UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

| | |
|---|---|
| In re: OXYCONTIN ANTITRUST LITIGATION | 04-Md-1603 (SHS) |
| PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., and PURDUE PHARMACEUTICALS L.P.,<br>Plaintiffs,<br>-against-<br>AMNEAL PHARMACEUTICALS, LLC,<br>Defendant. | 13-Cv-3372 (SHS) |

# FINDINGS OF FACT AND CONCLUSIONS OF LAW

**TABLE OF CONTENTS**

## TABLE OF ABBREVIATIONS

| | |
|---|---|
| '060 Patent | U.S. Patent No. 8,309,060 |
| '888 Patent | U.S. Patent No. 8,337,888 |
| '963 Patent | U.S. Patent No. 6,488,963 |
| 2014 Stip. | Stipulations or Agreed Statements of Fact or Law, Joint Pretrial Order, No. 04-Md-1603, Dkt. No. 572, filed June 23, 2014 |
| ANDA | Abbreviated New Drug Application |
| API | active pharmaceutical ingredient |
| Bastin | International Application No. WO 95/20947 |
| C. | Celsius |
| cP | centipoise |
| CPM | chlorpheniramine maleate |
| FDA | U.S. Food and Drug Administration |
| Hoffmeister | U.S. Patent No. 4,070,494 |
| HPMC | hypromellose K100M |
| Joshi | U.S. Patent Application Publication No. US 2002/0187192 |
| NDA | New Drug Application |
| OROS | osmotically controlled-release oral delivery system |
| PEO | polyethylene oxide |
| PTO | U.S. Patent and Trademark Office |
| Royce | U.S. Patent No. 5,273,758 |
| Shaw | U.S. Patent No. 3,980,766 |
| USP | United States Pharmacopeia |

SIDNEY H. STEIN, U.S. District Judge.

## PART 1. INTRODUCTION

This action concerns the infringement and validity of United States Patent No. 8,337,888 ("the '888 Patent"), which is associated with the opioid pain reliever OxyContin. The '888 Patent claims a controlled release oral dosage form containing oxycodone that forms a gel when dissolved in an aqueous liquid. The gelling properties of the invention enable it to resist abuse by injection, snorting, and oral ingestion.

Plaintiffs, led by OxyContin manufacturer Purdue Pharma L.P., allege that defendant Amneal, which produces generic pharmaceutical products, has infringed several claims of the patent by seeking approval from the U.S. Food and Drug Administration ("FDA") to sell a generic version of OxyContin. Amneal responds that its proposed product does not infringe plaintiffs' patent and that even if it did, the asserted claims of the patent are invalid. The parties presented factual support for their contentions during a week-long bench trial before this Court.

Applying the relevant legal standards to the evidence adduced at trial, the Court concludes that although Amneal has infringed the '888 Patent, the asserted claims are invalid as obvious and indefinite.

## I. THE RECORD AND RELEVANT PROCEEDINGS

### *A. The '888 Patent and Asserted Claims*

The '888 Patent issued on December 25, 2012. (PTX 4002 [hereinafter "'888 Patent"] at (45).) It claims priority to a provisional application, Serial No. 60/310,534, filed August 6, 2001. (Stipulations or Agreed Statements of Fact or Law, Joint Pretrial Order, No. 04-Md-1603, Dkt. No. 664, filed June 23, 2014, at ¶ 24 [hereinafter "2014 Stip."].)

Purdue[1] alleges that Amneal's proposed formulation infringes claims 5, 7, 23, and 24 of the '888 Patent. Independent claim 1, from which all asserted claims depend, claims a controlled release oral dosage form containing the active pharmaceutical ingredient ("API") oxycodone and a gelling agent comprising polyethylene oxide ("PEO"). ('888 Patent at 40:22-29.) When the dosage form is dissolved in a small amount of aqueous liquid, it attains a viscosity of at least about ten centipoise ("cP"), thereby hindering attempts at injection, snorting, or swallowing. (*Id.* at 2:64-3:30, 40:22-29.) The dosage form of claim 1 also provides a therapeutic effect for at least about twelve hours when orally administered to a human patient. (*Id.* at 40:30-32.)

The asserted dependent claims specify that the aqueous liquid is water (claim 5), that the dissolved dosage form achieves a viscosity of at least about 60 cP (claim 7), and that tampering includes crushing (claim 23) or dissolution in an aqueous liquid with heating greater than 45° Celsius ("C.") (claim 24). ('888 Patent at 40:45-46, 40:51-52, 42:10-17.)

### *B. The 2013 Teva Trial*

In September and October of 2013, the Court held a bench trial in the consolidated actions of *Purdue Pharma L.P. et al. v. Teva Pharmaceuticals USA, Inc.*, Nos. 11-Cv-2037 and 12-Cv-5083; *Purdue Pharma L.P. et al. v. IMPAX Labs., Inc.*, No. 11-Cv-2400; and *Purdue Pharma L.P. et al. v. Sandoz Inc.*, Nos. 11-Cv-4694 and 12-Cv-5082. Because the evidence presented at the 2013 trial relates to the claims and defenses at issue here, the parties have agreed to adopt the entire record as part of the factual record in this action. (Joint Pretrial Order, No. 4-Md-1603, Dkt. No. 664, filed June 23, 2014, at 20 ¶ 14.)

### *C. Claim Construction*

After extensive briefing and a claim construction hearing, this Court issued a Claim Construction Opinion and Order in May 2014, which construed

[1] This Opinion refers to plaintiffs collectively as "Purdue."

the patent claims at issue to resolve the parties' disputes as to their meaning. *See In re OxyContin Antitrust Litig.*, No. 04-Md-1603, 2014 WL 2198590 (S.D.N.Y. May 27, 2014) [hereinafter "*Claim Construction*"]. All parties to this action participated in litigating the claim constructions; consequently, for purposes of this trial, that Opinion and Order "define[s] the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quotation marks omitted).

During trial, several new issues of claim construction arose that the parties had not fully presented to the Court during its earlier claim construction hearing. The Court must resolve these claim construction disputes before analyzing the infringement and validity of the '888 Patent. *See Rockwell Int'l Corp. v. United States*, 147 F.3d 1358, 1362 (Fed. Cir. 1998).

### *D. The 2014 Trial*

The bench trial in this action began on July 14, 2014. Over the course of five days, the Court heard live testimony from nine witnesses and admitted hundreds of exhibits. Purdue's expert witnesses included Dr. Martyn Davies, an expert in drug delivery systems, including the development and testing of controlled-release formulations (Davies 2013 Tr. 683-84[2]; Davies Tr. 326), and Dr. Jerry Hausman, an expert in economics and econometrics (Hausman Tr. 272). Serving as expert witnesses for Amneal were Dr. Mohan Rao, an expert in economic analysis, including commercial success (Rao 2013 Tr. 1576; Rao Tr. 657-58); Dr. Fernando Muzzio, an expert in the design, development, and analysis of pharmaceutical products and processes, as well as rheology and the measurement of viscosity (Muzzio Tr. 489); and Dr. Michael Maurin, an expert in pharmacy practice, the syringeability of drug products, and pharmaceutical formulation and testing, specifically *in vivo* and *in vitro* testing as related to therapeutic effect (Maurin Tr. 741).

[2] Citations to "2013 Tr." refer to the transcript of the 2013 trial, No. 04-Md-1603, Dkt. Nos. 599-621.

Another defendant, Teva Pharmaceuticals USA, Inc., also participated in the 2014 trial but has since entered into a settlement with Purdue. Purdue accused Teva of infringing both the '888 Patent and U.S. Patent No. 8,309,060 ("the '060 Patent"). The '060 Patent claims an abuse-proofed dosage form with a high breaking strength that prevents crushing; it may optionally contain additional abuse-deterring components, such as gelling agents. (PTX 4000 at 6:24-48; 21:5-14, 21:37-46.) Purdue and Teva entered into a consent judgment after the conclusion of the trial. (No. 13-Cv-4606, Dkt. No. 92.) The Court therefore does not set forth findings of fact and conclusions of law regarding Teva's alleged infringement of the '888 and '060 Patents or the validity vel non of the '060 Patent. However, the Court draws on the evidence presented at trial on those issues to the extent it relates to the validity of the '888 Patent and Amneal's alleged infringement.

### *E. This Opinion*

On the basis of the record established by the parties and the applicable law, the Court enters these findings of fact and conclusions of law pursuant to Rule 52(a) of the Federal Rules of Civil Procedure. To the extent that any findings of fact may be deemed conclusions of law, they shall also be considered conclusions of law; to the extent that any conclusions of law may be deemed findings of fact, they shall also be considered findings of fact. *Cf. Miller v. Fenton*, 474 U.S. 104, 113-14 (1985).

## II. LEGAL STANDARDS[3]

### *A. Procedural Context and the Hatch-Waxman Act*

This litigation arises under the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C.

[3] Except where the law has evolved, the following discussion is taken largely from the Court's findings of fact and conclusions of law resulting from the 2013 trial. *See In re OxyContin Antitrust Litig.*, 994 F. Supp. 2d 367, 378-84 (S.D.N.Y. 2014).

§§ 301 *et seq.*) ("Hatch-Waxman Act"). The Hatch-Waxman Act provides a streamlined regulatory pathway for generic pharmaceutical companies to seek approval of their drugs, while giving branded pharmaceutical companies an opportunity to sue to defeat approval of the generic drugs.

Pursuant to the Hatch-Waxman Act, a pharmaceutical company can seek FDA approval for a generic drug based on an already-approved branded drug by filing an Abbreviated New Drug Application ("ANDA"). 21 U.S.C. § 355(j)(2)(A), (8)(B). As the name suggests, an ANDA does not require the detailed showings necessary for the pioneer New Drug Application ("NDA"), such as proof of safety and effectiveness. *See id.* Where a branded manufacturer's patent has not yet expired but a generic manufacturer nonetheless wants to enter the market, the generic must file a pre-expiration challenge (known colloquially as a "Paragraph IV" certification, after the relevant paragraph number in the legislation). *Id.* § 355(j)(2)(A)(vii)(IV). A generic firm's Paragraph IV certification must establish bioequivalence of the proposed generic version with the approved branded version of the drug. *See* 21 C.F.R. § 314.94(a)(9). The Paragraph IV certification must also state and explain at least one of the following claims: that the generic product would not infringe the branded firm's patent, or that the branded firm's patent is invalid. *See* 21 U.S.C. § 355(j)(2)(B)(iv)(II).

As the U.S. Court of Appeals for the Second Circuit has explained, the mere filing of "[a]n ANDA-IV certification itself constitutes an act of infringement, triggering the branded manufacturer's right to sue." *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 101 (2d Cir. 2010) (citing 35 U.S.C. § 271(e)(2)(A)). When a branded manufacturer files suit pursuant to that right within 45 days of receiving notice of the Paragraph IV certification, the litigation automatically stays the generic's entry to the market. 21 U.S.C. § 355(j)(5)(B)(iii). At its core, then, the Hatch-Waxman Act "redistributes the relative risks between the patent holder and the generic manufacturer, allowing generic manufacturers to challenge the validity of the patent without incurring the costs of market entry or the risks of damages from

infringement." *Ark. Carpenters Health & Welfare Fund*, 604 F.3d at 101. More significantly for purposes of this litigation, this structure allows the parties to try the dueling issues of patent infringement and patent invalidity simultaneously.

### *B. Claim Construction*

"[T]he claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips*, 415 F.3d at 1312 (quotation marks omitted). "Generally, a claim term is given the ordinary and customary meaning as understood by a person of ordinary skill in the art at the time of invention." *InTouch Techs., Inc. v. VGO Commc'ns, Inc.*, 751 F.3d 1327, 1339 (Fed. Cir. 2014).

Because ordinary and customary meaning cannot be determined "in a vacuum," the Federal Circuit has stressed "the importance of intrinsic evidence" to claim construction. *Phillips*, 415 F.3d at 1313, 1317 (quotation marks and citations omitted). The analysis "must begin and remain centered on the claim language itself." *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004) (quotation marks and alterations omitted). "Claims, however, must be construed in light of the appropriate context in which the claim term is used." *Aventis Pharm. Inc. v. Amino Chems. Ltd.*, 715 F.3d 1363, 1373 (Fed. Cir. 2013). That context includes the specification, which "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (quotation marks and citation omitted).

The prosecution history also constitutes intrinsic evidence and "has an important role in claim construction by supplying context to the claim language." *Aventis*, 715 F.3d at 1373. Because the prosecution history "represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation," it is often less helpful than the specification for purposes of claim construction. *Phillips*, 415 F.3d at 1317.

Nonetheless, the prosecution history may "provide[] evidence of how the PTO and the inventor understood the patent." *Id.*

Courts may also look to extrinsic evidence—"all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317 (quotation marks and citations omitted). Such evidence, however, may not be used "to contradict claim meaning that is unambiguous in light of the intrinsic evidence." *Id.* at 1324. "Ultimately, the construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Takeda Pharm. Co. Ltd. v. Zydus Pharm. USA, Inc.*, 743 F.3d 1359, 1363 (Fed. Cir. 2014) (quotation marks, citations, and alterations omitted).

Although claim construction is a question of law, it often presents subsidiary factual issues where, as here, the court must consult extrinsic evidence to understand the underlying science or the meaning of a term of art. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015).

### *C. Claims of Patent Infringement*

Patent infringement "is an issue of fact, which the patentee must prove by a preponderance of the evidence." *Siemens Med. Solutions USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.*, 637 F.3d 1269, 1279 (Fed. Cir. 2011). "In order to prove infringement, a patentee must show that every limitation of the claims asserted to be infringed is found in the accused device." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1565 (Fed. Cir. 1997).

The infringement inquiry involves two steps: (1) "the claim must be properly construed to determine its scope and meaning" and (2) "the claim as properly construed must be compared to the accused device or process." *Absolute Software, Inc. v. Stealth Signal, Inc.*, 659 F.3d 1121, 1129 (Fed. Cir. 2011) (quotation marks omitted). The Court's Claim Construction Opinion and Order of May 27, 2014, as well as the Court's resolution of other outstanding claim construction disputes *infra*, embody the first step.

"The second step in [this two-step] analysis is to apply the claims to the accused device." *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1345 (Fed. Cir. 2002). Because the allegedly infringing product in a Hatch-Waxman Act case is not yet on the commercial market, the infringement inquiry focuses on what is likely to be sold following FDA approval. *See Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002). The accused device infringes a claim "when each of the claim limitations 'reads on,' or in other words is found in, the accused device." *Id.* A patentee may prove infringement by either direct or circumstantial evidence. *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1326 (Fed. Cir. 2009).

### *D. The Affirmative Defense of Patent Invalidity*

A defendant "in any action involving . . . infringement of a patent" may plead as an affirmative defense that the asserted patent is invalid. 35 U.S.C. § 282(b)(2)-(3); *see also Microsoft Corp. v. i4i L.P.*, 131 S. Ct. 2238, 2242 (2011). Because "[a] patent shall be presumed valid," "[t]he burden of establishing invalidity . . . rest[s] on the party asserting such invalidity." 35 U.S.C. § 282(a). A defendant asserting patent invalidity must demonstrate invalidity by clear and convincing evidence. *Microsoft Corp.*, 131 S. Ct. at 2242.

#### 1. Novelty and Anticipation

An invention must be novel in order to receive a valid patent. 35 U.S.C. § 102(a) (2006). "Invalidity based on lack of novelty (often called 'anticipation') requires that the same invention, including each element and limitation of the claims, was known or used by others before it was invented by the patentee." *Hoover Grp., Inc. v. Custom Metalcraft, Inc.*, 66 F.3d 299, 302 (Fed. Cir. 1995). A patent is therefore invalid due to anticipation when "a single prior art reference . . . expressly or inherently disclose[s] each claim limitation." *Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1334 (Fed. Cir. 2008). The doctrine's application is encapsulated in the old chestnut: "[t]hat which infringes, if later, would anticipate, if earlier." *Upsher-Smith Labs., Inc. v. Pamlab, LLC*, 412 F.3d

1319, 1322 (Fed. Cir. 2005) (quoting *Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (1889) (internal quotation marks omitted)).

The anticipating reference need not explicitly spell out each element of the anticipated patent claim, but rather can teach a claim limitation if the "teaching is inherent in the [] prior art reference." *Corning Glass Works v. Sumitomo Elec. USA, Inc.*, 868 F.2d 1251, 1262 (Fed. Cir. 1989). To show inherent anticipation, a defendant must demonstrate clearly and convincingly that a claim limitation not disclosed in the anticipating reference will always be present when the prior art is practiced as taught in that reference. *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047-48 (Fed. Cir. 1995). "Inherent anticipation requires that the missing descriptive material is 'necessarily present,' not merely probably or possibly present" in the anticipating reference. *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002).

Anticipation and its subsidiary issues are questions of fact. *Amkor Tech., Inc. v. Int'l Trade Comm'n*, 692 F.3d 1250, 1254 (Fed. Cir. 2012) (anticipation); *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1328 (Fed. Cir. 2001) (inherency).

**2. Obviousness and Nonobviousness**

A patent for an invention may not be obtained "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a) (2006). "The ultimate judgment of obviousness is a legal determination." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 427 (2007). That legal determination rests on "underlying factual inquiries including: (1) the scope and content of the prior art, (2) the differences between the claimed invention and the prior art, (3) the level of ordinary skill in the art, and (4) objective indicia of nonobviousness." *Pregis Corp. v. Kappos*, 700 F.3d 1348, 1354 (Fed. Cir. 2012); *see also Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966).

For purposes of obviousness, the hypothetical person of skill in the art is presumed to know all of the teachings of the prior art in the field of the invention at the time of the patent's priority date. *See, e.g.*, *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). Moreover, "[a] reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem." *In re ICON Health & Fitness, Inc.*, 496 F.3d 1374, 1379-80 (Fed. Cir. 2007) (quotation marks and citation omitted).

"Generally, a party seeking to invalidate a patent as obvious must demonstrate by clear and convincing evidence that a skilled artisan would have been motivated to combine the teaching of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *OSRAM Sylvania, Inc. v. Am. Induction Techs., Inc.*, 701 F.3d 698, 706 (Fed. Cir. 2012) (quotation marks omitted). The court may "look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR*, 550 U.S. at 418. The overall obviousness inquiry must remain "expansive and flexible," and "a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* at 415, 418.

In assessing obviousness, courts must avoid the use of hindsight and ought not "simply retrace[] the path of the inventor." *See Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008). To guard against the prejudice of hindsight bias, the court must consider objective indicia of nonobviousness. *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 711 F.3d 1348, 1368 (Fed. Cir. 2013). "Objective evidence of nonobviousness can include copying, long felt but unsolved need, failure of others, commercial

success, unexpected results created by the claimed invention, unexpected properties of the claimed invention, licenses showing industry respect for the invention, and skepticism of skilled artisans before the invention." *Id.* In order for commercial success to provide an objective indication of nonobviousness, the patentee must demonstrate that the success of the commercial product arises from the patent claims at issue. *See, e.g.*, *King Pharm., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1281 (Fed. Cir. 2010); *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000) ("A nexus between commercial success and the claimed features is required."). And in considering whether there was "a long-felt, unmet need" that the invention satisfied, the starting point is "the date of an articulated identified problem and evidence of efforts to solve that problem." *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1332-33 (Fed. Cir. 2009).

**3. Definiteness**

A valid patent must "particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention." 35 U.S.C. § 112 (2006). The requirement of definiteness entails a "delicate balance." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2128 (2014) (quotation marks omitted). "Some modicum of uncertainty" is inevitable, and a patent is not indefinite merely because "readers could reasonably interpret the claim's scope differently." *Id.* at 2128. However, the patent "must be precise enough to afford clear notice of what is claimed." *Id.* at 2130. Therefore, "a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Id.* at 2124. This standard "mandates clarity, while recognizing that absolute precision is unattainable." *Id.* at 2129.

Indefiniteness problems may arise when "results can dramatically differ according to which of several quantitative techniques for applying a claim term is chosen, and the patent does not make clear which technique is meant." *Frans Nooren Afdichtingssystemen B.V. v. Stopaq Amcorr Inc.*, 744 F.3d 715, 724 (Fed.

Cir. 2014). In other words, if the choice of measurement technique or sample preparation method determines whether or not an accused product falls within the scope of a patent's claims, and the ordinarily skilled artisan cannot discern any guidance on which method or technique to utilize, the patent is invalid for indefiniteness. *See Takeda*, 743 F.3d at 1366, 1367 & n.4; *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1254-55 (Fed. Cir. 2008); *Howmedica Osteonics Corp. v. Tranquil Prospects, Ltd.*, 401 F.3d 1367, 1371 (Fed. Cir. 2005); *Honeywell Int'l, Inc. v. Int'l Trade Comm'n*, 341 F.3d 1332, 1339-40 (Fed. Cir. 2003); *In re OxyContin Antitrust Litig.*, 994 F. Supp. 2d 367, 433-35 (S.D.N.Y. 2014).

Although patent indefiniteness is a question of law that is intricately related to claim construction, *see Cordis Corp. v. Boston Sci. Corp.*, 561 F.3d 1319, 1331 (Fed. Cir. 2009), courts may make factual findings in support of their legal conclusions, *see HTC Corp. v. IPCom GmbH & Co., KG*, 667 F.3d 1270, 1279 (Fed. Cir. 2012) (noting that such factual findings are reviewed for clear error).

### *E. Attorney's Fees*

In a lawsuit for patent infringement, "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party." 35 U.S.C. § 285. The U.S. Supreme Court has explained section 285's limitation to "exceptional cases" in this way:

> An "exceptional" case is simply one that stands out from others with respect to the substantive strength of a party's litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated. District courts may determine whether a case is "exceptional" in the case-by-case exercise of their discretion, considering the totality of the circumstances.

*Octane Fitness, LLC v. ICON Health & Fitness*, 134 S. Ct. 1749, 1756 (2014). In order for a court to award fees to the prevailing party, that party must demonstrate by a preponderance of the evidence that the case is exceptional. *See id.* at 1758.

## PART 2. FINDINGS OF FACT AND CONCLUSIONS OF LAW

### I. CLAIM CONSTRUCTION

In its Claim Construction Opinion and Order, the Court construed independent claim 1 of the '888 Patent as follows:

> 1. A controlled release oral dosage form comprising:
>
> . . .
>
> 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; such dissolution having optionally been accompanied by tampering with the dosage form through mechanical, thermal, and/or chemical means of manipulation which changes the physical properties of the dosage form, e.g., to liberate the opioid agonist for immediate release if it is in sustained release form, or to make the opioid agonist available for inappropriate use such as administration by an alternate route, e.g. parenterally; the tampering can be, e.g., by means of crushing, shearing, grinding, chewing, dissolution in a solvent, heating (e.g., greater than about 45° C.), or any combination thereof;
>
> . . .

*Claim Construction*, 2014 WL 2198590, at *5-6.

During trial, two additional claim construction issues arose that the Court must resolve before addressing the infringement and validity of the '888 Patent. First, the parties disagree on the method an ordinarily skilled artisan would use to assess whether the 10 cP viscosity limitation—which the Court will refer to as the "viscosity test"—has been met. Specifically, their dispute concerns the appropriate shear rate, tampering temperature, testing temperature, and extent of dissolution. Second, the parties disagree on which substance must impart the requisite 10 cP of viscosity: Amneal contends that it

is the PEO alone, while Purdue argues that it is the "gelling agent" more broadly, which must include PEO but may also comprise other substances.

The Court must construe the '888 Patent from the perspective of a person of ordinary skill in the art. *See, e.g.*, *Teva Pharm. USA, Inc.*, 135 S. Ct. at 841. The parties agree that for purposes of this litigation, an ordinarily skilled artisan has a degree in one or more fields of medicine, chemical engineering, chemistry, pharmaceutical science, polymer chemistry, pharmaceutics, pharmaceutical technology, pharmacokinetics, and/or pharmacology, and/or a number of years of industry training or experience in one or more of those fields. (Tr. 1033-34.)

### *A. Method of Testing Viscosity*

Independent claim 1 provides that the dosage form must attain a viscosity of at least about 10 cP when dissolved in about 0.5 to about 10 milliliters of an aqueous liquid. ('888 Patent at 40:25-29.) All of the asserted claims of the '888 Patent depend from claim 1 and therefore incorporate this viscosity test. Claim 7 specifies that a viscosity of at least about 60 cP is required. (*Id.* at 40:51-52.)

The parties agree that a person of skill in the art would conduct the viscosity test using a standard piece of laboratory equipment known as a rheometer.[4] (Davies Tr. 344; Muzzio Tr. 608.) Rheometers feature a spindle that fits inside a cup, which is filled with the liquid whose viscosity is being tested. (Davies Tr. 360; Muzzio Tr. 510.) The width of the gap between the cup and the spindle varies. (*See* Muzzio Tr. 510.) As the spindle rotates inside the cup, the rheometer measures the liquid's resistance to the movement of the spindle. (Davies Tr. 360.) The more viscous the liquid, the greater its resistance and the

[4] Although the parties and witnesses to the trial often used the terms "viscometer" and "rheometer" interchangeably (*see, e.g.*, Maurin Tr. 885), it appears that the latter is the relevant instrument for purposes of the '888 Patent and that all experts used rheometers in their tests (*id.*; Muzzio Tr. 653).

more force needed to make it flow. (*Id.*) Viscosity is expressed in a unit of measurement known as centipoise. (*Id.* 340.)

The parties disagree as to the guidance the patent provides on a number of testing parameters that may affect viscosity. The '888 Patent's claims do not expressly identify the shear rate that should be employed, the temperature at which the dissolved dosage form should be tampered or tested, or the extent to which the dosage form must be dissolved. Purdue proposes specific values for each of these variables, while Amneal contends that the patent's viscosity test embraces a much wider range of reasonable choices.

**1. The viscosity test is not limited to zero shear viscosity and includes, at a minimum, shear rates ranging from .01 to 100 reciprocal seconds.**

The dosage forms contemplated by the '888 Patent are pseudo-plastic, non-Newtonian solutions, which means that their viscosity depends to some degree on shear rate. (Davies Tr. 360-61; Muzzio Tr. 511, 513-14.) In mathematical terms, shear rate equals the speed of the rotating spindle divided by the distance between the spindle and the cup. (Muzzio Tr. 511; *see* PTX 4232 at PRF0029326.) Shear rate is expressed in reciprocal seconds. (*See, e.g.*, Davies Tr. 416; Muzzio Tr. 499.) As illustrated by Figure 1 below, pseudo-plastic solutions follow a viscosity curve that features three "regions" corresponding to shear rate. (Davies Tr. 972-73; PTX 4232 at PRF0029330.) At very low shear rates, viscosity is independent of shear rate, as shown by the plateau in region I; this region is also known as "zero shear viscosity." (Davies Tr. 361, 972; PTX 4232 at PRF0029329-30.) Notably, zero shear viscosity (or "zero shear") spans a range of shear rates. (Davies Tr. 928-29.) In region II, viscosity decreases dramatically as shear rate increases. (Davies Tr. 360-61, 972; PTX 4232 at PRF0029329-30.) At the very high shear rates of region III, however, viscosity levels out and again becomes independent of shear rate. (Davies Tr. 972-73; PTX 4232 at PRF0029329-30.)

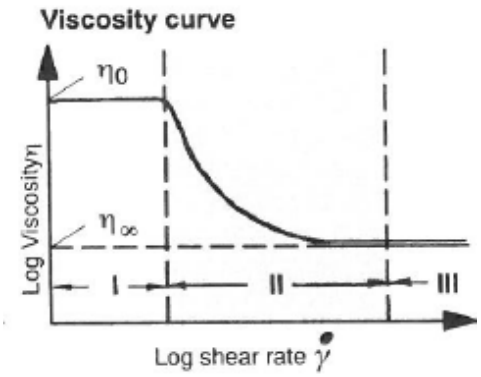


Figure 1 (PTX 4232 at PRF0029330)

Purdue argues that an ordinarily skilled artisan practicing the '888 Patent would measure viscosity at zero shear. Amneal, on the other hand, contends that the patent provides no guidance on shear rate and that persons of skill in the art could reasonably measure viscosity over a much wider range of shear rates.

The Court turns first to the claim language and the specification, which nowhere mention the term shear rate. Nor do they provide information from which shear rate can be determined, namely rheometer model, cup size, spindle size, and test speed. (Muzzio Tr. 514; *see* DTX 9173 at 0021.)

Example 3 contains the specification's only detailed description of the viscosity test, and it too is silent on shear rate. The example explains that when a placebo OxyContin tablet was mixed with citrus pectin (a gelling agent) and small amounts of water, "all the extracts were hard or difficult to pull into an insulin syringe." ('888 Patent at 32:3-6, 32:26-27.) In Purdue's view, Example 3 proves that the patent requires the use of zero shear viscosity because the solutions were in a static state at the time they were pulled into the syringe, and the viscosity of solutions at rest is comparable to their viscosity at zero shear. (Davies Tr. 929-30.) But an unspoken limitation from a single example in the specification does not serve to narrow the scope of claim 1. *See SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1340 (Fed. Cir. 2001). The '888 Patent contemplates abuse by injection, snorting, and oral

ingestion ('888 Patent at 2:44-47, 2:64-3:1), and the Court has heard no evidence that all three methods of abuse necessarily require solutions at rest. Even if they did, there is little reason to believe that ordinarily skilled artisan would be aware of that fact and therefore interpret claim 1 to require the use of zero shear.

Because neither the claim language nor the specification provide any guidance on shear rate, the Court must resort to extrinsic evidence to construe the claim. Purdue relies heavily on a rheology textbook by Schramm to support its zero shear construction. Schramm describes the pseudo-plastic viscosity curve and states that at very low shear rates (region I in Figure 1), liquids have a viscosity "independent of shear rate—often called the 'zero shear viscosity.'" (PTX 4232 at PRF00229329.) Schramm teaches that as a result, "most fluids" have very similar viscosities at shear rates between .001 and .01 reciprocal seconds. (*Id.*) Similarly, because viscosity is also independent of shear rate at very high shear rates (region III in Figure 1), Schramm states that "one may expect" that the viscosity at 100 reciprocal seconds "would be similar to the viscosity at a shear rate ten times higher." (*Id.*) According to Purdue, ordinarily skilled artisans would conduct the viscosity test at a range of shear rates up to 100 reciprocal seconds in order to locate zero shear, but they would consider only the viscosity values that fell within that zero shear region to be relevant for purposes of the '888 Patent.

Purdue reads the Schramm reference for far more than it is worth. Schramm never states that zero shear serves as the default when shear rate is not specified, nor does it grant zero shear preferred status among the three viscosity regions it describes. Purdue incorrectly asserts that zero shear is the only one of the three viscosity regions that Schramm identifies by a term of art, as region III is (somewhat confusingly) called the "second Newtonian range." (PTX 4232 at PRF00229329-30.) For these reasons, the Court finds that Schramm does not support the proposition that persons of skill in the art understand that the viscosity of pseudo-plastic solutions should be measured at zero shear.

In the end, the only evidence that supports Purdue's position is its own expert's testimony. At trial, Davies cited only Schramm in support of his opinion; and notably, in his deposition, Davies could not identify a single piece of scientific literature that substantiated his view. (Davies Tr. 971.) If persons of skill in the art truly regarded zero shear as the definitive shear rate for testing the viscosity of pseudo-plastic solutions, Purdue could be expected to have adduced at least some authoritative evidence to prove it.[5]

On the basis of the intrinsic and extrinsic evidence, the Court concludes that claim 1 is not confined to zero shear and that a person of ordinary skill in the art could therefore reasonably measure viscosity across a broader range of shear rates. At the barest minimum, an ordinarily skilled artisan would interpret this range as encompassing .01 to 100 reciprocal seconds—the approximate upper and lower bounds, respectively, of region I and region III of Schramm's viscosity curve. (PTX 4232 at PRF00229329-30.) Because Schramm implies that not all pseudo-plastic solutions conform to these exact contours of the viscosity curve (*id.* at PRF00229329), however, a person of skill in the art would also understand that more extreme shear rates may be relevant.[6] The evidence before the Court simply does not allow it to ascertain

---

[5] In its post-trial submissions, Purdue cited an article by Bailey on the properties of PEO in aqueous solutions to support its argument that ordinarily skilled artisans measure viscosity at zero shear. (DTX 2019.) Bailey states that it determined the "[i]ntrinsic viscosities" of PEO and other polymer solutions "by extrapolation of zero shear rate reduced viscosities to infinite dilution." (*Id.* at 0001.) No expert at trial testified on the meaning of intrinsic viscosity, which appears to be a specific type or measure of viscosity. There is no other evidence in the record from which the Court can conclude that intrinsic viscosity corresponds to the '888 Patent's viscosity test. Moreover, the article did not confine its testing to zero shear but also reported viscosity "at high shear rates." (*Id.* at 0005.) Consequently, the Court finds that the Bailey reference does not lend support to Purdue's proposed claim construction.

[6] Indeed, the zero shear region for many of the tablets Davies tested fell outside .001 to .01 reciprocal seconds (Davies Tr. 369, 928-29), the range that Schramm identifies as

the precise boundaries of the acceptable range. Whether this renders the claim indefinite, as Amneal argues, is an issue the Court will confront in the invalidity portion of this Opinion, *infra*.

**2. Tampering temperature is not limited to 25° C. and includes temperatures above 45° C.**

The Court must next determine the temperature at which the dosage form should be tampered by dissolution, *i.e.*, dissolved. Purdue contends that because the claims do not explicitly identify a tampering temperature, persons of skill in the art would employ what Purdue asserts is the scientific convention of 25° C., or approximate room temperature. Amneal, by contrast, argues that the patent provides no guidance on tampering temperature and that a range of temperatures are therefore reasonable.

The language and structure of the '888 Patent's claims establish that tampering temperature is not limited to 25° C. Claim 24, which depends from claim 1, recites that "the dosage form is subjected to tampering by dissolution in the aqueous liquid with heating greater than 45° C." ('888 Patent at 42:16-17.) Under the doctrine of claim differentiation, dependent claims are presumed to have a more limited scope than independent claims. *See Alcon Research, Ltd. v. Apotex Inc.*, 687 F.3d 1362, 1367 (Fed. Cir. 2012). Because claim 24 presumptively does not include subject matter that claim 1 prohibits, claim 1 necessarily encompasses tampering temperatures above 45° C. The Court can discern no evidence in the specification or prosecution history that the patentees intended to disavow this general rule.

The specification also confirms that Purdue's proposed construction is incorrect. In its Claim Construction Opinion and Order, the Court construed claim 1 as optionally including heating "greater than about 45° C." *Claim*

---

the zero shear region for "most fluids" (PTX 4232 at PRF00229329). Similarly, some of the tablets had not yet reached region III at shear rates of 100 reciprocal seconds (Davies Tr. 973), the lower limit that Schramm identifies for that viscosity region (PTX 4232 at PRF00229329).

*Construction*, 2014 WL 2198590, at *5. The Court based this construction on the specification's definition of "tampered dosage form." ('888 Patent at 4:15-25.) In fact, in its claim construction brief, Purdue urged the Court to adopt this exact construction. (Pls.' Opening Claim Construction Br., 13-Cv-3372, Dkt. No. 15, at 11.) Its newfound conviction that claim 1 is limited to tampering at 25° C. fails in light of the patent's clear guidance on this issue.

Based on the intrinsic evidence, the Court concludes that tampering temperature for purposes of claim 1 is not limited to 25° C. and includes temperatures above 45° C. As with shear rate, however, the Court is not able to discern the exact upper and lower limits of the range of tampering temperatures that the claim allows.

**3. Testing temperature is not limited to 25° C. but does not extend to temperatures at or near boiling.**

The parties also dispute the temperature at which viscosity should be tested. Purdue argues that because the claims do not specify a particular testing temperature, persons of skill in the art would follow what Purdue asserts is the scientific convention of measuring viscosity at room temperature or 25° C. Amneal again contends that the patent provides no guidance on this issue and that the viscosity test permits a much wider range of testing temperatures.

The language of the claims do not provide any guidance on testing temperature. Although claim 24 requires "heating greater than 45° C." ('888 Patent at 42:15-17), it is undisputed that this 45° C. limitation refers only to tampering temperature.

The specification provides slightly more direction by suggesting that the viscosity test should not be conducted at temperatures approaching boiling. The specification explains that the invention is designed to reduce abuse by injection, inhalation, and oral ingestion. ('888 Patent at 2:18-26, 2:44-47, 2:64-3:1.) It also states that drug abusers may dissolve and heat the dosage form in order to make it more suitable for injection, inhalation, and oral consumption. ('888 Patent at 5:31-35.) An ordinarily skilled artisan would understand as a

matter of common sense, however, that abusers do not inject, snort, or swallow extremely hot liquids. While the specification provides no guidance on how hot is too hot, it is obvious that, at the very least, abusers would not administer solutions at or near boiling temperature.

Because the specification does not identify the temperature or range of temperatures that *should* be utilized, the Court must turn to extrinsic evidence. The parties disagree on the guidance provided by the United States Pharmacopeia ("USP"), a standard reference monograph for pharmaceutical scientists. (Davies Tr. 350.) In its section titled "General Notices," the USP states that "all measurements are made at 25° unless otherwise indicated." (PTX 4233 at PRF0029337.) Purdue argues that this passage proves that an ordinarily skilled artisan would conduct the '888 Patent's viscosity test at 25° C. Amneal vigorously disagrees, pointing out that another section of the USP titled "Viscosity" provides that "[t]he specifying of temperature is important because viscosity changes with temperature." (DTX 9149 at 0018.)

The Court agrees with Amneal that persons of skill in the art would not interpret the USP to prescribe a generally applicable testing temperature of 25° C. The USP states that its "General Notices" section provides "the basic guidelines for the interpretation and application of the standards, tests, assays, and other specifications of the *United States Pharmacopeia* and eliminate the need to repeat throughout the book those requirements that are pertinent in numerous instances." (*Id.* at 0005.) By its plain terms, then, the USP's default testing temperature of 25° C. only applies to the content of the USP itself;[7] the General Notices section does not purport to set forth a conventional testing temperature that readers should utilize in all contexts. In fact, the USP's explicit warning that temperature should be specified teaches away from a conclusion

[7] As Davies himself testified, the General Notices section "aids or guides the pharmaceutical scientist in undertaking the tests described in the USP." (Davies Tr. 350.)

that persons of skill in the art know that an unstated temperature equates to 25° C.

The testimony and practice of the expert witnesses also tilts against Purdue's proposed construction. Although Davies opined that pharmaceutical scientists conduct tests at 25° C. when no other temperature is specified, he cited only the USP's General Notices section in support. (Davies Tr. 350-51, 362-63.) Muzzio disagreed with Davies, stating that the choice of testing temperature depends on the particular application at issue. (Muzzio Tr. 499, 528.) And although Maurin conducted his viscosity tests at 25°, he opined that Muzzio's decision to test at temperatures between 20° and 60° was a reasonable interpretation of the '888 Patent. (Maurin Tr. 883-84.) Because the opinions of Maurin and Muzzio are more consistent with the '888 Patent's specification and the USP, the Court assigns them greater weight than Davies's testimony.

Finally, Purdue and Amneal present two additional types of extrinsic evidence that the Court declines to consider for purposes of claim construction. First, the parties attempt to support their proposed constructions with evidence on the specific temperature of solutions that addicts typically inject. But the '888 Patent contains no information on this issue, and there is no evidence to suggest that persons of skill in the art possess any independent understanding of the customary practices of drug abusers.[8] Evidence of real-world abuse conditions, at least with respect to testing temperature, therefore

[8] Although Muzzio and Davies based their opinions of testing temperature partly on their beliefs regarding the temperature of liquids that addicts inject, they appear to have derived that knowledge from reports and testimony by drug abuse experts who served as witnesses during the 2013 trial. (Muzzio Tr. 527; Davies Tr. 988.) There is no reason to believe that persons of ordinary skill in the art, most of whom presumably have not participated in litigation involving drug abuse, would possess similar knowledge. And unlike the common sense conclusion that abusers do not administer boiling solutions, the specific temperature they *do* utilize is not a matter of common knowledge.

cannot inform the Court's conclusion on how persons of skill in the art would interpret the '888 Patent.

Second, Amneal supports its proposed construction with certain laboratory tests of Reformulated OxyContin in which Purdue measured viscosity at room temperature, 37° C., 95° C., and boiling temperature. (DTX 9169 at 0070-71; PTX 4221 at PRF1191128; Weingarten Tr. 190.) Because there is no evidence that Purdue conducted these tests in accordance with the '888 Patent as opposed to some other protocol designed to serve some other goal, the Court assigns them no weight for purposes of claim construction. (*See* Davies Tr. 468.) Even if these tests bore some relationship to the '888 Patent, the Court would disregard Purdue's use of 95° C. and boiling temperature because the intrinsic evidence forbids such testing temperatures. *See Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1382 (Fed. Cir. 2008) ("A court may look to extrinsic evidence so long as the extrinsic evidence does not contradict the meaning otherwise apparent from the intrinsic record.").

Ultimately, as with shear rate, the only real evidence that Purdue has amassed in support of its proposed claim construction consists of Davies's largely unsupported opinion that ordinarily skilled artisans simply know to test viscosity at 25° C. Because the weight of the relevant extrinsic evidence demonstrates that persons of skill in the art would not interpret the '888 Patent's silence to require a testing temperature of 25° C., the Court concludes that the viscosity test is not limited to that temperature. Although the '888 Patent clearly permits a range of testing temperatures (excluding those at or near boiling), the Court is again unable to ascertain the precise boundaries of that range.

**4. The viscosity test is conducted after a visual inspection confirms that the soluble components of the dosage form have dissolved, although insoluble particles may remain.**

Finally, the Court must determine the extent of dissolution that the viscosity test requires. Purdue argues that the soluble components of the

dosage form must be completely dissolved before viscosity may be tested. Amneal counters that the patent provides no guidance on the necessary extent of dissolution.

The specification's only discussion of this issue occurs in Example 3. It explains that when a placebo OxyContin tablet and citrus pectin are dissolved in water, "[t]he tablet's coating is suspended in the mixture resembling a paste. All the samples have a creamy texture and milk like color. Additionally, the filtration with cotton cannot remove the suspended material." ('888 Patent at 32:30-34.) According to the specification, the tablet's coating may include a water-insoluble material such as a wax, shellac, or zein. (*Id.* at 20:1-4.) The specification therefore instructs that the dissolved dosage form may be tested for viscosity even when insoluble components, such as the tablet's coating, remain suspended in the solution.

The testimony and practice of the expert witnesses shed additional light on this claim construction issue. Maurin, Muzzio, and Davies all conducted the viscosity test after visually inspecting the samples to determine that the soluble components had dissolved. (Muzzio Tr. 603-04; Maurin Tr. 797-98; Davies Tr. 352-53.) In light of their consistent approach, the Court credits Davies's opinion that this procedure represents standard practice. (Davies Tr. 353, 927.)

Based on the intrinsic and extrinsic evidence, the Court concludes that the viscosity test requires ordinarily skilled artisans to visually inspect samples to confirm that the soluble components of the dosage form have dissolved. Insoluble particles, however, may remain.

### *B. The Gelling Agent as a Whole May Confer the Requisite Viscosity.*

Having clarified the method by which persons of skill in the art would conduct the '888 Patent's viscosity test, the Court must now address which substance—the "gelling agent" or PEO more specifically—must impart the requisite 10 cP of viscosity.

The Court begins with the language of the claim, which it finds to be ambiguous. It is not immediately clear whether "in an effective amount to impart a viscosity of at least about 10cP" ('888 Patent at 40:25-26) refers to PEO or the gelling agent more broadly. Although Amneal urges that its construction represents the plain and ordinary meaning of the claim, Purdue's interpretation is equally reasonable, especially in light of the fact that Amneal's construction renders the term "gelling agent" unnecessary. See *Becton, Dickinson & Co. v. Tyco Healthcare Grp., LP*, 616 F.3d 1249, 1257 (Fed. Cir. 2010) ("Claims must be interpreted with an eye toward giving effect to all terms in the claim.") (quotation marks and citation omitted); *In re Gabapentin Patent Litig.*, 503 F.3d 1254, 1263 (Fed. Cir. 2007).

The specification lends support to Purdue's construction by repeatedly teaching that the dosage form as whole, rather than one specific component, should be tested for the requisite viscosity. For example, the specification states that "the dosage form forms a viscous gel after the dosage form is tampered with, dissolved in an aqueous liquid . . . , causing the *resulting mixture* to have a viscosity of at least about 10 cP." ('888 Patent at 7:21-25 (emphasis added)). Similarly, the specification teaches that in some embodiments of the invention, "the dosage form forms a viscous gel after the dosage form is tampered with, dissolved in an aqueous liquid . . . and then heated (e.g., greater than about 45° C.), causing the resulting mixture to have a viscosity of at least about 10 cP." (*Id.* at 7:28-33.) These passages indicate that PEO alone need not produce the required viscosity because (1) the dissolved dosage form must achieve a viscosity of 10 cP and (2) the dosage form may include both PEO and other gelling agents.

Example 3 further suggests that the patent requires the dosage form as a whole, rather than PEO in isolation, to be tested for the necessary viscosity. In Example 3, the inventors reported the viscosity that resulted from adding citrus pectin to a placebo OxyContin tablet and small amounts of water. ('888 Patent at 32:3-25.) Importantly, the inventors tested the viscosity of a dosage form and a gelling agent (pectin) together, rather than measuring the viscosity

of pectin mixed solely with water. (*See id.* at 32:10-12.) Amneal's proposed construction would run contrary to the testing method the inventors used in Example 3 by requiring the viscosity of PEO to be measured separately from the other components of the dosage form.

The prosecution history corroborates the teachings of the specification. The '888 Patent issued from an application filed on January 12, 2012, Serial No. 13/349,449 ("the '449 Application"). (2014 Stip. ¶ 39.) Independent claim 1 of the '449 Application claimed a dosage form "further including a gelling agent in an effective amount to impart a viscosity unsuitable for administration . . . when the dosage form is crushed and mixed with from about 0.5 to about 10 ml of an aqueous liquid." (*See* DTX 9001 at 0488.) Following an interview with the Examiner, the applicants amended claim 1 in the following manner:

> ~~said dosage form further including~~ 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 ~~crushed and mixed with~~ from about 0.5 to about 10 ml of an aqueous liquid"

(*Id.*) As this amendment demonstrates, the applicants overcame the Examiner's objections to the '449 Application by clarifying that the gelling agent must "compris[e] polyethylene oxide" and by specifying a quantitative viscosity requirement of at least about 10 cP. (*See id.* at 0498; 2014 Stip. ¶ 51.)

It is clear that neither the patent applicants nor the Examiner believed that the amendment required PEO alone to impart 10 cP of viscosity. In their statement of the substance of the interview, the applicants explained that the "Examiner agreed with Applicants' position that the Kao reference (i) does not teach or suggest a gelling agent comprising polyethylene oxide, . . . and (iii) is silent as to the *dosage forms* described therein achieving a viscosity of at least 10 cP when tampered in accordance with the present invention." (DTX 9001 at 0493 (emphasis added).) This account confirms that the applicants understood that the dosage form as a whole, rather than PEO exclusively, must achieve a viscosity of at least 10 cP. Similarly, in her reasons for allowance, the Examiner

stated that "[t]he prior art does not teach or suggest the claimed invention as a controlled release dosage form comprising a drug susceptible for abuse . . . that also comprises a gelling agent to impart the viscosity unsuitable for injections or nasal administrations." (*Id.* at 0522.) Even after the applicants added the PEO limitation, then, Examiner interpreted the amended claim to mean that the gelling agent more broadly—and not PEO by itself—could produce the necessary viscosity.

Finally, expert testimony confirms that Purdue's construction is correct. Davies explained that it would be very difficult to measure the viscosity imparted by PEO alone when a tablet includes both PEO and another gelling agent (Davies Tr. 920, 1019), which the patent expressly allows ('888 Patent at 5:18-21, 40:25). Amneal agrees, admitting that "[t]here is no direct means of determining the viscosity imparted by the PEO in Amneal's products," which utilize both PEO and the gelling agent hypromellose K100M ("HPMC"). (Defs.' Responsive Post Trial Br. at 12; *see also* Muzzio Tr. 548, 553-55; 2014 Stip. ¶ 75.) The Court finds that under Amneal's proffered construction, a person of ordinary skill in the art could not determine whether a dosage form featuring both PEO and another gelling agent satisfied claim 1 because they could not isolate the amount of viscosity produced by PEO alone. It is unlikely that an ordinarily skilled artisan would interpret the claim to require something that is beyond the level of skill in the art.

In sum, the specification, prosecution history, and expert testimony confirm that the viscosity of the dissolved dosage form—which may include both PEO and other gelling agents—is what matters for purposes of claim 1. The Court therefore construes claim 1 of the '888 Patent to read:

> 1. A controlled release oral dosage form comprising:
>
> . . .
>
> a gelling agent comprising polyethylene oxide, said gelling agent 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. . . .

## II. FACTUAL BACKGROUND: ABUSE OF OXYCONTIN AND PURDUE'S RESPONSE[9]

Now that the Court has construed the '888 Patent's claims, it must determine whether Amneal has infringed the patent and whether the patent is valid. The following factual background, which the Court bases on evidence presented at both the 2013 and 2014 trials, provides useful context for the infringement and validity analyses that follow.

Abuse of opioids is a stubborn problem that dates back centuries. (Sellers 2013 Tr. 78-80.) In the past two decades, the United States has seen a sharp rise in the abuse of prescription opioids, to such an extent that the FDA considers opioid abuse and misuse "a public health epidemic." (PTX 2157 at 4; *see generally* PTX 2189.) In 2010, prescription opioid overdoses accounted for 16,651 deaths, greater than three-quarters of all prescription drug overdose deaths in the United States. (PTX 2157 at 4.)

Among the prescription opioids at the center of that epidemic has been OxyContin, viewed by abusers as "a suitable substitute for heroin." (PTX 2147 at 1.) Approved in 1995, what OxyContin added in pharmaceutical value was its aggregate strength and extended release profile, providing sustained pain relief over an extended period of time. (Oshlack Tr. 62; Sellers 2013 Tr. 81-82.) It combined several doses worth of oxycodone—a powerful opioid—into a single tablet that released the oxycodone over time. (Sellers 2013 Tr. 81-82.) Thus, a twelve-hour extended-release OxyContin tablet holds twice as much oxycodone as a six-hour oxycodone tablet does, and it releases the API over twice as long a time period. (*See id.*)

---

[9] Significant portions of this discussion are drawn from the Court's findings of fact and conclusions of law resulting from the 2013 trial. *See In re OxyContin Antitrust Litig.*, 994 F. Supp. 2d at 413-16.

The original formulation of OxyContin (which Purdue stopped selling in 2010) was susceptible to tampering, since abusers could crush the tablets easily into powder, thereby destroying the time-release aspect of the formulation and causing immediate release of the opioid. (Oshlack Tr. 46; Sellers 2013 Tr. 70-71, 74, 81-82.) If the abuser snorted the powder, or dissolved the powder into a liquid and injected the solution intravenously, then the abuser would experience an opioid "high." (PTX 2189 at 224.) The first wide-scale public acknowledgements of the trend of OxyContin abuse came in January 2001, from the Department of Justice. (*See* Sellers 2013 Tr. 82-83, 99; PTX 2147.) In July 2001, Purdue and the FDA changed the label of OxyContin to warn doctors about the potential for abusers' tampering with the dosage form. (Sellers 2013 Tr. 100-01; PTX 2148.) By 2003, the College of Problems on Drug Dependence referred to the "substantial amount of public attention" paid to OxyContin abuse, and it noted a significant increase in abuse, especially in 2001 (the most recent year for which it had complete data). (PTX 2189 at 222.)

Purdue began investigating ways to reformulate OxyContin to deter abuse. It had begun to develop abuse-deterrent technologies in 1997. (Kaiko 2013 Tr. 134.) Those initial efforts focused on other frequently abused drugs besides OxyContin and on addressing other methods of abuse besides snorting and injecting. (*Id.* at 135-36.) When the abuse of Original OxyContin drew Purdue's attention in 2001, its research and development team considered, among other ideas, creating a tablet that featured physical obstacles to tampering and abuse. (*Id.* at 154-56; *see* Oshlack Tr. 47.) One idea it had early on was to include a gelling agent in the tablet that, when the tablet was mixed with a small amount of liquid, caused the solution to form a gel too viscous to pull into a syringe. (Oshlack Tr. 49-50.)

Purdue submitted a New Drug Application ("NDA") to the FDA in November 2007, proposing a Reformulated OxyContin. (PTX 2424 at PRF2397743.) The FDA initially rejected the NDA. (*Id.*) The rejection letter suggested further studies that might overcome the deficiencies in the NDA. (*Id.* at PRF2397743-45.) Purdue obliged, conducting seven further *in vitro*

studies and producing thousands of pages of results. (Weingarten 2013 Tr. 236-38.) Those studies went into an "NDA re-submission package" in March 2009. (*Id.*; *see also* PTX 2137.) At a September 2009 briefing to the FDA Advisory Committee, Purdue explained the results, calling Reformulated OxyContin an "incremental improvement" but conceding that the impact of the abuse-proof formulation would remain unknown until it hit the market. (Weingarten 2013 Tr. 246; *see generally* PTX 1941.)

In April 2010, the FDA approved Reformulated OxyContin. (Weingarten 2013 Tr. 246; PTX 2132.) Purdue launched the new product and simultaneously discontinued sales of Original OxyContin in the United States. (Gasdia 2013 Tr. 483-84; Weingarten 2013 Tr. 247.) Reformulated OxyContin featured dual abuse deterrence mechanisms: high breaking strength (to resist crushing) and the ability to gel when mixed with water (to hinder injection and inhalation). (Weingarten Tr. 162; PTX2137A at 2-4; PTX2431 at 1156027.) Purdue believed that even if an abuser managed to crush an OxyContin tablet, the tablet's ability to gel upon contact with liquid would frustrate the abuser's attempt to achieve a high through snorting or injection. (*See* PTX2137A at 2-4.)

The 2010 market debut of Reformulated OxyContin was not marked by fanfare, because the FDA would not approve any changes to the drug's label until it saw the real-world effects of the new formulation. (Sellers 2013 Tr. 95; Weingarten 2013 Tr. 248-51.) Russell Gasdia, Purdue's Vice President for Sales and Marketing, explained during the 2013 trial that when Purdue first introduced Reformulated OxyContin on the market, "if a health care professional asked what was different between the reformulation [and] the original, the most the [sales] rep could say is the intent of the reformulation was to minimize abuse through manipulation, but that until the package insert reflected any specific information, there was nothing else they could share." (Gasdia 2013 Tr. 485; *see also* Gasdia Tr. 205.) This official silence on abuse deterrence did not mean that the market was completely ignorant: third-party analysts, trade journals, and a press release described the changes to the formulation. (Gasdia 2013 Tr. 485.)

Almost immediately upon Reformulated OxyContin's entrance in the market, Purdue and the FDA began the task of designing a post-marketing epidemiological study to understand the new product's real-world effectiveness at deterring abuse. (Weingarten 2013 Tr. 247-50; Weingarten Tr. 170-71.) Purdue undertook several long-term studies and began sending regular updates to the FDA. (Weingarten 2013 Tr. 250.) By July 2012, those updates noted reductions in OxyContin's diversion, abuse, and street price. (*Id.*; *see generally* PTX 2134.) Although abusers tried to evade the abuse-deterrent properties of the drug (Rao 2013 Tr. 1615-16), the more significant trend was abusers' substituting other opiates in the place of OxyContin (*id.* at 1614; PTX 2732). Purdue's studies also showed a significant reduction in OxyContin prescriptions written by "problematic" physicians linked to the OxyContin abuse epidemic. (Weingarten Tr. 173-74; PTX 4225 at PRF0029051-52.)

At Purdue's request, on April 16, 2013, the FDA announced that it would withdraw approval of Original OxyContin and stop accepting ANDAs that proposed generic versions of the drug. (PTX 2157 at 7; Hausman Tr. 293-94.) The FDA reasoned that, with Reformulated OxyContin available to provide the same benefits with lower risks of abuse and misuse, "the benefits of original OxyContin no longer outweigh its risks." (PTX 2157 at 7.) On the same day, the FDA approved a new label that finally allowed Purdue to market Reformulated OxyContin on the basis of its abuse-deterrent properties. (*See* PTX 2133.) The FDA's "Orange Book" lists the '888 Patent as covering Reformulated OxyContin. (2014 Stip. ¶ 59.)

## III. INFRINGEMENT

For the reasons that follow, the Court concludes that Amneal infringes all asserted claims of the '888 Patent.

### *A. Findings of Fact*

In July 2011, Amneal filed an ANDA seeking approval to market various dosage strengths of generic Reformulated OxyContin. (*See* 2014 Stip. ¶ 61.) The

Court finds that Purdue has shown by a preponderance of the evidence that Amneal's proposed tablets meet all the limitations of the asserted claims of the '888 Patent.

**1. Amneal's tablets meet the limitations of claim 1 because their gelling agents impart a viscosity of at least 10 cP.**

With respect to claim 1—the independent claim from which all the asserted claims depend—Amneal stipulates that its proposed tablets are controlled release oral dosage forms that contain from about 2.5 milligrams to about 320 milligrams oxycodone or a pharmaceutically acceptable salt thereof. (2014 Stip. ¶¶ 64-66, 72-73; *see* '888 Patent at 40:21-24.) Amneal further stipulates that its tablets provide a therapeutic effect for at least about 12 hours when orally administered to a human patient. (2014 Stip. ¶ 79; *see* '888 Patent at 40:30-32.)

Amneal's tablets also meet the 10 cP viscosity requirement of claim 1 as the Court has construed that claim. Amneal utilizes two different gelling agents: PEO and HPMC. (Muzzio Tr. 548; PTX 4010 at AMLOXY00408; *see* 2014 Stip. ¶ 75.) Amneal stipulates that when its tablets are subjected to tampering by dissolution in from about .5 to about 10 milliliters of an aqueous liquid, a viscosity of at least about 10 cP results. (2014 Stip. ¶ 77.) Muzzio attributed this viscosity to the gelling agents HPMC and PEO. (Muzzio Tr. 548.)

Viscosity testing by Davies confirms that Amneal's proposed tablets are significantly more viscous than 10 cP when tampered according to claim 1. (Davies Tr. 370; PTX 4198.) Davies crushed three tablets of each dosage strength and dissolved them in 30 milliliters of water at 25° C., which equates to one tablet per 10 milliliters. (Davies Tr. 348-51.) He mixed the solutions with a standard mechanical stirrer and visually inspected them to ensure that the soluble components of the dosage form had dissolved. (*Id.* at 352-53.) Davies then quantitatively measured the viscosity of each sample at 25° C. using a commercially available rheometer, whose accuracy he had verified by testing a fluid of known viscosity called a "viscosity standard." (*Id.* at 351, 359; *see also*

Muzzio Tr. 492.) All samples exceeded 10 cP at .01 to 100 reciprocal seconds, the range of shear rates that Davies utilized. (PTX 4198.)

The Court credits Davies's testing protocol as reliable, unbiased, and consistent with the teachings of the '888 Patent. In accordance with the specification's guidance on tampering, Davies crushed the tablets prior to dissolving them. (*See* '888 Patent at 4:22-25; Davies Tr. 349.) Although Davies dissolved three tablets in 30 milliliters instead of one tablet in ten milliliters, as claim 1 directs, he made that choice because the rheometer he used requires a minimum volume of 22 milliliters. (Davies Tr. 351.) The Court finds that Davies's method is equivalent to that prescribed by the '888 Patent.

To the extent the '888 Patent does not specify the exact shear rate, testing temperature, and tampering temperature that should be utilized—as discussed in the Court's claim construction, *supra*—the Court concludes that Davies's choices fall within the permissible range. There is no dispute that the patent allows tampering and testing temperatures of 25° C., and the range of shear rates that Davies utilized is consistent with the Schramm reference. (*See* PTX 4232 at PRF00229329.) Tellingly, Amneal does not take issue with Davies's methodology with respect to claim 1; its sole non-infringement argument turns on the claim construction issue regarding the "gelling agent" that the Court has already resolved.

In light of Amneal's stipulations and Davies's testing results, the Court concludes by a preponderance of the evidence that Amneal's tablets satisfy the limitations of independent claim 1.

**2. Amneal's tablets meet the limitations of claim 5 because they attain a viscosity of at least about 10 cP when dissolved in water.**

Dependent claim 5 claims "[t]he controlled release oral dosage form of claim 1, wherein the aqueous liquid is water." ('888 Patent at 40:45-46.) Because Davies's viscosity testing demonstrates that Amneal's tablets achieve a viscosity of at least about 10 cP when dissolved in water (Davies Tr. 349, 370;

PTX 4198), the Court concludes by a preponderance of the evidence that Amneal's tablets meet the limitations of this claim.

**3. Amneal's tablets meet the limitations of claim 7 because they obtain a viscosity of at least about 60 cP.**

Dependent claim 7 recites "[t]he controlled release oral dosage form of claim 1, wherein a viscosity of at least about 60 cP is imparted." ('888 Patent at 40:51-52.) Davies's tests show that all dosage strengths of Amneal's tablets achieved viscosities well above 60 cP. (Davies Tr. 370; PTX 4198.) Consequently, the Court finds by a preponderance of the evidence that Amneal's tablets meet the limitations of claim 7.

**4. Amneal's tablets meet the limitations of claim 23 because they achieve the requisite viscosity when crushed and dissolved in water.**

Dependent claim 23, as previously construed by the Court, claims "[t]he controlled release oral dosage form of any of claims 2, 4, 5, 6 and 7, wherein the requisite viscosity is obtained when the dosage form is subjected to tampering that includes crushing and dissolution in the specified volume of aqueous liquid." *Claim Construction*, 2014 WL 2198590, at *7. Claim 23 exhibits a "multiple dependent claim" structure because it "refers back in the alternative to more than one preceding independent or dependent claim." MPEP § 608.01(n) (9th ed., Mar. 2014). Therefore, claim 23 contains all the limitations imposed by whichever of claims 2, 4, 5, 6, or 7 is being considered. *See* 35 U.S.C. § 112(e) ("A multiple dependent claim shall be construed to incorporate by reference all the limitations of the particular claim in relation to which it is being considered."). Because Purdue does not assert claims 2, 4, and 6 against Amneal, only claims 5 and 7 are relevant to the infringement inquiry.

Davies's viscosity testing proves that Amneal's tablets satisfy all the limitations of claim 23. Davies tampered the tablets by crushing them, as claim 23 requires. (Davies Tr. 349; '888 Patent at 42:10-13.) After Davies dissolved the tablets in the required amount of water (claim 5), all dosage strengths exhibited

viscosities greater than 10 cP (claim 5) and greater than 60 cP (claim 7). (Davies Tr. 370; PTX 4198.) The Court therefore finds by a preponderance of the evidence that all the limitations of claim 23 are found in Amneal's tablets.

**5. Amneal's tablets meet the limitations of claim 24 because they obtain the requisite viscosity when dissolved in water heated above 45° C.**

Dependent claim 24 also features a multiple dependent structure. As construed by the Court, that claim refers to "[t]he controlled release oral dosage form of any of claims 2, 4, 5, 6 and 7, wherein the requisite viscosity is obtained when the dosage form is subjected to tampering that includes dissolution in the specified volume of aqueous liquid with heating greater than 45° C." *Claim Construction*, 2014 WL 2198590, at *7. Again, only claims 5 and 7 are relevant to the infringement inquiry here.

Purdue has met its burden of proof with respect to claim 24. First, the Court credits Davies's opinion that because all of Amneal's tablets have viscosities greater than 10 cP (claim 5) and 60 cP (claim 7) when dissolved in water at a temperature of 25° C., they would have an even higher viscosity when dissolved in water heated above 45° C., cooled to 25° C., and then tested. (Davies Tr. 923.) This is because heating the dissolved dosage forms above 45° C. would cause some of the water to evaporate and thereby increase the viscosity of the solutions. (*Id.*) Although the '888 Patent does not prescribe a specific range of testing temperatures for claim 24, there is no dispute that a testing temperature of 25° C. falls within the acceptable range.

A set of viscosity tests that Davies conducted on Amneal's 40 milligram and 60 milligram tablets also contributes to the Court's finding of infringement. Davies followed essentially the same protocol he used to test infringement of claims 1, 5, 7, and 23, except that he dissolved Amneal's tablets in water heated to 50° C. (Davies Tr. 374.) He then allowed the solutions to cool to 25° C. and measured their viscosities, which registered well above 60 cP. (*Id.* at 374-75; PTX 4199.)

Amneal contends that Purdue has not met its burden of proof because Davies did not test the remainder of Amneal's dosage strengths at tampering temperatures above 50° C. The Court disagrees. Amneal's 40 milligram and 60 milligram tablets contain the lowest and highest amounts of gelling agent (combined PEO and HPMC), respectively. (PTX 4010 at AMLOXY00408; Davies Tr. 374-75.) Since both those tablets achieved viscosities above 60 cP, the Court credits Davies's opinion that Amneal's other tablets would, too. (*Id.* 375.)

For these reasons, the Court finds by a preponderance of the evidence that all dosage strengths of Amneal's tablets meet the limitations of claim 24.

### *B. Conclusions of Law*

Because all limitations of the asserted claims 5, 7, 23, and 24 of the '888 Patent read on Amneal's tablets, the Court concludes that Amneal infringes those claims.

## IV. INVALIDITY

### *A. Novelty Pursuant to 35 U.S.C. § 102*

Amneal has attempted to show that the '888 Patent fails to satisfy the novelty requirement of 35 U.S.C. § 102 because it is anticipated by two separate prior art references. The Court finds that Amneal has not met its burden of proof with respect to either reference.

#### 1. Findings of Fact

##### a) The '963 Patent does not disclose all the limitations of the '888 Patent.

Amneal contends that the '888 Patent is invalid as anticipated by a prior art reference by Dr. James McGinity and Dr. Feng Zhang. In 1995, Dr. McGinity and Dr. Zhang developed a process for the manufacture of sustained-release tablets comprising PEO. (*See generally* Zhang 2013 Tr. 319-47.) They memorialized their work in an application to the World Intellectual Property

Organization ("the Application"), published on December 31, 1997. (DTX 2562 at (43).) McGinity and Zhang later received U.S. Patent No. 6,488,963 ("the '963 Patent") for their invention. (*See* PTX 1600.) The '963 Patent claims priority from the Application (*compare id.* at (60), *with* DTX 2562 at (30), (60)), and the parties agree that the Application is prior art to the '888 Patent (2014 Stip. ¶ 134). For purposes of this litigation, the '963 Patent is essentially equivalent to the Application, and the Court will refer to them interchangeably. (Muzzio Tr. 493; Maurin Tr. 744.) The Court made extensive factual findings on the disclosures of the '963 Patent and the Application following the 2013 trial, which it relies on here. *See In re OxyContin Antitrust Litig.*, 994 F. Supp. 2d at 421-27.

The Court previously found that the Application discloses controlled-release dosage forms containing oxycodone. *Id.* at 421, 423. The parties disagree whether it also discloses oxycodone in an amount "from about 2.5 mg to about 320 mg," which claim 1 of the '888 Patent requires. ('888 Patent at 40:23-24.) The Court credits Maurin's testimony that (1) the dosage strengths of Original OxyContin available in 2001 had between 10 and 160 milligrams of oxycodone and (2) there were no "controlled-release oxycodone products that were commercially-available before 2001" that contained less than 2.5 or more than 320 milligrams of oxycodone. (Maurin Tr. 764-65). But the fact that the pharmaceutical products on the market all contained oxycodone in amounts between 2.5 and 320 milligrams does not prove that ordinarily skilled artisans would interpret the Application to *preclude* dosage forms that fall outside that range. In other words, nothing in the Application limits this aspect of the invention to what was already extant in the art.

Amneal also relies on Example 4 of the Application, which describes tablets containing the antihistamine chlorpheniramine maleate ("CPM") and varying amounts of PEO and polyethylene glycol. (DTX 2562 at 19:5-8.) The amount of CPM was held constant at 6 weight percent, which Amneal contends falls into the '888 Patent's claimed range of about 2.5 to about 320 milligrams. (*Id.* at 19:7-8.) But Example 4 does not disclose the total weight of

the tablets; therefore, it is not possible to determine whether substituting oxycodone for CPM would result in tablets containing the necessary amount of oxycodone. If Example 4's tablets had a total weight of only 30 milligrams, for example, a 6 weight percent formulation would yield only 1.8 milligrams of oxycodone, less than the '888 Patent requires.

In sum, the Court finds that Amneal has not shown by clear and convincing evidence that the Application necessarily discloses about 2.5 to about 320 milligrams of oxycodone, as claim 1 of the '888 Patent requires. That determination ends the inquiry into whether the Application and the '963 Patent anticipate the '888 Patent. *See Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1367 (Fed. Cir. 2004) (quotation marks and citation omitted) (noting that the prior art reference must "disclose[], either expressly or inherently, all of the limitations of the claim").

**b) The '591 Application does not disclose all limitations of the asserted claims of the '888 Patent.**

Amneal also contends that the '888 Patent is anticipated by an application to the World Intellectual Property Organization, WO 99/44591 ("the '591 Application"), which was published in September 1999. (DTX 9003 at (43).) The '591 Application is prior art to the '888 Patent. (2014 Stip. ¶ 140.) It discloses extended release dosage forms that deliver an API at a linear rate of release. (*Id.* at 3:23-25.)

Amneal did not argue at trial that the '591 Application anticipates the '888 Patent, and the Court is reluctant to make a finding of invalidity based on testimony that was not subject to cross-examination specifically tailored to the subject of novelty. Even so, the trial evidence, which Amneal marshalled in support of an anticipation argument in its post-trial submissions, fails to meet the clear and convincing standard.

First, although Example 11 of the '591 Application expressly discloses a tablet containing PEO and 100 milligrams of oxycodone (DTX 9003 at 34:23-29, 37:1-6), it does not disclose a 12-hour therapeutic effect. It is true that the '591

Application is directed at controlled-release dosage forms and that Example 8—which sets out the composition and manufacturing process used in Example 11—states that its morphine-based tablet exhibits "a linear profile over 12 h[ou]rs at a constant rate of release." (*Id.* at 34:21-22.) But Example 11, which covers a wide range of different APIs, does not disclose any release profile and contains no *in vitro* or *in vivo* dissolution data. (*See* Maurin Tr. 898.) Even if Example 11 incorporates by reference the same 12-hour release rate of Example 8, the Court hesitates to infer that that release profile would provide the necessary therapeutic effect. (*See id.* at 896-97.) In the absence of these disclosures, the Court is unable to find by clear and convincing evidence that the dosage form of Example 11 would necessarily satisfy the therapeutic effect limitation of claim 1 of the '888 Patent. (*See* '888 Patent at 40:30-32.)

Second, even if the '591 Application disclosed the necessary therapeutic effect, Amneal has not presented clear and convincing evidence that the tablet of Example 11 would meet the 10 cP and 60 cP viscosity limitations. Maurin testified that if the tablet was dissolved in 10 milliliters of water, it would yield a solution much more viscous than 60 cP due to the presence of PEO. (Maurin Tr. 809-10.) Although Maurin's testimony certainly carries some intuitive appeal, the Court finds that it does not rise to the level of clear and convincing evidence of the '591 Application's anticipation of the '888 Patent's quantitative viscosity limitations.

Amneal tries to substantiate Maurin's predictions about the viscosity of Example 11's dosage forms by pointing to his viscosity tests of Concerta, a drug for the treatment of attention deficit hyperactive disorder. (*See* Sellers 2013 Tr. 94.) Concerta utilizes an osmotically controlled-release oral delivery system ("OROS"), the same type of drug delivery system disclosed in the '591 Application. (Maurin Tr. 772, 781-82.) Maurin tested the viscosity of several dosage strengths of Concerta after dissolving them in both 3 and 10 milliliters of water. (Maurin Tr. 796-804.) Each sample had a viscosity much greater than 60 cP. (Maurin Tr. 802, 806.) Although it is undisputed that Concerta and the '591 Application involve the same type of drug delivery system, the Court has

heard no evidence that Concerta actually practices the '591 Application. Moreover, Maurin did not record the shear rate he utilized in his viscosity tests, so the Court cannot determine whether his chosen shear rate falls within the '888 Patent's acceptable (albeit fairly large) range. For these reasons, the Court finds that Maurin's viscosity tests of Concerta do not show that the dosage forms of the '591 Application would satisfy the '888 Patent's 10 cP and 60 cP viscosity limitations.

#### 2. Conclusions of Law

Based on the above findings of fact, the Court concludes that Amneal has not shown by clear and convincing evidence that the '963 Patent and the '591 Application disclose all the limitations of the asserted claims of the '888 Patent. Therefore, the Court concludes that the '888 Patent is not invalid for lack of novelty.

### *B. Obviousness Pursuant to 35 U.S.C. § 103*

At trial, Amneal attempted to prove that the '888 Patent is invalid as obvious over the prior art. Purdue, meanwhile, introduced evidence on several objective indicia of nonobviousness. Because the claimed invention would have been obvious to persons of ordinary skill in the art as of August 2001, the Court concludes that the asserted claims of the '888 Patent are invalid pursuant to 35 U.S.C. § 103(a).

#### 1. Findings of Fact

##### a) Level of Ordinary Skill in the Art

As noted above, for purposes of the asserted claims of the '888 Patent, a person of ordinary skill in the art has a degree in one or more fields of medicine, chemical engineering, chemistry, pharmaceutical science, polymer chemistry, pharmaceutics, pharmaceutical technology, pharmacokinetics, and/or pharmacology, and/or a number of years of industry training or experience in one or more of those fields. (Tr. 1033-34.)

In addition, the Court finds that as of the '888 Patent's priority date of August 2001, ordinarily skilled artisans understood how to adjust pharmaceutical formulations to provide the desired rate of release and level of therapeutic efficacy. (*See* Davies Tr. 1008-09.) They also knew how to determine the quantitative level of viscosity at which solutions become difficult to inject, which would have involved nothing more than conducting simple tests on the syringeability of viscosity standards. (Maurin Tr. 785.)

**b) Scope and Content of the Prior Art**[10]

***(1) The prior art teaches that gelling agents reduce abuse potential.***

Several prior art patents or patent applications teach that gelling agents reduce the abuse potential of pharmaceutical formulations. U.S. Patent No. 3,980,766 ("Shaw"), issued in 1976, is directed to oral dosage forms containing methadone, an API used for the treatment of narcotic drug addiction. (DTX 1492 at [45], 1:15-24.) Shaw discloses the addition of thickening agents to a dosage form, which "help[s] prevent injection abuse by increasing viscosity of a composition" such that "attempts at evaporation of an aqueous solution . . . will produce a highly viscous concentrate incapable of being handled by a syringe." (*Id.* at 1:65-2:2, 2:26-32.) Shaw states that when a tablet containing 40 milligrams of methadone was dispersed in 120 milliliters of water, filtered, and concentrated to 10 milliliters, "a viscous gummy mass resulted." (*Id.* at 6:3-21.) The concentrated solution could not be drawn into a syringe with a number 18 needle. (*Id.* at 6:21-23.) Shaw therefore teaches that thickening agents can prevent the syringeability of a solution that has been filtered and concentrated.

U.S. Patent No. 4,070,494 ("Hoffmeister"), issued in 1978, aims to reduce parenteral abuse of pharmaceutical compositions containing analgesics and other substances with abuse potential. (DTX 2170 at [45], 1:17-28.) Hoffmeister

[10] Except where otherwise noted, the parties have stipulated that the references discussed in this section are prior art to the '888 Patent. (2014 Stip. ¶¶ 134-140.)

teaches a method of preventing aqueous extraction of the API through the use of a "nontoxic, aqueously gelable material" in a "quantity at least sufficient to form a gel with substantially no residual filterable liquid" when the dosage form is dissolved in water. (*Id.* at 2:3-8.) Hoffmeister therefore uses gelling agents to deter abuse by preventing extraction of the API and by reducing or eliminating the amount of solution that can be filtered for intravenous administration. (*See id.* at 1:66-2:6, 2:32-44.)

International Application No. WO 95/20947 ("Bastin"), published in 1995, attempts to remedy the perceived shortcomings of Hoffmeister, specifically the gelling agent's tendency to retard the release of the API. (DTX 1927 at (43), 1:22-29.) Bastin discloses a tablet in which the API and the gelling agent are separated into different layers in order to reduce their interaction. (*Id.* at 1:31-2:3.) Bastin further explains that the gelling agent has a viscosity in the range of 1,000 to 100,000 cP (*id.* at 3:24-26) and should be present in an amount "such that substantially no filterable material remains when the tablet is triturated with the minimal amount of aqueous medium needed to extract the drug" (*id.* at 4:6-10). Like Hoffmeister, then, Bastin relies on a gelling agent to prevent the extraction and filtration of drugs with abuse potential.

U.S. Patent Application Publication No. US 2002/0187192 ("Joshi"), filed in 2001, is titled "Pharmaceutical Composition Which Reduces or Eliminates Drug Abuse Potential."[11] (DTX 2611 at (54).) Joshi is directed at reducing the abuse potential of central nervous system stimulants such amphetamines. (*Id.* at [0008].) The application teaches that a "gel forming polymer reduces or

[11] Although the parties did not stipulate that the Joshi publication qualifies as prior art to the '888 Patent, Purdue has never argued that it does not. Joshi was filed August 30, 2001 but claims priority to Provisional Application No. 60/287,509, filed April 30, 2001. With respect to the Court's obviousness analysis, the disclosures of the provisional application are identical to those of the non-provisional application. (*Compare* DTX 1497, *with* DTX 2611; *see also* Maurin Tr. 762-63). Therefore, Joshi qualifies as prior art to the '888 Patent. *See* 35 U.S.C. § 102(e) (2006); 35 U.S.C. § 119(e)(1) (2006); *see generally In re Giacomini*, 612 F.3d 1380 (Fed. Cir. 2010).

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.* at [0009].) Joshi identifies PEO as a preferred gel forming polymer. (*Id.* at [0021].) It reports that "[g]el formation occurs" when a tablet containing PEO and a stimulant was crushed to form a powder, added to one milliliter of water, and stirred for one minute. (*Id.* at [0036], [0042].) The Examiner of the '888 Patent did not consider the Joshi publication. (Pls.' Responsive Post Trial Br., Dkt. No. 64, at 15 n. 10.)

***(2) The prior art teaches that PEO functions as both a rate controlling agent and a gelling agent.***

Several prior art references teach that PEO has rate controlling properties that may be employed in sustained release dosage forms. (*See* DTX 2013 at 0001; DTX 2361 at 8:52-9:4; PTX 1600 at 4:13-15; PTX 2359 at UT0001007.) For example, U.S. Patent No. 5,273,758 ("Royce"), issued in 1993, discloses that "polyethylene oxide has an adjustable rate control effect on the release of medicament from the dosage form, enabling in particular the preparation of sustained release dosage forms." (DTX 2344 at [57]; *see also id.* at [45], 2:43-48.) By 2001, PEO was also a known rate controlling agent in OROS formulations. (Oshlack Tr. 78-83.) In OROS systems, water enters the tablet and is absorbed by PEO; the swelling of the PEO causes the buildup of osmotic pressure, which pushes the API out through a hole in the tablet. (Maurin Tr. 772-73.) In addition, a 1999 dissertation by Zhang, one of the inventors of the '963 Patent, details how the molecular weight and amount of PEO influences the release profiles of various pharmaceutical formulations. (PTX 2359 at UT0001009-13.) The '591 Application goes a step beyond these references by explicitly disclosing controlled release dosage forms containing oxycodone in which PEO functions as a rate controlling agent. (DTX 9003 at 34:23-29, 37:1-6; Maurin Tr. 781-83.)

The gelling properties of PEO were also well-known in the art. An article published in 1958 in a scientific journal describes "the truly enormous thickening action of high molecular weight poly(ethylene oxide) in water." (DTX 9151A at 0008.) A photograph in the article depicts a thick, viscous PEO solution flowing slowly out of a jar, with a caption explaining that "[a] little Polyox resin goes a long way." (*Id.* at 0006.) In addition, the Royce patent explains that a one percent aqueous solution of 5-6 million molecular weight PEO has a viscosity of 7,200 to 10,000 cP. (DTX 2344 at 3:19-23.) And the Joshi publication, which is specifically directed toward abuse-resistant formulations, identifies polyethylene oxide as a preferred gel forming polymer. (DTX 2611 at 0021.) Notably, Benjamin Oshlack, one of the inventors of the '888 Patent, testified that he and his colleagues were aware that PEO had gelling properties even without conducting any testing. (Oshlack Tr. 75-76.)[12]

**c) Differences Between the '888 Patent and the Prior Art**

***(1) The '888 Patent differs from the prior art by claiming oxycodone and requiring a quantitative level of viscosity.***

The '888 Patent differs from the relevant prior art in a few key respects. First, the Court finds that the prior art does not explicitly teach that gelling agents prevent the abuse of oxycodone specifically. Shaw, Hoffmeister, Bastin, and Joshi (collectively, the "gelling patents") reference drugs such as methadone, analgesics, and central nervous system stimulants, but do not disclose oxycodone specifically. Importantly, however, these patents all involved APIs with abuse potential, and Hoffmeister notes that its gelling improvement "can be utilized with any medicinal agent which can be given orally but which has the potential for parenteral abuse." (DTX 2170 at 1:20-

[12] Although Amneal also argues that the gel-forming properties of Concerta (which contains PEO) were known among persons of skill in the art by August 2001, the Court cannot make that finding from the evidence in the record.

22.)[13] Consequently, although the '888 Patent differs from the prior art through its focus on oxycodone, the Court finds that this departure is not especially significant.

Second, the Court finds that, unlike the '888 Patent, the prior art does not disclose the quantitative level of viscosity that the gelling agent must produce. Even though several of the gelling patents described viscous solutions that could not be filtered or drawn into a syringe, none of them reported the quantitative viscosity (in centipoise) of those solutions.

***(2) The '888 Patent does not represent a departure from the prior art in other significant ways.***

At trial, Purdue presented evidence on three additional differences between the '888 Patent and the prior art that it contends are significant. The Court finds that these distinctions are either absent or overstated.

First, the Court cannot find that the prior art did not recognize PEO as a potential solution to the problems of drug abuse, as the '888 Patent does. Joshi lists PEO as a preferred gel forming polymer and explains that a tablet containing PEO formed a gel when mixed with water. (DTX 2611 at [0021], [0036], [0042].) Joshi is specifically directed toward abuse-resistant pharmaceutical formulations. (*Id.* at [0001].) Consequently, the '888 Patent is

[13] Purdue also relies on a 2003 report by the College on Problems of Drug Dependence Taskforce to demonstrate that gelling was not considered a solution to the problem of OxyContin abuse. While the report does not constitute prior art to the '888 Patent, it is true that it does not discuss gelling. The article did note, however, that it may be possible to prevent abuse of OxyContin "by designing formulations that are less vulnerable to tampering." (PTX 2189 at 224.) In any event, the report has limited probative value in light of the lack of evidence that its authors qualify as persons of skill in the art for purposes of the '888 Patent.

not the first publication in the art to utilize PEO as a gelling agent in order to deter abuse.

Second, the Court rejects Purdue's argument that the '888 Patent departs from the prior art because it does not rely on filters. Shaw teaches that gelling agents prevent the syringing of solutions that have been filtered and concentrated; in other words, gelling apparently does not occur until after a filter has been employed. (*See* DTX 1492 at 6:20-24.) Filtration is not a necessary precursor to gel formation in the other gelling patents, however. Hoffmeister and Bastin added gelling agents to their dosage forms in order to produce solutions that were too viscous to pass through a filter. (*See* DTX 1927 at 4:6-10, 25:7-26:9; DTX 2170 at 2:9-17.) And Joshi does not discuss filters at all. (*See generally* DTX 2611.) Importantly, the dosage forms described in Hoffmeister, Bastin, and Joshi become viscous without the aid of a filter—just like the '888 Patent. The Court therefore finds that the '888 Patent's lack of reliance on filters does not separate it from the prior art in a meaningful way.

Finally, Purdue alleges that the prior art embraces the "conventional wisdom" that gelling agents are incompatible with controlled release formulations. (Davies Tr. 951-52.) Purdue relies on Bastin, one of the gelling patents, to support this argument. Bastin explains that combining an API and a gelling agent in the same layer "has the disadvantage that the gelling action is likely to retard the release of the drug in a manner similar to some known sustained release products which include water-swellable high molecular weight polymers to retard drug release." (DTX 1927 at 5:30-35.) Purdue argues that this disadvantage would have deterred persons of skill in the art from utilizing gelling agents in controlled release formulations. (*See* Davies Tr. 951-52.)

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. (*See* DTX 1927 at 5:21-27; Davies Tr. 942.) By drawing an explicit comparison between gelling agents and the swelling properties of rate

controlling high molecular weight polymers[14] (DTX 1927 at 5:29-35), Bastin in fact implies that gelling agents are well-suited to controlled release dosage forms. And although all of the gelling patents focus primarily on immediate release tablets, Bastin notes that its invention may include a sustained release coating or "materials known in the art intended for the modification of release characteristics of the drug." (DTX 1927 at 5:1-3, 5:10-13.) 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.

**d) Objective Indicia of Nonobviousness**

Purdue urges the Court to consider several objective indicia of nonobviousness, specifically commercial success, copying, long-felt but unmet need, skepticism, and industry acclaim.[15]

***(1) There is insufficient evidence of the '888 Patent's commercial success.***

The parties appear to agree that Reformulated OxyContin qualifies as a commercial success. (Hausman Tr. 282; Rao Tr. 660-61.) In 2009, Original OxyContin garnered net sales around $2.3 billion. (Rao Tr. 660.) After Reformulated OxyContin debuted in 2010, the opioid market in general began

[14] Although Bastin does not expressly disclose PEO, the Court finds that persons of skill in the art would have immediately recognized PEO as a "water-swellable high molecular weight polymer[] to retard drug release." (DTX 1927 at 5:34-35; *see* Oshlack Tr. 81-82.)

[15] Purdue has also presented evidence on the "medical success" of Reformulated OxyContin in the form of epidemiological studies showing a decrease in OxyContin abuse. (*See generally* PTX 4225.) The Court declines to consider such evidence here because no court has ever deemed "medical success" to be an objective indication of nonobviousness. Rather, the relevant criterion appears to be "unexpected results." *See Power Integrations, Inc.*, 711 F.3d at 1368. The Court does not find that Reformulated OxyContin's success in reducing abuse was unexpected or surprising.

suffering from a secular decline. (*Id.* at 661.) Nonetheless, Reformulated OxyContin's sales have surpassed $1.8 billion dollars annually, qualifying it as a "blockbuster" drug in the pharmaceutical industry. (Hausman Tr. 282; Rao Tr. 660; Gasdia Tr. 217.) Reformulated OxyContin enjoys the highest net sales and is the most-prescribed branded extended release opioid on the market. (Gasdia Tr. 230; Hausman Tr. 282.)

The commercial success of Reformulated OxyContin, however, is meaningless unless it can be attributed to the claimed features of the '888 Patent. *See Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1369-70 (Fed. Cir. 2011). The weight of the evidence presented at trial demonstrates that the required nexus is lacking. Prior to April 2013, Purdue did not market OxyContin on the basis of its abuse-deterrent properties. (Gasdia Tr. 234-36.) Even after that date, when the FDA permitted Purdue to describe these properties on the drug's label, Purdue's marketing message remained centered on the efficacy and side effect profile of Reformulated OxyContin. (*Id.* at 206.) And since the April 2013 label change, OxyContin's market share has not risen but instead has remained stable. (Hausman Tr. 283; *see also* Gasdia Tr. 230.) Hausman, Purdue's expert, admitted that as of July 2014 (the time of trial), it was too soon to tell whether or how the label change had affected sales. (Hausman Tr. 302.) Similarly, there is no data on whether the demand for OxyContin has increased or decreased as a result of its abuse-deterrent features. (*Id.* at 304-05.) Nor did Purdue raise the price of OxyContin to account for its new gelling properties. (*Id.* at 304.) This evidence strongly suggests that the commercial success of Reformulated OxyContin is not a result of the '888 Patent's claimed features but rather its bioequivalence to Original OxyContin. (*See* Rao Tr. 679.)

Purdue attempts to prove a nexus by linking commercial success to the FDA's April 2013 decision to prohibit generic versions of Original OxyContin, which was based partly on the new availability of abuse-deterrent Reformulated OxyContin. (*See* PTX 2157 at 7.) Hausman testified that but for the FDA's decision, sales of Reformulated OxyContin would have fallen by

approximately $500 million to $1.6 billion. (Hausman Tr. 275-76, 287-91.) This is because Reformulated OxyContin would have faced significant competition from generic versions of Original OxyContin. (*Id.* at 287.) Although Hausman's predictions as to the amount of lost sales are somewhat speculative, the Court credits his testimony that the current sales and market share of Reformulated OxyContin would be significantly lower if the FDA had not precluded generic competition on the basis of the product's abuse-deterrent features.

But even assuming the FDA decision supplies the required connection between the '888 Patent's gelling properties and the profitability of Reformulated OxyContin, the Court is not convinced that the '888 Patent itself can be considered a commercial success. Purdue concedes that if Reformulated OxyContin (which embodies the '888 Patent) had to compete with generic versions of Original OxyContin (which do not), Reformulated OxyContin would suffer significant declines in sales and market share. This indicates that physicians and patients either would not distinguish between Reformulated OxyContin and the generics or would not value the abuse-deterrent features of Reformulated OxyContin enough to pay a price premium. (*See* Rao Tr. 720-22.)

It is clear that the '888 Patent's gelling features allowed Purdue to achieve *regulatory* success in the form of the FDA decision, and that this regulatory success spared Purdue from facing generic competition and possibly a poor reception in the marketplace. But the Court is hesitant to equate regulatory success to commercial success when Purdue's own evidence shows that the '888 Patent would not be nearly as successful if consumers had the choice to reject Reformulated OxyContin in favor of a bioequivalent generic product not covered by the patent.

For these reasons, the Court finds that the evidence presented at trial is not sufficient to prove that the '888 Patent is a commercial success.

***(2) Amneal's alleged copying of the invention is not an indication of nonobviousness.***

Purdue has presented evidence to show that Amneal copied the gelling properties of the '888 Patent and Reformulated OxyContin. (*See, e.g.*, Davies Tr. 964.) The Court finds that this evidence does not serve as an indication of the patent's nonobviousness, as "evidence of copying in the ANDA context is not probative of nonobviousness because a showing of bioequivalence is required for FDA approval." *Bayer Healthcare Pharm., Inc. v. Watson Pharm., Inc.*, 713 F.3d 1369, 1377 (Fed. Cir. 2013).

***(3) The '888 Patent did not fulfill a long-felt but unmet need.***

The evidence does not support a finding that the '888 Patent fulfilled a long-felt but unmet need for abuse-resistant oxycodone dosage forms.[16] The public health crisis caused by oxycodone tampering and abuse began in early 2001, when the government and Purdue first acknowledged the problem. (*See* Sellers 2013 Tr. 82-83; PTX 2147; PTX 2148.) The inventors of the '888 Patent filed their provisional application that same year. ('888 Patent at (60).) The very short period of time that elapsed between the recognition of the need for abuse-deterrent oxycodone formulations and the invention that matured into the '888 Patent simply does not indicate any long-felt need. *See In re OxyContin Antitrust Litig.*, 994 F. Supp. 2d at 400-01, 428. Similarly, Purdue has presented no evidence that others tried but failed to develop abuse-resistant oxycodone products. *See In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent*

[16] Purdue frames the issue too broadly by urging that an unmet need for "abuse-deterrent formulations" dates back at least to the 1970s, when the Shaw gelling patent was issued. But the '888 Patent's claims are directed at reducing the abuse potential of oxycodone alone ('888 Patent at 40:22-24), not at the abuse of drugs in general. The evidence in the record shows that the need for abuse-resistant formulations of oxycodone did not begin until 2001.

*Litig.*, 676 F.3d 1063, 1082 (Fed. Cir. 2012) (noting that failure of others is closely related to long-felt need).

***(4) Although Purdue received some acclaim for its invention, persons of skill in the art did not express skepticism.***

The Court cannot find that persons of ordinary skill in the art expressed skepticism of the '888 Patent's invention. Although Purdue contends that there was concern that gelling agents could hinder the release of the API, that worry existed only with respect to immediate release dosage forms. *See supra.* The prior art, as discussed above, actually supported the idea that certain gelling agents were compatible with—and in fact advantageous to—controlled release formulations.

The Court finds, however, that the '888 Patent's inventors received some acclaim for their invention. By approving language on abuse deterrence for Reformulated OxyContin's label, the FDA recognized the formulation's gelling properties. (PTX 2158; Davies Tr. 964.) And in a letter to the FDA, the National Association of Attorneys General lauded the development of "tamper-resistant drugs" and expressed hope that "[a]dding new physical and chemical features to prescription opioids" would reduce abuse. (PTX 4237 at PRF0029508.) The Court finds that this evidence amounts to industry acclaim of the '888 Patent's gelling properties.

**2. Conclusions of Law**

**a) It would have been obvious to respond to the oxycodone abuse crisis by creating a controlled release dosage form that utilizes PEO as a gelling and rate control agent.**

Based on the findings of fact set forth above, the Court concludes that the claimed invention of the '888 Patent would have been obvious to persons of ordinary skill in the art as of August 2001. First, the OxyContin abuse crisis—

which was publicly known by early 2001—provided motivation to produce an abuse-deterrent oxycodone formulation. In particular, persons of skill in the art would have been motivated to invent controlled release oxycodone tablets that resist injection, snorting, and oral ingestion, the known methods of abuse. (PTX 2147 at PRF0022156; *see* Sellers 2013 Tr. 99.)

To fulfill this goal, persons of ordinary skill in the art would have turned first to prior art that addresses abuse-deterrent formulations. Viewed together, Shaw, Hoffmeister, Bastin, and Joshi teach that gelling agents frustrate the extraction and injection of dissolved dosage forms. And Joshi—which was not before the Examiner of the '888 Patent—specifically identifies PEO as a preferred gelling agent in abuse-resistant tablets. (DTX 2611 at [0021].) These references would have given an ordinarily skilled artisan motivation to incorporate a gelling agent, and more specifically PEO, into an oxycodone dosage form.

Moreover, the prior art confirmed that PEO was entirely compatible in controlled release formulations. Indeed, persons of skill in the art would have recognized PEO as an ideal component of an abuse-deterrent controlled release tablet in light of PEO's gelling and rate controlling properties, both of which had long been known in the art. Bastin, in fact, discloses that high molecular weight polymers such as PEO function as both gelling and rate control agents. *See supra*.

Moreover, the McGinity and Zhang Application and the '591 Application provided a strong starting point for producing a gel-forming, controlled release oxycodone dosage form. Although these references are not directed toward the reduction of abuse potential, they relate to the field of the endeavor because they provide detailed information on PEO-based controlled release dosage forms. *See In Re ICON*, 496 F.3d at 1379-80. In fact, the inventors relied on prior art concerning OROS dosage forms, which are covered by the '591 Application, in the '888 Patent. ('888 Patent at 22:50-25:37; Oshlack Tr. 78, 83.) Upon reading either the '591 Application or the McGinity and Zhang Application, ordinarily skilled artisans would have immediately suspected

that the disclosed dosage forms would produce extremely viscous solutions due to the presence of high molecular weight PEO.[17] (Muzzio Tr. 506; Maurin Tr. 748, 786-87.) They would also have had a strong expectation of success in incorporating oxycodone into these dosage forms (*see* Maurin Tr. 867-69), which the '591 Application expressly discloses.

Finally, it was well within the level of skill in the art to design an abuse-resistant oxycodone dosage form to achieve a therapeutic effect lasting at least about twelve hours. The '591 Application explains that its dosage forms "provide a therapeutically effective blood level of the medicament for 30 minutes to 24 hours." (DTX 9003 at 5:4-6.) Persons of skill in the art could also have looked to Original OxyContin and its associated patents for guidance, since that drug produced at least twelve hours of therapeutic efficacy. (*See* Davies Tr. 1007.) The evidence adduced at trial does not show that ordinarily skilled artisans would have feared that including PEO or oxycodone in the dosage form would have posed a significant obstacle to obtaining the desired therapeutic effect. (*See* Davies 1007-13; Maurin Tr. 748-51, 811-12.) The Court therefore concludes that an ordinarily skilled artisan would have had a reasonable expectation of success in attaining a 12-hour therapeutic effect from a controlled release, PEO-based oxycodone dosage form.

In sum, although no single prior art reference discloses an abuse-deterrent controlled release oxycodone dosage form containing the gelling agent PEO, persons of skill in the art would have been motivated to combine the teachings of the prior art to arrive at such an invention and would have had a reasonable—indeed, a strong—expectation of success in doing so. *See OSRAM Sylvania, Inc.*, 701 F.3d at 706; *see also KSR*, 550 U.S. at 418 (noting that the

[17] The fact that Amneal did not prove by clear and convincing evidence that the '591 Application inherently discloses very viscous dosage forms does not vitiate the reference's relevance to the obviousness analysis. The Court is satisfied that an ordinarily skilled artisan reading the '591 Application (and the '963 Patent) would suspect that its tablets form gels and undertake further study to confirm that hypothesis.

obviousness analysis may "take account of the inferences and creative steps that a person of ordinary skill in the art would employ").

**b) The remaining features of the claimed invention are obvious.**

The Court concludes that the remaining features of the claimed invention, specifically the patent's quantitative viscosity and tampering limitations, are also obvious. First, it would have required very little effort for persons of skill in the art to determine the quantitative level of viscosity at which syringing and injection became difficult. Arriving at the 10 cP and 60 cP viscosity limitations would have involved nothing more than simple experimentation of the syringeability of viscosity standards. (Maurin Tr. 784-85.) Consequently, although the '888 Patent was the first to specify numerical viscosity requirements for abuse-resistant dosage forms, that feature does not represent a nonobvious advancement over the prior art. *Cf. Abbott Labs. v. Sandoz*, 544 F.3d 1341, 1379 (Fed. Cir. 2008).

Second, the patent's tampering limitations, which provide that the requisite viscosity results when the dosage form is tampered and dissolved in a small amount of aqueous liquid ('888 Patent at 40:25-29, 42:10-17), are also obvious. Persons of ordinary skill in the art would have known, as a result of their training and experience, that tablets containing PEO would form a gel with a viscosity of at least about 10 cP or 60 cP when crushed and dissolved in less than 10 milliliters of water or other aqueous liquid. (*See* Maurin Tr. 813.) And they would have known that using heated dissolution would result in even higher viscosity values. (*See* Davies Tr. 923.) The '888 Patent's tampering limitations, therefore, would have been obvious at the time of the invention.

**c) All asserted claims of the '888 Patent are invalid as obvious.**

In conclusion, the Court finds by clear and convincing evidence that all asserted claims of the '888 Patent are invalid as obvious. Viewed in light of the level of skill in the art and the extensive body of relevant prior art references,

the '888 Patent essentially embodies the "predictable result[]" of the "combination of familiar elements according to known methods." *KSR*, 550 U.S. at 398. Having considered the objective indicia of nonobviousness and found sufficient evidence of only one criterion, industry acclaim, the Court is satisfied that hindsight has not influenced its obviousness analysis. Consequently, because the invention is obvious, the asserted claims of the '888 Patent are invalid pursuant to 35 U.S.C. § 103(a).

### *C. Indefiniteness Pursuant to 35 U.S.C. § 112*

At trial, Amneal attempted to prove that the '888 Patent's lack of specific guidance on shear rate, tampering and testing temperature, and extent of dissolution renders its viscosity test indefinite. The Court concludes that Amneal has met its burden of proof only with respect to claim 7.

#### 1. Findings of Fact

##### a) Shear Rate

In its claim construction *supra*, the Court determined that although the '888 Patent's viscosity test allows a shear rate range of at least .01 to 100 reciprocal seconds, the patent does not identify specific upper and lower limits for that range. Amneal contends that this deficiency is fatal to the asserted claims of the patent.

###### *(1) Shear rate determines whether some accused products meet claim 5's 60 cP viscosity limitation.*

The viscosity testing that Davies conducted on the 30 milligram tablets produced by Teva (Amneal's co-defendant at trial) demonstrates that infringement, at least in some cases, depends on shear rate. Davies utilized the same testing protocol that he used for Amneal's tablets, which the Court described in detail in its findings on infringement. (Davies Tr. 348-60.) When tampered and tested at 25° C., all dosage strengths of Teva's proposed tablets

had viscosities above 10 cP at shear rates ranging between .01 and 100 reciprocal seconds. (Davies Tr. 368-69; PTX 4204.) Teva's 30 milligram tablet, however, began to fall below 60 cP at shear rates above 25 reciprocal seconds, dropping to 50.1 cP at a shear rate of 100 reciprocal seconds. (DTX 9179 at 0097; Davies Tr. 415-16; PTX 4204 at CATTEV0000276.) The Court finds by clear and convincing evidence that the choice of shear rate—specifically, whether to test above or below 25 reciprocal seconds, which is within the range of shear rates the patent allows—determines whether Teva's 30 milligram tablet meets the 60 cP viscosity limitation of claim 5.

Moreover, the viscosity of all of Teva's dosage strengths fell as shear rate approached 100 reciprocal seconds, indicating that viscosity would continue to decline. (PTX 4204.) The Court credits Muzzio's testimony that at least some of Teva's tablets would have fallen below 60 cP at shear rates slightly above 100 reciprocal seconds, had Davies continued testing them. (Muzzio Tr. 526.) Davies himself admitted that at a shear rate of 100 reciprocal seconds, the viscosity of all of Teva's tablets had not yet reached region III of the pseudo-plastic viscosity curve described in Schramm. (Davies Tr. 973; *see also* PTX 4204 at CATTEV0000278-79.) Amneal's tablets exhibited the same pattern. (*See generally* PTX 4198.) The Court finds by clear and convincing evidence that the viscosity of Amneal's tablets would have continued to decline at shear rates above 100 reciprocal seconds before finally leveling out. (PTX 4232 at PRF0029329-30; *see* Davies Tr. 973-74.)

***(2) Specifying shear rate is standard practice among ordinarily skilled artisans.***

The Court also finds that specifying shear rate is standard practice among ordinary skilled artisans. The scientific literature utilized by persons of skill in the art highlights the importance of identifying shear rate or information from which shear rate may be determined (*i.e.*, rheometer model, cup size, spindle size, and test speed). The manual for the instrument that the '888 Patent's inventors used for Example 3 states that "[a] repeatable viscosity test should control or specify . . . shear rate." (DTX 9173 at 0021.) The brochure for PolyOx,

Dow's brand of polyethylene oxide, reports the viscosity of different grades of polyethylene oxide along with the viscometer model, spindle size, and test speed. (DTX 9117 at 0018.) Similarly, the '060 Patent—which Purdue asserted against Teva during trial—links the viscosity of PEO and other polymers to a specific viscometer model, spindle size, and test speed. (PTX 4000 at 6:2-9.) A patent to Royce includes the same information when reporting the viscosity of certain grades of PolyOx. (DTX 2344 at 3:14-23.) Although these latter three references omit cup size, only one cup size (a 600 milliliter beaker) may be used with the particular viscometer at issue. (DTX 9173 at 0027; Muzzio Tr. 651-53.)

Purdue attempts to downplay the significance of these references by pointing to other instances in which shear rate was not specified. First, Amneal utilized as a trial exhibit a website printout listing the approximate viscosities of common household items such as milk, motor oil, honey, and mustard. (DTX 9146.) The fact that this list does not identify shear rate proves nothing, as it clearly functions as an illustration of viscosity for the casual reader and not as an authoritative reference for the ordinarily skilled artisan. (Muzzio Tr. 620-22.) Second, Purdue points out that Maurin did not record shear rate in his viscosity tests of Concerta. (Maurin Tr. 886.) Although this observation carries some weight, it is not enough to alter the Court's finding, by clear and convincing evidence, that specifying shear rate in viscosity testing represents standard practice among persons of ordinary skill in the art—even if the occasional artisan fails to live up to that standard.

**b) Tampering and Testing Temperature**

Amneal also contends that the '888 Patent is indefinite for failing to provide specific guidance on the range of acceptable tampering and testing temperatures. It is essentially undisputed that tampering and testing temperature affect viscosity. (Muzzio Tr. 527; Davies Tr. 982.) The Court finds, however, that Amneal has not shown by clear and convincing evidence that the choice of tampering or testing temperature influences whether or not an accused product infringes the '888 Patent.

To support Amneal's indefiniteness argument, Muzzio prepared tablets of different weights containing CPM, PEO, and magnesium stearate. (Muzzio Tr. 530; DTX 9111 at 0003.) He ground the tablets, added 10 milliliters of water to each, placed them on a shaker table until they had dissolved, and then measured the viscosity of the solutions using a standard rheometer. (Muzzio Tr. 530; DTX 9111 at 0007.) Muzzio tested the tablets at 20°, 30°, 40°, 50°, and 60° C. (Muzzio Tr. 527), temperatures that are significantly lower than boiling and therefore represent reasonable choices. He used two different shear rates: 30 and 85 reciprocal seconds, which are also within the patent's permissible range. (DTX 9113 at 0003.) Muzzio's results show that the choice of testing temperature determines whether the tablets met the patent's 10 cP and 60 cP viscosity limitations. (DTX 9113 at 0003; Muzzio Tr. 530-31.) One of his formulations had a viscosity above 10 cP at both 20° and 30° C., but fell below 10 cP when tested at 40°, 50°, and 60° C. (DTX 9113 at 0003.) Another formulation attained a viscosity above 60 cP at 20°, but dropped below that level at 30°, 40°, 50°, and 60° C. (*Id*.)

The Court gives only modest weight to Muzzio's viscosity tests because his tablets do not meet all the limitations of the '888 Patent. First, because his laboratory did not have a federal license to use oxycodone, Muzzio substituted CPM. (Muzzio Tr. 501.) Second, Muzzio's tablets do not appear to be controlled release dosage forms that provide a therapeutic effect for at least about 12 hours. Nonetheless, the Court has not been presented with convincing evidence that Muzzio would have obtained different viscosity results if his tablets had featured oxycodone instead of CPM, possessed controlled release properties, and provided a 12-hour therapeutic effect. Although Muzzio's tablets do not embody certain aspects of the '888 Patent, the Court accords his tests some weight on the basis that the differences may not be critical.

To further support its argument that tampering and testing temperature constitute outcome-determinative factors, Amneal contrasts the viscosity tests of Reformulated OxyContin conducted by Purdue scientists with those conducted by Davies. Davies found that temperature did not influence

whether Reformulated OxyContin satisfied the '888 Patent's viscosity limitations. Using the same testing protocol described in the Court's findings on infringement, Davies tampered all dosage strengths of Reformulated OxyContin at both 25° C. and 50° C.; he then measured viscosity at 25° C. (Davies Tr. 348-59.) The samples tampered at 50° C. were more viscous than those tampered at 25° C., but the viscosity of all tablets was above 60 cP. (Davies Tr. 366-67.) In other words, Davies found that varying tampering temperature (while keeping testing temperature constant) did not affect whether Reformulated OxyContin met the '888 Patent's quantitative viscosity limitations.

At first glance, Purdue's viscosity tests appear to contradict Davies's findings. Purdue measured the viscosity of 80 milligram Reformulated OxyContin tablets that had been dissolved in 10 milliliters of boiling water. (DTX 9169 at 0037, 0070; Davies Tr. 984.) Purdue then tested the viscosity of these solutions at both 95° and 37° C. (DTX 9169 at 0070-71.) At some shear rates, the viscosity of the solutions tested at both temperatures was less than 60 cP, although viscosity never dropped below 10 cP. (*Id.*; *see also* Davies Tr. 985.) According to Amneal, Purdue's tests prove that tampering and testing temperature directly influence whether an accused product infringes the '888 Patent.

The Court does not assign any weight to Purdue's viscosity tests for two reasons. First, the tests that Purdue conducted at 95° C. are not probative of the validity of the '888 Patent because persons of skill in the art would not utilize that testing temperature. *See supra.* Second, the results that Purdue obtained for the tablets tested at 37° C. are largely a function of shear stress rather than tampering or testing temperature. At shear rates of 40, 63, and 100 reciprocal seconds,[18] one sample attained viscosities between 53 and 56 cP. (DTX 9169 at 0071.) Yet the viscosity of a second sample tested at those exact same shear rates was significantly higher, in the range of 531 to 825 cP. (*Id.*) While Purdue

[18] The Court has rounded these figures to the nearest whole number.

tested the first sample at shear stresses between 2.23 to 5.61 Pascals, shear stress for the second sample ranged from 32.8 to 53.1 Pascals. (*Id.*) Although the parties did not focus on the concept of shear stress at trial, it is clear that shear stress—rather than tampering or testing temperature—likely caused the discrepancy between the two samples. The Court therefore assigns no weight to Purdue's test results for the purpose of indefiniteness.

With Purdue's viscosity tests out of the picture, the only evidence suggesting that tampering and testing temperature are outcome-determinative factors consists of Muzzio's tests of his CPM tablets. Because those tablets do not satisfy all the limitations of claim 1, the Court concludes that Muzzio's test results do not rise to the level of clear and convincing evidence that temperature determines whether an accused product achieves a viscosity of 10 cP or 60 cP.

**c) Extent of Dissolution**

Finally, Amneal argues that the '888 Patent is indefinite because viscosity fluctuates based on the extent to which the dosage form has dissolved. The Court has already determined that the patent's viscosity test requires persons of skill in the art to visually inspect the sample to confirm that the soluble components of the dosage form have dissolved. Amneal has not shown by clear and convincing evidence that ordinarily skilled artisans cannot successfully carry out this inspection. Although the solutions contemplated by the patent may be opaque or cloudy, Davies, Muzzio, and Maurin were all able to determine the point at which the dosage form had adequately dissolved and was ready for viscosity testing. (Davies Tr. 353, 925; Muzzio Tr. 603; Maurin Tr. 798.) Nor is there any evidence that this determination is completely dependent on an individual's subjective opinion. *See Halliburton*, 514 F.3d at 1249. Accordingly, the Court finds by clear and convincing evidence that the extent of dissolution neither determines infringement nor requires an assessment that an ordinarily skilled artisan simply cannot make.

**2. Conclusions of Law**

The Court concludes that the '888 Patent's failure to provide sufficient guidance on shear rate renders claim 7 indefinite. As the Court has construed it, the patent's viscosity test permits, at a minimum, shear rates ranging from .01 to 100 reciprocal seconds. Yet even within this range, the choice of shear rate determines whether Teva's 30 milligram tablet satisfy claim 7's viscosity limitation of 60 cP. *See supra.* In other words, shear rate directly impacts the results of the viscosity test and therefore the determination of infringement, yet the patent does not tell an ordinarily skilled artisan how to select shear rate. There is hardly a better example of indefiniteness. *See, e.g.*, *Frans Nooren Afdichtingssystemen B.V.*, 744 F.3d at 724; *see also In re OxyContin Antitrust Litig.*, 994 F. Supp. 2d at 433-34. The Court concludes by clear and convincing evidence that the viscosity test, as expressed in claim 7, "fail[s] to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus*, 134 S. Ct. at 2124.

The patent's shortcomings regarding shear rate do not automatically invalidate the remaining asserted claims, however. Claim 5 only requires a viscosity of 10 cP, and Amneal has not shown that the choice of shear rate impacts whether an accused product meets this limitation. Consequently, even though persons of skill in the art could reasonably choose different shear rates when conducting the viscosity test, they would still be able to ascertain the scope of claim 5. Likewise, claims 23 and 24, which are multiple dependent claims, are only indefinite with respect to shear rate when they depend from claim 7 and therefore incorporate the 60 cP viscosity limitation. When claims 23 and 24 depend from claims 2, 3, 5, or 6, the dosage form need only achieve a viscosity of 10 cP, and the choice of shear rate does not affect that limitation.[19]

[19] The Court declines Amneal's invitation to speculate about the viscosities that would result from shear rates up to 200,000 reciprocal seconds, which Muzzio testified might be encountered in a syringe. (Muzzio Tr. 518.) First, no expert at trial utilized such extreme shear rates in their tests. Second, the Schramm reference suggests that at very

Similarly, the Court cannot conclude by clear and convincing evidence that any of the asserted claims are indefinite with respect to tampering temperature, testing temperature, or extent of dissolution. Even though the '888 Patent does not set forth precise guidance on these testing variables, Amneal has not proven that the uncertainty is severe enough to make the viscosity test indefinite. Specifically, Amneal has not shown that these variables impact whether an accused product infringes the patent; rather, the evidence shows that even when persons of skill in the art fill the gaps in different ways, their choices do not produce conflicting results on infringement. *See Nautilus*, 134 S. Ct. at 2128 (suggesting that a claim is not ambiguous merely because readers "could reasonably interpret the claim's scope differently"). The Court concludes that despite the patent's lack of specific direction on tampering temperature, testing temperature, and extent of dissolution, persons of ordinary skill in the art can still discern, with reasonable certainty, the scope of the invention.

In conclusion, the Court finds by clear and convincing evidence that the patent's insufficient guidance on shear rate renders claim 7 of the '888 Patent indefinite pursuant to 35 U.S.C. § 112.

---

high shear rates above 100 reciprocal seconds or so, viscosity is largely independent of shear rate. (*See* PTX 4232 at PRF00229329.) Therefore, the Court cannot find that viscosity at 200,000 reciprocal seconds would differ from viscosity at 100 reciprocal seconds in a manner that renders the 10 cP limitation indefinite.

## PART 3. CONCLUSION AND RELIEF

The Court has found by a preponderance of the evidence that Amneal infringes the asserted claims of the '888 Patent. However, the Court also concludes that Amneal escapes liability for that infringement because it has shown by clear and convincing evidence that the '888 patent is invalid. Specifically, all of the asserted claims are invalid for obviousness, while clam 7 is also invalid for indefiniteness.

Based on the findings of fact and conclusions of law articulated above, the Court hereby ORDERS the following:

1. Plaintiffs' requests for relief are denied.
2. The following declaratory judgment shall enter in favor of Amneal Pharmaceuticals, LLC, and against plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc., and Purdue Pharmaceuticals L.P.: Claims 5, 7, 23, and 24 of U.S. Patent No. 8,337,888 are invalid.
3. Amneal's counterclaim for declaratory judgment of non-infringement of claims 5, 7, 23, and 24 of U.S. Patent No. 8,337,888 is denied.
4. No attorney's fees will be awarded because the prevailing party, Amneal Pharmaceuticals, LLC, has not demonstrated that this is an exceptional case.

Dated: New York, New York
April 8, 2015

SO ORDERED:

Sidney H. Stein, U.S.D.J.