1, 27–51, 155). Patent Owner also asserts that Petitioner's expert Dr. Palmieri admits the same. *Id*. (quoting Ex. 2012, 170:21–171:3), 21–22 (citing same)).[7]

Citing Dr. Burgess' testimony, Patent Owner discusses two clinical studies not disclosed in the '216 patent, designated Studies A and B. *Id*. at 18–21 (citing Ex. 2070 ¶¶ 33–50). Study A (Ex. 2013), submitted to the U.S. Food and Drug Administration as part of a New Drug Application for an immediate-release ("IR") oxymorphone tablet, determined single-dose bioavailability of 2x5 mg and 10 mg IR oxymorphone tablets, as compared to an oral oxymorphone solution. *Id*. at 18–19 (citing Ex. 2070 ¶¶ 33–34). Patent Owner reproduces Figure 1 in Exhibit 2013, which presents a mean plasma concentration of oxymorphone as a function of time upon administration of all three treatments. *Id*. at 19 (citing Ex. 2013, 19, Fig. 1).[8]

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[7] Patent Owner cites Exhibit 2011 (PO Resp. 17–18), but later refers to Exhibit 2012 (*id*. at 21–22), for Dr. Palmieri's deposition testimony. *See also* Tr. 53:11–19 (clarifying that Patent Owner quotes Exhibit 2012).

[8] Patent Owner refers to "Figure 2" in Exhibit 2013 (PO Resp. 19), but our review indicates that the figure in question is Figure 1 on page 19 of this exhibit. Exhibit 2013 is a 2002 clinical study report entitled "A Randomized, Single Dose, Three Period Crossover Comparison of the Oral Bioavailability of [] Tablets and an Oral

Patent Owner argues that this evidence establishes that all three formulations, i.e., both IR tablets and the oral solution, exhibited only a single peak within 12 hours of administration. *Id*. at 19–20 (citing Ex. 2070 ¶ 35).

Study B, presented in a scientific paper (Ex. 2014), examined the pharmacokinetics and dose proportionality of an IR tablet containing oxymorphone following single and multiple-dose administration in subjects. *Id*. at 19–20 (citing Ex. 2070 ¶ 37). Patent Owner reproduces Figure 1 in Exhibit 2014, which presents mean single-dose and steady-state plasma concentrations of oxymorphone IR for 5 mg, 10 mg, and 20 mg tablets in Study B. *Id*. at 20 (citing Ex. 2014, 97, Fig. 1). Patent Owner argues that this evidence illustrates that those IR tablets exhibited only a single peak within 12 hours of administration. *Id*. (citing Ex. 2070 ¶¶ 38–39). Thus, according to Patent Owner, evidence of record establishes that not all oxymorphone compositions necessarily exhibit "two or three" plasma concentration peaks of oxymorphone within about 12 hours of administration. *Id*. at 21.

In response, Petitioner again asserts that multiple peaks are an inherent characteristic of any oxymorphone formulation, and therefore present in the oxymorphone controlled release ("CR") formulations of Maloney. Reply 7. In relation to Study A, Petitioner asserts that the study measured plasma concentrations too infrequently to detect more than one peak, citing a Declaration by Dr. Gonzalez. *Id*. at 8 (citing Ex. 1031 ¶¶ 34–39). Specifically, Petitioner contends that Study A did not measure plasma concentrations between hours 8 and

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Oxymorphone Solution Under Fasting Conditions." *See also* Ex. 2070 ¶¶ 33–35 (referring to Figure 1 in Ex. 2013).

12, the time period when one would expect a second plasma peak. *Id*. According to Petitioner, "[b]ecause the second peak would be expected to have a low magnitude, the study's lack of plasma concentration measurements between hours 8 and 12 effectively masks the presence of a second peak." *Id*. (citing Ex. 1031 ¶ 38).

In relation to Study B, Petitioner asserts that Patent Owner's expert, Dr. Burgess, reviewed only a summary article presenting a "plasma concentration time curve graph that was compressed such that the second peak was not apparent," again citing Dr. Gonzalez's Declaration. *Id*. (citing Ex. 2014, 97, Fig. 1; Ex. 1031 ¶¶ 40–42). In addition, according to Petitioner, when "presented with the uncompressed graph from the full study report" (Ex. 1041) during a deposition, Dr. Burgess "confirmed that the IR formulations did, in fact, display multiple plasma peaks." *Id*. (citing Ex. 1042, 208:2–213:22).[9] Petitioner also argues that Dr. Burgess did not know of any CR oxymorphone formulations lacking multiple peaks. *Id*. (citing Ex. 1042, 70:8–15).

In his Declaration, Dr. Gonzalez testifies that data disclosed in the '216 patent leads him to conclude that "the reduced data points in Study A *may* obscure the presence of a second peak." Ex. 1031 ¶ 37 (emphasis added). Dr. Gonzalez also opines that Patent Owner has "cited no additional information disputing the inherency of multiple peaks other than Study A." *Id*. Reliance on this testimony

[9] In its Reply, Petitioner cited Exhibit 1042, 199:2–203:22 (Reply 8), but clarified during the oral hearing that it inserted a typographical error regarding the pin-point cite, and intended to cite pages 203–208 of Dr. Burgess' deposition transcript (Ex. 1042). Tr. 17:3–11.

by Petitioner ignores the fact that Petitioner has the burden to establish by a preponderance of the evidence that the "two or three peaks" limitation of claim 1 is inherent to any oxymorphone formulation, as Petitioner asserts when making its case. Pet. 17; Reply 7. We are not persuaded that Petitioner has met its burden in this regard.

In pointing to evidence regarding Study A, Patent Owner provides evidence indicating that certain oxymorphone formulations, as tested in Study A, do not present more than one peak of oxymorphone plasma concentration. PO Resp. 19 (citing Ex. 2013, Fig. 1). By contrast, Petitioner and its experts rely on data presented in Figures 5–7 in the '216 patent to show that all oxymorphone formulations, including IR compositions, exhibit multiple peaks. Pet. 17–19 (discussing Figs. 6 and 7); Ex. 1003 ¶ 84 (stating that "Figure 6 shows peaks at about 3 hours and about 12 hours after administration" for an IR formulation), ¶ 95; Reply 7–8 (citing Ex. 1031 ¶¶ 34–39 (discussing Fig. 5)).

The '216 patent, when discussing Figures 5 and 6, describes IC formulations as showing "a classical curve, with a high and relatively narrow peak, followed by an exponential drop in plasma concentration," while stating that CR formulations exhibited "triple peaks in blood plasma concentration." Ex. 1001, 12:58–67 (Fig. 5); 14:47–3 (Fig. 6). Thus, it is not clear from the '216 patent itself that IC formulations always present a second "peak" at 12 hours, or that the alleged "peak" at 12 hours for the IC formulations, as asserted by Petitioner and its experts, actually signifies a "peak" as it relates to the "two or three peaks within about 12 hours" recited in claim 1.

In addition, as noted by Patent Owner, Petitioner's expert, Dr. Palmieri, provides testimony indicating that at least some oxymorphone compositions do not exhibit the "two or three peaks" recited in claim 1. PO Resp. 17–18. In response to a question about whether he determined "whether there are any published studies showing that some Oxymorphone compositions do not exhibit multiple peaks within 12 hours of administration," Dr. Palmieri responded that "[s]ometimes they're there, and sometimes they weren't there." Ex. 2012, 170:3–171:9. We are persuaded by Dr. Palmieri's testimony that some studies have shown that certain oxymorphone compositions do not exhibit two or three peaks within 12 hours of administration, even if he also testifies that "you have to wonder about the validity of the data," and that "[w]ith clinical studies there's always variation." *Id*.

In relation to Study B, Petitioner asserts that when Dr. Burgess was "presented with the uncompressed graph from the full study report, she confirmed that the IR formulations did, in fact, display multiple plasma peaks" citing deposition testimony of Dr. Burgess. Reply 8; Ex. 1042, 208:2–213:22. Our review of the cited testimony, however, indicates that Dr. Burgess did not confirm the existence of a second peak for the 5 mg IR formulation, and questioned the existence of a second peak for the 10 mg IR formulation. Ex. 1042, 212:6–213:9 (stating "definitely not for the last one" and "it's really hard to tell even with the 10 [mg] if that's a peak").

Thus, we are not persuaded that Petitioner has established by a preponderance of the evidence that "the presence of 2 or 3 peaks after administration of any oxymorphone formulation is an inherent property of all

oxymorphone compositions," as Petitioner argues. Pet. 17. Petitioner does not establish sufficiently that the "two or three peaks" limitation in claim 1 is "necessarily [] present, or the natural result of the combination of elements explicitly disclosed" in Maloney. *Par Pharm. Inc. v. TWI Pharms. Inc.*, 773 F.3d 1186, 1195–96 (Fed. Cir. 2014).

Based on the record before us, we conclude that Petitioner has not established by a preponderance of the evidence that claim 1, or any of claims 2, 6, and 12, which all depend from claim 1 and also require the "two or three peaks" limitation, would have been obvious over Maloney.

C. Obviousness over Oshlack and Handbook of Dissolution Testing

Petitioner contends that 1, 2, 6, 12–14, 17, 21–51, and 54–71 would have been obvious over Oshlack and the Handbook of Dissolution Testing, again relying on Declarations by Dr. Palmieri (Ex. 1003, Ex. 1104), Ms. Gray (Ex. 1002, Ex. 1025), and Dr. Gonzalez (Ex. 1031). Pet. 26–42; Reply 2–7, 9–15, Second Petition 7–24. Patent Owner contends otherwise, again relying on Declarations by Dr. Burgess (Ex. 2070, Ex. 2090) and Mr. Kelly (Ex. 2053). PO Resp. 14–15, 26–60; Supp. PO Resp. 1–7.

1. Oshlack (Ex. 1007)

Oshlack describes sustained-release oral formulations comprising an opioid analgesic, prepared using a melt extrusion technology. Ex. 1007, 1:10–15; 6:23–31. Oshlack describes "melt-extruded oral sustained-release dosage forms which comprise a pharmaceutically acceptable hydrophobic material, a retardant selected from waxes, fatty alcohols, and fatty acids, and a drug." *Id*. at 3:66–4:3. In certain embodiments, "the drug is incorporated into a melt-extruded strand which includes

a pharmaceutically acceptable hydrophobic material such as an alkylcellulose or an acrylic polymer or copolymer," as well as a plasticizer. *Id*. at 6:25–31.

In relation to opioid analgesics, Oshlack lists oxymorphone, among others. *Id*. at 7:9–34. In certain embodiments, "the hydrophobic material is selected from materials such as hydroxyalkylcelluloses such as hydroxypropylmethylcellulose [HPMC] and mixtures of the foregoing," referring to a list of acrylic polymers. *Id*. at 8:49–65. Oshlack discloses that the retardant material is "preferably a hydrophobic fusible carrier," such as one comprising "hydrophobic and hydrophilic polymers having hydrocarbon backbones." *Id*. at 8:66–9:23.

Oshlack also states that in "certain preferred embodiments" of opioid analgesic formulations:

> dosage forms will provide an *in-vitro release (when assessed by the USP Paddle or Basket Method at 100 rpm at 900 ml aqueous buffer (pH between 1.6 and 7.2) at 37º C. from about 1 to about 42.5% opioid released after one hour*, from about 5 to about 65% opioid release after 2 hours, from about 15 to about 85% opioid released after 4 hours, from about 20 to about 90% opioid released after 6 hours, from about 35 to about 95% opioid released after 12 hours, from about 45 to about 100% opioid released after 18 hours, and from about 55 to about 100% opioid released after 24 hours, by weight. Such formulations may further be characterized by a peak plasma level at from about 2 to about 8 hours after oral administration, and preferably from about 4 to about 6 hours after administration. Such formulations are further characterized by a W_{50} from about 4 to about 12 hours.

Id. at 11:60–12:12 (emphasis added).

Oshlack's claim 11 (which depends on its claims 1, 2, 7, and 10) similarly discloses a sustained-release pharmaceutical formulation comprising an opioid analgesic, such as oxymorphone, which:

> provides *an in-vitro release when assessed by the USP Paddle or Basket Method at 100 prm at 900 ml aqueous buffer (pH between 1.6 and 7.2) at 37º C. from about 1 to about 42.5% opioid release after one hour*, from about 5 to about 65% opioid released after 2 hours, from about 15 to about 85% opioid released after 4 hours, from about 20 to about 90% opioid released after 6 hours, from about 35 to about 95% opioid released after 12 hours, from about 45 to about 100% opioid released after 18 hours, and from about 55 to about 100% opioid released after 24 hours, by weight.

Id. at 25:40–26:49 (emphasis added).

2. Handbook of Dissolution Testing (Ex. 1008)

Chapter 3 in the Handbook describes dissolution methods for solid dosage forms, including the "Basket" and "Paddle" methods. Ex. 1008, 27–42.[10] When addressing "Stirring Rate (rpm)" in relation to both methods, the Handbook states: "As specified in individual monographs—but for general purposes when not otherwise specified—*rates of 50 rpm for the paddle and 100 rpm for the basket are recommended and have proved to be roughly equivalent* to one another in producing dissolution." *Id*. at 35 (emphasis added).

3. Analysis

As discussed above, claims 1, 2, 6, and 12 all require the "two or three peaks" limitation as recited in claim 1. Claims 67 and 70 similarly require two

[10] When citing to the Handbook of Dissolution Testing (Ex. 1008), we cite the original pagination in the document, rather than exhibit page numbers.

peaks of blood plasma levels of oxymorphone. While Petitioner provides little explanation or analysis in relation to the "two or three peaks" limitation in particular in this ground (Pet. 27–32, 37–42), Petitioner appears to rely on the same contentions discussed above in relation to all multiple "peaks" limitations, i.e., that the '216 patent establishes that all oxymorphone formulations exhibit two or more peaks upon administration. *See* Pet. 36 ("As discussed in Ground 1, the data the '216 patent show that even immediate release formulations have at least two oxymorphone blood profile peaks," and "the presence of 2 or 3 peaks after administration of any oxymorphone formulation is an inherent property of all oxymorphone compositions") (citing Ex. 1003 ¶ 84). As discussed above, Petitioner does not establish by a preponderance of the evidence that the multiple "peaks" feature of claims 1, 2, 6, and 12 is an inherent property of all oxymorphone compositions.

Petitioner also argues that the *in vitro* dissolution profiles of Oshlack's CR oxymorphone composition overlap those recited in challenged claims 13, 14, 17, 21–51, and 54–71. Pet. 26, 32, 38–42; Second Petition 18–20. In support, Petitioner relies on teaching in claim 11 of Oshlack, i.e., where it discloses "an in-vitro release when assessed by the USP Paddle or Basket Method at 100 [rpm] at 900 ml aqueous buffer (pH between 1.6 and 7.2) at 37° C. from about 1 to about 42.5% opioid release after one hour." Ex. 1007, 26:39–43. According to Petitioner, this disclosure renders obvious an *in vitro* release using the Paddle Method "at 50 rpm in 500 ml media having a pH of 1.2 to 6.8 at 37º C, about 15% to about 50%" of oxymorphone release after one hour, as required in all independent claims except claim 1. Pet. 28–29 (citing Ex. 1007, 26:39–43), 31–34

(citing Ex. 1007, 26:39–43; Ex. 1002 ¶¶ 84, 85, 87, 92, 93; Ex. 1003 ¶ 110), 38–42; Second Petition 18–20. Citing claim 11 in Oshlack, Petitioner similarly contends that Oshlack renders obvious other dissolution profiles, such as those recited in challenged dependent claims. Pet. 29, 32–34, 40–42; Second Petition 18–20.

In further support, Petitioner contends that an ordinary artisan would have known, as indicated in the Handbook, that the Paddle method at 50 rpm (recited in challenged claims) is "roughly equivalent" to the Basket method at 100 rpm, as disclosed in Oshlack. Pet. 40 (citing Ex. 1008, 35). Petitioner acknowledges that Oshlack teaches a media volume of 900 ml, while the challenged claims recite 500 ml, but contends that an ordinary artisan "would have understood that the size of the dissolution media volume would not result in any substantial differences in the *in vitro* dissolution profiles obtained for oxymorphone." Pet. 33–34 (citing Ex. 1002 ¶ 87).

Patent Owner responds that Petitioner has not established that Oshlack and the Handbook teach or suggest, expressly or inherently, an oxymorphone composition having the dissolution profiles recited in all challenged independent claims except claim 1, i.e., recited percentage by weight ranges of oxymorphone released over time in an "in vitro dissolution test comprising USP Paddle Method at 50 rpm in 500 ml media having a pH of 1.2 to 6.8 at 37 ºC." PO Resp. 31–45; Supp. PO Resp. 1, 3–7. Patent Owner cites evidence indicating that the Paddle method at 50 rpm (recited in challenged claims) and the Basket method at 100 rpm (disclosed in Oshlack) are not equivalent, despite the Handbook's unsupported statement that the two methods "have proved to be roughly equivalent to one

another in producing dissolution." PO Resp. 31–45 (citing Ex. 2070 ¶¶ 61–113); Ex. 1008, 35 (part of labeled page 16); *see also* labeled page 2 (indicating a copyright date of 1991); Supp. PO Resp. 3–7 (citing Ex. 2090 ¶¶ 17–26; Ex. 1080, 8568).

For example, Patent Owner refers to a scientific article entitled *Comparison of Operational Characteristics of Different Dissolution Testing Systems*, published in 1978, indicating that "direct comparison" of such methods is "often . . . impossible" because of "differences in parameters such as the dissolution medium or relative levels of agitation." *Id*. at 33 (citing Ex. 2024, 1732). Patent Owner also cites an excerpt from a textbook entitled *Applied Biopharmaceutics & Pharmacokinetics*, published in 1999, which states that "there is no simple correlation among dissolution results obtained with various [dissolution testing] methods." *Id*. at 33–34 (citing Ex. 2020, 145).

In addition, Patent Owner cites an excerpt from a textbook entitled *Remington: The Science and Practice of Pharmacy*, published in 2000, which states that the "relationship between intensity of agitation and the rate of dissolution varies considerably according to the type of agitation used, degree of laminar and turbulent flow in the system, shape and design of the stirrer . . . ." *Id*. at 34–35 (citing Ex. 2026, 662); *see also* Ex. 2026 (indicating a copyright date of 2000). Patent Owner asserts, citing testimony by Dr. Burgess in support, that based on these and other variables that influence dissolution rates, such as a "dead zone" of fluid flow existing underneath a paddle rotating at 50 rpm, "no mathematical correlation—empirical or theoretical—exists between the dissolution observed by different apparatus at different agitation rates." *Id*. at 35–36 (citing

Ex. 2070 ¶¶ 68–76 (citing Ex. 2027, 171)).

Patent Owner also contends that, during a deposition, Petitioner's expert, Ms. Gray, testified that results of dissolution tests in the Basket and Paddle methods may differ on a "case by case" basis. *Id*. at 36, 45 (quoting Ex. 2029, 72:8–16). According to Patent Owner, Ms. Gray agreed that the Handbook's "roughly equivalent" statement is unsupported, and she testified that formulations themselves can cause dissolutions to differ in the Basket and Paddle methods. *Id*. at 43–45 (citing Ex. 2029, 196:1–204:10, 63:8–11, 60:10–61:5).

Patent Owner also cites an article entitled *Comparative Dissolution Testing of Paracetamol Commercial Tablet Dosage Forms*, published in 2000, presenting dissolution testing results of nine acetaminophen tablets carried out using the Paddle method at 50 rpm and Basket method at 100 rpm at various pHs. *Id*. at 37–38 (citing Ex. 2030; Ex. 2070 ¶¶ 88–93 (citing Ex. 2030, 34–36, Figs. 1–4, and presenting a summary Table 1)). Citing testimony by Dr. Burgess, Patent Owner contends that this article indicates that "with some tablets dissolution is faster with the basket method and others with the paddle method." *Id*. at 37–38 (citing Ex. 2070 ¶¶ 90–91). Patent Owner cites other articles, presenting dissolution testing results for theophylline or ranitidine tablets, or a dimenhydrinate CR formulation, also showing disparities between the Basket and Paddle methods. *Id*. at 38–39 (citing Exs. 2031, 2032, 2033, 2034; Burgess Decl., Ex. 2070 ¶¶ 94–106).

Thus, according to Patent Owner, Petitioner has not provided sufficient evidence demonstrating that the dissolution profile of any Oshlack formulation, when using the Basket (or Paddle) method at 100 rpm, would fall within the recited dissolution profiles. *Id*. at 41. In addition, Patent Owner contends that because no

correlation exists between the Basket and Paddle methods, Petitioner has not provided sufficient evidence demonstrating that a person of ordinary skill in the art would have understood how Oshlack dissolution profiles related to the claimed dissolution profiles. *Id*. at 41–42.

In its Reply, Petitioner argues that certain references cited by Patent Owner (Exs. 2030, 2031, 2033, 2034, 2020) do not establish significant differences between the Basket and Paddle methods because, for example, they relate to dissolution profiles after only 5 minutes (rather than 30 minutes), or to IR tablets "with a release mechanism so different from Oshlack's controlled-release technology that it [] has no bearing" on the issue. *Id*. at 5–6. Petitioner also argues that Patent Owner "never asserts that the oxymorphone CR formulations taught by the prior art would have *in vitro* dissolution profiles that are materially different than those claimed by the '216 patent." *Id*. at 4; *see also* Supp. Reply 3–4 (stating "there is no evidence that the correlation is *not* applicable to oxymorphone formulations" and Patent Owner admits "it is *possible* that the two methods might give equivalent dissolution results"). In addition, Petitioner contends that "[o]bviousness does not depend upon the art showing a mathematical correlation between these testing methodologies; the law requires only a reasonable expectation of success, not absolute certainty." Reply 4–5, 6–7.

Here, Petitioner does not dispute that Oshlack and the Handbook do not exemplify a CR oxymorphone formulation having the recited dissolution profiles in an "in vitro dissolution test comprising USP Paddle Method at 50 rpm in 500 ml media having a pH of 1.2 to 6.8 at 37 ºC." Rather, Petitioner relies on claim 11 of Oshlack disclosing opioid analgesic formulations with "an in-vitro release when

assessed by the USP Paddle or Basket Method at 100 [rpm] at 900 ml aqueous buffer (pH between 1.6 and 7.2) at 37° C. from about 1 to about 42.5% opioid release after one hour." Ex. 1007, 26:39–43; Pet. 28–29, 33–34, 40.

Relying on its assertion that the Handbook establishes that the Paddle and Basket methods are "roughly equivalent" generally, Petitioner asserts that the dissolution release percentages ranges disclosed in claim 11 of Oshlack overlap with ranges recited in the challenged claims. Pet. 33, 40–42; Second Petition 18–19. Thus, according to Petitioner, an ordinary artisan would have arrived at the CR oxymorphone formulations recited in the challenged claims upon reading Oshlack. Pet. 38, 40. Alternatively, according to Petitioner, an ordinary artisan would have been able to use routine optimization to develop the recited formulations from the teachings of Oshlack, and would have had a reasonable expectation of success in doing so. *Id.* at 38–42.

Petitioner's position presumes, however, that Oshlack's claim 11 expressly or inherently discloses a CR oxymorphone formulation having the recited dissolution profiles, or that an ordinary artisan had reason to make a CR oxymorphone formulation having the recited dissolution profiles. On its face, "USP Paddle or Basket Method at 100 [rpm] at 900 ml aqueous buffer (pH between 1.6 and 7.2) at 37° C." (claim 11 of Oshlack) is not the same as "USP Paddle Method at 50 rpm in 500 ml media having a pH of 1.2 to 6.8 at 37º C." (recited in challenged claims). Thus, Oshlack's claim 11 does not disclose expressly a CR oxymorphone formulation having the recited dissolution profiles. Consequently, Petitioner relies, at least in part, on an inherency position to make its case.

Our reviewing court has clarified, in order to rely on inherency in an obviousness analysis, "the limitation at issue necessarily must be present, or the natural result of the combination of elements explicitly disclosed by the prior art." *Par*, 773 F.3d at 1196. In other words, Petitioner must establish in this case that an ordinary artisan following the teachings of Oshlack and the Handbook would have necessarily produced a CR oxymorphone formulation having the recited dissolution profiles "in an in vitro dissolution test comprising USP Paddle Method at 50 rpm in 500 ml media having a pH of 1.2 to 6.8 at 37º C," or that producing such a formulation would have been a natural result of following the teachings of those references. Petitioner has not provided an adequate showing in this regard.

Petitioner relies on the Handbook, which, as Patent Owner notes, cites no evidence in support of its statement that "rates of 50 rpm for the paddle and 100 rpm for the basket . . . have proved to be roughly equivalent to one another in producing dissolution." Ex. 1008, 35. By contrast, Patent Owner provides abundant scientific evidence indicating that the Paddle method at 50 rpm and the Basket method at 100 rpm are not equivalent as Petitioner contends, and that dissolution results obtained with one method do not necessarily provide information about dissolution results of the other. We credit the evidence cited by Patent Owner in this regard, notwithstanding Petitioner's criticism of a few references.

For example, among other references, Petitioner does not address adequately relevant literature indicating that "differences in parameters such as the dissolution medium or relative levels of agitation, recognized as having profound influence on dissolution results [], often make direct comparison impossible" (Ex. 2024, 1732),

or stating that "there is no simple correlation among dissolution results obtained with various methods" (Ex. 2020, 145), *see also id.* (stating that "[a]t 100 rpm, the basket method failed to pick up formulation differences detected by the paddle method"). Likewise, Petitioner does not address testimony by its own expert, Ms. Gray, who agreed, on a "case by case" basis, that "in some circumstances, depending on the drug, or the size, structure, etcetera, the results of the dissolution tests based on the basket method or paddle method may be different." Ex. 2029, 72:8–16.

Thus, Petitioner does not establish by a preponderance of the evidence that the dissolution profiles of claim 11 in Oshlack, as assessed by the Paddle or Basket Method at 100 rpm in 900 ml buffer, expressly or inherently disclose the dissolution profiles recited in the challenged claims, as assessed by the Paddle method at 500 rpm in 500 ml media. Likewise, Petitioner does not establish sufficiently that the dissolution profiles of claim 11 in Oshlack necessarily overlap the recited profiles, or that such overlap would be the natural result of the formulation of claim 11 in Oshlack. Moreover, because Petitioner does not establish sufficiently that the dissolution profiles taught in Oshlack (alone or in combination with the Handbook) are equivalent to the dissolution profiles recited in the challenged claims, Petitioner does not establish sufficiently that one would have had a reason to optimize the formulation of claim 11 in Oshlack to produce a CR oxymorphone tablet formulation having the dissolution profiles required by the challenged claims in the first place.[11]

[11] We also note that claim 11 in Oshlack depends on claims 1, 2, 7, and 10. Thus,

For the reasons given above, and in light of the record before us, Petitioner does not establish by a preponderance of the evidence that independent claims 1, 13, 21, 31, 38, 49, 55, or 66 of the '216 patent, nor any corresponding challenged dependent claims, would have been obvious over Oshlack and the Handbook of Dissolution Testing.

D. Patent Owner's Contingent Motions to Amend

Patent Owner has filed two Contingent Motions to Amend. Paper 29 (proposing to substitute claims 83 and 84 for original claims 21 and 31); Paper 67 (proposing to substitute claims 85 and 86 for original claims 44 and 47). Both Motions are contingent on a determination by the Board that Petitioner establishes by a preponderance of the evidence that original claims 21, 31, 44, and 47 are unpatentable. Because we determine that Petitioner has not established that those claims are unpatentable, we dismiss both Motions to Amend as moot.

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claim 11 is directed to a formulation encompassing a number of different opioid analgesics (claim 10 in Oshlack) and many different hydrophobic material and carriers (claim 1 in Oshlack), where the unit dose is "contained within a gelatin capsule" (claim 7 in Oshlack). Ex. 1007, 25:40–26:49. *See also* PO Resp. 26 (citing Ex. 1007, 5:27–31 (defining "sustained release" generally); 7:35–39 (describing a number of opioid analgesics); 8:62–65 (listing HPMC ("hydroxypropylmethylcellulose") among many hydrophobic materials, *id*. at 8:53–65). For the reasons discussed above, Petitioner does not explain sufficiently why an ordinary artisan would have had reason to optimization the *opioid analgesic capsule* formulation of claim 11 to have the recited dissolution profiles, much less an *oxymorphone tablet* formulation having those profiles, as recited in independent claims 13, 21, 31, 38, 49, 55, 66, and 71 of the '216 patent.

E. Motions to Exclude

In its Motion to Exclude, Patent Owner seeks to exclude certain paragraphs of the Declarations of Petitioner's expert, Ms. Gray, i.e., (1) paragraphs 94–97 of Exhibit 1002; (2) paragraphs 18 and 21 of Exhibit 1025; and (3) paragraphs 6 and 7–10 of Exhibit 1102. Paper 86, 1. Because we do not rely on those paragraphs of Ms. Gray's Declarations in this Final Written Decision, we dismiss Patent Owner's Motion to Exclude as moot.

In its Motion to Exclude, Petitioner seeks to exclude Patent Owner's Exhibit 2053, Mr. Kelly's Declaration, as well as Exhibits 2072, 2073, 2079, 2081, and 2082 relied upon by Mr. Kelly. Paper 90, 1–2. Petitioner asserts that those exhibits "contain hearsay and do not qualify as a hearsay exception." *Id*. Because we do not rely on those exhibits in this Final Written Decision, we dismiss Petitioner's Motion to Exclude as moot.

F. Patent Owner's Motion to Seal

Patent Owner has filed an Unopposed Motion for Entry of Protective Order (Paper 27) and two Motions to Seal evidence (Papers 30, 83). We grant the Unopposed Motion for Entry of Protective Order (Paper 27), and authorize Patent Owner to file an executed version of the proposed Protective Order (Exhibit 1 of Paper 27).

In its First Motion to Seal, Patent Owner requests that we seal unredacted versions of its Patent Owner Response (Paper 31), a Declaration by Dr. Burgess (Ex. 2070 "Confidential"), a Declaration of Marv Kelly (Ex. 2053 "Confidential"), and Exhibits 2013, 2016, 2019, 2036, 2052, 2063, 2066–2069, 2072–2082, 2087, and 2088. Paper 30, 1.

There is a strong public policy in favor of making information filed in an *inter partes* review open to the public, especially because the proceeding determines the patentability of claims in an issued patent and, therefore, affects the rights of the public. Under 35 U.S.C. § 316(a)(1) and 37 C.F.R. § 42.14, the default rule is that all papers filed in an *inter partes* review are open and available for access by the public; a party, however, may file a concurrent motion to seal and the information at issue is sealed pending the outcome of the motion. It is, however, only "confidential information" that is protected from disclosure. 35 U.S.C. § 316(a)(7); *see* Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,760 (Aug. 14, 2012). The standard for granting a motion to seal is "for good cause." 37 C.F.R. § 42.54(a). The party moving to seal bears the burden of proof in showing entitlement to the requested relief, and must explain why the information sought to be sealed constitutes confidential information. 37 C.F.R. § 42.20(c). As discussed during the oral hearing, confidential information filed under a motion to seal will become public if identified in this Final Written Decision. Tr. 4:14–5:7; Trial Practice Guide, 77 Fed. Reg. at 48,761.

We have reviewed the unredacted versions of the Patent Owner Response (Paper 31), Dr. Burgess' Declaration (Ex. 2070) and Mr. Kelly's Declaration (Ex. 2053), as well as Exhibits 2013, 2016, 2019, 2036, 2052, 2063, 2066–2069, 2072–2082, 2087, and 2088. We are persuaded that good cause exists to have some, but not all, of these documents remain under seal. The redacted portions of the Patent Owner Response and the aforementioned exhibits contain confidential information pertaining to either Patent Owner's non-public sales and prescription figures, or trade secrets relating to the research, development, and regulatory FDA approval of

Patent Owner's OPANA® ER products, and are tailored to redact confidential information.

In our analysis in this Final Written Decision, however, we discuss certain redacted portions of the Patent Owner Response (Paper 31, 17–18) (discussing Study A), and rely on certain redacted portions of Dr. Burgess' Declaration (Ex. 2070 ¶¶ 33–35) (discussing Study A) and Exhibit 2013 (Study A). Thus, those portions of the Patent Owner Response (Paper 31, 17–18) and Dr. Burgess' Declaration (Ex. 2070 ¶¶ 33–35) (discussing Study A) and Exhibit 2013 as filed (Study A) may not remain under seal.

Within two weeks from the date of this Final Written Decision, Patent Owner shall refile revised redacted versions of the Patent Owner Response (Paper 31) and Dr. Burgess' Declaration (Ex. 2070), such that pages 17–18 in the Patent Owner Response, and paragraphs 33–35 of Dr. Burgess' Declaration, discussing Study A, are unredacted.

After Patent Owner refiles those revised documents, the unredacted versions of the Patent Owner Response (Paper 31) and Dr. Burgess' Declaration (Ex. 2070 "Confidential"), as well as Mr. Kelly's Declaration (Ex. 2053) and Exhibits 2016, 2019, 2036, 2052, 2063, 2066–2069, 2072–2082, 2087, and 2088 will be maintained under seal under the terms of the Protective Order entered in this proceeding. Because we have identified and relied on certain information or evidence in this Final Written Decision, and in view of the public's interest in maintaining a complete and understandable record, however, the revised redacted versions of the Patent Owner Response and Dr. Burgess' Declaration (Ex. 2070),

as well Ex. 2013 as currently of record, will not be maintained under seal under the terms of the Protective Order entered in this proceeding.

In its Second Motion to Seal, Patent Owner requests that we seal an unredacted version of Exhibit 2093, i.e., an unredacted transcript of the deposition of Dr. Palmieri dated February 18, 2015, which took place in *Endo v. Amneal*, 12cv8115 (SDNY). Paper 83, 2–3. Patent Owner contends that the transcript "contains information related to confidential research, development, and commercial information and is subject to a protective order in the Southern District of New York litigation." *Id*. at 3. We grant this Motion, as we do not rely on Exhibit 2093 in this Final Written Decision.

III. CONCLUSION

For the foregoing reasons, Petitioner has not demonstrated by a preponderance of the evidence that claims 1, 2, 6, and 12 of the '216 patent would have been obvious over Maloney, or that claims 1, 2, 6, 12–14, 17, 21–51, and 54–71 would have been obvious over Oshlack and the Handbook of Dissolution Testing.

IV. ORDER

For the reasons given, it is

ORDERED that claims 1, 2, 6, 12–14, 17, 21–51, and 54–71 of the '216 patent are not held unpatentable;

FURTHER ORDERED that Patent Owner's Contingent Motions to Amend are dismissed

FURTHER ORDERED that Petitioner's and Patent Owner's Motions

to Exclude Evidence are dismissed;

FURTHER ORDERED that Patent Owner's Unopposed Motion for Entry of Protective Order is granted;

FURTHER ORDERED that Patent Owner's First Motion to Seal is granted-in-part;

FURTHER ORDERED that Patent Owner shall Owner shall refile revised redacted versions of its Patent Owner Response (Paper 31) and Dr. Burgess' Declaration (Ex. 2070), such that pages 17–18 in the Patent Owner Response, and paragraphs 33–35 of Dr. Burgess' Declaration, are unredacted, as discussed above;

FURTHER ORDERED that Patent Owner's Second Motion to Seal is granted; and

FURTHER ORDERED that, because this is a Final Written Decision, the 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.

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