PUBLIC

ORIGINAL

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

Commissioners: **Maureen K. Ohlhausen, Acting Chairman**
Terrell McSweeny

In the Matter of	)	
Impax Laboratories, Inc., a corporation,	)	**DOCKET NO. 9373**
Respondent	)	

COMPLAINT COUNSEL'S MOTION FOR PARTIAL SUMMARY DECISION

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Dated: August 3, 2017

COMPLAINT COUNSEL'S MOTION FOR PARTIAL SUMMARY DECISION

TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

Please take notice that, pursuant to Federal Trade Commission Rule of Practice 3.24, Complaint Counsel hereby respectfully move for partial summary decision in this action.

By this Motion, Complaint Counsel seek partial summary decision holding that certain justifications Respondent Impax Laboratories, Inc. has asserted in defense of its challenged conduct fail as a matter of law and cannot serve as defenses to the violation alleged in the Complaint. Impax has asserted that its alleged reverse-payment patent settlement with Endo Pharmaceuticals, Inc. was procompetitive because it: (1) granted Impax the right to sell its generic product eight months before the expiration of patents that Endo had asserted against Impax and years before the expiration of patents that Endo obtained after the date of their agreement; (2) provided Impax with certainty that it could launch its generic product free from the risk of patent infringement liability as to Endo's existing and future patents; and (3) enabled Impax to continue to sell its generic product despite a court ruling that two of the patents Endo obtained after the settlement were valid and infringed. Complaint Counsel seek an order holding that none of these proffered justifications is a legally cognizable defense to the conduct challenged in the Complaint.

This Motion is supported by the accompanying Memorandum and the authorities cited therein. For the reasons set forth in the accompanying Memorandum, this motion should be granted. A Proposed Order is attached.

Respectfully submitted,

Dated: August 3, 2017

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MEMORANDUM OF LAW IN SUPPORT OF COMPLAINT COUNSEL'S MOTION FOR PARTIAL SUMMARY DECISION

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Introduction

This antitrust case involves the application of the Supreme Court's decision in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), to an agreement between generic drug manufacturer Impax Laboratories and branded-drug maker Endo Pharmaceuticals. *Actavis* holds that patent settlement agreements are anticompetitive when a patentee uses a large and unjustified reverse payment to induce a would-be generic rival to abandon its patent challenge and thereby eliminate "the risk of competition." *Id.* at 2236. The complaint here alleges that Respondent Impax's agreement with Endo constitutes an unlawful reverse-payment agreement under *Actavis*. In response, Impax has asserted that its agreement with Endo had countervailing procompetitive justifications that make the agreement lawful, even if Complaint Counsel establish a prima facie case of competitive harm.

This motion seeks partial summary decision rejecting Impax's asserted procompetitive justifications because they are not legally cognizable defenses under *Actavis*. Impax contends its agreement with Endo was procompetitive because it: (1) granted Impax the right to sell its generic product eight months before the expiration of patents that Endo had asserted against Impax and years before the expiration of patents that Endo obtained after the date of their agreement; (2) provided Impax with certainty that it could launch its generic product free from the risk of patent infringement liability as to Endo's existing and future patents; and (3) enabled Impax to continue to sell its generic product despite a court ruling that two of the patents Endo obtained after the settlement were valid and infringed. But *Actavis* made it clear that it is inappropriate to "determine antitrust legality by measuring the settlement's anticompetitive effects" against "what the holder of a valid patent could do." *Id.* at 2230-31. Such an approach, the Court explained, cannot answer the antitrust question because the patent "may or may not be valid, and may or may not be infringed." *Id*. at 2231. *Actavis* likewise rejected the argument that

the benefits that accompany any settlement of patent litigation render lawful the use of large reverse payments. Finally, *Actavis* makes clear that the antitrust question is *not* who would have won the patent litigation, but instead whether the parties agreed to maintain and share the brand's supra-competitive profits preserved by an agreement to avoid "the risk of competition." *Id.* at 2236.

Because the facts underlying these purported justifications are not in dispute, and they fail as a matter of law, partial summary decision is warranted. Dismissing these defenses now will focus the trial and implement the Supreme Court's directive in *Actavis* that lower courts structure litigation in reverse payment cases to efficiently distinguish between anticompetitive and procompetitive agreements. *Id*. at 2237-38.

Summary of Undisputed Facts

Opana ER is an extended-release opioid used to treat moderate and severe pain. (Complaint Counsel's Statement of Undisputed Facts ¶¶ 1-4.) Its active ingredient is oxymorphone. (*Id*.) Endo received FDA approval to market Opana ER, NDA No. 021610, in June 2006 and launched the product in July 2006. (*Id.* ¶¶ 4, 5.) [redacted] (*Id*. ¶ 6.) The '143 patent was set to expire in September 2008. (*Id*.)

Impax initially filed an Abbreviated New Drug Application ("ANDA") in June 2007 seeking FDA approval to market a generic version of Opana ER. (*Id.* ¶ 9.) In October 2007, Endo listed three additional patents in the Orange Book as covering Opana ER: No. 5,662,933 and No. 5,958,456, which would expire in August 2013, and No. 7,276,250, which would expire in February 2023. (*Id*. ¶ 7.) All three patents concern the controlled-release mechanism of the formulation. (*Id*. ¶ 8.)

Impax subsequently re-submitted its ANDA, No. 79087, with Paragraph IV certifications asserting that its generic product did not infringe the newly-listed patents and that the newly-listed patents were invalid. (*Id*. ¶¶ 10-11.) The FDA accepted Impax's application as of November 23, 2007. (*Id*. ¶ 11.) Impax was the first company to file a Paragraph IV ANDA for the five best-selling dosages of Opana ER. (*Id*. ¶ 12.) Because of its first-filer status, Impax was eligible for the Hatch-Waxman 180-day exclusivity period. (*Id*. ¶ 13.) If granted, the FDA could not approve any other ANDA for a generic version of Opana ER for those five dosages until 180 days after Impax launched. (*Id.*) Endo, however, would still be able to market its own "authorized generic" version of Opana ER during Impax's exclusivity period. (*Id*.)

Endo sued Impax for infringement of the '933 and the '456 patents, triggering a 30-month stay on FDA approval of Impax's ANDA. (*Id*. ¶ 15.) Impax received tentative FDA approval in May 2010. (*Id*. ¶ 16.) Trial in the infringement case began on June 3, 2010. (*Id*. ¶ 17.) The 30-month stay was set to expire June 14, 2010, at which time the FDA could grant final approval of Impax's ANDA. (*Id*. ¶ 15.) On June 8, 2010, Impax and Endo settled the patent infringement case and executed the Settlement and License Agreement. (*Id*. ¶ 18, 20.) At the time of settlement, the outcome of Endo's infringement suit was uncertain. (*Id*. ¶ 18.)

Under the Settlement and License Agreement, Impax agreed that it would abandon its patent challenge and refrain from selling its generic Opana ER product until January 1, 2013, eight months before the two patents at issue in Endo's infringement suit would expire. (*Id.* ¶¶ 7, 15, 21.) Endo agreed that it would not launch an authorized generic version of Opana ER during Impax's first six months on the market. (*Id.* ¶ 23.) The Settlement and License Agreement also included a provision called the "Endo Credit." (*Id*. ¶ 24.) The Endo Credit provision required Endo to make a cash payment to Impax if sales of Endo's existing version of Opana ER

("original Opana ER") dropped by more than 50% from (a) the highest sales quarter during the period from the third quarter of 2010 through the third quarter of 2012 to (b) the quarter just before the agreed-upon Impax entry date (fourth quarter 2012). (*Id*.)

At the time of the settlement, Endo had pending applications for patents relating to Opana ER. (*Id*. ¶¶ 22.) The Settlement and License Agreement provides that the license to Impax to sell its generic version of original Opana ER would cover not only Endo's existing patents, but also additional patents that Endo might obtain after the date of settlement. (*Id*.)[1] At the time of settlement in June 2010, it was uncertain whether any additional patents would ultimately issue, or whether any patents that Endo might obtain in the future would cover Impax's ANDA product. (*Id*.)

Endo ultimately obtained additional patents that it has asserted cover original Opana ER as well as a reformulated version that Endo launched in the spring of 2012. (*Id*. ¶¶ 29-31.) Patent No. 8,309,122 and Patent No. 8,309,060 issued on November 13, 2012, and Patent No. 8,329,216 issued on December 11, 2012. (*Id*. ¶¶ 32-33.) In December 2012, Endo began asserting these patents against generic drug manufacturers. (*Id*. ¶ 34.) At the time, Endo did not assert these later-issued patents against Impax's generic version of original Opana ER. (*Id*.) In August 2015, the district court hearing the infringement actions ruled that two of the asserted patents were valid and infringed by other companies' generic versions of original and reformulated Opana ER and by Impax's ANDA for the reformulated version. (*Id.* ¶ 36.) The court issued an injunction barring all of the defendant generic drug manufacturers except Impax

[1] Impax and Endo are currently litigating a dispute concerning the Agreement's provisions relating to future Endo patents. *See Endo Pharm., Inc. v. Impax Labs., Inc*., No. 16-cv-2526 (JLL), 2016 WL 6246773 (D.N.J. Oct. 25, 2016). That dispute has no significance for the legal issue presented by this motion, and therefore for purposes of this motion only, we assume Impax's position in that dispute is correct.

from selling a generic version of original Opana ER until 2029. (*Id*.) The court's rulings are currently on appeal to the Federal Circuit. (*Id*.)

The Current Case

The Commission issued the Complaint in this case on January 19, 2017. The Complaint alleges that the settlement agreement between Impax and Endo was an anticompetitive reverse-payment agreement. As *Actavis* explains, "the relevant anticompetitive harm" from such agreements is that the payment is used "to prevent the risk of competition." 133 S. Ct. at 2236. Such a payment "maintain[s] supracompetitive prices to be shared among the patentee and the challenger rather than face what *might have been* a competitive market." *Id.* (emphasis added). *Actavis* thus makes clear that in Hatch-Waxman patent settlements, as in other settings, "the law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition." 12 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 2030b (3d ed. 2010) (hereinafter "Areeda").

The Complaint here alleges that in exchange for a large and unjustified reverse payment, Impax agreed to abandon its patent challenge and refrain from launching its generic version of Opana ER for two and half years, until January 2013. The alleged payment took two forms: First, Endo agreed not to sell an authorized generic version of Opana ER during Impax's initial 180 days of marketing ("the no-AG commitment"), effectively giving Impax a monopoly on generic sales during that period. Endo further agreed to make a direct cash payment to Impax if Endo diminished the value of this no-AG commitment before Impax's exclusivity period could begin ("the Endo Credit"). (Leefer Decl. Ex. A, Complaint ¶¶ 50, 53-59.) Second, Endo agreed to pay Impax $10 million up front as part of a development and co-promotion deal for a drug Impax was seeking to develop. (*Id*. ¶¶ 60-61.) The administrative trial is scheduled to begin October 24, 2017.

Impax's Proffered Justifications

The subject of this motion is Affirmative Defense No. 8 in Impax's Answer to the Complaint, which states:

> The alleged conduct had substantial pro-competitive justifications, benefited consumers and the public interest, and avoided potential infringement of valid patents. These pro-competitive justifications outweigh any alleged anticompetitive effects of the alleged conduct. There were no less restrictive alternatives that could have achieved these same pro-competitive outcomes.[2]

In response to a motion to compel Impax to respond to interrogatories concerning this Eighth Affirmative Defense, Impax directed Complaint Counsel to its submissions during the pre-complaint investigation and its statements at the Initial Pretrial Conference, asserting that no further response was required until after the close of discovery.[3] In these materials, Impax points to essentially three procompetitive justifications for the Settlement and License Agreement.[4]

Entry before patent expiration: Impax contends that the Agreement allowed it to introduce generic original Opana ER earlier than it likely would have otherwise done so, before the expiration date of the patents at issue in the parties' litigation, and before the expiration date of patents Endo subsequently obtained.[5] At the Initial Pretrial Conference, Impax characterized

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[2] Leefer Decl. Ex. B (Answer of Respondent Impax Laboratories Inc. to the Federal Trade Commission's Administrative Complaint, Dkt. 9373 (Feb. 7, 2017)), Eighth Defense.

[3] Leefer Decl. Ex. C. (Respondent Impax Laboratories, Inc.'s Opposition to Complaint Counsel's Motion to Compel Responses to Interrogatory Nos. 2 & 3, Dkt. 9373 (June 8, 2017)) at 2-3, 5-8.

[4] Impax has asserted that the $10 million upfront payment under the development and co-promotion agreement was justified as payment for services rendered by Impax to Endo. That justification, which raises disputed issues of fact, is not at issue in this motion.

[5] Leefer Decl. Ex. D (Impax's Narrative Responses to Specifications 4, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 17, 20, 21, 22, 23, 24, 26, 37, 39, 41, 42, and 46, and Amended Responses to Specifications 36 and 44) at 16-17 [redacted] *See also* Leefer Decl. Ex. C (Respondent Impax Laboratories, Inc.'s Opposition to Complaint Counsel's Motion to Compel Responses to Interrogatory Nos. 2 & 3, Dkt. 9373 (June 8, 2017)) at 3 ("[T]he SLA is

the Agreement as providing Impax with "an early entry date," in that it was "earlier than when the patents expired."[6]

Certainty that it could enter without risk of infringement: The Settlement and License Agreement also facilitated competition, Impax states, because it eliminated the risk of patent infringement liability and damages to Endo.[7]

Post-settlement patent rulings: Impax also contends that Endo's success in enforcing some of its later-acquired patents against other generic drug manufacturers demonstrates that the Agreement is procompetitive.[8]

At issue in this motion is the legal validity of these asserted procompetitive defenses. This is a purely legal question and is ripe for summary decision.

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procompetitive because it allowed Impax to begin selling a licensed version of generic Opana ER earlier that it otherwise could have.").

[6] Leefer Decl. Ex. E (Initial Pretrial Conference Tr., Dkt. 9373 (Feb. 16, 2017)) at 61:1-9 ("What Impax got and what Impax negotiated for was an early entry date. They got a date that allowed them to come onto the market earlier than when the patents expired."); 85:23-24 ("We came in earlier than the date the patent would have allowed.").

[7] Leefer Decl. Ex. D (Impax's Narrative Responses to Specifications 4, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 17, 20, 21, 22, 23, 24, 26, 37, 39, 41, 42, and 46, and Amended Responses to Specifications 36 and 44) at 16-17 [redacted]

[8] *See, e.g.*, Leefer Decl. Ex. E (Initial Pretrial Conf. Tr., Dkt. 9373 (Feb. 16, 2017)) at 23:22-24:16 ("Endo has won two cases related to those after-acquired patents. But as we stand here today, Impax is the only company selling Opana ER."), 57:10-60:13 ("So the bottom line is, other than Impax, Endo has been successful in keeping other generics out of the market for this drug or a related drug."), 69:20-24 ("[T]he reason our agreement or one of the reasons our agreement is procompetitive is because from January 1, 2013, until 2029, we will be selling this drug and we will be the only generic on the market . . . ."), 71:8-15 ("So the bottom line is here, consumers have benefited, and they have benefited greatly from this agreement, and so they have benefited because Impax has this broad license. To be sure, Impax has benefited as well. I don't hear the FTC challenging the broad patent license, but in terms of the procompetitive or anticompetitive effects of this agreement, this is procompetitive.").

Standard for Summary Decision

Rule 3.24 of the Commission's Rules of Practice provides that a party may move for a summary decision "upon all or any part of the issues being adjudicated." 16 C.F.R. § 3.24(a)(1) (2017). The standard applied to such motions is essentially the same as that applied to motions for summary judgment under Federal Rule of Civil Procedure 56. *In re North Carolina State Board of Dental Examiners*, 151 F.T.C. 607, 610-11 (2011). Thus, summary decision is warranted if the moving party demonstrates that there is no genuine dispute as to any material fact and it is entitled to judgment as a matter of law. *Id.* Partial summary decision is particularly appropriate to weed out legally insufficient defenses prior to trial. *See. e.g.*, Opinion and Order of the Commission Granting Complaint Counsel's Motion For Partial Summary Decision at 2, *In re 1-800 Contacts, Inc.*, Dkt. 9372 (Feb. 1, 2017) (rejecting *Noerr* defense); *Dental Examiners*, 151 F.T.C. at 617 (rejecting state action defense).

Argument

In a case challenging a reverse-payment agreement, the plaintiff "must prove its case as in other rule-of-reason cases." *Actavis*, 133 S. Ct. at 2237. In any rule of reason case, once the plaintiff shows likely harm to competition, "the burden shifts to the defendant to show that the restraint in fact serves a legitimate objective." Areeda, *supra*, ¶ 1504(b). In a reverse payment case, "[a]n antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason." *Actavis*, 133 S. Ct. at 2236. An antitrust plaintiff may rebut such a showing by demonstrating that the challenged restraint is not reasonably necessary to achieve the asserted objective. Areeda, *supra*, ¶ 1505.

Actavis specified two ways that a defendant may seek to "explain" and thereby justify the "challenged term," *i.e.*, the reverse payment: showing that the payment (1) "amount[s] to no

more than a rough approximation of the litigation expenses saved through the settlement"; or (2) "reflect[s] compensation for other services that the generic has promised to perform." 133 S. Ct. at 2236. Such evidence indicates that "the parties may have provided for a reverse payment without having sought or brought about" anticompetitive consequences. *Id.* "There may be other justifications," the Supreme Court stated. *Id.* But any other justifications for a reverse payment must at the very least be consistent with the logic of *Actavis*—including the Supreme Court's reasons for rejecting antitrust immunity for patent settlements using reverse payments—as well as the rule of reason principles upon which the Court relied.

Here, Impax contends that, even if Complaint Counsel prove a prima facie case of harm to competition, the Opana ER Settlement and License Agreement had countervailing procompetitive benefits that render it lawful under the rule of reason. Impax asserts that the agreement increased competition and benefitted consumers because it:

(1) permitted Impax to sell its generic version of original Opana ER eight months before the patents at issue in the infringement suit were set to expire and years before the expiration date of other patents relating to Opana ER that Endo obtained after the settlement;

(2) eliminated uncertainty that Impax faced about potential liability for infringement of patents that Endo had or might obtain; and

(3) enabled Impax to continue selling its generic product after two patents that Endo obtained after the settlement were held valid and infringed by other generic drug makers.[9]

None of these arguments presents a legitimate justification for a reverse-payment settlement. As discussed below, *Actavis* forecloses each of these justifications.

[9] *See supra* notes. 8-11.

I. *Actavis* forecloses Impax's "entry-before-patent-expiration" defense

Impax's argument that its settlement is procompetitive because it allows generic entry before the expiration of Endo's patents directly conflicts with *Actavis*. It improperly treats the patent as valid and infringed and assumes that any generic entry before patent expiration must be procompetitive because the generic might have been excluded for the full length of the patent term if the patent holder prevailed in the litigation. But, as the Supreme Court explained, the brand's patent "may or may not be valid, and may or may not be infringed." 133 S. Ct. at 2231. "The parties' settlement ended th[e] litigation" that had put the "patent's validity at issue, as well as its actual preclusive scope." *Id.* Thus, considering "what the holder of a valid patent could do" does not "answer the antitrust question." *Id.* at 2230-31. Instead, the antitrust inquiry examines whether the payment "seeks to prevent the risk of competition," which itself "constitutes the relevant anticompetitive harm." *Id.* at 2236. A reverse-payment settlement that allows the generic to enter the market before patent expiration eliminates the risk of competition prior to the agreed-upon entry date.

Decisions applying *Actavis* confirm that companies cannot defend a reverse-payment agreement on the ground that it allowed entry before patent expiration. As the Third Circuit noted in *King Drug Co. of Florence v. Smithkine Beecham Corp.*, 791 F.3d 388, 408 (3d Cir. 2015), "the settlement in *Actavis* itself" permitted entry "65 months before patent expiration." "Notwithstanding such 'early entry,'" however, "the antitrust problem was that, as the [Supreme] Court inferred, entry might have been earlier, and/or the risk of competition not eliminated, had the reverse payment not been tendered." *Id.*

The California Supreme Court reached the same conclusion. In *In re Cipro Cases I & II*, 348 P.3d 845, 864 (Cal. 2015), the defendant generic drug manufacturer argued that the competitive effect of a settlement "must be measured by comparison to the entire remaining life

of the patent." Relying on *Actavis*, the court rejected this argument as matter of law: "An antitrust defendant cannot argue a settlement is procompetitive simply because it allows competition earlier than would have occurred if the brand had won the patent action." *Id.* at 870. And more recently, the court in *In re Aggrenox Antitrust Litigation*, 94 F. Supp. 3d 224, 245 (D. Conn. 2016), held that "the anticompetitive harm described in *Actavis* is not measured by the exclusionary scope of the patent—that test was explicitly rejected."

Impax's "entry before patent expiration" defense is merely a repackaging of the "scope of the patent" test that the Supreme Court rejected in *Actavis*, now labeled as a procompetitive justification. Under that test, a reverse-payment settlement was "immune from antitrust attack so long as its anticompetitive effects f[ell] within the scope of the exclusionary potential of the patent." 133 S. Ct. at 2230. As noted above, *Actavis* rejected this approach because it improperly treats the patent as valid and infringed, when at the time of the settlement, validity and infringement were uncertain. In so doing, the Supreme Court necessarily rejected the proposition that a reverse-payment settlement could be rendered lawful because it allowed for entry prior to patent expiration.

This fatal flaw in Impax's entry-before-patent-expiration justification holds as to both the patents that were the subject of Endo's infringement suit against Impax and the later patents that Endo obtained. Like the license to the patents at issue in Endo's infringement suit, the provision for a license to future patents provides "early" entry only in the sense that it permits entry before patent expiration. But such entry is only "early" if one assumes a subsequently issued patent would otherwise bar Impax from selling its product. At the time of the settlement, however, it was uncertain whether any future patents claiming original Opana ER would issue, let alone whether any such patent would be valid and infringed by Impax's generic product.

Actavis makes clear that in an antitrust analysis of a reverse-payment agreement, it is improper to assume away that uncertainty and treat the patent as ironclad. As the Third Circuit observed in *King Drug*, "*Actavis* embraces the concept that a patent 'may or may not be valid, and may or may not be infringed,' and holds that the anticompetitive harm is not *certain* consumer loss through higher prices, but rather the patentee's 'avoid[ance of] the risk of patent invalidation or a finding of noninfringement'—that is, 'prevent[ion of] the risk of competition.'" 791 F.3d at 410 (quoting *Actavis*, 133 S. Ct. at 2231, 2236). Impax's entry-before-patent-expiration defense thus fails as a matter of law.

II. *Actavis* forecloses elimination of patent uncertainty as a justification for a reverse payment agreement

Impax also suggests that its agreement with Endo had procompetitive benefits because it gave Impax the ability to enter and remain on the market free from the risk that it might be found to infringe and owe damages to Endo.[10] This argument fails for two reasons.

First, *Actavis* rejected the argument that the benefits of settlement should render lawful the use of reverse payments in settlement. 133 S. Ct. at 2234-37. It acknowledged that patent litigation can be complex and expensive, and it deemed the desirability of settlements a "strong consideration." *Id.* at 2234, 2237. The Supreme Court nonetheless concluded that the enhanced litigation and business certainty that settlements can provide did not justify the significant risk of substantial anticompetitive effects that reverse payments pose. In so concluding, the Court observed that drug companies "may, as in other industries, settle in other ways, for example, by

[10] *See, e.g.*, Leefer Decl. Ex. D (Impax's Narrative Responses to Specifications 4, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 17, 20, 21, 22, 23, 24, 26, 37, 39, 41, 42, and 46, and Amended Responses to Specifications 36 and 44) at 16-17 [redacted]

allowing the generic manufacturer to enter the patentee's market prior to patent expiration, without the patentee paying the challenger to stay out prior to that point." *Id.* at 2237. Thus, as post-*Actavis* decisions have observed, it would be wholly at odds with *Actavis* to permit defendants to justify a reverse-payment agreement based on the litigation certainty that settlements provide.[11]

Second, the general rule of reason principles that are the foundation of *Actavis* lead to the same conclusion. In any rule of reason case, once the plaintiff meets its initial burden to show anticompetitive effects, the defendant must then show the challenged restraint promotes a legitimate, procompetitive objective; a plaintiff may rebut such a showing by demonstrating that the restraint is not reasonably necessary to achieve that objective.[12] Impax cannot explain how the challenged restraint here bears any logical relationship to its asserted procompetitive goal, nor is the restraint here reasonably necessary to achieve that goal.

It is the alleged reverse payment that creates the antitrust concern, and it is that payment that requires justification. *See Actavis*, 133 S. Ct. at 2236 (antitrust defendant's burden is to justify "the challenged term"). Thus, as the Commission stated in its amicus brief filed in *In re Wellbutrin XL Antitrust Litigation*, "the antitrust question" in a reverse-payment case is not

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[11] *See, e.g., King Drug*, 791 F.3d at 411 (district court's conclusion that a no-AG agreement was "justified" because "the consideration . . . [wa]s reasonably related to the removal of the uncertainty created by the dispute," is "in tension with *Actavis* in that, without proper justification, the brand cannot pay the generic to eliminate the risk of competition") (internal citation omitted); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 393 (D. Mass. 2013) ("The lone conceivable benefit of reverse payment agreements—namely, the settlement of patent disputes—cannot overcome the anticompetitive consequences" of such agreements).

[12] *See, e.g., NCAA v. Bd. of Regents of Univ. of Okla.*, 468 U.S. 85, 113-14 (1984) (rejecting justification where the defendants failed to show that the restraint on televised games in fact served the objective of maintaining competitive balance among teams); *Realcomp II, Ltd. v. FTC*, 635 F.3d 815, 835 (6th Cir. 2011) (rejecting free riding justification where "Realcomp has not demonstrated a connection between the website policy and the prevention of free riding"); *United States v. Brown Univ.*, 5 F.3d 658, 669 (3d Cir. 1993) (once antitrust plaintiff establishes a prima facie, "the burden shifts to the defendant to show that the challenged conduct promotes a sufficiently pro-competitive objective"); Areeda, *supra*, ¶ 1505a ("An allegedly legitimate objective is, of course, entirely immaterial unless it is served by the challenged restraint.").

whether a settlement includes provisions that facilitate the generic's ability to enter the market and compete, but whether the benefits are attributable to the payment.[13] Tellingly, Impax's various statements describing procompetitive benefits of the Settlement and License Agreement nowhere explain how the payment provisions in the Agreement served to achieve the patent certainty benefits that it obtained from the licenses Endo granted.

It would be wholly illogical to suggest such a link. Endo agreed to grant the license provisions Impax relies on *and* agreed to the alleged reverse payment to Impax. The inescapable conclusion is that Endo would have agreed to grant that same protection to Impax without having to make a reverse payment. Impax simply cannot explain how the asserted procompetitive benefits of the Agreement are attributable to the challenged reverse payment. Moreover, were Impax to take the position that it would have been unwilling to accept the settlement absent the alleged reverse-payment provisions of the Settlement and License Agreement, that position would simply confirm the anticompetitive character of the challenged agreement. The use of a large reverse payment to induce the generic to accept a settlement restricting its entry into the market is the very thing that *Actavis* explains is "the relevant anticompetitive harm." 133 S. Ct. at 2236.

A generic drug manufacturer may have a legitimate desire to avoid patent litigation risk. But it may not avoid such risk by accepting a reverse payment that "maintain[s] and . . . share[s] patent-generated monopoly profits." *Id*. at 2237. That is the essence of the antitrust violation under *Actavis*, not a defense to such an arrangement.

[13] Brief of Federal Trade Commission as Amicus Curiae in Support of No Party at 23, *In re Wellbutrin XL Antitrust Litig.*, Nos. 15-3559, 15-3591, 15-3681 & 15-3652 (3d Cir. Mar. 11, 2016).

III. Post-settlement patent rulings cannot justify a reverse payment

Impax's argument that the challenged reverse-payment agreement was procompetitive relies heavily on the fact that a district court subsequently held that two of the patents Endo obtained after the settlement were valid and infringed by other generic companies' original Opana ER products (and by Impax's ANDA for the reformulated version).[14] But a patent ruling occurring after the settlement cannot retroactively justify a reverse payment. *Actavis* itself makes clear that the assessment of a reverse-payment agreement's competitive effects focuses on circumstances at the time the agreement was entered—that is, on an *ex ante basis*. The *Actavis* framework accepts as a baseline the proposition that at the time of settlement the outcome of the patent litigation was uncertain. The antitrust question is not who would have won the patent litigation, but instead whether the parties agreed to maintain and share the brand's supra-competitive profits preserved by an agreement to avoid "the risk of competition." 133 S. Ct. at 2236.

Decisions after *Actavis* confirm this *ex ante* approach. *In re Cipro Cases I & II* applied the *Actavis* framework in a case in which the patent underlying the challenged settlement was later ruled valid in litigation involving patent challenges by other generic drug manufacturers. 348 P.3d at 859 n.8. Noting the general principle that agreements "must be assessed as of the time they are made," the court explained that "consideration of whether the agreement is justified as procompetitive will not turn on whether the patent would ultimately have been proved valid or invalid." *Id.* at 870. Accordingly, it concluded that "[j]ust as later invalidation of a patent does

[14] *See supra*. notes 8-11.

not prove an agreement when made was anticompetitive . . . later evidence of validity will not automatically demonstrate an agreement was procompetitive." *Id.*[15]

In re Aggrenox likewise observed that, under *Actavis*, the "salient question is not whether the fully-litigated patent would ultimately be found valid or invalid." 94 F. Supp. 3d at 241. Rather, the relevant question is "whether the settlement included a large and unjustified reverse payment leading to the inference of profit-sharing to avoid the risk of competition." *Id.*

More recently, *Apotex, Inc. v. Cephalon, Inc.*, No. 2:06-cv-2768, 2017 WL 2473148, at *5 (E.D. Pa. June 8, 2017), held that a post-settlement patent ruling should play no role in assessing the competitive effects of a reverse-payment agreement given "the ex ante framework mandated by the *Actavis* rule of reason analysis." The court squarely rejected the plaintiffs' effort to use a judicial determination made years after the settlement that the patent at issue in the underlying infringement suit was invalid and unenforceable. The court relied on both the general antitrust principle that agreements are assessed at the time they are entered, as well as the application of that principle in the context of other reverse-payment cases. *Id.*

Commentators have likewise agreed that, whether undertaken in later patent litigation or in the antitrust case itself, *ex post* determinations about patent validity or infringement do not "answer the antitrust question" under *Actavis*.[16] Moreover, treating such determinations as relevant would be not only inconsistent with *Actavis*, but also wholly unworkable in practice. For

[15] The Eleventh Circuit's pre-*Actavis* decision in *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1306-07 (11th Cir. 2003), rejected the plaintiffs' argument that a subsequent judicial determination that the patent at issue was invalid rendered the reverse payment agreements at issue *per se* unlawful. The court rested that conclusion on the general antitrust principle that "the reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into." *Id.* at 1306 (citing *Polk Bros., Inc. v. Forest City Enters., Inc.*, 776 F.2d 185, 189 (7th Cir. 1985)); *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1207-08 (2d Cir. 1981).

[16] *See, e.g.*, Aaron Edlin et al., *The Actavis Inference: Theory and Practice*, 67 Rutgers U. L. Rev. 585, 617 (2015) ("[T]he correct antitrust analysis must be based on what was reasonably known to the parties about patent validity and infringement *at the time they entered their settlement*.") (emphasis in original) (cited in *Apotex*, 2017 WL 2473148, at *5).

under Impax's theory, a Federal Circuit reversal in the now-pending appeal of the district court ruling that Impax relies on would negate the claimed procompetitive benefits. The resulting uncertainty from such an approach would undermine drug companies' ability to settle patent cases as well as the ability of courts and enforcement agencies to conduct the antitrust inquiry that *Actavis* mandates.

As the *Apotex* decision reflects, a post-settlement patent ruling may be relevant in suits by private parties, who must not only prove an antitrust violation but also establish that they suffered an antitrust injury attributable to the violation. 2017 WL 2473148, at *6. But, questions of antitrust injury and causation do not arise in a government enforcement action. As the First Circuit emphasized in a reverse-payment case brought by private plaintiffs, proof of a violation and proof of antitrust injury "are distinct matters that must be shown independently." *In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 60 (1st Cir. 2016) (quoting *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 344 (1990)). "Private plaintiffs and the FTC as government enforcer stand in different shoes. . . . 'The interest of private plaintiffs is to remediate an injury they have suffered or may suffer. The interest of the government is to prevent and restrain violations of the antitrust laws along with the attendant social costs such violations can cause.'" *Id*. (internal citation omitted). Thus, whatever role post-settlement judicial rulings on later-issued patents might play in an antitrust injury inquiry in a private suit, they cannot provide a legitimate justification under the *Actavis* rule of reason framework.

Impax's reliance on post-settlement patent rulings, like its "early entry" defense, reflects a fundamental misunderstanding of the nature of the competitive harm that requires justification under *Actavis*. As discussed in Part I, the relevant harm to competition under *Actavis* is not that, absent the reverse payment, generic entry would necessarily have been earlier, but rather that the

payment served to eliminate the *risk* (even if "small") that competition would have been earlier. 133 S. Ct. at 2236. A post-settlement ruling upholding a patent thus cannot provide a defense when parties use a large reverse payment to prevent that risk of competition.

IV. The issue is ripe for partial summary disposition

The issue presented by this motion is a pure question of law: whether three justifications that Impax has asserted for the alleged reverse payment in the Settlement and License Agreement are legally cognizable under *Actavis*. This question is appropriate for summary decision and is ripe for resolution at this stage of the proceeding. The facts underlying the justifications at issue in this motion are basic facts about the litigation, the Settlement and License Agreement, and the Endo patents. While Impax may assert additional justifications after the close of discovery, there is no reason to delay a decision of the legal viability of those addressed in this motion. Granting partial summary decision will narrow the issues for trial and provide valuable guidance to the industry and the public on the proper application of *Actavis*.

Complaint Counsel respectfully request that the Commission grant the motion for partial summary decision.

Respectfully submitted,

/s/ Charles A. Loughlin

Counsel Supporting the Complaint

Dated: August 3, 2017

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of	)	
Impax Laboratories, Inc., a corporation,	)	**DOCKET NO. 9373**
Respondent	)	

[PROPOSED] ORDER

Having carefully considered Complaint Counsel's Motion For Partial Summary Decision, Respondent's Opposition thereto, Complaint Counsel's Reply, and all supporting evidence, and the applicable law, Complaint Counsel's Motion For Partial Summary Decision as to these justifications is hereby GRANTED. It is hereby ORDERED AND ADJUDGED that *FTC v. Actavis*, 133 S. Ct. 2223 (2013) forecloses arguments by Respondent to justify or otherwise defend the alleged reverse-payment agreement in Respondent's Settlement and License Agreement with Endo Pharmaceuticals, Inc. on the grounds that: (1) the Agreement permitted Respondent to sell its generic version of original Opana ER before the expiration of patents that Endo had or subsequently obtained; (2) the Agreement eliminated uncertainty about Respondent's potential liability to Endo for patent infringement; and (3) absent the Agreement, post-settlement court rulings would have prevented Respondent from selling its generic version of original Opana ER.

ORDERED:

By the Commission.

_____
Donald S. Clark
Secretary

SEAL

ISSUED:

CERTIFICATE OF SERVICE

I hereby certify that on August 3, 2017, I filed the foregoing documents electronically using the FTC's E-Filing System, which will send notification of such filing to:

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The Honorable D. Michael Chappell
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Dated: August 3, 2017

By: /s/ Nicholas Leefer
Attorney

CERTIFICATE FOR ELECTRONIC FILING

I certify that the electronic copy sent to the Secretary of the Commission is a true and correct copy of the paper original and that I possess a paper original of the signed document that is available for review by the parties and the adjudicator.

August 3, 2017

By: /s/ Nicholas A. Leefer
Attorney

1410004

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Maureen K. Ohlhausen, Acting Chairman**
Terrell McSweeny

In the Matter of **Impax Laboratories, Inc.,** **a corporation.**	**Docket No. 9373**

COMPLAINT COUNSEL'S STATEMENT OF UNDISPUTED FACTS

Pursuant to Rule 3.24, Complaint Counsel submits, in support of its motion for partial summary decision, the following statement of material facts as to which there is no genuine dispute:

Opana ER & Endo Patents

1. Oxymorphone is a semi-synthetic opioid used to relieve pain.[1]

2. The U.S. Food & Drug Administration ("FDA") first approved oxymorphone in 1960.[2]

3. Opana ER is an extended-release formulation of oxymorphone.[3]

[1] Leefer Decl. Ex. A (Compl., *In re Impax Labs., Inc.*, Dkt. 9373 (Jan. 19, 2017)) ¶ 27; Leefer Decl. Ex. B (Answer, *In re Impax Labs., Inc.*, Dkt. 9373 (Feb. 7, 2017)) ¶ 27.

[2] Leefer Decl. Ex. F (U.S. Food & Drug Administration, Drugs@FDA, "Numorphan," NDA No. 011738, *available at* https://www.accessdata fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process).

[3] Leefer Decl. Ex. A (Compl., *In re Impax Labs., Inc.*, Dkt. 9373 (Jan. 19, 2017)) ¶ 28; Leefer Decl. Ex. B (Answer, *In re Impax Labs., Inc.*, Dkt. 9373 (Feb. 7, 2017)) ¶ 28.

4. The FDA approved Opana ER (NDA No. 021610) in June 2006 "for the relief of moderate to severe pain in patients requiring continuous, around-the clock opioid treatment for an extended period of time."[4]

5. Endo announced commercial availability of Opana ER in July 2006.[5] Endo offered Opana ER in seven dosage strengths (5, 7.5, 10, 15, 20, 30 and 40 mg).[6]

6. [redacted] The '143 patent was set to expire in September 2008.[8]

7. In October 2007, Endo listed three additional patents in the Orange Book as covering Opana ER: U.S. Patent Nos. 7,276,250, 5,662,933, and 5,958,456.[9] The '933 and '456 patents expired in August 2013.[10] The '250 patent will expire in February 2023.[11]

[4] Leefer Decl. Ex. G (U.S. Food & Drug Administration, Drugs@FDA, "Opana ER," NDA No. 021610, *available at* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=021610); Leefer Decl. Ex. H (Opana ER (NDA No. 021610) Label (Aug. 2, 2006), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021610s001,021611s001lbl.pdf) at 1.

[5] Leefer Decl. Ex. I (Endo Pharmaceuticals press release, *Endo Announces Commercial Availability of Opana® ER (oxymorphone HCl) Extended-Release and Opana® (oxymorphone HCl) Immediate-Release Tablets CII* (July 24, 2006).

[6] Leefer Decl. Ex. A (Compl., *In re Impax Labs., Inc.*, Dkt. 9373 (Jan. 19, 2017)) ¶ 29; Leefer Decl. Ex. B (Answer, *In re Impax Labs., Inc.*, Dkt. 9373 (Feb. 7, 2017)) ¶ 29.

[7] Leefer Decl. Ex. J (Letter from C. Manogue (Endo) to G. Buehler (FDA) re: NDA No. 21-610 – Opana® ER (oxymorphone HCl) extended release tablets and ANDA No. 79-087 (Impax Laboratories), dated Oct. 25, 2007), EPI001604423 at -4424.

[8] Leefer Decl. Ex. A (Compl., *In re Impax Labs., Inc.*, Dkt. 9373 (Jan. 19, 2017)) ¶ 32; Leefer Decl. Ex. B (Answer, *In re Impax Labs., Inc.*, Dkt. 9373 (Feb. 7, 2017)) ¶ 32.

[9] Leefer Decl. Ex. A (Compl., *In re Impax Labs., Inc.*, Dkt. 9373 (Jan. 19, 2017)) ¶¶ 33-35; Leefer Decl. Ex. B (Answer, *In re Impax Labs., Inc.*, Dkt. 9373 (Feb. 7, 2017)) ¶¶ 33-35.

[10] Leefer Decl. Ex. K (FDA Tentative Approval Letter (5, 10, 20, and 40 mg), ANDA No. 079087, dated June 14, 2010), Impax_Opana_PartIII_0045550 at -5553.

[11] *Id*.

8. The '250, '933, and '456 patents all pertain to the controlled-release mechanism of the oxymorphone formulation.[12]

Impax Application and Endo Lawsuit

9. Impax filed an Abbreviated New Drug Application ("ANDA") for a generic version of Opana ER (No. 79-087) in June 2007.[13] [redacted] As of June 2007, the '143 patent was the only patent covering Opana ER listed in the Orange Book.

10. Following Endo's listing of the additional patents in the Orange Book in October 2007, Impax amended its ANDA to include Paragraph IV certifications for the '250, '933, and '456 patents, attesting that Impax's product did not infringe the patents and/or that the patents were invalid.[15]

11. The FDA rescinded its original acceptance of Impax's ANDA for substantive review. Impax re-submitted its ANDA, which the FDA accepted on November 23, 2007.[16]

12. Impax was the first company to file an ANDA with Paragraph IV certifications for the 5, 10, 20, 30, and 40 mg dosages of Opana ER.[17] [redacted]

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[12] Leefer Decl. Ex. N (U.S. Patent No. 7,276,250, (filed Jul. 3, 2002)); Leefer Decl. Ex. L (U.S. Patent No. 5,662,933, (filed Nov. 3, 1995)); Leefer Decl. Ex. M (U.S. Patent No. 5,958,456, at (filed Jul. 1, 1997)).

[13] Leefer Decl. Ex. O (Impax Laboratories, Inc. press release, *IMPAX Announces FDA Acceptance of ANDA for Generic Version of Opana® ER* (Dec. 17, 2007).

[14] Leefer Decl. Ex. P, CX2967 (Impax-Opana-CID00009918 at -9934.

[15] Leefer Decl. Ex. Q (Impax Laboratories, Inc. press release, *IMPAX Comments on Lawsuit Related to Generic Version of Opana® ER* (Nov. 19, 2007); Leefer Decl. Ex. R (Compl., *Endo Pharm. Inc. v. Impax Labs., Inc.*, 09-cv-00831-KSH-PS (D. Del. Nov. 15, 2007)) ¶ 31; Leefer Decl. Ex. S (Compl., *Endo Pharm. Inc. v. Impax Labs., Inc.*, 09-cv-00832-KSH-PS (D. Del. Jan. 25, 2008)) ¶ 17; Leefer Decl. Ex. T (Compl., *Endo Pharm. Inc. v. Impax Labs., Inc.*, 09-cv-00833-KSH-PS (D. Del. July 25, 2008)) ¶ 17.

[16] Leefer Decl. Ex. B (Answer, *In re Impax Labs., Inc.*, Dkt. 9373 (Feb. 7, 2017)) ¶ 37.

13. Impax was eligible for first-filer exclusivity for the 5, 10, 20, 30, and 40 mg dosages,[19] meaning that, if the FDA ultimately granted such exclusivity, the FDA would not be able to approve another ANDA for a generic version of Opana ER in those dosages until 180 days after Impax began selling its product. Endo, however, as the holder of the approved NDA for Opana ER, would be able to market its own "authorized generic" version of Opana ER during Impax's exclusivity period.[20]

14. On December 13, 2007, Impax sent Endo notice of its Paragraph IV certifications for the '250, '933, and '456 patents.[21] In its notice, Impax asserted that its ANDA product did not infringe these patents.[22]

15. Endo sued Impax on January 25, 2008, alleging that Impax's ANDA product infringed the '456 and '933 patents.[23] Endo's lawsuit triggered a statutory 30-month stay, meaning that the FDA could not approve Impax's ANDA until the earlier of the expiration of

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[17] *Id.* ¶ 40.

[18] Leefer Decl. Ex. U (Levin IH Tr. (Nov. 13, 2014)) at 60:8-20; Leefer Decl. Ex. V(Email from T. Smolenski to C. Mengler re: opana ER, dated Nov. 11, 2009), CX0203, IMPAX-OPANA-CID00006922.

[19] Leefer Decl. Ex. K (FDA Tentative Approval Letter (5, 10, 20, and 40 mg), ANDA No. 079087, dated June 14, 2010), Impax_Opana_PartIII_0045550 at -5553.

[20] U.S. Food & Drug Administration, *FDA List of Authorized Generic Drugs* (last accessed Aug. 2, 2017), https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/abbreviatednewdrugapplicationandagenerics/ucm126389 htm.

[21] Leefer Decl. Ex. B (Answer, *In re Impax Labs., Inc.*, Dkt. 9373 (Feb. 7, 2017)) ¶ 38; Leefer Decl. Ex. W (Letter from M. Shaw (Impax) to Endo Pharmaceuticals Inc. and Penwest Pharmaceuticals Co. re: Paragraph IV Patent Certification Notice U.S. Patent Nos. 5,662,933; 5,958,456; and 7,276,250, dated Dec. 13, 2007), CX 2714, IMPAX-OPANA-CID00024463-4490.

[22] Leefer Decl. Ex. W (Letter from M. Shaw (Impax) to Endo Pharmaceuticals Inc. and Penwest Pharmaceuticals Co. re: Paragraph IV Patent Certification Notice U.S. Patent Nos. 5,662,933; 5,958,456; and 7,276,250, dated Dec. 13, 2007), CX2714, IMPAX-OPANA-CID00024463 at -4464.

[23] Leefer Decl. Ex. B (Answer, *In re Impax Labs., Inc.*, Dkt. 9373 (Feb. 7, 2017)) ¶ 39.

thirty months or resolution of the patent dispute in Impax's favor.[24] The 30-month stay was set to expire on June 14, 2010.[25]

16. The FDA granted tentative approval to Impax's ANDA on May 14, 2010.[26]

17. Trial began in Endo's patent infringement action against Impax on June 3, 2010.[27]

18. Impax and Endo settled the patent dispute on June 8, 2010.[28] At the time of settlement, the outcome of Endo's infringement suit was uncertain.

19. The FDA granted final approval to Impax's ANDA for generic Opana ER for the 5, 10, 20, and 40 mg dosages on June 14, 2010.[29] The FDA granted final approval to Impax's ANDA for the 30 mg dosage on July 22, 2010.[30]

The Impax-Endo Agreements

20. On June 8, 2010, Impax and Endo entered into the Settlement and License Agreement and the Development and Co-Promotion Agreement.

21. The Settlement and License Agreement granted Impax a license to sell its generic version of Opana ER beginning on January 1, 2013, [redacted]

[24] *Id.*

[25] Leefer Decl. Ex. X (Email and attachment from T. Engle to C. Mengler, L. Hsu, C. Hildenbrand, J. Camargo, R. Ting, M. Shaw, T. Smolenski, and M. Snowden re: Quarterly Launch Planning Meeting May 20, 2010 Agenda Materials, dated May 20, 2010), CX0007 IMPAX-OPANA-CID00002150 at -2152.

[26] Leefer Decl. Ex. Y (Impax Laboratories, Inc. press release, *Impax Laboratories Receives Tentative FDA Approval for Generic Opana(R) ER 5, 7.5, 10, 20, 30 and 40 mg Tablets* (May 14, 2010).

[27] *See* Leefer Decl. Ex. Z (Dkt. No. 244, *Endo Pharm. Inc. v. Impax Labs., Inc.*, No. 09-cv-831 (D.N.J. June 3, 2010).

[28] Leefer Decl. Ex. B (Answer, *In re Impax Labs., Inc.*, Dkt. 9373 (Feb. 7, 2017)) ¶ 49.

[29] *Id.* ¶ 52.

[30] *Id.*

[redacted]

22. Section 4.1(a) of the Settlement and License Agreement sets forth the scope of the license, granting Impax a license both to the "Opana ER Patents" (meaning the '933, '456, and '250 patents) and to "any patents and patent applications owned by Endo or Penwest . . . that cover or could potentially cover the manufacture, use, sale, offer for sale, importation, marketing or distribution of products . . . that are the subject of the Impax ANDA . . . ."[32] The Settlement and License Agreement identified "the patent applications (and any patents issued thereunder)" as the "Pending Applications."[33] At the time of settlement in June 2010, it was uncertain whether any additional patents would ultimately issue, or whether any patents that Endo might obtain in the future would cover Impax's ANDA product. At the time of the settlement, Endo had pending applications for patents relating to Opana ER.[34]

23. Endo also granted Impax an "Exclusivity Period." For the dosages for which Impax was the first-filer, Endo agreed not to "sell offer to sell, import, or distribute any generic version of products that are the subject of the Opana® NDA" during Impax's 180-day exclusivity period or to license or authorize a third party to do the same.[35]

24. Under a provision called the "Endo Credit," Endo also agreed to pay Impax a cash amount, determined by a formula included in the Settlement and License Agreement, if certain

[31] Leefer Decl. Ex. AA (Settlement and License Agreement) §§ 1.1, 4.1(a), CX2638, IMPAX-OPANA-CID00012071-132.

[32] *Id.* § 4.1(a).

[33] *Id.*

[34] Leefer Decl. Ex. OO (U.S. Patent No. 8,309,122 (filed Feb. 28, 2007)); Leefer Decl. Ex. PP (U.S. Patent No. 8,329,216 (filed Jun. 29, 2006)).

[35] Leefer Decl. Ex. AA (Settlement and License Agreement) § 4.1(c).

market events occurred.[36] Specifically, if, by the fourth quarter of 2012, sales of Opana ER sold under NDA No. 021610 ("original Opana ER") fell by more than 50% from the peak quarterly sales between the third quarter of 2010 and the third quarter of 2012, Endo would pay Impax a cash amount determined by the formula included in the agreement.[37]

25. Under the Development and Co-Promotion Agreement, Impax and Endo entered a deal concerning a potential treatment for Parkinson's disease using a combination of a [redacted].[38]

26. Endo agreed to pay Impax an "Upfront Payment" of $10 million within five days of the agreement's effective date.[39]

27. Endo also agreed to pay Impax up to $30 million in additional "Milestone Payments" for achieving events in the development and commercialization of the product.[40]

28. [redacted]

Reformulated Opana ER

29. In July 2010, Endo filed a supplemental New Drug Application (No. 201655) for a reformulated version of Opana ER ("reformulated Opana ER").[42] The FDA approved the application in December 2011.[43]

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[36] *Id.* § 4.4.

[37] *Id.* §§ 1.1, 4.4.

[38] Leefer Decl. Ex. A (Compl., *In re Impax Labs., Inc.*, Dkt. 9373 (Jan. 19, 2017)) ¶ 60; Leefer Decl. Ex. B (Answer, *In re Impax Labs., Inc.*, Dkt. 9373 (Feb. 7, 2017)) ¶ 60; Leefer Decl. Ex. AA (Development and Co-Promotion Agreement Recitals), IMPAX-OPANA-CID00012099-2132.

[39] Leefer Decl. Ex. AA (Development and Co-Promotion Agreement) § 3.1.

[40] *Id.* § 3.2.

[41] *Id.* (Settlement and License Agreement) § 9.3; Leefer Decl. Ex. BB (Respondent Impax Laboratories, Inc.'s Objections and Response to Complaint Counsel's Second Set of Interrogatories) at No. 15.

[42] Leefer Decl. Ex. CC (FDA Approval Letter, Opana ER, NDA No. 201655 (Dec. 9, 2011)) at 4.

30. In 2012, Endo ceased selling original Opana ER and began selling a "new formulation" of Opana ER (NDA No. 201655).[44]

Post-Settlement Patents and Litigations

31. After entering the Settlement and License Agreement, Endo obtained additional patents and patent licenses that it has asserted cover both original and reformulated Opana ER.[45]

32. The Patent and Trademark Office issued Patent Nos. 8,309,060 and 8,309,122 to Endo on November 13, 2012.[46]

33. The Patent and Trademark Office issued Patent No. 8,329,216 to Endo on December 11, 2012.[47]

34. In December 2012, Endo began asserting the '060, '122, and '216 patents against drug manufacturers seeking to market generic versions of Opana ER.[48] At that time, Endo did not assert these patents against Impax's generic version of original Opana ER.

35. The Patent and Trademark Office issued U.S. Patent No. 8,808,737 to Endo on August 19, 2014.[49] The Patent and Trademark Office issued U.S. Patent No. 8,871,779 on October 28, 2014.[50] Endo acquired an exclusive field-of-use license to the '779 patent from Mallinkcrodt.[51]

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[43] *Id.* at 1.

[44] Leefer Decl. Ex. DD (Endo Pharmaceuticals press release, *Endo Completes Transition of OPANA® ER Franchise to New Formulation Designed to be Crush Resistant*, Endo Pharmaceuticals (June 14, 2012).

[45] Leefer Decl. Ex. EE (Endo Health Solutions, Inc., Annual Report (Form 10-K), at F-65 (Mar. 1, 2013).

[46] Leefer Decl. Ex. NN (U.S. Patent No. 8,309,060 (filed Jan. 9, 2012)); Leefer Decl. Ex. OO (U.S. Patent No. 8,309,122 (filed Feb. 28, 2007)).

[47] Leefer Decl. Ex. PP (U.S. Patent No. 8,329,216 (filed Jun. 29, 2006)).

[48] Leefer Decl. Ex. FF (Compl., *Endo Pharm. Inc. v. Par Pharm. Co.*, No. 1:12-cv-09261-UA (S.D.N.Y. Dec. 19, 2012)) ¶¶ 61-75.

[49] Leefer Decl. Ex. QQ (U.S. Patent No. 8,808,737(filed Mar. 3, 2010)).

[50] Leefer Decl. Ex. GG (U.S. Patent No. 8,871,779 (filed Mar. 3, 2007)).

[51] Leefer Decl. Ex. HH (*Endo Pharm. Inc. v. Amneal Pharm., LLC*, 224 F. Supp. 3d 368, 383-84 (D. Del. 2016)).

36. In August 2015, the U.S. District Court for the Southern District of New York held that the ’122 and ’216 patents were not invalid and were infringed by other companies’ generic versions of original Opana ER and by generic versions of reformulated Opana ER, including Impax’s.[52] The court issued an injunction barring all defendants except Impax from selling their generic versions of original Opana ER until 2029.[53] The ruling is currently on appeal to the Federal Circuit.[54]

37. In November 2015, the U.S. District Court for the District of Delaware held that the ’737 patent was invalid.[55] The ruling is currently on appeal to the Federal Circuit.[56]

38. In October 2016, the U.S. District Court for the District of Delaware held that the ’779 patent was not invalid and was infringed by a generic version of reformulated Opana ER.[57] The ruling is currently on appeal to the Federal Circuit.[58]

Respectfully submitted,

Dated: August 3, 2017 */s/ Charles A. Loughlin*

[52] Leefer Decl. Ex. II (*Endo Pharm., Inc. v. Amneal Pharm., LLC*, No. 12-cv-8115, 2015 WL 9459823, at *3 (S.D.N.Y. Aug. 18, 2015)).

[53] *Id.* at *66.

[54] Leefer Decl. Ex. JJ (*Endo Pharm. Inc. v. Teva Pharm. USA, Inc.*, No. 15-2021 (Fed. Cir. appeal docketed Sept. 15, 2015)).

[55] Leefer Decl. Ex. KK (*Endo Pharm., Inc. v. Actavis Inc.*, No. 14-1381-RGA, 2015 U.S. Dist. LEXIS 155034, at *1 (D. Del. Nov. 17, 2015)).

[56] Leefer Decl. Ex. LL (Dkt. No. 209, *Endo Pharm. Inc. v. Actavis LLC*, No. 14-cv-01381-RGA (D. Del. Apr. 7, 2017)).

[57] Leefer Decl. Ex. HH (*Endo Pharm. Inc. v. Amneal Pharm., LLC*, 224 F. Supp. 3d 368, 387 (D. Del. 2016)).

[58] Leefer Decl. Ex. MM (*Endo Pharm. Inc. v. Amneal Pharm. LLC*, No. 17-1094 (Fed. Cir. appeal docketed Oct. 24, 2016)).

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Counsel Supporting the Complaint

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of	)	
Impax Laboratories, Inc., a corporation,	)	**DOCKET NO. 9373**
Respondent	)	

DECLARATION OF NICHOLAS A. LEEFER

1. I am an attorney at the Federal Trade Commission and Complaint Counsel in this proceeding. Attached to this declaration are the exhibits submitted in support of Complaint Counsel's Memorandum in Support of its Motion for Partial Summary Decision.
2. I have personal knowledge of the facts set forth in this declaration, and if called as a witness I could and would testify competently under oath to such facts.
3. Exhibit A is a true and correct copy of the public version of the Complaint filed in the above captioned matter.
4. Exhibit B is a true and correct copy of the Answer filed in the above captioned matter.
5. Exhibit C is a true and correct copy of excerpts of the public version of Impax Laboratories, Inc's Opposition to Complaint Counsel's Motion to Compel Responses to Interrogatory Nos. 2 & 3, filed in the above captioned matter.
6. Exhibit D is a true and correct copy of excerpts from Impax's Narrative Responses to Specifications 4, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 17, 20, 21, 22, 23, 24, 26, 37, 39, 41,

42, and 46, and Amended Responses to Specifications 36 and 44 from the FTC's investigation, File No. 1410004.

7. Exhibit E is a true and correct copy of excerpts from the transcript of the February 16, 2017 Initial Pretrial Conference in the above captioned matter.
8. Exhibit F is a true and correct copy of a printout of the Drugs@FDA search for Numorphan, NDA 011738.
9. Exhibit G is a true and correct copy of a printout of the Drugs@FDA search for Opana ER, NDA 021610.
10. Exhibit H is a true and correct copy of excerpts from the Opana ER labeling downloaded from Drugs@FDA for NDA 021610.
11. Exhibit I is a true and correct copy of Endo Pharmaceuticals press release, Endo Announces Commercial Availability of Opana® ER (oxymorphone HCl) Extended-Release and Opana® (oxymorphone HCl) Immediate-Release Tablets CII (July 24, 2006).
12. Exhibit J is a true and correct copy of a document bearing bates numbers EPI001604423-30.
13. Exhibit K is a true and correct copy of a document bearing bates number Impax_Opana_PartIII_0045550-57.
14. Exhibit L is a true and correct copy of excerpts from U.S. Patent No. 5,662,933.
15. Exhibit M is a true and correct copy of excerpts from U.S. Patent No. 5,958,456.
16. Exhibit N is a true and correct copy of excerpts from U.S. Patent No. 7,276,250.

17. Exhibit O is a true and correct copy of Impax Laboratories, Inc. press release, IMPAX Announces FDA Acceptance of ANDA for Generic Version of Opana® ER (Dec. 17, 2007).
18. Exhibit P is a true and correct copy of excerpts from a document marked CX2967, bearing bates numbers Impax-Opana-CID00009918-10400.
19. Exhibit Q is a true and correct copy of Impax Laboratories, Inc. press release, IMPAX Comments on Lawsuit Related to Generic Version of Opana® ER (Nov. 19, 2007)
20. Exhibit R is a true and correct copy of excerpts from the Complaint filed in *Endo Pharm. Inc. v. Impax Labs., Inc.*, 09-cv-00831-KSH-PS (D. Del. Nov. 15, 2007).
21. Exhibit S is a true and correct copy of excerpts from the Complaint filed in *Endo Pharm. Inc. v. Impax Labs., Inc.*, 09-cv-00832-KSH-PS (D. Del. Jan. 25, 2008).
22. Exhibit T is a true and correct copy of excerpts from the Complaint filed in *Endo Pharm. Inc. v. Impax Labs., Inc.*, 09-cv-00833-KSH-PS (D. Del. July 25, 2008).
23. Exhibit U is a true and correct copy of excerpts from the November 13, 2014 Investigational Hearing transcript of Alan Levin.
24. Exhibit V is a true and correct copy of a document marked CX0203, bearing bates number IMPAX-OPANA-CID00006922.
25. Exhibit W is a true and correct copy of a document marked CX2714, bearing bates numbers IMPAX-OPANA-CID00024463-90.
26. Exhibit X is a true and correct copy of a document marked CX0007, bearing bates numbers IMPAX-OPANA-CID00002150-55.

27. Exhibit Y is a true and correct copy of Impax Laboratories, Inc. press release, Impax Laboratories Receives Tentative FDA Approval for Generic Opana(R) ER 5, 7.5, 10, 20, 30 and 40 mg Tablets (May 14, 2010).
28. Exhibit Z is a true and correct copy of Docket Entry No. 244, *Endo Pharm. Inc. v. Impax Labs., Inc.*, Civil Action No. 09-cv-831 (D.N.J. June 3, 2010).
29. Exhibit AA is a true and correct copy of a document marked CX2638, bearing bates numbers IMPAX-OPANA-CID00012071-132.
30. Exhibit BB is a true and correct copy of excerpts from Respondent Impax Laboratories, Inc's Objections and Responses to Complaint Counsel's Second Set of Interrogatories.
31. Exhibit CC is a true and correct copy of FDA Approval Letter, Opana ER, NDA No. 201655 (Dec. 9, 2011).
32. Exhibit DD is a true and correct copy of Endo Pharmaceuticals press release, Endo Completes Transition of OPANA® ER Franchise to New Formulation Designed to be Crush Resistant (June 14, 2012).
33. Exhibit EE is a true and correct copy of excerpts from Endo Health Solutions, Inc.'s Annual Report (Form 10-K), at F-65 (Mar. 1, 2013).
34. Exhibit FF is a true and correct copy of excerpts from the Complaint filed in *Endo Pharm. Inc. v. Par Pharm., Inc., et al.*, 12-cv-09261-UA (S.D.N.Y. Dec. 19, 2012).
35. Exhibit GG is a true and correct copy of excerpts from U.S. Patent No. 8,871,779.
36. Exhibit HH is a true and correct copy of *Endo Pharm. Inc. v. Amneal Pharm., LLC*, 224 F. Supp. 3d 368 (D. Del. 2016).
37. Exhibit II is a true and correct copy of *Endo Pharm. Inc. v. Amneal Pharm., LLC*, No. 12-cv-8115, 2015 WL 9459823 (S.D.N.Y. Aug. 18, 2015).

38. Exhibit JJ is a true and correct copy of Notice of Docketing *Endo Pharm. Inc. v. Teva Pharm. USA, Inc.*, No. 15-2021 (Fed. Cir. appeal docketed Sept. 15, 2015).
39. Exhibit KK is a true and correct copy of *Endo Pharm. Inc. v. Actavis Inc.*, Civil Action No. 14-1381, 2015 U.S. Dist. LEXIS 155034 (D. Del. Nov. 17, 2015).
40. Exhibit LL is a true and correct copy of Docket Entry No. 209, *Endo Pharm. Inc. v. Actavis Inc. et al.*, 14-cv-01381-RGA (D. Del. Apr. 7, 2017).
41. Exhibit MM is a true and correct copy of Notice of Docketing *Endo Pharm. Inc. v. Amneal Pharm. LLC*, No. 17-1094 (Fed. Cir. appeal docketed Oct. 24, 2016).
42. Exhibit NN is a true and correct copy of excerpts from U.S. Patent No. 8,309,060.
43. Exhibit OO is a true and correct copy of excerpts from U.S. Patent No. 8,309,122.
44. Exhibit PP is a true and correct copy of excerpts from U.S. Patent No. 8,329,216.
45. Exhibit QQ is a true and correct copy of excerpts from U.S. Patent No. 8,808,737.

I declare under the penalty of perjury that the foregoing is true and correct to the best of my knowledge. Executed this 3rd day of August, 2017 in Washington, DC.

/s/ Nicholas A. Leefer

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Counsel Supporting the Complaint

EXHIBIT A

PUBLIC

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Edith Ramirez, Chairwoman**
Maureen K. Ohlhausen
Terrell McSweeny

In the Matter of	**Docket No. 9373**
Impax Laboratories, Inc. **a corporation**	**Public Record Version**

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by said Act, the Federal Trade Commission ("Commission"), having reason to believe that Impax Laboratories, Inc. ("Impax"), a corporation, hereinafter sometimes referred to as "Respondent," has violated the provisions of said Act, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its complaint stating its charges in that respect as follows:

Nature of the Case

1. This action challenges an anticompetitive reverse-payment agreement between Impax and Endo Pharmaceuticals Inc. ("Endo") to obstruct lower-cost generic competition to Opana ER, one of Endo's core branded prescription drug products. In 2009, Opana ER was responsible for $172 million of Endo's net sales, comprising approximately 12% of Endo's total annual revenues. The threat of generic entry to Opana ER posed significant financial risks for Endo. Endo knew that generic competition would decimate its Opana ER sales and that any delay in generic competition would be highly profitable for Endo, but very costly for consumers.

2. By 2010, generic entry appeared imminent. Several years earlier, Impax had submitted an application with the U.S. Food and Drug Administration to market a generic version of Opana ER. In that application, Impax asserted that Endo's Opana ER patents were either invalid or would not be infringed by Impax's generic version of Opana ER. Endo sued Impax for alleged patent infringement. Throughout the first half of 2010, with the patent infringement trial approaching, Impax prepared to launch its generic Opana ER product as soon as it received regulatory approval. Faced with Impax's threat to its lucrative Opana ER franchise, Endo bought off its potential competitor.

3. In June 2010, Endo agreed to pay Impax to abandon its patent challenge and forgo entering the market with its lower-cost generic version of Opana ER for 2½ years, until January 2013. This payment included two separate components. First, Endo guaranteed that Impax would receive supracompetitive profits by being the only seller of generic Opana ER during its first 180 days on the market. Even though Endo had the legal right and financial incentive to compete with an authorized generic version of Opana ER as soon as Impax entered with its generic product, Endo agreed that it would refrain from offering an authorized generic Opana ER product during Impax's initial 180 days of marketing (a "no-AG commitment"). If market conditions were to change to devalue this no-AG commitment, Endo further agreed to pay Impax a cash amount based on Impax's expected profits for that six-month period of generic exclusivity. Second, Endo agreed to pay Impax up to $40 million purportedly for an independent development and co-promotion deal. The financial terms of this deal, however, made no business or economic sense for Endo independent of Impax's agreement to stay off the market for over 2½ years. To date, Endo has paid Impax over $112 million from these two components.

4. The purpose and effect of this anticompetitive agreement was to ensure that Endo would not face generic competition for Opana ER until at least January 2013. As a result, patients were denied the opportunity to purchase lower-cost generic versions of Opana ER, forcing them and other purchasers to pay hundreds of millions of dollars a year more for this medication.

Respondent

5. Respondent Impax Laboratories, Inc. is a for-profit Delaware corporation, with its principal place of business at 30831 Huntwood Avenue, Hayward, California 94544. Impax engages in the business of, among other things, developing, manufacturing, and marketing generic drugs. Impax entered into the anticompetitive agreement challenged in this complaint.

Jurisdiction

6. Respondent is, and at all times relevant herein has been, a corporation, as "corporation" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

7. Respondent's general business practices and the unfair methods of competition alleged herein are "in or affecting commerce" within the meaning of Section 5 of the FTC Act, 15 U.S.C. § 45.

Background

A. Federal law facilitates approval of generic drugs

8. The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. §§ 355(b)(2) and 355(j) and 35 U.S.C. § 271(e), establishes procedures designed to facilitate competition from lower-priced generic

drugs, while maintaining incentives for pharmaceutical companies to invest in developing new drugs.

9. A company seeking to market a new pharmaceutical product must file a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") demonstrating the safety and efficacy of the new product. These NDA-based products generally are referred to as "brand-name drugs" or "branded drugs."

10. The FDA requires NDA holders to identify any patents that the NDA holder believes reasonably could be asserted against a generic company that makes, uses, or sells a generic version of the branded drug. The NDA holder must submit these patents for listing in an FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the Orange Book) within 30 days of issuance of the patent. 21 C.F.R. § 314.53.

11. A company seeking to market a generic version of a branded drug may file an Abbreviated New Drug Application ("ANDA") with the FDA. The generic applicant must demonstrate that its generic drug is therapeutically equivalent to the brand-name drug that it references and for which it seeks to be a generic substitute. Upon showing that the generic drug is therapeutically equivalent to the already-approved branded drug, the generic company may rely on the studies submitted in connection with the already-approved branded drug's NDA to establish that the generic drug is safe and effective. 21 U.S.C. § 355(j)(2)(A)(iv).

12. The FDA assigns a generic drug an "AB" rating if it is therapeutically equivalent to a brand-name drug. An AB-rated generic drug is the same as a brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. A generic drug also must contain identical amounts of the same active ingredient(s) as the brand-name drug, although its inactive ingredients may vary.

13. When a brand-name drug is covered by one or more patents listed in the Orange Book, a company seeking to market a generic version of that drug before the patents expire must make a "paragraph IV certification" in its ANDA certifying that the patents are invalid, unenforceable, and/or will not be infringed by the generic drug.

14. If a company makes a paragraph IV certification, it must notify the patent holder of its certification. If the patent holder initiates a patent infringement suit against the company within 45 days of receiving such notice, the FDA may not grant final approval of the ANDA until the earliest of: (1) patent expiry; (2) district court resolution of the patent litigation in favor of the generic company; or (3) the expiration of an automatic 30-month stay.

15. When a generic drug otherwise meets the FDA's criteria for approval but final approval is blocked by statute or regulation, such as the Hatch-Waxman 30-month stay, the FDA may tentatively approve the relevant ANDA. Tentative approval does not permit an ANDA filer to market its generic version of the drug. The FDA can issue final approval of a tentatively-approved drug once the relevant 30-month stay expires.

16. The Hatch-Waxman Act provides the first generic company or companies filing an ANDA containing a paragraph IV certification ("first filer") with a period of protection from competition with other ANDA filers. This is referred to as the "180-day exclusivity" or "first-filer exclusivity" period. The Supreme Court observed that the 180-day exclusivity period "can prove valuable, possibly worth several hundred million dollars" to the first filer.

17. A brand drug company can market a generic version of its own brand product at any time, including during the first filer's exclusivity period. In that case, no ANDA is necessary because the brand company already has approval to sell the drug under its NDA. Such generics commonly are known as "authorized generics." An authorized generic is chemically identical to the brand drug, but is sold as a generic product, typically through either the brand company's subsidiary or through a third party.

18. In the absence of generic competition, a brand drug company typically will not undercut the profits on its branded drug by introducing a lower-priced authorized generic version of that drug. When an ANDA filer enters, however, an authorized generic may become attractive to the NDA holder as a means of maintaining some of the revenue it otherwise would lose to the generic competitor.

19. If an NDA holder discontinues the relevant drug, then the FDA moves the drug covered by the NDA to the Orange Book's Discontinued Drug Product List. Generic drugs referencing the discontinued NDA still may be sold, but they will not be listed in the Orange Book as AB-rated to any branded product.

B. State law encourages substitution of AB-rated generic drugs for brand drugs

20. All 50 states and the District of Columbia have drug substitution laws that encourage and facilitate substitution of lower-cost AB-rated generic drugs for branded drugs. When a pharmacist fills a prescription written for a branded drug, these laws allow or require the pharmacist to dispense an AB-rated generic version of the drug instead of the more expensive branded drug, unless a physician directs or the patient requests otherwise. Conversely, these laws generally do not permit a pharmacist to substitute a non-AB-rated generic for a branded drug unless the physician specifically prescribes it by writing the chemical name of the drug, rather than the brand name, on the prescription.

21. State substitution laws were enacted in part because the pharmaceutical market does not function well. In a well-functioning market, a consumer selects and pays for a product after evaluating the product's price and quality. In the prescription drug market, however, a patient can obtain a prescription drug only if the doctor writes a prescription for that particular drug. The doctor who selects the drug, however, does not pay for it and generally has little incentive to consider price when deciding which drug to prescribe. Instead, the patient, or in most cases a third-party payer such as a public or private health insurer, pays for the drug. But these purchasers have little input over what drug is actually prescribed.

22. State substitution laws are designed to correct this market imperfection by shifting the drug selection choice from physicians to pharmacists and patients who have greater financial incentives to make price comparisons.

C. Competition from lower-priced generic drugs saves American consumers billions of dollars a year

23. The Hatch-Waxman Act and state substitution laws have succeeded in facilitating generic competition and generating large savings for patients, healthcare plans, and federal and state governments. The first generic competitor's product is typically offered at a 20% to 30% discount to the branded product. Subsequent generic entry creates greater price competition with discounts reaching 85% or more off the brand price. According to a 2010 Congressional Budget Office report, the retail price of a generic is 75% lower, on average, than the retail price of a brand-name drug. In 2015 alone, the Generic Pharmaceutical Association reported that use of generic versions of brand-name drugs saved the U.S. healthcare system $227 billion.

24. Because of these price advantages and cost savings, many third-party payers of prescription drugs (e.g., health insurance plans and Medicaid programs) have adopted policies to encourage the substitution of AB-rated generic drugs for their branded counterparts. As a result of these policies and lower prices, many consumers routinely switch from a branded drug to an AB-rated generic drug upon its introduction. Consequently, AB-rated generic drugs typically capture over 80% of a branded drug's unit and dollar sales within six months of market entry.

25. Consumers also benefit from competition between an authorized generic drug and an ANDA-based generic drug. Empirical evidence shows that competition from an authorized generic drug during the first-filer's 180-day exclusivity results, on average, in retail prices that are 4% to 8% lower and wholesale prices that are 7% to 14% lower than prices without authorized generic competition.

26. Competition from an authorized generic also typically has a significant financial impact on the first ANDA entrant. An authorized generic typically takes a significant share of the first ANDA entrant's generic sales, thereby reducing revenues during its 180-day exclusivity period by an average of 40% to 52%. Thus, if a brand company agrees to refrain from launching an authorized generic, it can double the first filer's revenues during the 180-day exclusivity period. This financial impact is well-known in the pharmaceutical industry.

Anticompetitive Conduct

A. Opana ER was a successful and rapidly growing branded drug

27. Oxymorphone is a semi-synthetic opioid, originally developed over one hundred years ago. Opioids are one of the world's oldest known classes of drugs, and they have long been used to relieve pain. The FDA first approved oxymorphone in 1960.

28. Opana ER is an extended-release formulation of oxymorphone. The FDA approved Opana ER (NDA No. 021610) in June 2006 "for the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time." Unlike immediate-release drugs, extended-release medications like Opana ER have special coatings or ingredients that control how fast the active ingredient is released from the pill into the patient's body. Compared to an immediate-release oxymorphone formulation, Opana ER provides longer-lasting, 12-hour pain relief that allows the patient to take fewer pills each day.

29. Endo launched Opana ER in 2006 as the only extended-release version of oxymorphone on the market. The drug, available in seven dosage strengths (5, 7.5, 10, 15, 20, 30, and 40 mg), is used to treat pain for a wide variety of conditions, ranging from chronic back problems to cancer.

30. Opana ER quickly became Endo's second best-selling drug. After a modest start of $5 million in sales in 2006, sales grew to $172 million in 2009. First quarter 2010 sales of $66 million indicated continued growth.

31. Endo sells Opana ER at prices far above Endo's cost of manufacturing the product, making Opana ER highly profitable. Even accounting for other direct expenses Endo allocates to selling and marketing Opana ER, Endo's profit margin on Opana ER, ranging between [redacted] and [redacted], is substantial.

B. Potential generic competition from Impax threatened Endo's growing Opana ER business

32. Opana ER's increasing sales drew the attention of numerous generic companies. Opana ER was an attractive target for generic drug makers because oxymorphone had been available for decades and was not subject to any meaningful patent protection. When Endo launched Opana ER in 2006, it only listed a single patent, No. 5,128,143 (the "'143 patent"), in the Orange Book covering Opana ER. The '143 patent was not a meaningful, long-term barrier to generic competition because it was set to expire in September 2008. Endo's New Dosage Form exclusivity was set to expire in June 2009. With growing sales and no meaningful patent protection identified in the Orange Book, numerous generic entrants began preparing ANDAs for generic versions of Opana ER.

33. Following notice that a generic company had filed an ANDA to market a generic version of Opana ER, Endo listed three additional patents in the Orange Book in October 2007, well over a year after launching Opana ER.

34. On October 2, 2007, Endo listed Patent No. 7,276,250 (the "'250 patent") relating to a mechanism for controlling the release of a drug's active ingredient over an extended period of time. This patent expires in 2023.

35. On October 19, 2007, Endo listed two additional patents pertaining to a controlled release mechanism—No. 5,662,933 (the "'933 patent") and No. 5,958,456 (the "'456 patent"). These patents had been issued by the U.S. Patent and Trademark Office up to a decade earlier—in 1997 and 1999, respectively. Endo failed to list the '456 and '933 patents in

the Orange Book within 30 days of the FDA approving Endo's NDA for Opana ER as required under 21 C.F.R. § 314.53. The '933 and '456 patents expired in August 2013.

36. Eventually, at least nine companies submitted ANDAs seeking approval to market a generic version of Opana ER, including Impax, Actavis, and Watson. Each company included a paragraph IV certification asserting that its proposed generic product did not infringe Endo's patents and/or that Endo's patents were invalid or unenforceable. In response to each paragraph IV certification, Endo filed a patent infringement case, asserting that the generic product infringed either the '456 patent, the '933 patent, or both. Endo never asserted that any of the generic products infringed the '250 patent.

37. Impax submitted its ANDA, No. 79-087, on June 29, 2007 seeking approval to market a generic version of Opana ER. Although the FDA initially accepted the ANDA for substantive review, it later rescinded that acceptance due to certain deficiencies. Impax re-submitted ANDA No. 79-087, and the FDA accepted the application as of November 23, 2007.

38. On December 13, 2007, Impax notified Endo that it had submitted ANDA No. 79-087 with a paragraph IV certification stating that Impax's proposed generic product did not infringe Endo's '933 or '456 patents.

39. On January 25, 2008, Endo sued Impax for allegedly infringing the '456 and '933 patents. Because Endo sued Impax within 45 days of its paragraph IV notification, an automatic 30-month stay resulted. This stay prevented the FDA from granting final approval to Impax's ANDA until June 14, 2010, absent an earlier court finding that Impax's product did not infringe Endo's patents or that the patents were invalid or unenforceable.

40. Impax was the first generic company to file an ANDA with a paragraph IV certification for the 5, 10, 20, 30, and 40 mg strengths of Opana ER. Impax received first-filer exclusivity for those dosage strengths, precluding the FDA from approving any other generic versions of Opana ER until 180 days after Impax's generic launch. These dosage strengths account for over 95% of all Opana ER sales. Given Impax's first-filer status, if Endo could delay Impax's entry, Endo would delay all generics from entering the market for those dosages of Opana ER.

C. Endo paid Impax to drop its patent challenge and refrain from competing until January 2013

41. Throughout the first half of 2010, Impax prepared to launch its generic version of Opana ER at the expiration of the Hatch-Waxman 30-month stay on June 14, 2010, even if the patent challenge remained unresolved. Such generic entry is commonly referred to as an "at-risk launch."

42. On May 13, 2010, the FDA tentatively approved Impax's application for a generic version of Opana ER; final approval had to wait one month for the expiration of the Hatch-Waxman stay. Following the FDA's grant of tentative approval, the prospect of an Impax at-risk launch gained momentum. On May 13, 2010, Impax CEO Larry Hsu

instructed his top executives to "alert" the Board of Directors of a "potential oxymorphine [*sic*] launch" and that "we will have a special Board conference call when we do decide to launch at risk on a later date." In materials presented to the Board of Directors that same month, Impax changed the "Current Assumption[]" for Opana ER from "no launch" to "At Risk Launch."

43. As of May 20, 2010, Impax had completed process validation, demonstrating that its manufacturing process was capable of consistently producing commercial quantities of generic Opana ER. Process validation is one of the final steps required by the FDA before launch. In addition, Impax had produced nine of the 17 lots required for launch quantities (equivalent to three months of generic market supply) and had sufficient inventory of active pharmaceutical ingredient to complete the remaining lots. Impax had also requested authorization from the Drug Enforcement Agency to purchase the additional active pharmaceutical ingredient needed to produce larger quantities of generic oxymorphone ER.

44. Impax's impending launch presented a substantial risk to Endo's Opana ER monopoly. Endo knew that entry of AB-rated generic versions of Opana ER would cause Endo's Opana ER sales to drop rapidly and dramatically—possibly by as much as 85% within a year.

45. To protect and extend its Opana ER franchise in the face of potential generic entry, Endo had been working on a reformulated "crush resistant" version of Opana ER ("Reformulated Opana ER") that would not be subject to automatic substitution from generic versions of its original formulation of Opana ER ("Original Opana ER"). Endo did not publicly disclose its reformulation plans.

46. Endo knew that the success of Reformulated Opana ER would hinge on whether Endo could introduce the product before it faced AB-rated generic competition for Original Opana ER. It is well known in the pharmaceutical industry that if generic versions of the original product (here, Original Opana ER) enter the market before the brand's follow-on product (here, Reformulated Opana ER), the follow-on product is likely to be much less successful. Indeed, Endo predicted that if a generic version of Original Opana ER were already on the market when it introduced Reformulated Opana ER, the reformulated version would capture only 30% to 32% of the Original Opana ER volumes.

47. In contrast, if Endo were to launch Reformulated Opana ER before generic entry, then Endo could expect to convert virtually the entire franchise to its reformulated product. Given these market realities, industry analysts have observed that "it is essential that the brand holder switch their patents to the new formulation before generic launch."

48. Endo knew, however, that it would be unable to obtain FDA approval for its Reformulated Opana ER and convert the market before Impax could enter with its generic version of Original Opana ER. Endo, therefore, decided to purchase the time it needed by paying Impax not to compete until January 2013.

49. On or about June 8, 2010—just a week before Impax was expected to receive final FDA approval for its generic Opana ER and two days into the patent infringement trial—Endo and Impax reached a settlement embodied in two documents: (1) a Settlement and License Agreement; and (2) a Development and Joint Promotion Agreement (hereinafter, together the "Opana ER Agreement").

50. Under the Opana ER Agreement, Endo agreed to pay Impax to abandon its patent challenge and to refrain from launching its generic version of Opana ER until January 1, 2013, approximately eight months before the expiration of the patents asserted in the infringement suit. This payment included two separate components. First, Endo guaranteed that Impax would receive a cash value commensurate with the supracompetitive profits that come with being the only seller of generic Opana ER for 180 days ("Guaranteed No-AG Payment"). Second, Endo agreed to pay Impax up to $40 million purportedly for an independent development and co-promotion deal ("Side Deal Payment").

51. Impax could not have obtained the Guaranteed No-AG Payment and the Side Deal Payment even if it had won the patent infringement litigation with Endo.

52. The FDA granted final approval to Impax's ANDA for generic Opana ER for the 5, 10, 20, and 40 mg dosages on June 14, 2010, and for the 30 mg dosage on July 22, 2010. Absent the Opana ER Agreement, Impax would have been legally permitted to launch its generic product at risk.

1. Guaranteed No-AG Payment

53. Endo had the legal right and financial incentive to compete with an authorized generic version of Opana ER as soon as Impax entered with its generic product. Under the Opana ER Agreement, however, Endo agreed not to offer a competing authorized generic Opana ER product during Impax's 180-day exclusivity period for the 5, 10, 20, 30, and 40 mg strengths.

54. The no-AG commitment was extremely valuable to Impax. With a no-AG commitment, the first filer's revenue will approximately double on average compared to what the first filer would make if it faced authorized generic competition. A first filer makes significantly more without generic competition because: (1) the authorized generic takes a significant share of generic sales from the first filer; and (2) competition between the first-filer generic and the authorized generic drives down generic drug prices. The financial effects of an authorized generic on the first-filer generic are well known in the pharmaceutical industry.

55. The no-AG commitment was costly to Endo. Brand companies often introduce AGs to stem the large losses that result from the rapid shift from sales of branded drugs to cheaper generic products. Before settlement, Endo had been planning to launch an authorized generic if Impax launched at risk, estimating $25 million in authorized generic revenues during the first six months following generic entry. Endo forecasted that launching an authorized generic would recoup as much as 35% of the branded Opana ER revenues it expected to lose during that time.

56. Impax suspected, however, that Endo was planning to shift the market to a reformulated version of Opana ER before the negotiated entry date and recognized that such a move would both undermine the value of the no-AG commitment as well as decimate the potential sales for Impax's first-to-file generic product. Endo denied any plans to introduce a reformulated version of Opana ER, despite its active efforts to do so.

57. Notwithstanding Endo's assurances, Impax sought to "protect [itself] from making no money." Impax proposed ways to address its concern through provisions that would expedite generic entry if Endo successfully introduced a reformulated product. Endo, however, rejected these proposals in favor of a so-called "Endo Credit."

58. Under the Endo Credit arrangement, Endo agreed to a "make good payment" to ensure that Impax would receive the supracompetitive profits that come with being the only seller of generic Opana ER even if Endo devalued the no-AG commitment by shifting the market to Reformulated Opana ER. Specifically, if, by the fourth quarter of 2012, Original Opana ER sales fell by more than 50% from the peak quarterly sales between the third quarter of 2010 and the third quarter of 2012, Endo would provide Impax with a cash payment. The dollar value of the Endo Credit was based on a formula designed to approximate Impax's expected profits as the only seller of a generic version of Opana ER assuming Endo had not launched Reformulated Opana ER. As Endo itself has explained, the Endo Credit was to ensure that Impax received "the expected bargained for benefit" of the no-AG commitment.

59. Ultimately, Endo introduced Reformulated Opana ER and discontinued Original Opana ER before Impax's generic Opana ER entry date under the settlement. Consequently, the value of the no-AG commitment fell and triggered Endo's obligation to pay Impax the Endo Credit, resulting in a payment from Endo to Impax of more than $102 million.

2. Side Deal Payment

60. On or about the same day that Endo and Impax entered into the Settlement and License Agreement, Endo and Impax also entered into a development and co-promotion deal concerning a potential treatment for Parkinson's disease, code-named IPX-203. At the time of the deal, IPX-203 was still in the very early stages of pre-clinical development: Impax had not yet developed a formulation for the product, submitted an Investigational New Drug application to the FDA, or initiated any sort of clinical trials. Fewer than 1% of drugs in pre-clinical development ultimately receive FDA approval.

61. The development and co-promotion deal provided Impax with immediate cash, plus the potential for more in the future. Under the deal, Endo agreed to pay Impax $10 million in cash up front and up to $30 million in additional milestone payments. If Impax succeeded in developing the drug and obtaining FDA approval, Endo would have the right to co-promote the product in the United States to non-neurologists and to receive [redacted] to 100% of the profits generated by prescriptions from those doctors.

D. Endo's payment to Impax is large

62. At the time of the settlement, Impax expected to, and did, derive significant value from the Opana ER Agreement in the form of: (1) a Side Deal Payment of at least $10 million and up to $40 million; and (2) a Guaranteed No-AG Payment of at least $37 million and potentially more than $100 million. To date, Endo has paid Impax more than $112 million under the Opana ER Agreement.

63. Endo's payment to Impax, both expected and actual, is large. First, the $10 million payment under the development and co-promotion deal was guaranteed and non-refundable.

64. Second, the structure of the Guaranteed No-AG Payment ensured that Impax would derive significant financial value from either the no-AG commitment or the Endo Credit or both. Indeed, as Impax's chief negotiator explained, the possibility that Impax would receive little value from either the no-AG commitment or the Endo Credit was "so unlikely it wasn't worth worrying about."

65. Before the settlement, Impax expected that Endo would launch an authorized generic to compete with Impax's generic Opana ER product. According to Impax's internal forecasts, competition from an authorized generic would take 40% to 50% of Impax's expected unit sales and decrease the price of the remaining sales by more than 36%. With the no-AG commitment, Impax would not face this competition, retaining all generic Opana ER sales for six months at a supracompetitive price. At the time of the Opana ER Agreement, the value of the no-AG commitment to Impax ranged from $37 to $77 million.

66. If, however, consistent with its strategic plan, Endo destroyed the market opportunity for Impax's generic version of Original Opana ER, including the value of the no-AG commitment, then Impax would receive a cash payment under the Endo Credit. The Endo Credit payment was based on various factors affecting Impax's expected profits during the no-AG commitment period, including the generic substitution rate, expected generic pricing as a percentage of brand pricing, and Impax's net profit margin. If triggered, Endo's likely payment under the Endo Credit would be at least $46 million and could exceed $100 million (as actually occurred).

67. Thus, as of the time the parties entered into the Opana ER Agreement, the total value of Endo's expected payment, including the Guaranteed No-AG Payment (at least $37 million) and the Side Deal Payment (at least $10 million), was at least $47 million and potentially greater than $100 million.

68. Endo's actual and likely payment to Impax far exceeds any reasonable measure of avoided litigation costs in the parties' underlying patent litigation. The settlement occurred late in the litigation, after trial had begun. By that time, Endo already had expended more than $7 million in litigation fees and costs. Any remaining litigation costs would have been a small fraction of Endo's payment, whether measured against the actual amount paid ($112 million) or any amount anticipated at the time of the Opana ER Agreement.

69. Endo's payment was designed to, and did, induce Impax to abandon its Opana ER patent challenge and agree to refrain from marketing its generic Opana ER product until January 2013. Impax's decision to settle was driven not by the strength of Endo's patent protection for Opana ER, but by the large payment Endo made to Impax. As Impax's president of generics stated to the CEO: "That money is really important as we all know."

70. Endo's payment to Impax exceeded the amount Impax projected to earn by launching its generic version of Opana ER. In May 2010—just a month before entering into the settlement—Impax projected its generic Opana ER product would generate about $48 million in profits in its first 2½ years on the market—less than half the amount Endo already has paid Impax under the Opana ER Agreement. In fact, Endo's payment exceeded the sales generated by Impax's five new generic launches in 2013, including its generic version of Original Opana ER. As Impax explained in an SEC filing, its net income growth in 2013 was "primarily attributable" to Endo's $102 million cash payment under the Opana ER Agreement.

71. Endo was willing to make this large payment to Impax because the January 2013 entry date would enable Endo to maintain monopoly prices for Opana ER throughout that period and beyond.

E. Endo's large payment to Impax is not justified

72. Endo's large payment to Impax cannot be justified solely as compensation for the services to be performed by Impax.

73. The Guaranteed No-AG Payment is not compensation for goods or services provided by Impax to Endo. Indeed, Impax was not required to provide any goods or perform any service in exchange for the more than $102 million Guaranteed No-AG Payment.

74. The purpose and effect of Endo's Guaranteed No-AG Payment were to induce Impax to abandon its patent challenge and agree not to compete with a generic version of Original Opana ER until January 2013. The payment is explicitly part of the Settlement and License Agreement and makes no economic sense absent Impax's agreement not to market a generic version of Opana ER until January 2013. Endo would not have agreed to the Guaranteed No-AG Payment without also securing Impax's agreement not to market a generic version of Opana ER until January 2013. Likewise, Impax would not have agreed to a January 2013 entry without also securing Endo's commitment to the Guaranteed No-AG Payment.

75. In addition, Endo's Side Deal Payment cannot be justified solely as compensation for the services to be performed by Impax under the deal. Instead, the purpose and effect of Endo's payment were to induce Impax to abandon its patent challenge and agree not to compete with a generic version of Original Opana ER until January 2013. Endo would not have agreed to make the large Side Deal Payment without also securing Impax's agreement not to market a generic version of Opana ER until January 2013. Likewise, Impax would not have agreed to a January 2013 entry without also securing the large Side Deal Payment.

76. Substantial evidence shows the direct link between Endo's Side Deal Payment and Impax's agreement to the January 2013 entry date, including:

a. Endo and Impax never discussed a development agreement outside the context of settlement negotiations. Instead, the development deal and the Endo-Impax settlement agreement were negotiated and drafted at the same time, by the same people, and were held in escrow until both agreements were finalized.

b. Impax had tried unsuccessfully for years to find a partner willing to invest in the development of a neurological drug in return for the right to co-promote the drug only to non-neurologists. As Impax's CEO explained: [redacted]

c. Endo's substantial investment in the very early stages of drug development was contrary to the company's stated objective to invest in "marketed/market ready assets."

d. Despite the incompatibility with Endo's corporate development strategy, and the absence of any other interested investor, Endo was nonetheless willing to accept limited co-promotion rights for the early-stage development project.

e. The due diligence schedule for this purportedly independent business transaction was explicitly tied to the timing of the Opana ER patent trial and settlement negotiations. Due to the artificially compressed due diligence schedule and insufficient information on the proposed product, Endo based its financial valuation of the deal on a different Impax development project involving a wholly different drug.

f. The $10 million up-front payment was [redacted]

g. Endo received nothing in return for its payment. Impax's development of the subject project, IPX-203, has been significantly delayed. In December 2015, without a single clinical trial completed, the parties terminated the side deal "by mutual agreement."

77. In short, the financial terms of the development and co-promotion deal made no business or economic sense for Endo independent of Impax's agreement to defer generic Opana ER entry until January 2013. The development and co-promotion deal provided the vehicle for Endo to pay Impax cash immediately as part of an overall compensation package to abandon its patent litigation and agree to stay out of the market for over 2½ years.

78. There are no other procompetitive benefits, countervailing efficiencies, or increases in consumer welfare from the Opana ER Agreement that outweigh the significant competitive harm caused by eliminating the risk of Impax's generic entry until January 2013.

79. Moreover, Endo's large payment to Impax was not reasonably necessary to achieve any potential procompetitive objective of the Opana ER Agreement.

F. Endo settled with the other Opana ER first filer with no reverse payment, and a significantly earlier entry date

80. On or about June 8, 2007, Actavis submitted ANDA No. 79-046 to the FDA for its generic version of Opana ER for the 5, 10, 20, and 40 mg dosages. After Endo listed the three patents purportedly relating to Opana ER in the Orange Book, Actavis submitted a paragraph IV certification stating that its proposed generic product did not infringe Endo's patents and/or that Endo's patents were invalid or unenforceable. On February 12, 2008, Actavis notified Endo that it had submitted ANDA No. 79-046 with a paragraph IV certification. On March 28, 2008, Endo sued Actavis for alleged infringement of only the '456 patent. Because Endo sued Actavis within 45 days of its paragraph IV notification, an automatic 30-month stay resulted.

81. On or about May 29, 2008, Actavis notified Endo that it had amended its ANDA for a generic version of Opana ER to include 7.5 and 15 mg dosages and submitted a paragraph IV certification stating that its proposed generic product did not infringe Endo's patents. On July 11, 2008, Endo sued Actavis for alleged infringement of only the '456 patent. Because Endo sued Actavis within 45 days of its paragraph IV notification, an automatic 30-month stay resulted, preventing the FDA from granting final approval to Actavis's ANDA until November 2010, absent an earlier court finding that Actavis's product did not infringe Endo's patents or that the patents were invalid or unenforceable.

82. Actavis was the first generic company to file an ANDA with a paragraph IV certification for the 7.5 and 15 mg dosage strengths of Opana ER. As the first filer, Actavis was eligible for 180 days of exclusivity for those two dosage strengths as against any other ANDA product.

83. In February 2009, less than one year into the patent litigation, Endo settled its suit against Actavis. Under the terms of the settlement, Endo granted Actavis a covenant not to sue and a license for the sole asserted patent, the '456 patent, to begin marketing its generic version of Opana ER on July 15, 2011. In addition, Endo granted Actavis a covenant not to sue for the '250 and '933 patents—the two other patents listed in the Orange Book that Endo had not asserted in the litigation. That settlement involved no payment from Endo to Actavis.

84. Although Actavis had a license to enter in 2011, it was blocked from launching any of the five dosage strengths for which Impax was eligible for 180-day exclusivity (5, 10, 20, 30, and 40 mg), until such exclusivity expired or was otherwise lost.

Market Power

85. Until at least January 2013, Endo exercised market power in a relevant market that is no broader than extended-release oxymorphone ("oxymorphone ER") tablets approved by the FDA for sale in the United States. Endo shared its extended monopoly profits with Impax in exchange for its agreement to impede generic competition.

86. There is substantial evidence of Endo's market power. Both Endo and Impax had forecast a dramatic decline in the average price of oxymorphone ER following entry of an AB-rated generic version of Opana ER. For example, Impax estimated that within one year of generic entry, AB-rated generic versions of Opana ER would be priced at approximately 5% of the brand product's WAC and would capture up to 90% of unit sales.

87. Even without an AB rating, Endo expected generic entry to have a dramatic impact on Reformulated Opana ER's revenues and unit sales: "[I]f additional generic companies enter the market with generic non-crush resistant oxymorphone extended release tablets [original formulation], Endo will experience immediate, dramatic, and irreparable price erosion and loss of sales." Indeed, as Endo predicted, Impax's and Actavis's non-AB-rated generic oxymorphone ER products captured significant share from Reformulated Opana ER through competitive pricing, with discounts of up to 40% off the brand price. In 2013, Impax's and Actavis's generic versions of Opana ER accounted for approximately 28% of all oxymorphone ER unit sales for all dosage strengths in 2013, increasing to approximately 37% for the first half of 2014. These results are consistent with Endo's own prediction that even non-AB-rated generics eventually would capture 40% or more of branded Opana ER sales.

88. If Endo were already facing robust competition to Opana ER, then the entry of generic oxymorphone ER would not have eroded the sales volume of branded Opana ER or the price of oxymorphone ER products so rapidly and dramatically.

89. In addition, other long-acting opioid products used to relieve moderate to severe pain have not meaningfully constrained Endo's pricing or sales of Opana ER. From 2007 to 2012, despite the availability of several other long-acting opioid products, Endo regularly raised the wholesale acquisition cost of Opana ER, from about $9 per pill (40 mg) to over $12 per pill (40 mg) without impacting sales. During that same period, the entry of new branded long-acting opioid products, such as Embeda and Exalgo, had no discernable impact on Opana ER prices or unit sales.

90. Moreover, oxymorphone ER is not reasonably interchangeable with other pain relief medications used to treat the same or similar conditions. As Endo itself represented to the FDA and the medical community, "there is no therapeutically equivalent or pharmaceutically alternative substitutable product" to Opana ER. The abrupt discontinuation of an opioid product can result in severe withdrawal symptoms. Switching a patient from one opioid to another presents serious underdosing and overdosing risks to the patient and requires careful medical monitoring. Therefore, patients that have begun a successful course of treatment with an opioid such as Opana ER are unlikely to switch to another pain medication for economic reasons.

91. From its launch in 2006 through 2012, Opana ER accounted for 90% to 100% of the unit sales of oxymorphone ER products. By the end of 2013, even with competition from Impax's and Actavis's generic oxymorphone ER products, Endo's branded Opana ER retained a 70% share of all oxymorphone ER unit sales because Endo converted the market to Reformulated Opana ER prior to generic entry.

92. Substantial barriers to entry exist in the oxymorphone ER market. Potential new branded drug competitors need to conduct expensive clinical trials and obtain FDA approval. Potential sellers of generic oxymorphone ER also face substantial barriers to entry, including the need to obtain FDA approval, costly specialized equipment and facilities, and Endo's ability to trigger an automatic 30-month stay of FDA approval by filing a patent infringement lawsuit.

VII. Harm to Consumers and Competition

93. By impeding generic competition, Respondent's agreement with Endo denied consumers and other purchasers of Opana ER access to AB-rated generic versions of Opana ER that would offer the same therapeutic benefit as branded Opana ER but at a fraction of the price.

94. The agreement between Impax and Endo precluding Impax from launching a generic version of Opana ER until January 2013 harmed competition and consumer welfare by eliminating the risk that Impax would have marketed its generic version of Opana ER before that date. Through its agreement with Endo, Impax eliminated the potential that: (1) Impax would have launched its generic version of Opana ER before January 2013; or (2) Endo would have agreed to settle the patent litigation on terms that did not compensate Impax, but provided for generic entry earlier than January 2013.

95. Before the Opana ER Agreement, Impax had been preparing to enter with a generic version of Opana ER as early as FDA approval, which it received in June 2010. That entry would have quickly and significantly reduced Endo's market share, promoted economic efficiency, and led to significant price reductions for extended-release oxymorphone products. Impax abandoned its generic entry plans because it received a share of Endo's monopoly profits in the form of the Guaranteed No-AG Payment and the Side Deal Payment. Without the large payment, Impax would have launched its generic version of Opana ER prior to January 2013.

96. Entry of Impax's generic product would have given consumers the choice between branded Opana ER and lower-priced AB-rated substitutes for Opana ER. Many consumers would have purchased lower-priced AB-rated generic drugs rather than higher-priced branded Opana ER. Endo's contemporaneous forecasts assumed that approximately 85% of Opana ER unit sales would switch to an AB-rated generic version of Opana ER. Consumers likely would save hundreds of millions of dollars by purchasing generic versions of Opana ER. By entering into the anticompetitive agreement, Impax shared in Endo's additional monopoly profits at the expense of consumers.

97. Impax's agreement with Endo also prevented competition from other potential generic oxymorphone ER products for the most prescribed strengths of generic Opana ER, comprising 95% of total Opana ER sales. Under the Hatch-Waxman Act, Impax had 180-day exclusivity for those strengths, which prohibited the FDA from approving any other generic versions of Opana ER for those strengths until Impax's 180-day exclusivity period either expired or was forfeited. Because of Impax's anticompetitive agreement with Endo, the 180-day exclusivity period did not begin to run until January 2013, the entry date Endo paid Impax to accept. The Opana ER Agreement, therefore, precluded all generic Opana ER competition for the most prescribed strengths until January 2013. As a result of this conduct, Endo maintained its market power over oxymorphone ER products for 2½ years, allowing it to charge supracompetitive prices for Opana ER.

98. Absent injunctive relief, there is a cognizable danger that Impax will engage in similar violations causing future harm to competition and consumers. Respondent knowingly entered into and carried out a collusive anticompetitive scheme to preserve and share in Endo's monopoly profits. Impax did so conscious of the fact that this agreement would greatly enrich Impax and Endo at the expense of consumers.

99. Impax has incentives and the demonstrated interest to continue to enter such agreements in the future. Impax has entered into other similar reverse-payment agreements. For example, Impax has been sued for entering into a reverse-payment settlement involving the drug Solodyn.

100. Impax continues to develop and manufacture pharmaceutical products. Impax is regularly involved in multiple patent litigations relating to different drugs. Each of these patent litigations provides the incentive and opportunity to enter into another reverse-payment agreement.

Violation Alleged

101. As set forth above, Impax agreed to restrain competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

102. The acts and practices of Respondent, as alleged herein, constitute an unfair methods of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. Such acts and practices, or the effects thereof, will continue or recur in the absence of appropriate relief.

NOTICE

Notice is hereby given to Respondent that the nineteenth day of September, 2017, at 10:00 a.m., is hereby fixed as the time and Federal Trade Commission offices, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580, as the place when and where a hearing will be had before an Administrative Law Judge of the Federal Trade Commission, on the charges set forth in this complaint, at which time and place you will have the right under the Federal Trade Commission Act to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in the complaint and prohibiting you from future violations of the law similar to those charged in the complaint.

You are notified that the opportunity is afforded you to file with the Commission an answer to this complaint on or before the fourteenth (14th) day after service of it upon you. An answer in which the allegations of the complaint are contested shall contain a concise statement of the facts constituting each ground or defense; and specific admission, denial, or explanation of each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the complaint not thus answered shall be deemed to have been admitted.

If you elect not to contest the allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material allegations to be true. Such an answer shall constitute a waiver of hearing as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the Commission shall issue a final order disposing of the proceeding. In such answer, you may, however, reserve the right to submit proposed findings of fact and conclusions of law under § 3.46 of said Rules.

Failure to file an answer within the time above provided shall be deemed to constitute a waiver of your right to appear and to contest the allegations of the complaint, and shall authorize the Commission, without further notice to you, to find the facts to be as alleged in the complaint and to enter a final decision containing appropriate findings and conclusions and a final order disposing of the proceeding.

The Administrative Law Judge shall hold a prehearing scheduling conference not later than ten (10) days after an answer is filed by Respondent. Unless otherwise directed by the Administrative Law Judge, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the prehearing scheduling conference, and Rule 3.31(b) obligates counsel for each party, within five (5) days of receiving the answer of Respondent, to make certain initial disclosures without awaiting a formal discovery request.

NOTICE OF CONTEMPLATED RELEIF

Should the Commission conclude from the record developed in any adjudicative proceedings in this matter that Respondent has violated or is violating Section 5 of the FTC Act, as amended, as alleged in the complaint, the Commission may order such relief against Respondent as is supported by the record and is necessary and appropriate, including, but not limited to:

1. Ordering Respondent to cease and desist from the conduct alleged in the complaint to violate Section 5 of the FTC Act, and to take all such measures as are appropriate to correct or remedy, or to prevent the recurrence of, the anticompetitive practices engaged in by Respondent, or similar practices.

2. Prohibiting Respondent from entering into or attempting to enter into an agreement settling a patent infringement dispute in which: (i) the brand drug company provides to the generic drug company anything of the value *other than* the right to market its generic drug product prior to the expiration of the patent that is the basis of the patent litigation; and (ii) the generic drug company agrees not to research, develop, manufacture, market, or sell the generic drug product that is the subject of the patent litigation for any period of time.

3. Prohibiting Respondent from entering into an agreement with another drug company that, in form or substance, prevents, restricts, or disincentives the brand drug company from competing with an authorized generic version of its drug product for some period of time.

4. Ordering Respondent to submit at least one report to the Commission sixty days after issuance of the Order, and other reports as required, describing how it has complied, is complying, and will comply in the future.

5. Requiring, for a period of time, that Respondent document all communications with parties in which it is engaged in Hatch-Waxman patent litigation to document all settlement discussions, including the persons involved, the nature of the communication, and its duration, and that Respondent submit such documentation to the Commission.

6. Ordering Respondent to file annual compliance reports to the Commission describing its compliance with the requirements of the order. The order would terminate twenty years from the date it becomes final.

7. Requiring that Respondent's compliance with the order may be monitored at Respondent's expense by an independent monitor, for a term to be determined by the Commission.

8. Any other relief appropriate to prevent, correct, or remedy the anticompetitive effects in their incipience of any or all of the conduct alleged in the complaint.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this nineteenth day of January, 2017, issues its complaint against Respondent.

By the Commission.

Donald S. Clark
Secretary

SEAL:

EXHIBIT B

PUBLIC

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of **Impax Laboratories, Inc.,** **a corporation**

Docket No. 9373

Public

ANSWER OF RESPONDENT IMPAX LABORATORIES INC. TO THE FEDERAL TRADE COMMISSION'S ADMINISTRATIVE COMPLAINT

Respondent Impax Laboratories, Inc. ("Impax"), through its undersigned counsel, answers the Administrative Complaint (the "Complaint") filed by the Federal Trade Commission ("FTC") as follows. Except to the extent specifically admitted herein, Impax denies each and every allegation contained in the Complaint, including all allegations contained in headings or otherwise not contained in one of the Complaint's 102 numbered paragraphs. Specifically, Impax denies that it has engaged in conduct that violates Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, and denies that this proceeding is in any way in the public interest.

NATURE OF THE CASE

1. Impax denies the allegations in paragraph 1. Impax lacks sufficient knowledge to admit or deny the allegations regarding Endo and therefore denies them. To the extent the allegations in paragraph 1 are legal conclusions, no response is required.

2. Impax admits that it submitted an abbreviated new drug application ("ANDA") to the U.S. Food and Drug Administration (the "FDA") to market a generic version of Opana ER in certain dosage strengths. Impax admits that, as part of that ANDA, it made a Paragraph IV certification

as to the '250, '456, and '933 patents and Impax's ANDA and the Paragraph IV certification speak for themselves. Impax admits that Endo sued it for patent infringement. To the extent any further response is required, Impax denies all other allegations in the paragraph.

3. Impax denies that Endo agreed to pay or paid Impax to abandon its patent challenge or to forgo entering the market for generic Opana ER. To the extent the allegations in paragraph 3 make reference to any contracts between Impax and Endo, including but not limited to the Settlement and License Agreement and Development and Co-Promotion Agreement, such contracts are the best evidence of their contents and Impax states, therefore, that no response to the allegations is required. To the extent a further response is required, Impax denies the remaining allegations in paragraph 3.

4. Impax denies the allegations in paragraph 4.

Respondent

5. Impax admits that it is a for-profit Delaware corporation, with its principal place of business at 30831 Huntwood Avenue, Hayward, California 94544, that engages in the business of, among other things, developing, manufacturing, and marketing generic drugs. Impax denies that it has entered into any anticompetitive agreement.

Jurisdiction

6. Impax admits that it is a for-profit Delaware corporation. Except as otherwise admitted, the allegations in paragraph 6 reflect a legal conclusion to which no response is required.

7. The allegation in paragraph 7 is a legal conclusion to which no response is required.

Background

A. Federal law facilitates approval of generic drugs

8. To the extent the allegations in paragraph 8 purport to describe the FDCA, the Hatch-Waxman Act, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or any other laws, rules, or regulations, those laws, rules, and regulations are the best evidence of their contents, and no response is necessary. To the extent the allegations in paragraph 8 constitute legal conclusions, no response is required.

9. To the extent the allegations in paragraph 9 constitute legal conclusions, no response is required. To the extent the allegations in paragraph 8 purport to describe the FDCA, the Hatch-Waxman Act, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or any other laws, rules, or regulations, those laws, rules, and regulations are the best evidence of their contents, and no response is necessary. Impax admits certain pharmaceutical products sold pursuant to an NDA may sometimes be referred to as "brand-name drugs" or "branded drugs." To the extent any further response is required, Impax denies all other allegations in the paragraph.

10. To the extent the allegations in paragraph 10 constitute legal conclusions, no response is required. To the extent the allegations in paragraph 10 purport to describe the FDCA, the Hatch-Waxman Act, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or any other laws, rules, or regulations, those laws, rules, and regulations are the best evidence of their contents, and no response is necessary. Impax admits that the publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* is commonly known as the Orange Book. To the extent any further response is required, Impax denies all other allegations in the paragraph.

11. To the extent the allegations in paragraph 11 are legal conclusions no response is required. To the extent the allegations in paragraph 11 purport to describe the FDCA, the Hatch-Waxman Act, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or any other laws, rules, or regulations, those laws, rules, and regulations are the best evidence of their contents, and no response is necessary. To the extent any further response is required, Impax denies all other allegations in the paragraph.

12. To the extent the allegations in paragraph 12 are legal conclusions no response is required. To the extent paragraph 12 purports to describe laws, regulations, or rules governing generic drugs, including their rating as "AB" to other drugs, such laws, rules, and regulations are the best evidence of their contents, and no response is necessary. Impax admits that generic drugs have the same active ingredients as their brand name counterparts. To the extent any further response is required, Impax denies all other allegations in the paragraph.

13. To the extent the allegations in paragraph 13 are legal conclusions, no response is required. To the extent the allegations in paragraph 13 purport to describe the FDCA, the Hatch-Waxman Act, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or any other laws, rules, or regulations, those laws, rules, and regulations are the best evidence of their contents, and no response is necessary.

14. To the extent the allegations in paragraph 14 are legal conclusions no response is required. To the extent the allegations in paragraph 14 purport to describe the FDCA, the Hatch-Waxman Act, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or any other laws, rules, or regulations, those laws, rules, and regulations are the best evidence of their

contents, and no response is necessary. To the extent any further response is required, Impax denies all other allegations in the paragraph.

15. To the extent the allegations in paragraph 15 are legal conclusions no response is required. To the extent the allegations in paragraph 15 purport to describe the FDCA, the Hatch-Waxman Act, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or any other laws, rules, or regulations, those laws, rules, and regulations are the best evidence of their contents, and no response is necessary. To the extent any further response is required, Impax denies all other allegations in the paragraph.

16. To the extent the allegations in paragraph 16 constitute legal conclusions, no response is required. To the extent the allegations in paragraph 16 purport to describe the FDCA, the Hatch-Waxman Act, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or any other laws, rules, or regulations, those laws, rules, and regulations are the best evidence of their contents, and no response is necessary. To the extent the allegations in paragraph 16 purport to quote from a United States Supreme Court decision that opinion is the best evidence of its contents, and no response is necessary. To the extent any further response is required, Impax denies all other allegations in the paragraph.

17. To the extent the allegations in paragraph 17 are legal conclusions, no response is required. To the extent the allegations in paragraph 17 purport to describe the FDCA, the Hatch-Waxman Act, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or any other laws, rules, or regulations, those laws, rules, and regulations are the best evidence of their contents, and no response is necessary. Impax admits that the term "authorized generic" can

refer to a generic product marketed under an NDA. To the extent any further response is required, Impax denies all other allegations in the paragraph.

18. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 18, and on that basis denies them.

19. To the extent the allegations in paragraph 19 are legal conclusions no response is required. To the extent the allegations in paragraph 19 purport to describe the FDCA, the Hatch-Waxman Act, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or any other laws, rules, or regulations, those laws, rules, and regulations are the best evidence of their contents, and no response is necessary. To the extent any further response is required, Impax denies all other allegations in the paragraph.

B. State law encourages substitution of AB-rated generic drugs for brand drugs

20. To the extent the allegations in paragraph 20 are legal conclusions no response is required. To the extent the allegations in paragraph 20 purport to describe any state laws, rules, or regulations, those laws, rules, and regulations are the best evidence of their contents, and no response is necessary.

21. Impax admits that a patient can obtain a prescription drug only if a doctor (or someone who is authorized to write prescriptions) writes a prescription for that particular drug. Impax lacks sufficient knowledge or information to admit or deny all other allegations in paragraph 21, and on that basis denies them.

22. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 22, and on that basis denies them.

C. Competition from lower-priced generic drugs saves American consumers billions of dollars a year

23. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 23, and on that basis denies them. To the extent the allegations in paragraph 23 refer to any Congressional Budget Office Report or Generic Pharmaceutical Association report, those reports are the best evidence of their contents, and no response is required. To the extent a response is required, Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 23, and on that basis denies them.

24. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 24, and on that basis denies them.

25. To the extent the allegations contained in Paragraph 25 constitute legal conclusions, no response is required. Impax lacks sufficient knowledge or information to admit or deny all other allegations in this paragraph, and on that basis denies them.

26. To the extent the allegations contained in Paragraph 25 constitute legal conclusions, no response is required. Impax lacks sufficient knowledge or information to admit or deny all other allegations in this paragraph, and on that basis denies them.

Anticompetitive Conduct

A. Opana ER was a successful and rapidly growing branded drug

27. Impax admits that Oxymorphone is a semi-synthetic opioid that may be used to relieve pain. Impax lacks sufficient knowledge or information to admit or deny all other allegations in this paragraph, and on that basis denies them.

28. Impax admits that the product known by the brand name Opana ER is an extended-release formulation of oxymorphone. Impax admits that extended-release medications have attributes that moderate the rate at which the medications' active ingredients are absorbed in the patient's body. Impax admits that, as compared to immediate-release oxymorphone, extended-release oxymorphone has attributes that moderate the rate at which the medication's active ingredient is absorbed into the body. Impax admits that patients who take extended-release medications, including oxymorphone extended-release, often take fewer pills each day than would be the case if they took immediate-release formulations of the same medication. To the extent the allegations in paragraph 28 refer to NDA No. 021610 and/or the FDA's approval of NDA No. 02160, that NDA and that approval are the best evidence of their contents, and no response is necessary. To the extent a response is necessary, Impax denies any characterization or interpretation thereof.

29. Impax lacks sufficient knowledge or information to admit or deny the allegations in the first sentence of paragraph 29, and on that basis denies them. Impax admits the allegations in the second sentence of paragraph 29.

30. Impax lacks sufficient knowledge or information to admit or deny the allegations in this paragraph, and on that basis denies them.

31. Impax lacks sufficient knowledge or information to admit or deny the allegations in this paragraph, and on that basis denies them.

B. Potential generic competition from Impax threatened Endo's growing Opana ER business

32. Impax denies that Opana ER or oxymorphone ER "was not subject to any meaningful patent protection." To the extent the remaining allegations in paragraph 32 constitute legal conclusions, no response is required. Impax admits that patent No. 5,128,143 was set to expire in September 2008. Impax lacks sufficient knowledge or information to admit or deny all other allegations in paragraph 32, and on that basis denies them.

33. Impax admits that Endo listed three patents for Opana ER in the Orange Book in October 2007. Impax lacks sufficient knowledge or information to admit or deny all other allegations in paragraph 33, and on that basis denies them.

34. Impax admits that Endo listed the '250 patent in the Orange Book on October 2, 2007. To the extent the allegations in paragraph 34 refer to the '250 patent, that patent is the best evidence of its contents, and no response is required. To the extent a response is required, Impax denies any characterization or interpretation thereof. The remaining allegations in paragraph 34 are legal conclusions to which no response is required.

35. Impax admits that Endo listed the '933 patent and the '456 patent in the Orange Book on October 19, 2007. To the extent the allegations in paragraph 34 refer to the '933 patent or the '456 patent, those patents and the Orange Book are the best evidence of their respective contents, and no response is required. To the extent a response is required, Impax denies any characterization or interpretation thereof. The remaining allegations in paragraph 35 are legal conclusions to which no response is required.

36. Impax admits that it submitted and ANDA seeking approval to market its generic version of Opana ER and included a paragraph IV certification. To the extent paragraph 36 purports to describe the contents of ANDAs submitted by companies other than Impax, or complaints filed by Endo, those documents are the best evidence of their contents, and no response is required. To the extent a response is required, Impax lacks sufficient knowledge or information to admit or deny the allegations, and on that basis denies them.

37. Impax admits that it submitted ANDA No. 79-087 to the FDA in 2007, the FDA initially accepted ANDA No. 79-087 for substantive review, then rescinded that acceptance, after which Impax re-submitted ANDA No. 79-087, and the FDA accepted it on November 23, 2007.

38. Impax admits that on December 13, 2007, Impax notified Endo that it had submitted ANDA No. 79-087 with a paragraph IV certification including the '933 and '456 patents. Impax's Paragraph IV certification speaks for itself.

39. To the extent the allegations in paragraph 39 are legal conclusions, no response is required. Impax admits that Endo sued Impax on January 25, 2008 alleging infringement of the '456 and '933 patents. Impax admits that the litigation resulted in what is commonly known as a "30 month stay." Impax states that the pleadings in the lawsuit referenced in Paragraph 39 speak for themselves, as do the pertinent statutes and regulations.

40. Impax admits it was the first generic company to file an ANDA with a Paragraph IV certification for the 5, 10, 20, 30, and 40 mg strengths of original Opana ER. The allegations in the second sentence of Paragraph 40 constitute legal conclusions, therefore no response is required. Impax further states that the pertinent statutes and regulations speak for themselves.

Impax lacks sufficient knowledge or information to admit or deny the remaining allegations in paragraph 40, and on that basis denies them.

C. Endo paid Impax to drop its patent challenge and refrain from competing until January 2013

41. Impax admits that launching a generic product before a relevant patent challenge is resolved is commonly known as an "at-risk launch." Impax denies all other allegations in paragraph 41.

42. Impax admits that on May 13, 2010, the FDA tentatively approved Impax's application for a generic version of Opana ER in the certain dosage strengths. To the extent the allegations in paragraph 42 constitute legal conclusions, no response is required. To the extent the allegations in paragraph 42 refer to purported communications and/or documents, those communications and/or documents are the best evidence of their contents, and no response is necessary. To the extent a response is necessary, Impax denies all other allegations in paragraph 42.

43. Impax admits that it had completed process validation for generic Opana ER in certain dosage strengths and had produced certain lots of generic Opana ER product by May 20, 2010. Impax admits that, as of May 20, 2010, Impax had an outstanding request to the Drug Enforcement Agency for authorization to purchase additional quantities of oxymorphone. Impax denies all other allegations in paragraph 43.

44. Impax denies that there was any "impending launch" of generic Opana ER as of May 20, 2010. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 44 regarding Endo, and on that basis denies them. To the extent any further response is required, Impax denies all other allegations in the paragraph.

45. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 45, and on that basis denies them.

46. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 46, and on that basis denies them.

47. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 47, and on that basis denies them.

48. Impax denies that it was paid not to compete. Impax lacks sufficient knowledge or information to admit or deny the remaining allegations in paragraph 48, and on that basis denies them.

49. Impax admits that it settled a patent case with Endo on June 8, 2010 two days into a patent infringement trial; and that the litigation settlement was memorialized in the parties' Settlement and License Agreement ("SLA"). Impax admits that Impax and Endo separately entered into a Development and Co-Promotion Agreement ("DCPA"). To the extent that the allegations in paragraph 49 constitute legal conclusions, no response is required. To the extent any further response is required, Impax denies all other allegations in the paragraph.

50. Impax denies the allegations in paragraph 50.

51. Impax denies the allegations in paragraph 51.

52. Impax admits that the FDA granted final approval to Impax's ANDA for generic Opana ER for the 5, 10, 20, and 40 mg dosages on June 14, 2010, and for the 30 mg dosage on July 22, 2010. Impax denies all other allegations in paragraph 52.

1. Guaranteed No-AG Payment

53. The allegations in paragraph 53 constitute legal conclusions to which no response is required. To the extent the allegations in the second sentence purport to refer to the SLA and/or the DCPA, those agreements are the best evidence of their contents, and no response is required. To the extent a response is required, Impax denies the allegations in paragraph 53.

54. Impax denies the allegations in the first sentence of paragraph 54. Impax lacks sufficient knowledge or information to admit or deny the remaining allegations in paragraph 54, and on that basis denies them.

55. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 55, and on that basis denies them.

56. Impax admits that an Endo employee represented that Endo had no plans to introduce a reformulated version of Opana ER. Impax denies all other allegations in paragraph 56.

57. Impax admits that it negotiated in good faith for license terms that would allow it to begin selling generic Opana ER, free from patent risk, at the earliest date possible. Impax admits that the SLA includes a provision or provisions describing an "Endo Credit." To the extent the allegations in paragraph 57 refer to the SLA and/or written communications relating to the SLA, the SLA and any such written communications are the best evidence of their contents, and no response is required. To the extent any further response is required, Impax denies all other allegations in paragraph 57.

58. To the extent the allegations in paragraph 58 purport to describe the SLA, and/or written communications relating to the SLA, the SLA and any such written communications are the best

evidence of their contents, and no response is required. Impax lacks sufficient knowledge or information to admit or deny the allegations regarding Endo in the final sentence of paragraph 58, and on that basis denies them. To the extent any further response is required, Impax denies all other allegations in paragraph 58.

59. Impax admits that Endo introduced a reformulated version of Opana ER, and that Endo discontinued its original Opana ER product, before Impax's license to manufacture and sell generic original Opana ER took effect. Impax admits that pursuant to the terms of the SLA, and as a result of unforeseen events and circumstances that Impax could not have reasonably anticipated, and over which Impax had no control, Impax received a payment of approximately $102 million from Endo in April 2013. To the extent any further response is required, Impax denies all other allegations in paragraph 59.

2. Side Deal Payment

60. Impax admits the allegations in the first sentence of paragraph 60. Impax admits that as of June 8, 2010, it had not completely finalized a formulation for IPX-203, submitted an Investigational New Drug Application for IPX-203, or initiated clinical trials for IPX-203. Impax lacks sufficient knowledge to admit or deny the allegations in the final sentence of paragraph 60, and on that basis denies them. To the extent any further response is required, Impax denies all other allegations in the paragraph.

61. To the extent the allegations in paragraph 61 purport to describe the DCPA, the DCPA is the best evidence of its contents, and no response is required. To the extent a response is required, Impax denies any characterization or interpretation of the DCPA. To the extent any further response is required, Impax denies all other allegations in the paragraph.

D. Endo's payment to Impax is large

62. Impax denies the allegations in paragraph 62.

63. Impax denies the allegations in the first sentence of paragraph 63. To the extent the allegations in paragraph 63 purport to describe the DCPA, the DCPA is the best evidence of its contents, and no response is required. To the extent any further response is required, Impax denies all other allegations in the paragraph.

64. Impax denies the allegations in the first sentence of paragraph 64. To the extent the unattributed words between the quotation marks in the final sentence of paragraph 64 appear in any document, that document speaks for itself, and Impax denies any characterization or interpretation of such document or documents. To the extent any further response is required, Impax denies all other allegations in paragraph 64.

65. To the extent the allegations in paragraph 65 purport to describe unidentified "internal forecasts," any such "internal forecasts" are the best evidence of their contents, and no response is required. To the extent any further response is required, Impax denies all other allegations in paragraph 65.

66. To the extent the allegations in paragraph 66 purport to describe the SLA, the SLA is the best evidence of its contents, and no response is required. To the extent a response is required, Impax denies any characterization or interpretation of the SLA contained in paragraph 66. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 66 as they relate to Endo. To the extent any further response is required, Impax denies all other allegations in paragraph 66.

67. Impax denies the allegations in paragraph 67.

68. Impax admits that Impax and Endo executed the SLA after trial had begun in the parties' underlying patent infringement litigation. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 68 as they relate to Endo and on that basis denies those allegations. Impax denies all other allegations in paragraph 68.

69. To the extent the words between the quotation marks in the final sentence of paragraph 69 appear in any document, that document speaks for itself, and Impax denies any characterization or interpretation thereof. Impax denies all other allegations in paragraph 69.

70. To the extent the allegations in paragraph 70 purport to describe unidentified projections, SEC filings, or other documents, any such SEC filings, and documents speak for themselves, and Impax denies any characterization or interpretation thereof. Impax denies all other allegations in paragraph 70.

71. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 71, and on that basis denies them.

E. Endo's large payment to Impax is not justified

72. Impax denies the allegations in paragraph 72.

73. Impax denies the allegations in paragraph 73.

74. To the extent the allegations in paragraph 74 reflect the views or goals of Endo, Impax lacks sufficient knowledge or information to admit or deny the allegations, and on that basis denies them. Impax denies all other allegations in paragraph 74.

75. To the extent the allegations in paragraph 74 reflect the views or goals of Endo, Impax lacks sufficient knowledge or information to admit or deny the allegations, and on that basis denies them. Impax denies all other allegations in paragraph 75.

76. Impax denies the allegations in paragraph 76.

77. Impax denies the allegations in paragraph 77.

78. Impax denies the allegations in paragraph 78.

79. Impax denies the allegations in paragraph 79.

F. Endo settled with the other Opana ER first filer with no reverse payment, and a significantly earlier entry date

80. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 80, and on that basis denies them.

81. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 81, and on that basis denies them.

82. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 82, and on that basis denies them.

83. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 83, and on that basis denies them.

85. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 85, and on that basis denies them.

Market Power

85. Impax denies the allegations in paragraph 85.

86. To the extent the allegations in paragraph 86 purport to describe an unidentified estimate or other documents, any such estimate and documents speak for themselves, and Impax denies any characterization or interpretation thereof. Impax denies all other allegations in paragraph 86.

87. Impax lacks sufficient knowledge or information to admit the allegations in paragraph 87, and on that basis denies them.

88. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 88, and on that basis denies them. To the extent any further response is required, Impax denies the allegations in paragraph 88.

89. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 89, and on that basis denies them.

90. Impax denies that oxymorphone ER is not reasonably interchangeable with several other medications used to treat the same or similar conditions. Impax admits that patients and medical professionals must use care to manage withdrawal symptoms and dosing issues when a patient discontinues certain prescription medications (including opioids) or switches from one medication to another. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 90 as they relate to Endo, and on that basis denies them. To the extent any further response is required, Impax denies the allegations in paragraph 90.

91. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 91 and on that basis denies them.

92. Impax admits that drug companies typically must conduct clinical trials as a precondition to receiving FDA approval and that FDA approval is required in order to sell generic drug products in the U.S. Impax admits that manufacturing pharmaceutical products requires specialized equipment and facilities. The remaining allegations in paragraph 92 constitute legal conclusions, to which no response is required. To the extent any further response is required, Impax denies all other allegations in paragraph 92.

VII. Harm to Consumers and Competition

93. Impax denies the allegations in paragraph 93.

94. Impax denies the allegations in paragraph 94.

95. Impax denies the allegations in paragraph 95.

96. Impax lacks sufficient knowledge or information to admit or deny the allegations as they relate to Endo and its alleged forecasts, and on that basis denies them. Impax denies all other allegations in paragraph 96.

97. To the extent the allegations in paragraph 97 purport to interpret or describe the Hatch-Waxman Act, the Hatch-Waxman Act is the best evidence of its contents, and no response is required. To the extent the allegations in paragraph 97 constitute legal conclusions concerning the meaning, interpretation, or effect of the Hatch-Waxman Act, no response is required. Impax denies all other allegations in paragraph 97.

98. Impax denies the allegations in paragraph 98.

99. Impax admits that private plaintiffs have brought lawsuits against Impax and other drug companies relating to the drug Solodyn. Impax also admits that the FTC investigated Impax's

conduct relating to Solodyn for over two years, and in November 2015, closed the investigation without taking any enforcement action. Impax denies all other allegations in paragraph 99.

100. Impax admits that it continues to develop and manufacture pharmaceutical products, and that—like virtually all pharmaceutical companies—it is sometimes involved in patent litigation related to various drugs. Impax denies the remaining allegations in paragraph 100.

Violation Alleged

101. Impax denies the allegation in paragraph 101.

102. Impax denies the allegations in paragraph 102.

AFFIRMATIVE DEFENSES

FIRST DEFENSE

1. The Complaint fails to state a claim upon which relief can be granted.

SECOND DEFENSE

2. The Complaint should be dismissed for lack of jurisdiction because of mootness. The Complaint alleges activity that ended years ago, and the Complaint fails to allege facts to suggest that there is a likelihood that the alleged conduct will recur.

THIRD DEFENSE

3. The FTC's causes of action are barred in whole or in part by the relevant statute(s) of limitations.

FOURTH DEFENSE

4. The Complaint fails to allege a relevant market.

FIFTH DEFENSE

5. The Complaint fails to allege market power.

SIXTH DEFENSE

6. The Complaint fails to allege any harm to competition.

SEVENTH DEFENSE

7. The Complaint fails to allege any harm to consumers or consumer welfare.

EIGHTH DEFENSE

8. The alleged conduct had substantial pro-competitive justifications, benefited consumers and the public interest, and avoided potential infringement of valid patents. These pro-competitive justifications outweigh any alleged anticompetitive effects of the alleged conduct. There were no less restrictive alternatives that could have achieved these same pro-competitive outcomes.

NINTH DEFENSE

9. Neither the filing of this administrative action nor the contemplated relief are in the public interest, pursuant to 15 U.S.C. § 45.

TENTH DEFENSE

10. The claims against Respondent are barred, in whole or in part, by laches.

RESERVATION OF RIGHTS

10. Impax reserves the right to assert other defenses as discovery proceeds.

Impax respectfully requests that the Administrative Law Judge (i) deny the FTC's contemplated relief, (ii) dismiss the Complaint in its entirety with prejudice, (iii) award Impax its costs of suit, and (iv) award such other and further relief as the Administrative Law Judge may deem proper.

Dated: February 7, 2017

Respectfully Submitted,

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Counsel for Impax Laboratories, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on February 7, 2017, I filed the foregoing documents by hand to the FTC, which will send notification of such filing to:

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Secretary of the Commission
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

The Honorable D. Michael Chappell
Chief Administrative Law Judge
Federal Trade Commission
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I also certify that I emailed a copy of the foregoing to the following individuals:

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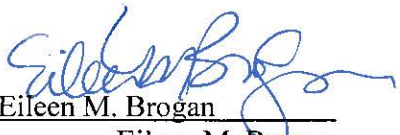

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EXHIBIT C

ORIGINAL

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of: IMPAX LABORATORIES, INC., a corporation.	**Docket No. 9373**

RESPONDENT IMPAX LABORATORIES, INC.'S OPPOSITION TO COMPLAINT COUNSEL'S MOTION TO COMPEL RESPONSES TO INTERROGATORY NOS. 2 & 3

PUBLIC

I. INTRODUCTION

The Federal Trade Commission's Rules of Practice state that contention interrogatories "need not be answered until after designated discovery has been completed, but in no case later than 3 days before the final prehearing conference." 16 C.F.R. § 3.35(b)(2). Complaint Counsel has propounded a number of contention interrogatories, including the two at issue in its June 1, 2017 Motion to Compel ("Motion" or "Mot."), which seek information concerning the procompetitive effects of Impax's agreements with Endo. As permitted by Rule 3.35, Impax objects to answering these interrogatories before the close of discovery. Complaint Counsel asks the Court to disregard the Rule and order Impax to answer the interrogatories now, but does not provide any compelling reason for granting this request.

Complaint Counsel claims it needs responses now in order to "conduct meaningful discovery" (Mot. 1-2), but the truth is that Complaint Counsel ***already knows*** why the Impax/Endo agreements are procompetitive. In the course of Staff's two-year investigation, Impax explained the agreements' competitive benefits repeatedly and at length—in narrative CID responses, in white papers and letters, and in meetings with Staff, the acting Bureau Director, and five Commissioners. Impax again summarized these procompetitive benefits at the Initial Pretrial Conference. The notion that Complaint Counsel cannot conduct appropriate discovery without ***yet another*** explication of the agreements' benefits is disingenuous at best.

Because discovery is ongoing, any answers Impax provides would be incomplete and would require supplementation when discovery ends. Ordering multiple rounds of responses to the same interrogatories is unnecessary and inefficient.

The Court should deny Complaint Counsel's Motion.

PUBLIC

II. FACTUAL BACKGROUND

In early 2014, the FTC served a CID on Impax seeking documents and information relating to two agreements with Endo: the Settlement & License Agreement ("SLA"), and the Development & Co-Promotion Agreement ("DCA") (together, "Agreements"). Among other things, the CID requested that Impax produce documents relating to the Agreements' market effects; explain why certain settlement terms were included; and identify "each competitive and consumer benefit" resulting from other settlement terms. Impax produced over 21,000 pages of documents and provided extensive narrative answers to the CID's Specifications.

Impax subsequently submitted a 44-page memorandum to Staff, which explained at length why the Agreements were procompetitive. (Ex. A.) Impax further articulated these benefits in a supplemental memorandum to Staff and in letters to the Commissioners (Exs. B, C), as well as at in-person meetings with Staff, the acting Bureau Director, and each of five Commissioners. Impax again highlighted the Agreements' procompetitive effects at the Initial Pretrial Conference. (Ini. Pretrial Conf. Tr. 69:20–70:01.)

Throughout this process, Impax has clearly and consistently explained that the SLA is procompetitive because it allowed Impax to begin selling a licensed version of generic Opana ER earlier than it otherwise could have. Unlike other settling generic companies, Impax negotiated license terms that allowed it to enter and stay on the market, even though Endo subsequently obtained several more patents. Endo has successfully enforced those patents against other generic companies. Today, Impax is the ***only*** company selling a generic version of Opana ER—and likely will be until the last of Endo's patents expires in 2029.

The instant Motion seeks yet another explanation for why the Agreements are procompetitive, in the form of responses to the following contention interrogatories:

2. Identify all procompetitive justifications and benefits to consumers and the public interest referenced in the Eighth Defense in Your Answer to the Complaint in this case, and explain the factual basis for Your answer to this Interrogatory, including identifying all facts and documents You rely on in Your answer to this Interrogatory.

3. For each procompetitive justification and benefit identified in response to Interrogatory No. 2, explain how the No-AG Provision and the Endo Credit provision contained in the Opana ER Settlement and License Agreement were reasonably necessary to achieve that benefit, including identifying all facts and documents You rely on in Your answer to this Interrogatory.

Impax objected that responding to contention interrogatories is not required until the close of discovery, but agreed to "supplement its response to [Interrogatory Nos. 2 and 3] in due course." (Compl. Counsel Ex. B at 7-8.)

III. ARGUMENT

Contention interrogatories ask a party "to state what it contends; to state whether it makes a specified contention; to state all the facts upon which it bases a contention; to take a position, and explain or defend that position, with respect to how the law applies to facts; or to state the legal or theoretical basis for a contention." *B. Braun Med. Inc. v. Abbott Labs.*, 155 F.R.D. 525, 527 (E.D. Pa. 1994). Courts widely recognize that "[t]he interests of judicial economy and efficiency for the litigants dictate that contention interrogatories are more appropriate after a substantial amount of discovery has been conducted." *Fischer & Porter Co. v. Tolson*, 143 F.R.D. 93, 95 (E.D. Pa. 1992) (quotation omitted).

This policy is reflected in Rule 3.35(b)(2), which states that contention interrogatories "***need not*** be answered until after designated discovery has been completed." 16 C.F.R. § 3.35(b)(2) (emphasis added). The Rule is intended to "conform Commission practice with federal court practice and consistently allow a party to delay answering a contention interrogatory until fact discovery is almost complete." 74 Fed. Reg. 1804, 1815 (Jan. 13, 2009).

A. Impax Need Not Respond to Complaint Counsel's Interrogatory Nos. 2 and 3 Until the Close of Discovery.

Interrogatory Nos. 2 and 3 are classic contention interrogatories that ask Impax to "commit to a position and give factual specifics supporting its claims," *Ziemack v. Centel Corp.*, 1995 WL 729295, at *2 (N.D. Ill. Dec. 7, 1995). Indeed, the interrogatories invoke the rule of reason, requiring an "application of law to fact." 16 C.F.R. § 3.35(b)(2). Rule 3.35 permits Impax to defer responding until discovery concludes.

Complaint Counsel argues that different standards should apply because these interrogatories relate to Impax's defenses. According to the Motion, the fact that "Impax must already have [had] a good faith basis in fact and law" to plead procompetitive justifications in its Answer means Impax "must already know what it claims are the asserted procompetitive justifications and benefits and how the [alleged] payment provisions of the settlement agreement were reasonably necessary to achieve such benefits." (Mot. 5-6.) Moreover, Complaint Counsel says, Impax "has no need to conduct discovery on this issue" since the relevant information ostensibly resides with its own witnesses and documents. (*Id.* at 6.)[1]

These arguments don't hold water. To begin with, Complaint Counsel is wrong to suggest that all relevant facts are at Impax's fingertips. (Mot. 6.) Impax is still in the process of reviewing tens of thousands of documents in response to Complaint Counsel's requests for production, the most recent of which were served on May 30th. A dozen depositions of current and former Impax employees still remain, to say nothing of ongoing third-party depositions and document discovery. As of this filing, nine third-party depositions have been noticed (including of several Endo witnesses), but none have taken place. The claim that Impax "must already

[1] Complaint Counsel suggests, without authority, that the "logic" of the Rule governing initial disclosures applies to interrogatories. (Mot. 4.) Since the sufficiency of Impax's initial disclosures is not in dispute, Impax does not see how that Rule is relevant to the present Motion.

know" all it needs to answer the interrogatories, and that it "has no need to conduct discovery on this issue," is fundamentally untrue.

There is also no merit to Complaint Counsel's assertion that having a good faith basis to assert a claim or defense at the pleading stage subjects a party to early contention interrogatories. *See Carotek, Inc. v. Kobayashi Ventures, LLC*, 2010 WL 3291758, at *1 (S.D.N.Y. Aug. 9, 2010) ("while there must be a good faith basis for the filing of a pleading, the assertion of a claim need not wait until the claimant has fully developed an evidentiary record during discovery"); *Braun*, 155 F.R.D. at 527 & n.1 (refusing to compel defendants to "articulate theories of their case not yet fully developed" where interrogatories were directed at allegations in defendants' answer). Compelling a party to commit to a contention while the factual record is still in flux "would force an artificial narrowing of the issues, instead of an informed paring down"—which is contrary to the purpose of contention interrogatories. *In re Northfield Labs. Inc. Sec. Litig.*, 264 F.R.D. 407, 412 (N.D. Ill. 2009) (quotation omitted).

For this reason, courts routinely hold that contention interrogatories exploring a party's defenses need not be answered until the close of discovery. In *Novanta Corp. v. Iradion Laser, Inc.*, 2016 WL 4987110 (D. Del. Sept. 16, 2016), for example, the plaintiffs served interrogatories seeking the factual and legal basis for the defendant's affirmative defenses. *Id.* at *7. The court held that it was "premature" to require the defendant to "detail with specificity and finality the factual and legal bases" for its defenses. *Id.* at *8. Other decisions are in accord. *See, e.g., Dalmatia Import Grp., Inc. v. Foodmatch, Inc.*, 2016 WL 5721161, *2 (E.D. Pa. Oct. 3, 2016) (defendant not required to answer contention interrogatory regarding defenses until close of discovery); *Gorrell v. Sneath*, 292 F.R.D. 629, 636 (E.D. Cal. 2013) (requiring defendant to answer early contention interrogatory about defenses "would require speculation by

[defendant]"); *Scheffler v. Molin*, 2012 WL 3292894, at *6 (D. Minn. Aug. 10, 2012) (defendants not required to answer interrogatory asking for factual basis for defenses until "the close of fact discovery").

The cases cited by Complaint Counsel are not to the contrary. For example, while the court in *Dot Com Entm't Grp., Inc. v. Cyberbingo Corp.*, 237 F.R.D. 43 (W.D.N.Y. 2006), required the defendants to answer interrogatories relating to certain patent law defenses, its rationale was specific to those defenses. *Id.* at 45 ("contention interrogatories seeking the bases for Defendants' prior art and obviousness defenses are enforced, even at an early stage in such cases").[2] Subsequent decisions have recognized this limitation. *See United States v. Educ. Mgmt. LLC*, 2013 WL 3854458, at *25 (W.D. Pa. May 14, 2013) (noting that *Dot Com* enforced "contention interrogatories seeking the bases ***for a specific patent defense***," and "[l]aw that is specific to patent cases cannot be imputed to a case such as the one at hand").

In re POM Wonderful, 2011 FTC LEXIS 42 (F.T.C. Mar. 16, 2011), fares no better. There, the challenged interrogatory asked ***whether*** a party would make a certain contention—not the basis for a ***known*** contention. *Id.* at *8-9. Here, Impax has clearly and repeatedly disclosed its contention that the SLA was procompetitive because it allowed Impax to sell generic Opana ER earlier than would have otherwise been possible.

And though the court in *United States v. Blue Cross Blue Shield of Mich.*, 2012 WL 12930840 (E.D. Mich. May 30, 2012), held that an interrogatory relating to competitive effects was "not one that is best served at the end of discovery," *id.* at *5, substantial discovery had already taken place in that case at the time of decision. *See* Dkt. 67, No. 2:10-cv-14155 (E.D. Mich. Aug. 12, 2011) (scheduling order); *cf. Am. Needle, Inc. v. New Orleans*, 2012 WL

[2] *Intelligent Verification Sys., LLC v. Microsoft Corp.*, 2015 WL 846012 (E.D. Va. Feb. 24, 2015), likewise involved the prior art defense. *Id.* at *4.

4327395, at *1-2 (N.D. Ill. Aug. 17, 2012) (ordering defendants to answer interrogatories about procompetitive benefits where "[t]he end of fact discovery [was] near").

In short, the fact that Interrogatory Nos. 2 and 3 are directed to Impax's defenses provides no reason for straying from the requirements of Rule 3.35(b)(2).

B. Even as "Narrowed," Interrogatory Nos. 2 and 3 Are Premature Contention Interrogatories.

Complaint Counsel insists that Impax should at least be required to identify each procompetitive benefit and explain why certain settlement provisions were necessary to achieve those benefits. (Mot. 6-7.) Complaint Counsel asserts that because the "narrowed" interrogatories "simply seek[] the particularization of Impax's asserted affirmative defenses," they are "not contention interrogatories." (*Id.* at 7.)

This is a distinction without a difference. Plainly, asking Impax to "particularize" its defenses seeks a "contention that relates to fact." 16 C.F.R. § 3.35(b)(2); *see Ft. Worth Employees' Retirement Fund v. J.P. Morgan Chase & Co.*, 297 F.R.D. 99, 110 (S.D.N.Y. 2013) ("contention interrogatories help the parties focus their arguments after discovery is complete and trial is near by asking them to identify each claim or defense clearly"); *Braun*, 155 F.R.D. at 527 (contention interrogatories ask a party to "state what it contends," "take a position," or "explain or defend [a] position"). Likewise, to "explain 'how' the reverse payments … were necessary to achieving the purported procompetitive benefits" (Mot. 7) is an "application of law to fact"—specifically, an application of the rule of reason to the facts of this case.

Even as "narrowed," Complaint Counsel's requests remain contention interrogatories that "need not be answered" until the close of discovery under Rule 3.35(b)(2).

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C. Complaint Counsel Will Not Be Prejudiced If Impax Does Not Answer Interrogatory Nos. 2 and 3 Until the Close of Discovery.

Complaint Counsel is no ordinary litigant. It entered these proceedings with a wealth of prior disclosures from Impax. *See FTC v. Staples, Inc.*, 2016 WL 259642, at *5 (D.D.C. Jan. 21, 2016) (noting that FTC had "the benefit of completing a year-long investigation into the matter"). And yet the crux of Complaint Counsel's Motion is that without another explanation of why the Agreements are procompetitive, it will have to "seek[] discovery on every conceivable procompetitive justification" or forego discovery of competitive effects. (*Id.* at 5.) In light of Impax's CID responses, written submissions, and in-person meetings with FTC Staff and officials—not to mention Impax's presentation at the Initial Pretrial Conference—Complaint Counsel can hardly plead ignorance of Impax's reasons for contending that the SLA is procompetitive. It does not need immediate responses to Interrogatory Nos. 2 and 3 to conduct "appropriate discovery." (Mot. 7); *see In re N. Tex. Specialty Physicians*, 2004 WL 318270, at *2 (F.T.C. Jan. 22, 2004) (denying motion to compel responses to interrogatories that "ask[ed] Respondent to identify specific documents … that Respondent contends support certain contentions," since the interrogatories "d[id] not seek information that Complaint Counsel d[id] not already have from the documents").

D. Impax Will Be Prejudiced If Required to Respond to Interrogatory Nos. 2 and 3 Before the Close of Discovery.

As Complaint Counsel acknowledges, if Impax is required to respond to contention interrogatories now, it will inevitably have to supplement its responses at the close of fact discovery. (Mot. 6.) With over a dozen noticed depositions still to come, multiple sets of discovery requests outstanding, and tens of thousands of documents left to review, the factual record is far from complete. Requiring successive responses is inefficient and unduly burdensome, and Complaint Counsel has not shown a need for imposing those burdens.

IV. CONCLUSION

Impax respectfully requests that the Court deny the motion in full.

Dated: June 8, 2017

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I hereby certify that on June 8, 2017, I emailed a copy of the foregoing to the following individuals:

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EXHIBIT D

Redacted in entirety

EXHIBIT E

In the Matter of:

Impax Laboratories, Inc.

February 16, 2017
Initial Pretrial Conference

Condensed Transcript with Word Index

For The Record, Inc.
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UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of:)
IMPAX LABORATORIES, INC.,) Docket No. 9373
Respondent.)
---)

INITIAL PRETRIAL CONFERENCE
PUBLIC RECORD
February 24, 2017
2:00 p.m.

BEFORE THE HONORABLE D. MICHAEL CHAPPELL
Administrative Law Judge

Reported by: Susanne Bergling, RMR-CRR-CLR

APPEARANCES:

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P R O C E E D I N G S
- - - - -

JUDGE CHAPPELL: Okay. We'll call to order Docket 9373. I'll start with the appearances of the parties, the Government first.

MR. LOUGHLIN: Good afternoon, Your Honor. Charles Loughlin on behalf of Complaint Counsel.

JUDGE CHAPPELL: Is this -- is it "Impax" or "Impax"?

MR. LOUGHLIN: "Impax," Your Honor.

JUDGE CHAPPELL: Impax Laboratories, Inc. Okay, go ahead.

MR. LOUGHLIN: With me at counsel table is Ms. Maren Schmidt and Mr. Brad Albert.

JUDGE CHAPPELL: For Respondent?

MR. HASSI: Ted Hassi for Impax Labs, O'Melveny & Myers, and with me are Mike Antalics, Ben Hendricks, and Eileen Brogan.

JUDGE CHAPPELL: Thank you.

Mr. Hassi, is it correct that I read you are a former Navy jet pilot?

THE WITNESS: A former helicopter pilot, actually. Navy, yes.

JUDGE CHAPPELL: CH-54s or --

MR. HASSI: No, the H-2, the Seasprite, it's

a --

JUDGE CHAPPELL: Oh, I know. Thank you.

Okay, let's talk about the scheduling order. The parties received and reviewed a proposed scheduling order. It appears that everything is agreed to except one disagreement regarding deposition timing. Is that correct?

MR. LOUGHLIN: Yes, Your Honor.

MR. HASSI: Yes, Your Honor.

JUDGE CHAPPELL: All right. Since you don't agree on it, I will hear argument. I'll listen to both sides' presentations, I will decide how to deal with it, and my ruling will be in the order that we will issue shortly.

Who wants to go first?

MR. LOUGHLIN: Your Honor, I would like to go first.

JUDGE CHAPPELL: Okay.

MR. LOUGHLIN: Your Honor, we made a change to paragraph 13(c) or added paragraph 13(c). The reason is that --

JUDGE CHAPPELL: Well, I understand. It's how long you can take in deposing certain employees?

MR. LOUGHLIN: Yes, Your Honor. The specific issue is that the primary third party in this case is a

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MR. HASSI: Not today, Your Honor.
JUDGE CHAPPELL: It sounds like he's cross examining you.
MR. HASSI: And I am going to have to plead the Fifth. I don't know the answer to that question. As I said, O'Melveny & Myers is not counsel.
JUDGE CHAPPELL: So it sounds like his answer is not to his knowledge, there is no such agreement, okay?
MR. LOUGHLIN: Okay, Your Honor.
JUDGE CHAPPELL: All right. I would hope the parties have attempted to settle this matter. Does someone want to provide me a status of any settlement discussions?
MR. HASSI: I would be happy to, Your Honor. We have. We have had numerous settlement discussions going on before -- and maybe I should have mentioned this in the ancillary proceedings.
The Federal Trade Commission initially sued us in federal court, along with Endo, actually, where we were in that case codefendants. They decided -- they also sued several other parties in that case. They sued on two different drugs. We, in the federal court, made a motion to sever. The Court in the Eastern District of Pennsylvania, Judge Diamond, granted our

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motion to sever.
JUDGE CHAPPELL: Did that get to any discovery at all or did you get out before then?
MR. HASSI: We -- there was no -- excuse me. Discovery requests were served. No discovery was proffered. Well, I take it back. There were -- I think there were some interrogatories that may have been answered, but --
JUDGE CHAPPELL: When you said "we" were severed, "we" being Impax or "we" being Endo and Impax?
MR. HASSI: So Endo and Impax were severed and Endo and Watson were severed, but Endo was the common link in what we viewed as the two cases that the FTC brought together. We made a motion to sever, and the judge agreed that just because Endo was a defendant in both cases, the facts were -- they were two different drugs, they were two different settlements, et cetera.
The judge severed those cases, and we separately had a motion to dismiss pending. While that was pending, the FTC withdrew that case. We subsequently sued the Federal Trade Commission for a declaratory judgment, that they didn't have grounds to bring the case to begin with. Subsequent to that --
JUDGE CHAPPELL: That went away after they withdrew the petition?

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MR. HASSI: They -- when they filed in this Court, when the FTC voted out a complaint, we agreed that the relief we were seeking in that declaratory judgment action was moot.
JUDGE CHAPPELL: So all of that action involving Impax and the FTC is off the table, either withdrawn or dismissed?
MR. HASSI: It is withdrawn or dismissed. I believe -- we're filing a motion for costs and fees tomorrow in that case, so there's a little bit of ancillary action, if you will, in that case, but --
JUDGE CHAPPELL: Is this news or did they know that? Is this breaking news?
MR. HASSI: No, they know that. They know that. So that -- that ancillary case is -- as to us is done. There's a case against Endo and Watson, and I believe the case against Watson is still proceeding. Endo settled.
And to answer your initial question, we -- before all that started, we engaged in settlement discussions with the Federal Trade Commission and didn't reach a settlement for reasons that -- it's a little bit complicated, but the consent decree that the FTC has proffered and the one that Endo entered into we think bars procompetitive deals that are sometimes done

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in these settlements.
So these settlements are, you know, at the conclusion of or conclude a patent litigation between a brand company and, in Impax's case, typically a generic. Sometimes what Impax has asked for is a supply agreement whereby the brand, which is already making the drug, provides the drug for Impax to sell as a generic, and that brings Impax to market in a way that we think is procompetitive.
I think the FTC would concede that a supply agreement like that is pro -- can be procompetitive. The issue is, how do you police that? How do you police as to whether the drug that is being provided and the terms of the supply agreement are such that there isn't a disguised payment in there?
We've tried to get over that issue and we couldn't and ultimately decided that we were not going to settle for something that, by the way, isn't at issue in this case. You are not going to hear evidence in this case about a supply agreement. So the FTC was asking to bar activities that we think are procompetitive in a case where that issue isn't involved, and we couldn't agree with that.
And I'll add further that before this case was brought or at the time it was brought, we sort of

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re-engaged in those discussions. Right now, Impax is working with -- they have an interim CEO who's acting, and he looked at this and said, look, I don't really -- he's not from the industry. He said he didn't really understand the issues and is uncomfortable, as an interim CEO, entering into an order that would bar the company for ten, maybe 20 years, from doing something that they have done in the past, that has been legitimate, is procompetitive, and has gotten them, as a generic drug company, in the market earlier, which is, by the way, what all this stuff is about.

They want -- I mean, the FTC wants generic drug companies to come to market, so --

THE COURT: Okay, and I am going to hear from him, but I have a question. Are you saying that the settlement discussions hit an impasse or are at an impasse because the Government wanted your client to agree to something that wasn't listed among the allegations or violations in the complaint in this case?

MR. HASSI: What I think I would say is what the FTC was seeking was a broad consent that barred activities that are not at issue in this case. So I think the FTC would say -- and I don't know that I would disagree -- that in their efforts to enforce,

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they're taking a broad view of what should be prohibited. The specific actions that Impax wants to engage in are not at issue in this case.

In other words, a supply agreement where the brand provides either the drug or the active pharmaceutical ingredient, the API, at a fair market price is something that I think we both would agree is procompetitive. They don't know how to police that fair market price. That's not an issue in this case, but it is an issue in the relief that the FTC sought in that consent.

JUDGE CHAPPELL: Just so I'm clear, is your client, Impax, selling the drug labeled "Opana," or is it -- does it have a different name?

MR. HASSI: It's called -- it's the generic version of Opana, so it's called Opana. So interestingly, what happened here is --

JUDGE CHAPPELL: So we will call it generic Opana?

MR. HASSI: Generic Opana ER, technically, because what you will hear about, there is also a crush-resistant form, because this is an opioid, and so there were issues of whether this was being misused, and Endo came out with a crush-resistant form. In fact, that's one of the things --

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JUDGE CHAPPELL: ER for extended release?

MR. HASSI: Exactly, Your Honor, yes, extended release. So it's a long-lasting opioid.

JUDGE CHAPPELL: You don't know the generic name, do you?

MR. HASSI: I am pretty sure it's Opana. I'm pretty sure it's called Opana. I don't -- I mean, the name was --

THE COURT: Does anybody know?

MR. LOUGHLIN: It's called oxymorphone.

MR. HASSI: Oxymorphone is the -- but when we sell it, it's I think sold as Opana ER. I could be wrong.

JUDGE CHAPPELL: Oxymorphone?

MR. LOUGHLIN: That's the generic name.

JUDGE CHAPPELL: There are a number of those, though, right? That's actually the generic name, that a script would write oxymorphone?

MR. LOUGHLIN: Oxymorphone is the generic name for this molecule, so this specific opioid is called oxymorphone.

JUDGE CHAPPELL: Okay. Are there other generics to Opana in the market?

MR. HASSI: No, Your Honor, there are -- because in addition to the patents that were at issue

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in the litigation that was settled, Endo had other subsequently acquired patents, and as I mentioned, we got this broad patent license that allowed us to come onto the market and stay on the market.

Those patents that Endo acquired, had they not held, and so the only other generic that came to market was a company called Actavis. They have since been ordered off the market by a federal judge.

JUDGE CHAPPELL: For a patent violation?

MR. HASSI: For violating those patents. And Endo has won two cases related to those after-acquired patents. But as we stand here today, Impax is the only company selling Opana ER. In fact, Endo withdrew the drug to move to a crush-resistant formula, so right now, we are the only ones selling the drug. There is no A/B rated brand.

We don't get -- you asked about writing a script. We don't get automatically substituted. The company, after this settlement and after what Endo did -- and, again, this has been a bitter battle between these two companies -- the company had to go out, which is not something generic companies typically do, and detail it, convince people to write the script for Opana ER. So as we sit here today, 50 percent of every oxymorphone pill that is sold are sold by Impax,

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but we are the only seller of Opana ER.
JUDGE CHAPPELL: Who's selling the other 50 percent?
MR. HASSI: So Endo has this crush-resistant, and it's patented as Opana CRF.
JUDGE CHAPPELL: So it is being sold with the brand name, but it's a generic, that 50 percent.
MR. HASSI: That 50 percent -- it's the only generic. It's 50 percent of the oxymorphone that's sold.
JUDGE CHAPPELL: Okay.
MR. HASSI: There are other opioids that are sold, but the Opana is the CRF and the ER.
JUDGE CHAPPELL: Normally I would have asked this during your 15-minute spiel, but we got into it.
So now you are going to tell me about your settlement discussions.
MR. LOUGHLIN: Yes, Your Honor. So as I mentioned, we have settled through a consent decree with the branded company, Endo Pharmaceuticals. That consent decree was negotiated over several months. Impax was invited to those negotiations. They were kept apprised of those negotiations. They declined to participate.
The settlement that we -- the consent decree we

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entered into with Endo Pharmaceuticals bars them for ten years from entering into a reverse payment patent settlement. It does have certain exceptions, such as payments for saved litigation costs, up to $7 million --
JUDGE CHAPPELL: Did they agree to call it a reverse payment? I mean, I know that's the Government's term, but did Endo agree to the term "reverse payment," to that phrase?
MR. LOUGHLIN: Your Honor, I don't know if the phrase "reverse payment" appears in the consent decree. I think it probably just talks about payments, but the key point is, in response to Mr. Hassi's comments, is there was also an exception for supply agreements between -- from the branded company to the generic to supply active pharmaceutical ingredient. So we negotiated that and were able to reach an accommodation on that point.
We have offered to settle this case with Impax on the same terms, the same consent decree. So far, they have declined. We have not heard exactly why, any more than we heard today, but our offer is still open. We are still willing to talk with them about --
JUDGE CHAPPELL: But what you heard today you had heard before?

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MR. LOUGHLIN: We have heard that they have concerns about supply agreements. We don't have the details of -- I don't know the details of those concerns. I do know that the Endo agreement does allow for supply agreements between the branded and the generic company. So, you know, we have offered those -- that -- those same terms to Impax. They have not accepted them so far.
JUDGE CHAPPELL: So basically, if I understood you, you have offered Impax the same deal that Endo accepted?
MR. LOUGHLIN: Yes.
JUDGE CHAPPELL: And settlement discussions are ongoing, correct?
MR. HASSI: They are not at this time, Your Honor. We remain willing to talk, but this issue is a sticking point, and I would add -- we have been offered the same settlement as Endo -- the same settlement as Endo, but the two companies are somewhat differently situated, because Impax is primarily a generic company and Endo is primarily a brand company.
And so on this issue of supply agreements, they are much more important for a generic company. I mean, the brand is making the drug. They know how to make it. So when a brand settles one of these things, they

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are typically not interested in a supply agreement. So they are giving up something that doesn't have value to them.
Now, I know Endo has a generics division called Par, and they may well -- and I know that they have negotiated this issue heavily, but my point is is that for Impax, the way they look at it, they said, look, there are drugs that we've brought to market and are selling in the marketplace today, making money for Impax and being procompetitive for consumers, because we got supply agreements, and the provisions that the FTC was asking for were just too broad and too onerous in terms of -- in other words, their provisions related to monitor or you can go to the brand company and get information.
We wanted something as simple if the brand company says, in a negotiated document, that they are selling supply at or above their cost, we thought that should be enough. That's not something the FTC is willing to accept. We're not willing to accept being barred from entering into supply agreements when the company makes money doing that and it's manifestly procompetitive.
MR. LOUGHLIN: Your Honor, all I can say about that is Endo is one of the largest generic companies in

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attorney, your time gets extended when I ask questions.
MR. HASSI: Thank you, Your Honor. I'll try to provoke some questions.
Your Honor, I want to start by talking a little bit about Impax. They are a small generic drug company. They didn't have any patents here. They didn't have any way of eliminating the risk of competition Mr. Loughlin just talked about. They didn't have monopoly power. If there was monopoly power here -- and we are going to contest that, by the way -- there is lots of opioids in the market, and there is lots of other ways to relieve pain. So we are going to contest monopoly power, and I am not going to bore you with that this afternoon because we think there are more important things to talk about.
JUDGE CHAPPELL: In the scheme of things, where does Opana fit with Vicodin, Percocet --
MR. HASSI: I think its closest analog is OxyContin, Your Honor. Indeed, as I'll talk about, one of the reasons that payment that Complaint Counsel was just talking about was so large was, for a period of time, OxyContin was off the market, and sales of Opana shot up, and that was a benchmark for how -- what the payment that Endo ultimately made was, but I'll talk about that in a minute. So the two were interrelated,

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in other words.
JUDGE CHAPPELL: And Opana doesn't have anything like acetaminophen or ibuprofen added to the formulary? It's straight morphine?
MR. HASSI: I don't know the answer to that, Your Honor.
JUDGE CHAPPELL: Or I guess synthetic morphine is what it is?
MR. HASSI: I don't know enough about either the chemical composition or how it's taken.
JUDGE CHAPPELL: But would you consider it a direct competitor to Vicodin or Percocet? I know you said OxyContin, but what about the others?
MR. HASSI: Your Honor, I don't know what -- what the total -- there's a --
JUDGE CHAPPELL: When you mention the word "monopoly," I start asking about competitors, so --
MR. HASSI: Yes. I will come back to you on that, Your Honor. I'm not prepared to talk about, today, the other drugs that were in the market, because it's really -- that's an Endo issue, whether Endo had market power. There is no question that Impax didn't have market power.
JUDGE CHAPPELL: Well when you say there is no monopoly here, did you mean for Opana or what did you

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mean?
MR. HASSI: For Opana. I mean, Opana is not in a market unto itself, and so when they talk about sharing monopoly profits, there was no monopoly to share the profits from, but that's really what I mean by that.
JUDGE CHAPPELL: Have you got a percentage?
MR. HASSI: I don't, Your Honor, no.
JUDGE CHAPPELL: Okay.
MR. HASSI: I think Opana is a smaller fish than oxycodone and OxyContin, for example, but we will get you that when we get to trial.
JUDGE CHAPPELL: All right.
MR. HASSI: But the goal of Impax all along was to come to market. Impax makes money not by settling patent cases, but by selling generic drugs. That was their goal. They were laser-focused on that, and the goal was to get to market as early as they could but with patent pro -- with protection from patent challenges, and when it came on, they wanted to stay on, that was their goal.
And they went out and they challenged Endo's patents, and they took that case to trial, and while that case was at trial, it was a bitterly fought dispute, they entered into a settlement. Now,

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Complaint Counsel referred to it as agreeing to stay off the market until January 2013. The patents that were at issue in that suit were valid until September 2013.
JUDGE CHAPPELL: I don't want to get into anything that would be in camera, but was there an attempt to cut a deal for royalties or licensing before the lawsuit?
MR. HASSI: There was, Your Honor. Actually, there was a discussion several months prior to the trial starting, and the way that discussion was framed between Endo and Impax -- so Endo reached out to Impax, and they talked about settlement, and Impax said, you've got to give us -- you have got to give us an early entry date, earlier than the patents which expire in September 2013.
And Endo said, no, we're not -- you know, we're not going to give you -- the earliest we are going to give you is January 2013. That was their -- their opening position was you are not getting a date any earlier than 2013.
JUDGE CHAPPELL: They didn't want generic competition as long as they held the patent on the brand name drug.
MR. HASSI: They didn't want generic

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competition as long as they held the patent, and the patent life went until September 2013, so there was an effort to come in earlier, and Impax at that point said, well, what if we launched at risk?

And the response -- and you will hear testimony on this -- the fact that they laughed. Endo laughed at Impax, the idea that Impax would launch at risk.

JUDGE CHAPPELL: They scoffed at it.

MR. HASSI: They scoffed -- yes, Your Honor.

JUDGE CHAPPELL: Are you aware, were there other generic competitors buzzing around that were going to try to get into the Opana market?

MR. HASSI: There were, Your Honor. There were several other generics that either had approved ANDAs or were soon to get approved ANDAs, and there were others that were working on it.

JUDGE CHAPPELL: And what happened to those?

MR. HASSI: They are all sitting on the sidelines right now because Endo's patents have kept them off the market. I've got a demonstrative --

JUDGE CHAPPELL: Did anyone else file suit, any other generic file suit, other than Impax?

MR. HASSI: Yes, Your Honor. I mean, the way these cases start is when you file the ANDA with the FDA, you file what's called a Paragraph IV

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certification, and the Paragraph IV certification says the patents aren't valid and we are not going to infringe the patent, and then the brand actually files suit. So Endo filed suit here. They filed suit against Actavis in the litigation, and they settled that.

JUDGE CHAPPELL: But that's what I'm getting at. Are any of those -- what happened -- all of those were worked out? They went away? They were settled?

MR. HASSI: No, Endo won. They won a case in the District Court of New York --

JUDGE CHAPPELL: So they've got a verdict saying that their patent was valid?

MR. HASSI: They got an opinion from a Federal District Court Judge saying the patents are valid, yes, Your Honor. There are two different -- now, I want to be clear. These are different patents than the one that we are litigating, but there are two different District Court Judges that have opined that the patents Endo was asserting on Opana are valid.

There was Judge Briccetti in the Southern District of New York, and the other one I believe is in the District of Delaware. And Judge Griesa, in the Southern District of New York, said to Actavis, which was on the market at the time -- we were the first

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filer on certain dosages, and Actavis was the first filer on other dosages. Actavis was in a separate suit with Endo. They settled that suit, and they came to market on the 7.5- and 15-milligram dosages, but they didn't get the same settlement that we got.

The settlement that we got had this broad patent license, and the settlement that we got defended Impax not just against the patents that were in suit at the time but against later acquired patents, at least as to Opana ER.

And so when those patents were upheld, Judge Griesa said, Actavis, you have got to get off the market. So right now Actavis is on the sidelines, and that's --

JUDGE CHAPPELL: But if I understood everything, as of September 2013, the patent has expired.

MR. HASSI: The patents that were at suit in the 2010 litigation between Impax and Endo expired, but in the meantime, Endo went to the Patent Office and acquired additional patents --

JUDGE CHAPPELL: Crush-proof.

MR. HASSI: Not just on crush-proof, Your Honor. Actually, some of the patents apply to both. So Impax, for example, is a defendant in the Southern

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District of New York litigation. Impax lost that as to the crush-proof or the -- the reformulated, as the Complaint Counsel called it, since the FDA, I gather, has said you can't call it crush-proof, so I won't do that either.

But on the reformulated Opana, Impax was a defendant in that case and lost that case, as did Actavis, as did several other potential purveyors of Opana.

JUDGE CHAPPELL: So the bottom line is, other than Impax, Endo has been successful in keeping other generics out of the market for this drug or a related drug.

MR. HASSI: Yes, Your Honor.

JUDGE CHAPPELL: Are you familiar -- I know you don't represent Endo, but do they have other big ticket brand names, or is Opana their workhorse, bringing in the profits?

MR. HASSI: I believe they have some other -- some other drugs as well. Opana I think is a big drug for them, but I don't know what else is in their stable.

JUDGE CHAPPELL: All right.

MR. HASSI: But, Your Honor, the idea, in other words, that Impax agreed to stay off the market until

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2013, January 2013, is a falsehood. What Impax got and what Impax negotiated for was an early entry date. They got a date that allowed them to come onto the market earlier than when the patents expired. So this wasn't an agreement to stay off the market. This was an agreement to come onto the market earlier, because that's what they -- they were fighting against these patents that were valid until September, and they got to come on in January instead.

So they came in nine months -- eight to nine months before the patents expired, and there's not going to be any evidence in this case, not a single solitary shred of evidence, that suggests that we could have gotten an earlier date, that we could have come in earlier.

What you heard Complaint Counsel say is we would have launched at risk, which a small company like Impax doesn't do. Launching at risk means, okay, we're in litigation. We have told the judge -- and we told the judge in this case -- that we would not launch at risk, but notwithstanding the fact that we told a federal judge we were not going to launch at risk, notwithstanding the fact we are being sued over these patents, Complaint Counsel's theory is we would have thrown caution to the wind, gone to the market, and

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sold our drug.

And had we done that, for every pill we sold, we would have been liable for the damages, for the difference between -- I mean, the FTC wants us to sell the drugs for less, so if Opana -- the branded Opana is selling for a dollar and we sell it for 60 cents, for every pill we sell at 60 cents, if we lose, we owe 40 cents in damages for the brand. So we lose money on every pill we sell. The idea that we were going to launch at risk is folly.

I would further say that the idea that we would launch at risk, we have this 180-day exclusivity, and that's got a significant amount of value. There is no question about that. And I'm talking there about the exclusivity the FDA grants for being a first-filer.

If you launch one pill at risk, one pill, that 180-day clock starts ticking. So had we launched at risk while we were in litigation in June of 2010, as the FDA sug -- I mean as the FTC, excuse me, suggests, had we launched at risk at that point and sold one pill, and the Judge got up the next morning and said, whoa, whoa, we're litigating this case here, take your product back off the market, that 180-day clock is still clicking, and we lose the benefit of that.

So we might have sold one batch of pills to a

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CVS or somebody like that, gotten enjoined, and lost the value of that exclusivity. So I look forward to how they are going to prove that we would have launched at risk.

JUDGE CHAPPELL: The Actavis case you talked about, were they going to sell a generic Opana ER?

MR. HASSI: They were going to and they did sell a generic Opana ER.

JUDGE CHAPPELL: Did they launch at risk?

MR. HASSI: They did not launch at risk. They got a settlement and launched, but their settlement didn't include the after-acquired patents, and so that's why they were kicked back off the market.

Your Honor, I think one of the things that will be interesting about this case is you're going to have a chance to apply the law, and there's a big difference between the way the FTC sees this and the way we see it, because the cite that they gave you from Actavis, I think the one thing that is clear, coming out of the Supreme Court case in Actavis, what they said is "these complexities lead us to conclude that the FTC must prove its case as in other rule of reason cases."

JUDGE CHAPPELL: Just so we're clear, the Actavis Supreme Court case is completely different from the Actavis-Endo case.

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MR. HASSI: Yes, Your Honor. Same drug company, different case. And the rule of reason requires you, among other things, to take into account the effect of the agreement. What was the effect of this settlement agreement? And this settlement agreement was manifestly procompetitive, as we have just been talking about.

So we think the framework -- what Complaint Counsel has to do, because they are accusing Impax, as they have said, is to accept a payment in exchange for a delay in coming to market, and we think to find for Complaint Counsel, you are going to have to find, one, that Impax agreed to accept the payment in return for a delay in settling Opana.

They are going to have to show that we delayed, and they are going to have to show that had we not been paid, we would have entered sooner than January 1st, 2013, which is the date on which we did enter. And further, they are going to have to show that consumers would be better off. And so --

JUDGE CHAPPELL: Wait. When you say they have to show you delayed, you mean that you were ready, willing, and able and delayed for no other reason?

MR. HASSI: That we delayed because we took a payment from Endo and not for some other reason, that

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we would have launched at risk. To be clear, the company made preparations to launch once they were ready. Had they gotten a settlement that said you can come in the market now, we were working on being ready to do that, and we absolutely want Endo to think -- because this is a negotiation, we want to scare them into thinking we might launch at risk, so we want to be ready to do that.

We get all the necessary FDA approvals, we include -- we buy the ingredients to make the drug, we make sample batches to show the FDA we can do that, absolutely. Do we do that stuff? Yes. Was there some Opana sitting in a closet somewhere, ready to be sold? Yes. Did they make a decision to launch at risk? No.

JUDGE CHAPPELL: No, I understand --

MR. HASSI: We did not.

JUDGE CHAPPELL: -- that there is litigation regarding payment under the deal, but I keep hearing 2010, 2013. The last time I checked, this was 2017. Is this agreement relevant to anything right now other than your current dispute with Endo over payment?

MR. HASSI: Other than to us and the FTC, I'm not sure it is, Your Honor.

JUDGE CHAPPELL: I mean, what I'm saying is, is it affecting -- are there drug sales right now taking

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place that have anything to do with this agreement?

MR. HASSI: Oh, yes, Your Honor, because -- I'll -- so -- could I hand up a demonstrative? I just have one.

JUDGE CHAPPELL: Sure. You don't have the screen?

MR. HASSI: No, I don't have the screen. I'm sorry, Your Honor.

JUDGE CHAPPELL: Make sure he gets one.

MR. HASSI: I have several for the FTC.

So why this agreement is relevant to that and why this is relevant under the rule of reason is because one of the things that the FTC is going to have to prove is that this -- that this agreement was anticompetitive.

Now, as I mentioned, it gave us a broad patent license, so what you have at the top, you asked about other companies, and Watson has an approved ANDA. Watson has never sold pill one. They have never sold an Opana pill. Now, they can --

JUDGE CHAPPELL: This says "Highly Confidential." You understand we're not in camera.

MR. HASSI: It shouldn't say "Highly Confidential." This is all public information, Your Honor.

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Watson hasn't sold any pill. Now, they can when the patents that Endo has, that have been upheld, expire sometime in 2029, so maybe they will start selling in 2029. I hope I'm not worried about that then.

JUDGE CHAPPELL: I hope I'm still around.

MR. HASSI: I hope I'm still around, Your Honor. I may be taking Opana for some reason, but I just don't -- I don't want to care about it for these purposes. Don't tell my clients I said that.

Actavis, as we mentioned, did come on the market, and Actavis got a settlement date that allowed them to come on on July 15th, 2011, and they were kicked off the market by Judge Griesa, and that decision was entered originally by -- well, I don't know -- we will find out when the decision was entered, but it was effective as of September 6, 2016. Actavis had to remove its Opana from the market, and the patents that were at issue in this case expire sometime in 2029.

JUDGE CHAPPELL: All right. So if I understand your olive drab green here on the chart, Actavis was selling a generic equivalent during the litigation?

MR. HASSI: They were selling -- so they were not a defendant in the same litigation. They -- Endo

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filed against them in front of a different judge. That case moved at a different pace, and they got a settlement earlier -- earlier than Impax did. The case involving Impax was just Endo and Impax. And so we were in front of a different judge, proceeding at a different pace.

Indeed, one of the issues and one of the reasons we had to make a promise not to launch at risk with the judge is because of the 30-month stay that comes in place when Endo first sues Impax was due to expire in June. That's why the FTC will tell you we were going to launch --

JUDGE CHAPPELL: Well, I understood that Actavis lost that patent case.

MR. HASSI: Actavis lost that patent case.

JUDGE CHAPPELL: So did they have to pay damages for this drab green period?

MR. HASSI: I don't -- no, because -- well, I don't know the answer to that, Your Honor. I will have to check. I don't know whether -- the initial settlement that came into place in July of 2011 was on patents -- I believe on the same patents that Endo was suing us on. Those expired in 2013, and they got a license for those.

Endo subsequently acquired different patents

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and sued Actavis in the Southern District of New York. Those patents were upheld. Those are -- I mean, I can give you the numbers, but it's --

JUDGE CHAPPELL: I don't need the numbers, but -- we're bored enough talking about patents. To be clear, though, these new patents, these other patents are not an impediment to what you and Endo are doing right now, as far as selling your generic version of Opana ER.

MR. HASSI: That's correct, Your Honor. That's -- Your Honor, we started this because Your Honor asked me is this settlement agreement relevant today, and it's relevant today because it protects Impax's ability to sell these drugs -- this drug, Opana ER, against all patents.

I should add, there is a -- there was a third litigation that Endo brought against generic challengers in which additional patents were upheld. Endo's got a closet full of patents that have been upheld by two different judges, and the reason our agreement or one of the reasons our agreement is procompetitive is because from January 1, 2013, until 2029, we will be selling this drug and we will be the only generic on the market, and because they withdrew their drug, the original Opana ER, we're the only

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original oxymorphone on the market, period. So the terms of --

JUDGE CHAPPELL: Monopoly. Monopoly.

MR. HASSI: Well, we do compete with the brand, and we compete with OxyContin and other drugs, so I don't think we have a monopoly, but in terms of a benefit to consumers, we're talking about years and years of sales.

JUDGE CHAPPELL: So if I read this right and understand what you're saying, you're the only company that has the legal right to sell Opana ER until probably 2029?

MR. HASSI: The only other company -- other than Endo. Endo could come back on the market if they wanted to.

JUDGE CHAPPELL: All right.

MR. HASSI: And by the way, Endo -- they talked about this no-AG. Endo never launched a no-AG. The no-AG was a throw-away that Endo gave us in the negotiations.

What you will see when you see the history of the negotiations, they put it in the first term sheet; we never really talked about it. They gave it -- they gave it to us because they weren't planning on launching an authorized generic. They didn't --

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JUDGE CHAPPELL: Are you talking about what he called the Endo credit on the chart?

MR. HASSI: The Endo credit was something different, and I'll talk about that. If you want me to address it now, I can, or I'll talk about --

JUDGE CHAPPELL: That's okay. Stay on your agenda.

MR. HASSI: Okay. So the bottom line is here, consumers have benefited, and they have benefited greatly from this agreement, and so they have benefited because Impax has this broad license. To be sure, Impax has benefited as well. I don't hear the FTC challenging the broad patent license, but in terms of the procompetitive or anticompetitive effects of this agreement, this is procompetitive.

This olive drab bar that runs out to 2029, all the sales to consumers, the consumers today can go into a pharmacy and get oxymorphone ER at a generic price, can get it today because we settled that case.

So I want to talk for a second about an at launch risk. As I mentioned, there wasn't a chance we were going to launch at risk. There was the patent damages -- the patent damages issue. We're a small company. And what you're going to hear about is, as I said, we made preparations to be ready to launch, but

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the company never made a decision to launch at risk.

A launch at risk for a small company like ours is a big decision. It puts a lot of -- as the name says, it puts a lot of money at risk. It would have been a board-level decision. The board never considered it. You are not going to see a board slide that says, "here's what we're going to do about launching at risk."

Were they going to update the board that they had approval from the FDA? Yes. Were they going to be ready to launch should the opportunity arise? Yes. Did Impax ever make a decision to launch at risk? No.

JUDGE CHAPPELL: Where does Impax have factories that manufacture this drug?

MR. HASSI: I don't know the answer to that, Your Honor.

JUDGE CHAPPELL: So you can't tell me whether they had capacity?

MR. HASSI: I know that they were preparing -- I mean, they were preparing the drug. They had started manufacturing pills. I mean, to get -- you have to make what are called validation batches to get FDA approval. We made some of those validation batches. So there were pills -- there were absolutely -- you know, had we wanted to sell some pills and violate

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agreement. The joint development agreement was entered into in 2010. The parties continued to work together to 2015. It's on a new drug that's designed to be a replacement to Rytary. It's a drug that's prescribed for Parkinson's.

It's a drug that at the time Impax was estimating it would cost 80 to 100 million dollars to bring to market, and the market potential for it is huge. To this day, Impax is still working to develop that drug, but they have had some -- they have had some setbacks.

Developing a new drug is expensive, it's difficult, and it's risky. And what they did with Endo is offered them an opportunity to participate in the development of this drug and offer them some of the upside. We wanted to sell it to a particular group of doctors, and they can sell it to other -- they can sell it to other doctors, and they'd pay $10 million for that.

There were going to be other milestone payments had we reached success, but the drug today is in Phase II trials. It's not some sham. Endo stayed in that participation through the end of 2015. They worked -- they worked together to try and develop this drug, and at some point -- I suspect it has to do with this

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royalty litigation -- Endo finally parted ways with Impax on that, but the idea that that's somehow a sham, that that $10 million is somehow a sham payment, I think it's going to be interesting to see what the evidence shows on that.

Finally, Your Honor --

JUDGE CHAPPELL: So your client got the 10 million also.

MR. HASSI: Our client did get the 10 million, yes.

JUDGE CHAPPELL: That's 112 million and counting.

MR. HASSI: 112 million, yes, Your Honor. So the 10 million was paid as part of the joint development agreement, and that's in exchange for value, and you will hear more about that. The 102 million was unexpected, was paid much, much later, and there is no evidence that that was in exchange for delay. It was contingent, it was unexpected --

JUDGE CHAPPELL: What do you mean, it was unexpected? It was in the deal.

MR. HASSI: It was in the deal. There were lots of scenarios where not only would we not get a payment, but we would have been paying Endo, so the settlement agreement, in addition to the Endo credit --

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JUDGE CHAPPELL: You're talking about the final agreement?

MR. HASSI: I'm talking about the final agreement, the one that allows us to sell Opana ER today. If they grew the market for Opana ER, when -- and the market was larger at the time we came to market, we would owe them a royalty, and that royalty would depend on how big they grew the market.

If they shrank the market, they would pay us a penalty, because the idea is we want to come into a robust market. We wanted to sell Opana ER, and we want to substitute for their brand, so we want them to grow the market, not shift it to some new patented brand drug like they did.

JUDGE CHAPPELL: Was any penalty ever paid?

MR. HASSI: Yes, Your Honor. $102 was the penalty to pay to Impax.

JUDGE CHAPPELL: That's the penalty.

MR. HASSI: Several years after the fact.

JUDGE CHAPPELL: But no penalty was paid for diminishing the value of the drug.

MR. HASSI: The 102 was for diminishing the market for the drug.

JUDGE CHAPPELL: And that was the 102, all right.

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MR. HASSI: In other words, the idea was we want to come into a robust market. If they grew the market, we would pay them a royalty when we entered.

JUDGE CHAPPELL: And I haven't seen the agreement yet, but the basis of the 102 was the so-called crush-proof drug?

MR. HASSI: The basis of the 102, there was a benchmark that was set. It was how much Opana is selling in a period of time versus how much -- where the market is in January of 2013 when we came in, and so what happened is that benchmark, as I mentioned, went really high because of oxycodone coming off market and more Opana being sold, and then if they had gradually reduced it before January 2013, they would have been okay, they wouldn't have had to pay a penalty.

But what happened is they had a manufacturing problem, and they took it off the market entirely. So they reduced it from really high to really low and paid a really big penalty as a result, but none of that was in Impax's control. So if what we are doing is taking a bag of money and running by not being in the market -- and that's what the Supreme Court in Actavis talked about. They talked about it as taking the money and running. They talked about -- the idea is --

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that's not what Impax did here. We didn't take the money and run. We tried to get in the market at every turn. We fought to get in the market.

By the way, we continued fighting after we got in. When we got in, they filed a citizen petition, and we were in litigation with Endo over that. They took steps at the FDA to prevent us from coming on. They tried to prevent us from coming on with this crush-resistant. This isn't some back-room deal and a big payment in exchange for delay. This was Impax fighting at every turn to come into the market.

So in sum, Your Honor, the settlement that was entered into, if you look at the time the settlement was entered into, other than that 10 -- and the $10 million wasn't a part of the settlement, it was part of the joint development agreement, but other than the $10 million, there was no payment made at the time of the settlement.

No authorized generic doesn't necessarily have a value. The Endo credit, there are lots of scenarios where they didn't have to pay. More importantly, there's no evidence that we delayed our entry for any of those terms. We came in earlier than the date the patent would have allowed.

JUDGE CHAPPELL: Bottom line, your client has

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received $112 million under the deal, and there's an ongoing dispute over whether your client is going to have to pay Endo as a result of the deal.

MR. HASSI: There is on ongoing dispute as to whether we should be paying royalties for pills we are selling in the market now, yes.

JUDGE CHAPPELL: Is there anything other than the 112, the 102 plus the 10?

MR. HASSI: No, Your Honor. Maybe the FTC will come up with some other basis. I mean, you know, the -- this royalty-free license that we have certainly has value, and that's where --

JUDGE CHAPPELL: And whether or not it's royalty-free is in dispute right now?

MR. HASSI: It is in dispute, yes, Your Honor, but the point is is that's where this really breaks down. What Complaint Counsel is telling you is all we have got to show you is there was a settlement and Impax got some value in that settlement, and then there -- well, every settlement, we would be fools to enter into a settlement if we didn't get some value.

Every settlement is a negotiated -- is a negotiated outcome, and every settlement, you know, reduces for the brand the risk of competition, so I -- that standard is just not workable, and we look forward

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to engaging on that and on the law on this issue. Unless Your Honor has further questions, thank you.

MR. LOUGHLIN: Your Honor, could I address two misstatements by Mr. Hassi?

JUDGE CHAPPELL: Are you calling for a point of order here to respond?

MR. LOUGHLIN: I would like to address two things that he has addressed that were inaccurate.

JUDGE CHAPPELL: Go ahead.

MR. LOUGHLIN: First, Your Honor, Mr. Hassi said that it's our position that we have to prove that Impax would have launched at risk. In fact, we -- our position is the opposite. We don't know what would have happened absent this settlement. We don't know if they would have launched at risk, if they would have continued patent litigation, and if they did, who would have won it. We don't have to prove that. What the Supreme Court has said is that --

JUDGE CHAPPELL: Well you're talking the law now and that's fine, but whatever the legal requirements are going to be, we will figure that out.

MR. LOUGHLIN: Okay. Thank you, Your Honor.

JUDGE CHAPPELL: I'm not taking legal advice today. I'm just listening.

MR. LOUGHLIN: Okay, let me be clear then. The

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other misstatement is regarding what the Supreme Court says in Actavis regarding whether or not early patent entry is procompetitive or not. The Supreme Court in Actavis says the opposite of what Mr. Hassi said. It said that early entry under a patent is not a defense because that would assume that the patent is valid and infringed when the whole point of the reverse payment was to ensure that we wouldn't find out that answer, to avoid the risk of the patent being found --

JUDGE CHAPPELL: Are you saying it's not an absolute defense? Are you saying it's something that can't even be discussed under an analysis?

MR. LOUGHLIN: It is not something that can be discussed under an analysis. The Supreme Court has made clear that inquiries into the patent merits are not part of the antitrust analysis here. The issue is this is anticompetitive because it eliminated the risk of competition, it eliminated the risk that the patent would be determined to be invalid, and, therefore, generics would come on. That is the --

JUDGE CHAPPELL: Inquiry into the patent merits you said, but the merits of the patent may not be the same factual scenario as whether a company planned to get in or not, what their plans were, what their capacity was to get in the market. There could be a

EXHIBIT F

PUBLIC

Drugs@FDA: FDA Approved Drug Products

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New Drug Application (NDA): 011738
Company: ENDO PHARMS

Products on NDA 011738

CSVExcelPrint

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RL
NUMORPHAN	OXYMORPHONE HYDROCHLORIDE	5MG	SUPPOSITORY;RECTAL	Discontinued	None	No

PUBLIC

Showing 1 to 1 of 1 entries

Approval Date(s) and History, Letters, Labels, Reviews for NDA 011738

Original Approvals or Tentative Approvals

CSVExcelPrint

Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert	Notes
05/31/1960	ORIG-1	Approval	Type 3 - New Dosage Form	STANDARD		Label is not available on this site.

Showing 1 to 1 of 1 entries

Supplements

CSVExcelPrint

Action Date	Submission	Submission Classification	Letters, Reviews, Labels, Patient Package Insert	Note
09/25/2000	SUPPL-12	Manufacturing (CMC)-Control		Label is not available on this site.
10/29/1997	SUPPL-13	Labeling		Label is not available on this site.
10/15/1996	SUPPL-11	Labeling		Label is not available on this site.
05/11/1994	SUPPL-10	Manufacturing (CMC)-Control		Label is not available on this site.

PUBLIC

Action Date	Submission	Submission Classification	Letters, Reviews, Labels, Patient Package Insert	Note
11/04/1981	SUPPL-7	Manufacturing (CMC)		Label is not available on this site.

Showing 1 to 5 of 5 entries

EXHIBIT G

PUBLIC

Drugs@FDA: FDA Approved Drug Products

__ SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS&APPLNO=021610)

__ TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS&APPLNO=021610)

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__ EMAIL (MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS&APPLNO=021610)

Home (index.cfm) | Previous Page

New Drug Application (NDA): 021610
Company: ENDO PHARMS

__ EMAIL (MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=021610)

- Medication Guide (http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/021610s022lbl.pdf#page=25)
- REMS (http://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=17)

Products on NDA 021610 __

CSVExcelPrint

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS

PUBLIC

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
OPANA ER	OXYMORPHONE HYDROCHLORIDE	5MG **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**	TABLET, EXTENDED RELEASE;ORAL	Discontinued	None	No	No
OPANA ER	OXYMORPHONE HYDROCHLORIDE	10MG **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**	TABLET, EXTENDED RELEASE;ORAL	Discontinued	None	No	No
OPANA ER	OXYMORPHONE HYDROCHLORIDE	20MG **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**	TABLET, EXTENDED RELEASE;ORAL	Discontinued	None	No	No
OPANA ER	OXYMORPHONE HYDROCHLORIDE	40MG **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**	TABLET, EXTENDED RELEASE;ORAL	Discontinued	None	No	No

PUBLIC

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
OPANA ER	OXYMORPHONE HYDROCHLORIDE	7.5MG **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**	TABLET, EXTENDED RELEASE;ORAL	Discontinued	None	No	No
OPANA ER	OXYMORPHONE HYDROCHLORIDE	15MG **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**	TABLET, EXTENDED RELEASE;ORAL	Discontinued	None	No	No
OPANA ER	OXYMORPHONE HYDROCHLORIDE	30MG **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**	TABLET, EXTENDED RELEASE;ORAL	Discontinued	None	No	No

Showing 1 to 7 of 7 entries

Approval Date(s) and History, Letters, Labels, Reviews for NDA 021610

Original Approvals or Tentative Approvals

CSVExcelPrint

PUBLIC

Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert	Notes
06/22/2006	ORIG-1	Approval	Type 3 - New Dosage Form	STANDARD		Label is not available on this site.

Showing 1 to 1 of 1 entries

Supplements

CSVExcelPrint

Action Date	Submission	Submission Classification	Letters, Reviews, L Patient Package I
05/26/2017	SUPPL-24	REMS-Modified	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/ap**
12/16/2016	SUPPL-22	Labeling-Medication Guide, Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsat Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/ap**
09/30/2016	SUPPL-23	REMS - MODIFIED - D-N-A	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/ap**
04/20/2016	SUPPL-21	REMS-Modified	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/ap**
06/26/2015	SUPPL-20	REMS-Modified	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/ap**

PUBLIC

Action Date	Submission	Submission Classification	Letters, Reviews, L Patient Package I
08/19/2014	SUPPL-19	REMS-Modified	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/ap**
04/16/2014	SUPPL-18	Labeling-Medication Guide, Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsat Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/ap**
02/23/2014	SUPPL-17	Manufacturing (CMC)	
04/15/2013	SUPPL-14	REMS-Modified	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/ap**
07/09/2012	SUPPL-13	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsat Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/ap**
07/09/2012	SUPPL-12	REMS-Proposal	**Label (PDF) (https://www.accessdata.fda.gov/drugsat Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/ap**
10/04/2010	SUPPL-9	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/drugsat Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/ap**
02/29/2008	SUPPL-6	Labeling-Container/Carton Labels, Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsat Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/ap**
01/10/2008	SUPPL-5	Labeling-Container/Carton Labels, Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsat Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/ap**

PUBLIC

Action Date	Submission	Submission Classification	Letters, Reviews, L Patient Package I
07/09/2007	SUPPL-3	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/drugsat Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/ap**
08/02/2006	SUPPL-1	Labeling	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/lab Letter (PDF) (https://www.accessdata.fda.gov/drugsat 021611s001LTR.pdf)**

Showing 1 to 16 of 16 entries

Labels for NDA 021610

EXHIBIT H

OPANA® ER
(Oxymorphone Hydrochloride) Extended-Release Tablets
5 mg, 10 mg, 20 mg, and 40 mg

CII

Rx Only

WARNING:
OPANA ER contains oxymorphone, which is a morphine-like opioid agonist and a Schedule II controlled substance, with an abuse liability similar to other opioid analgesics.

Oxymorphone can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing OPANA ER in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion.

OPANA ER is an extended-release oral formulation of oxymorphone indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

OPANA ER is NOT intended for use as a prn analgesic.

OPANA ER TABLETS are to be swallowed whole and are not to be broken, chewed, dissolved, or crushed. Taking broken, chewed, dissolved, or crushed OPANA ER TABLETS leads to rapid release and absorption of a potentially fatal dose of oxymorphone.

Patients must not consume alcoholic beverages, or prescription or non-prescription medications containing alcohol, while on OPANA ER therapy. The co-ingestion of alcohol with OPANA ER may result in increased plasma levels and a potentially fatal overdose of oxymorphone.

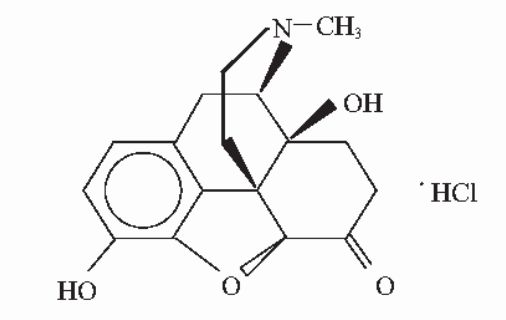
DESCRIPTION

OPANA ER (oxymorphone hydrochloride) extended-release, is a semi-synthetic opioid analgesic supplied in 5 mg, 10 mg, 20 mg, and 40 mg tablet strengths for oral administration. The tablet strength describes the amount of oxymorphone hydrochloride per tablet. The tablets contain the following inactive ingredients: hypromellose, iron oxide black, methylparaben, propylene glycol, silicified microcrystalline cellulose, sodium stearyl fumarate, TIMERx® -N, titanium dioxide, and triacetin. The 5 mg, 10 mg and 20 mg tablets also contain macrogol, and polysorbate 80. In addition, the 5 mg tablets contain iron oxide red. The 10 mg tablets contain FD&C yellow No. 6. The 20 mg tablets

contain FD&C blue No. 1, FD&C yellow No. 6, and D&C yellow No. 10. The 40 mg tablets contain FD&C yellow No. 6, D&C yellow No. 10, and lactose monohydrate.

Chemically, oxymorphone hydrochloride is 4, 5α -epoxy-3, 14-dihydroxy-17-methylmorphinan-6-one hydrochloride, a white or slightly off-white, odorless powder, which is sparingly soluble in alcohol and ether, but freely soluble in water. The molecular weight of oxymorphone hydrochloride is 337.80. The pK_a1 and pK_a2 of oxymorphone at 37°C are 8.17 and 9.54, respectively. The octanol/aqueous partition coefficient at 37°C and pH 7.4 is 0.98.

The structural formula for oxymorphone hydrochloride is as follows:



The tablet strengths, 5, 10, 20 and 40 mg, describe the amount of oxymorphone hydrochloride per tablet.

CLINICAL PHARMACOLOGY

Oxymorphone is an opioid agonist whose principal therapeutic action is analgesia. Other members of the class known as opioid agonists include substances such as morphine, oxycodone, hydromorphone, fentanyl, codeine, hydrocodone, and tramadol. In addition to analgesia, other pharmacological effects of opioid agonists include anxiolysis, euphoria, feelings of relaxation, respiratory depression, constipation, miosis, and cough suppression. Like all pure opioid agonist analgesics, with increasing doses there is increasing analgesia, unlike with mixed agonist/antagonists or non-opioid analgesics, where there is a limit to the analgesic effect with increasing doses. With pure opioid agonist analgesics, there is no defined maximum dose; the ceiling to analgesic effectiveness is imposed only by side effects, the more serious of which may include somnolence and respiratory depression.

Central Nervous System

The precise mechanism of the analgesic action is unknown. However, specific CNS (central nervous system) opioid receptors for endogenous compounds with opioid-like activity have been identified throughout the brain and spinal cord and play a role in the analgesic effects of this drug. In addition, opioid receptors have also been identified within the PNS (peripheral nervous system). The role that these receptors play in these drugs' analgesic effects is unknown.

Opioids produce respiratory depression likely by direct action on brain stem respiratory centers. The respiratory depression involves a reduction in the responsiveness of the brain

EXHIBIT I

PUBLIC

News Release

Endo Announces Commercial Availability of Opana(R) ER (oxymorphone HCl) Extended-Release and Opana(R) (oxymorphone HCl) Immediate-Release Tablets CII

Endo Also Launches New Comprehensive PROMISE(TM) Initiative to Support Appropriate and Responsible Opioid Use

CHADDS FORD, Pa., July 24 /PRNewswire-FirstCall/ -- Endo Pharmaceuticals Inc., a wholly owned subsidiary of Endo Pharmaceuticals Holdings Inc. (Nasdaq: ENDP), has announced the commercial availability of Opana(R) ER and Opana(R) tablets. Endo has begun shipments to its customers and is instituting a wholesale and retail stocking program to ensure these products are distributed to retail pharmacies across the U.S. over the next several weeks. Opana(R) ER and Opana(R) are extended-release and immediate-release formulations of oxymorphone hydrochloride (HCl) that were approved by the U.S. Food and Drug Administration on June 22, 2006.

A new oral extended-release opioid analgesic treatment option for patients, Opana(R) ER is indicated for the relief of moderate-to-severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time. Opana(R) ER is not intended to be used on an as-needed basis. This is the first time oxymorphone will be available in an oral, extended-release formulation and will be available in 5mg, 10mg, 20mg and 40mg tablets. Opana(R) (the immediate release version) is indicated for the relief of moderate-to-severe acute pain where the use of an opioid is appropriate and will be available in 5mg and 10mg tablets. Both Opana(R) ER and Opana(R) are available by prescription only.

This fall, Endo also plans to re-launch its injectable formulation of oxymorphone in the hospital setting under the new trade name. This will complete the "continuum of care" for Opana(R) by making it available in parenteral, short- and long- acting oral formulations.

"We are delighted to be able to provide physicians and patients with this new, much-needed option for patients with moderate-to-severe pain, and particularly for patients who have not found satisfaction with their current opioid treatment," said Peter A. Lankau, President and Chief Executive Officer, "As a leader in pain management, we also take very seriously our responsibility of helping physicians and caregivers appropriately manage pain. We are confident that Endo's PROMISE(TM) initiative, combined with our Risk Minimization

Action Plan developed in conjunction with the FDA and other outside experts, will effectively minimize the inherent risks of opioid misuse, abuse and diversion through comprehensive education and support programs for both patients and physicians."

Endo's Commitment to Responsible Pain Management: PROMISE(TM)

Endo is committed to providing healthcare professionals and patients with safe and effective opioid analgesic medications and support programs that will better ensure their appropriate and responsible use. Through extensive experience with opioid analgesics and working with the FDA and industry experts, Endo has developed a comprehensive risk minimization action plan for Opana(R) ER and Opana(R). Evolving from the risk minimization plan is a new initiative to further help reduce the inherent risk of misuse, abuse and diversion of opioid analgesics: The Partnership for Responsible Opioid Management through Information, Support, and Education (PROMISE(TM)). The PROMISE(TM) initiative contains essential information and guidance to healthcare professionals so that they can prescribe opioids to patients responsibly and appropriately. PROMISE(TM) includes educational support and practical patient management tools. For patients, the program raises the level of knowledge of those suffering from moderate-to-severe pain and empowers them to manage their condition with the help of their healthcare professional. More information about the PROMISE (TM) initiative is available at www.endopromise.com .

About Opana ER and Opana(R) Tablets

Opana(R) ER and Opana(R) tablets were formulated using oxymorphone hydrochloride, a semisynthetic, pure microgram-opioid agonist that had been available previously only as an injectable formulation. Both products have been proven to achieve effective relief in multiple moderate-to-severe pain models, in opioid-naive and opioid-experienced patients.

Opana(R) ER's clinical profile has demonstrated that it can be dosed consistently on a twice-daily basis and is well-tolerated when titrated effectively. Opana(R) ER has also shown maintenance of effective pain control at a stable dose over the three-month period of the pivotal clinical trials, which the company believes highlights the durability of its analgesic effect. Opana(R) ER utilizes a patented delivery system that was specifically developed to provide continuous delivery of medication over a 12-hour period, helping patients maintain a steady level of pain relief. Experts agree that patients suffering from moderate-to-severe chronic pain which is present much or all of the day need around-the-clock coverage with an analgesic agent to sustain pain relief.

Opana(R) ER has been studied in a wide range of chronic pain conditions, including low back pain, osteoarthritis pain, and cancer pain. Endo developed Opana(R) ER using Penwest Pharmaceuticals' proprietary time-release technology, TIMERx(R).

Opana(R) has been studied in multiple post-operative pain models, including orthopedic and abdominal procedures. Immediate-release Opana(R) is a proprietary product developed by Endo.

PUBLIC

Important Safety Information

Opana(R) ER and Opana(R) are opioid agonists and Schedule II controlled substances with an abuse liability similar to morphine. Opana(R) ER and Opana(R) can be abused in a manner similar to other opioid agonists, legal or illicit.

WARNING:

OPANA ER contains oxymorphone, which is a morphine-like opioid agonist and a Schedule II controlled substance, with an abuse liability similar to other opioid analgesics.

Oxymorphone can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing OPANA ER in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion.

OPANA ER is an extended-release oral formulation of oxymorphone indicated for the management of moderate to severe pain when a continuous, around-the- clock opioid analgesic is needed for an extended period of time.

OPANA ER is NOT intended for use as a prn analgesic.

OPANA ER TABLETS are to be swallowed whole and are not to be broken, chewed, dissolved, or crushed. Taking broken, chewed, dissolved, or crushed OPANA ER TABLETS leads to rapid release and absorption of a potentially fatal dose of oxymorphone.

Patients must not consume alcoholic beverages, or prescription or non- prescription medications containing alcohol, while on OPANA ER therapy. The co-ingestion of alcohol with OPANA ER may result in increased plasma levels and a potentially fatal overdose of oxymorphone.

Opana(R) ER is not indicated for pain in the immediate post-operative period (12-24 hours following surgery), or if pain is mild or not expected to persist for an extended period of time.

Opana(R) ER and Opana(R) are contraindicated in patients with a known hypersensitivity to oxymorphone hydrochloride, morphine analogs such as codeine, or any of the other ingredients of Opana(R) ER and Opana (R); in patients with moderate or severe hepatic impairment or in any situation where opioids are contraindicated.

Respiratory depression is the chief hazard of Opana(R) ER and Opana(R), particularly in elderly or debilitated patients.

The most common adverse drug reactions (greater than or equal to 10%) in clinical trials for Opana(R) ER were nausea, constipation, dizziness, vomiting, pruritus, somnolence, headache, increased sweating, and

sedation. The most common adverse drug reactions (greater than or equal to 10%) reported in clinical trials for Opana(R) were nausea and pyrexia.

For full prescribing information, visit www.opana.com .

About Endo

A wholly owned subsidiary of Endo Pharmaceuticals Holdings Inc., Endo Pharmaceuticals Inc. is a fully integrated specialty pharmaceutical company with market leadership in pain management products. The company researches, develops, produces and markets a broad product offering of branded and generic pharmaceuticals, meeting the needs of healthcare professionals and consumers alike. More information, including this and past press releases of Endo Pharmaceuticals Holdings Inc., is available online at www.endo.com .

This press release contains forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended, that are based on management's beliefs and assumptions, current expectations, estimates and projections. Statements that are not historical facts, including statements which are preceded by, followed by, or that include, the words "believes," "anticipates," "plans," "expects" or similar expressions and statements are forward-looking statements. Endo's estimated or anticipated future results, product performance or other non- historical facts are forward-looking and reflect Endo's current perspective on existing trends and information. Many of the factors that will determine the Company's future results are beyond the ability of the Company to control or predict. These statements are subject to risks and uncertainties and, therefore, actual results may differ materially from those expressed or implied by these forward-looking statements. The reader should not rely on any forward-looking statement. The Company undertakes no obligation to update any forward-looking statements whether as a result of new information, future events or otherwise. Several important factors, in addition to the specific factors discussed in connection with these forward-looking statements individually, could affect the future results of Endo and could cause those results to differ materially from those expressed in the forward-looking statements contained in this press release. Important factors that may affect future results include, but are not limited to: market acceptance of the Company's products and the impact of competitive products and pricing; dependence on sole source suppliers; the success of the Company's product development activities and the timeliness with which regulatory authorizations and product launches may be achieved; successful compliance with extensive, costly, complex and evolving governmental regulations and restrictions; the availability on commercially reasonable terms of raw materials and other third party manufactured products; exposure to product liability and other lawsuits and contingencies; dependence on third party suppliers, distributors and collaboration partners; the ability to timely and cost effectively integrate acquisitions; uncertainty associated with pre- clinical studies and clinical trials and regulatory approval; uncertainty of market acceptance of new products; the difficulty of predicting FDA approvals; risks with respect to technology and product development; the effect of competing products and prices; uncertainties regarding intellectual property

protection; uncertainties as to the outcome of litigation; changes in operating results; impact of competitive products and pricing; product development; changes in laws and regulations; customer demand; possible future litigation; availability of future financing and reimbursement policies of government and private health insurers and others; and other risks and uncertainties detailed in Endo's filings with the Securities and Exchange Commission, including its Registration Statement on Form S-3 filed with the SEC on March 21, 2006. Readers should evaluate any statement in light of these important factors.

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Web site: http://www.endo.com
http://www.opana.com
http://www.endopromise.com

EXHIBIT J

Redacted in entirety

EXHIBIT K

Redacted in entirety

EXHIBIT L

US005662933A

United States Patent [19]

Baichwal et al.

[11] **Patent Number: 5,662,933**

[45] **Date of Patent: *Sep. 2, 1997**

[54] **CONTROLLED RELEASE FORMULATION (ALBUTEROL)**

[75] Inventors: **Anand Baichwal**, Wappingers Falls, N.Y.; **Troy W. McCall**, New Milford, Conn.

[73] Assignee: **Edward Mendell Co., Inc.**, Patterson, N.Y.

[*] Notice: The term of this patent shall not extend beyond the expiration date of Pat. No. 5,455,046.

[21] Appl. No.: **553,008**

[22] Filed: **Nov. 3, 1995**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 118,924, Sep. 9, 1993, Pat. No. 5,455,046.

[51] **Int. Cl.**[6] **A61K 9/14**; A61K 9/22

[52] **U.S. Cl.** **424/457**; 424/468; 424/488; 514/777; 514/778; 514/779; 514/780; 514/781; 514/964; 514/965

[58] **Field of Search** 424/457, 468, 424/488; 514/777, 778, 779, 780, 781, 964, 965

[56] **References Cited**

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Primary Examiner—Nathan M. Nutter

Attorney, Agent, or Firm—Steinberg, Raskin & Davidson, P.C.

[57] **ABSTRACT**

A sustained release pharmaceutical formulation and methods of making and using the same are provided. The sustained release pharmaceutical formulation includes a sustained release excipient including a gelling agent, an inert pharmaceutical diluent, an optional hydrophobic material and/or hydrophobic coating, and a medicament for sustained oral administration.

48 Claims, 3 Drawing Sheets

EXHIBIT M

US005958456A

United States Patent [19]

Baichwal et al.

[11] **Patent Number: 5,958,456**

[45] **Date of Patent: *Sep. 28, 1999**

[54] **CONTROLLED RELEASE FORMULATION (ALBUTEROL)**

[75] Inventors: **Anand Baichwal**, Wappingers Falls, N.Y.; **Troy W. McCall**, New Milford, Conn.

[73] Assignee: **Edward Mendell Co., Inc.**, Patterson, N.Y.

[*] Notice: This patent is subject to a terminal disclaimer.

[21] Appl. No.: **08/886,496**

[22] Filed: **Jul. 1, 1997**

Related U.S. Application Data

[63] Continuation of application No. 08/553,008, Nov. 3, 1995, Pat. No. 5,662,933, which is a continuation-in-part of application No. 08/118,924, Sep. 9, 1993, Pat. No. 5,455,046.

[51] **Int. Cl.**[6] **A61K 9/14**

[52] **U.S. Cl.** **424/489**; 424/488; 424/457; 424/468

[58] **Field of Search** 424/489, 488, 424/457, 468

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,412,986	11/1983	Kawata et al.	424/80
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4,764,382	8/1988	Kydonieus et al.	424/449
4,765,990	8/1988	Sugimoto et al.	424/494
4,792,450	12/1988	Kydonieus et al.	424/449
4,792,452	12/1988	Howard et al.	424/475
4,808,413	2/1989	Joshi et al.	424/458
4,851,229	7/1989	Magruder et al.	424/457
4,867,985	9/1989	Heafield et al.	424/461
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4,940,587	7/1990	Jenkins et al.	424/480
4,942,040	7/1990	Ragnarsson et al.	424/486
4,973,469	11/1990	Mulligan et al.	424/461
4,994,276	2/1991	Baichwal et al.	424/440
5,007,790	4/1991	Shell	424/451
5,019,397	5/1991	Wong et al.	424/473
5,051,263	9/1991	Barry et al.	424/490
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5,135,757	8/1992	Baichwal et al.	424/465
5,145,683	9/1992	Rhodes	424/451
5,169,638	12/1992	Dennis et al.	424/457
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5,264,459	11/1993	Chelmicka-Schorr et al.	514/646
5,273,760	12/1993	Oshlack et al.	424/480
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1288049	8/1991	Canada .
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0232155	8/1997	European Pat. Off. .
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WO9206680	4/1992	WIPO .

Primary Examiner—Thurman K. Page
Assistant Examiner—William E. Benston, Jr.
Attorney, Agent, or Firm—Davidson,Davidson & Kappel,LLC

[57] **ABSTRACT**

A sustained release pharmaceutical formulation and methods of making and using the same are provided. The sustained release pharmaceutical formulation includes a sustained release excipient including a gelling agent, an inert pharmaceutical diluent, an optional hydrophobic material and/or hydrophobic coating, and a medicament for sustained oral administration.

16 Claims, 3 Drawing Sheets

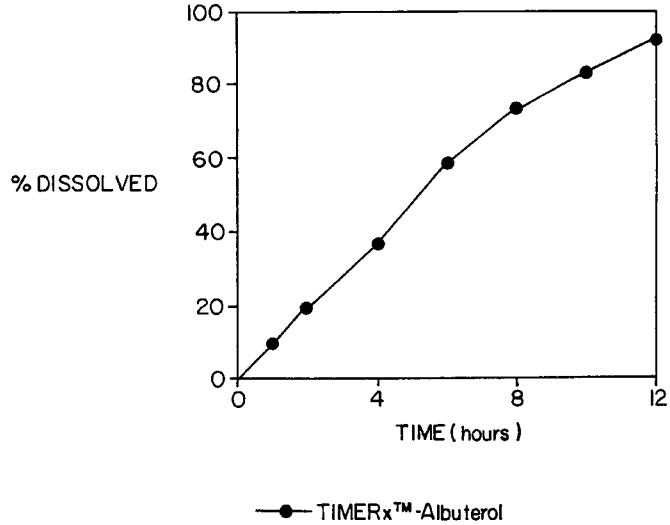

EXHIBIT N

US007276250B2

(12) **United States Patent**
Baichwal et al.

(10) **Patent No.: US 7,276,250 B2**
(45) **Date of Patent: Oct. 2, 2007**

(54) **SUSTAINED RELEASE FORMULATIONS OF OXYMORPHONE**

(75) Inventors: **Anand R. Baichwal**, Wappingers Falls, NY (US); **Huai-Hung Kao**, Syosset, NY (US); **Troy W. McCall**, Germantown, TN (US)

(73) Assignee: **Penwest Pharmaceuticals Company**, Danbury, CT (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 216 days.

(21) Appl. No.: **10/189,932**

(22) Filed: **Jul. 3, 2002**

(65) **Prior Publication Data**

US 2003/0129230 A1 Jul. 10, 2003

Related U.S. Application Data

(60) Provisional application No. 60/329,352, filed on Oct. 15, 2001, provisional application No. 60/329,426, filed on Oct. 15, 2001, provisional application No. 60/303,357, filed on Jul. 6, 2001.

(51) **Int. Cl.**
A61K 9/22 (2006.01)
A61K 9/26 (2006.01)
A61K 9/36 (2006.01)

(52) **U.S. Cl.** **424/468**; 424/470; 424/464; 424/479; 424/480; 424/481; 424/482

(58) **Field of Classification Search** 424/468, 424/474, 490, 475, 476, 477, 479, 480, 482, 424/491, 494, 495, 497, 498
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

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3,845,770 A 11/1974 Theeuwes et al.
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(Continued)

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(Continued)

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(Continued)

Primary Examiner—Lakshmi S. Channavajjala
(74) *Attorney, Agent, or Firm*—Wilmer Cutler Pickering Hale & Dorr, LLP

(57) **ABSTRACT**

Sustained release formulations of oxymorphone or pharmaceutically acceptable salts thereof; methods for making the sustained release formulations of oxymorphone or pharmaceutically acceptable salts thereof; and methods for using the sustained release formulations of oxymorphone or pharmaceutically acceptable salts thereof to treat patients suffering from pain are provided.

16 Claims, 1 Drawing Sheet

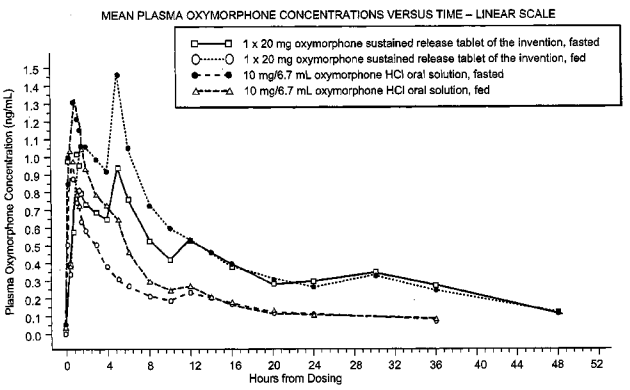

EXHIBIT O

PUBLIC

Press Release

IMPAX Announces FDA Acceptance of ANDA for Generic Version of Opana(R) ER

12/17/2007

HAYWARD, Calif.--(BUSINESS WIRE)--Dec. 17, 2007--IMPAX Laboratories, Inc. (OTC:IPXL) today announced that its Abbreviated New Drug Application (ANDA) for oxymorphone hydrochloride extended-release tablets CII, a generic version of Opana(R) ER, has been deemed acceptable for filing by the U. S. Food and Drug Administration (FDA) as of November 23, 2007. Despite the acceptance, the Company continues to believe that its ANDA as originally filed met all the requirements for acceptance and thus will continue to pursue its administrative remedies with the FDA to reinstate its original filing date of June 29, 2007.

"We also intend to continue to vigorously defend the ongoing patent litigation as previously announced with Endo and Penwest and look forward to prevailing and bringing this important generic product to market," said Larry Hsu, Ph.D., IMPAX's president and chief executive officer.

About IMPAX Laboratories, Inc.

IMPAX Laboratories, Inc. is a technology based specialty pharmaceutical company applying its formulation expertise and drug delivery technology to the development of controlled-release and specialty generics in addition to the development of branded products. IMPAX markets its generic products through its Global Pharmaceuticals division and markets its branded products through the IMPAX Pharmaceuticals division. Additionally, where strategically appropriate, IMPAX has developed marketing partnerships to fully leverage its technology platform. IMPAX Laboratories is headquartered in Hayward, California, and has a full range of capabilities in its Hayward and Philadelphia facilities. For more information, please visit the Company's Web site at: www.impaxlabs.com.

"Safe Harbor" statement under the Private Securities Litigation Reform Act of 1995:

To the extent any statements made in this news release contain information that is not historical, these statements are forward-looking in nature and express the beliefs and expectations of management. Such statements are based on current expectations and involve a number of known and unknown risks and uncertainties that could cause IMPAX's future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Such risks and uncertainties include, but are not limited to, possible adverse effects resulting from the delisting of and suspension of trading in IMPAX's stock, the SEC proceeding to determine whether to suspend or revoke the registration of IMPAX's securities under section 12 of the Securities Exchange Act, IMPAX's delay in filing its 2004 Form 10-K, its Form 10-Q for each of the first three quarters of 2005, 2006, and 2007, its Form 10-K for 2005 and 2006, the actual time that will be required to complete the filing of IMPAX's delinquent periodic reports, IMPAX's ability to obtain sufficient capital to fund its operations, the difficulty of predicting FDA filings and approvals, consumer acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, IMPAX's ability to successfully develop and commercialize pharmaceutical products, IMPAX's reliance on key strategic alliances, the uncertainty of patent litigation, the availability of raw materials, the regulatory environment, dependence on patent and other protection for innovative products,

exposure to product liability claims, fluctuations in operating results and other risks detailed from time to time in IMPAX's filings with the Securities and Exchange Commission. Forward-looking statements speak only as to the date on which they are made, and IMPAX undertakes no obligation to update publicly or revise any forward-looking statement, regardless of whether new information becomes available, future developments occur or otherwise.

CONTACT: IMPAX Laboratories, Inc.
Larry Hsu, Ph.D., President & CEO, 510-476-2000, x1111
Arthur Koch, CFO, 215-933-0351
www.impaxlabs.com
or
Investor Relations Contacts:
Lippert/Heilshorn & Associates, Inc.
Kim Sutton Golodetz, 212-838-3777
kgolodetz@lhai.com
Bruce Voss, 310-691-7100
bvoss@lhai.com
www.lhai.com

SOURCE: IMPAX Laboratories, Inc.

EXHIBIT P

Redacted in entirety

EXHIBIT Q

PUBLIC

Press Release

IMPAX Comments on Lawsuit Related to Generic Version of Opana(R) ER

11/19/2007

HAYWARD, Calif.--(BUSINESS WIRE)--Nov. 19, 2007--IMPAX Laboratories, Inc. (OTC:IPXL) today confirmed that Endo Pharmaceuticals Holdings Inc. and Penwest Pharmaceuticals Co. have filed a lawsuit against the Company in the United States District Court for the District of Delaware alleging patent infringement related to IMPAX's filing of an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA) for oxymorphone hydrochloride extended-release tablets CII, a generic version of Opana(R) ER.

IMPAX's submission includes a Paragraph IV certification stating the Company believes its product does not infringe U.S. Patent Nos. 7,276,250, 5,662,933 and 5,958,456 or that the patents are invalid or unenforceable. The suit alleges infringement of U.S. Patent Nost. 5,662,933 and 5,958,456 and also seeks declaratory judgment that the court to declare that the Paragraph IV Certification Notices that IMPAX served on Endo and Penwest are null, void and of no legal effect and that, therefore, the Court has no subject matter jurisdiction over the patent infringement claims.

"We believe that our Paragraph IV certification for generic Opana ER was proper, that our product does not infringe any valid, enforceable patent, and, as such, we will vigorously defend this lawsuit. Furthermore, we believe that the rescission of our ANDA by the FDA was inappropriate and we are continuing to work with the FDA to allow our ANDA to stand," said Larry Hsu, Ph.D., president and chief executive officer of IMPAX Laboratories.

Endo Pharmaceuticals Holdings Inc. and Penwest Pharmaceuticals Co. manufacture and market Opana ER for the treatment of moderate to severe pain. According to Wolters Kluwer Health, U.S. sales of Opana ER tablets were approximately $48.8 million in the 12 months ended September 30th, 2007.

About IMPAX Laboratories, Inc.

IMPAX Laboratories, Inc. is a technology based specialty pharmaceutical company applying its formulation expertise and drug delivery technology to the development of controlled-release and specialty generics in addition to the development of branded products. IMPAX markets its generic products through its Global Pharmaceuticals division and markets its branded products through the IMPAX Pharmaceuticals division. Additionally, where strategically appropriate, IMPAX has developed marketing partnerships to fully leverage its technology platform. IMPAX Laboratories is headquartered in Hayward, California, and has a full range of capabilities in its Hayward and Philadelphia facilities. For more information, please visit the Company's Web site at: www.impaxlabs.com.

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the results, performance or achievements expressed or implied by such forward-looking statements. Such risks and uncertainties include, but are not limited to, possible adverse effects resulting from the delisting of and suspension of trading in IMPAX's stock, the SEC proceeding to determine whether to suspend or revoke the registration of IMPAX's securities under section 12 of the Securities Exchange Act, IMPAX's delay in filing its 2004 Form 10-K, its Form 10-Q for each of the first three quarters of 2005, 2006, and 2007, its Form 10-K for 2005 and 2006, the actual time that will be required to complete the filing of IMPAX's delinquent periodic reports, IMPAX's ability to obtain sufficient capital to fund its operations, the difficulty of predicting FDA filings and approvals, consumer acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, IMPAX's ability to successfully develop and commercialize pharmaceutical products, IMPAX's reliance on key strategic alliances, the uncertainty of patent litigation, the availability of raw materials, the regulatory environment, dependence on patent and other protection for innovative products, exposure to product liability claims, fluctuations in operating results and other risks detailed from time to time in IMPAX's filings with the Securities and Exchange Commission. Forward-looking statements speak only as to the date on which they are made, and IMPAX undertakes no obligation to update publicly or revise any forward-looking statement, regardless of whether new information becomes available, future developments occur or otherwise.

CONTACT: IMPAX Laboratories, Inc.
Larry Hsu, Ph.D. President & CEO
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or
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Lippert/Heilshorn & Associates, Inc.
Kim Sutton Golodetz, 212-838-3777
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Bruce Voss, 310-691-7100
bvoss@lhai.com
www.lhai.com

SOURCE: IMPAX Laboratories, Inc.

EXHIBIT R

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENDO PHARMACEUTICALS INC. and PENWEST PHARMACEUTICALS CO.,	)	
Plaintiffs,	)	
	)	C. A. No. _____
v.	)	
IMPAX LABORATORIES, INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Endo Pharmaceuticals Inc. ("Endo") and Penwest Pharmaceuticals Co. ("Penwest"), for their Complaint against defendant Impax Laboratories, Inc. ("Impax"), allege as follows.

1. In this action, Endo and Penwest seek to block Impax's abuse of the statutory and regulatory system that Congress has carefully constructed for resolving patent disputes when a drug company seeks approval to market a generic version of a branded drug product by filing an Abbreviated New Drug Application ("ANDA").

2. As Impax has publicly acknowledged, it does not even have an ANDA actually on file with respect to Endo's OPANA® ER pain relief product. The U.S. Food and Drug Administration ("FDA") rescinded its initial acceptance of Impax's ANDA.

3. Undaunted by this fact, however, and in direct defiance of FDA's decision to rescind acceptance of its ANDA and direct violation of applicable FDA regulations, Impax has forged ahead and tried to trigger the ANDA litigation process. The reason for Impax's improper conduct is clear—Impax wants to gain an unfair and unlawful advantage against Endo, Penwest, and Impax's generic competitors, in the hope that it can reap the

31. Impax Notice 1 also advised Penwest and Endo that Impax's ANDA included a Paragraph IV Certification that, in Impax's opinion, the proposed manufacture, importation, use or sale of the generic oxymorphone hydrochloride extended-release tablets described in its ANDA would not infringe any claim of the '250 patent. Impax did not assert that the '250 patent was either invalid or unenforceable.

The Impax Press Release

32. On October 4, 2007, Impax issued a press release ("Impax Press Release") stating it had submitted an ANDA to FDA and had sent Penwest and Endo a Paragraph IV Notice.

33. In the Impax Press Release, Impax stated that its Paragraph IV Notice asserted that the proposed generic oxymorphone hydrochloride extended-release tablets described in its ANDA would not infringe any claim of the '250 patent, *and* that those claims are invalid and/or unenforceable. A true and correct copy of the Impax Press Release is attached as Exhibit D.

34. The Impax Press Release was false, as Impax Notice 1 does not assert that the '250 patent is invalid or unenforceable.

35. Furthermore, notwithstanding the fact that it had served a purported Paragraph IV Notice on Endo and Penwest, Impax admitted in the Impax Press Release that FDA *"has rescinded its initial acceptance"* of its ANDA and that its was *"working with the FDA to correct any deficiencies of the ANDA."*

36. Thus, no later than October 4, 2007, and upon information and belief before that date, Impax was well aware that it did not have a valid and subsisting ANDA that

EXHIBIT S

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENDO PHARMACEUTICALS INC. and PENWEST PHARMACEUTICALS CO.,	)	
Plaintiffs,	)	
v.	)	C. A. No. _____
IMPAX LABORATORIES, INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Endo Pharmaceuticals Inc. ("Endo") and Penwest Pharmaceuticals Co. ("Penwest"), for their Complaint against defendant Impax Laboratories, Inc. ("Impax"), allege as follows.

PARTIES

1. Endo is a Delaware corporation, having its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317. Endo is a specialty pharmaceutical company engaged in the research, development, sale and marketing of prescription pharmaceuticals used primarily to treat and manage pain, including OPANA® ER.

2. Penwest is a Washington corporation, having its principal place of business at 39 Old Ridgebury Road, Suite 11, Danbury, Connecticut 06810-5120. Penwest is a drug development company focused primarily on the identification, development and commercialization of products for diseases of the nervous system using its expertise in drug development and drug delivery technology, including the extended-release technology used in OPANA® ER.

3. Upon information and belief, Impax is a Delaware corporation, having its principal place of business at 30831 Huntwood Avenue, Hayward, California 94544.

oxymorphone hydrochloride extended-release tablets prior to the expiration of the '933 and '456 patents (the "Impax Notice").

17. The Impax Notice advised Penwest and Endo that Impax's ANDA included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "paragraph IV certification") that, in Impax's opinion, the proposed manufacture, importation, use or sale of the generic oxymorphone hydrochloride extended-release tablets described in its ANDA would not infringe any claim of the '933 or '456 patents.

18. In the Impax Notice, Impax did not assert that either patent is invalid.

COUNT I

INFRINGEMENT OF THE '456 PATENT

19. Plaintiffs incorporate each of the preceding paragraphs 1 to 18 as if fully set forth herein.

20. Impax's submission of an amended ANDA to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '456 patent under 35 U.S.C. § 271(e)(2)(A).

21. Impax's commercial manufacture, offer for sale or sale of its proposed generic oxymorphone hydrochloride extended-release tablets would infringe the '456 patent.

22. Upon information and belief, Impax was aware of the existence of the '456 patent as demonstrated by its reference to that patent in its ANDA, and was aware that the filing of its Paragraph IV Certification with respect to the '456 patent constitutes infringement of that patent. This is an exceptional case.

EXHIBIT T

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENDO PHARMACEUTICALS INC. and PENWEST PHARMACEUTICALS CO.,	)	
Plaintiffs,	)	C. A. No. _____
v.	)	
IMPAX LABORATORIES, INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Endo Pharmaceuticals Inc. ("Endo") .and Penwest Pharmaceuticals Co. ("Penwest"), for their Complaint against defendant Impax Laboratories, Inc. ("Impax"), allege as follows.

PARTIES

1. Endo is a Delaware corporation, having its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317. Endo is a specialty pharmaceutical company engaged in the research, development, sale and marketing of prescription pharmaceuticals used primarily to treat and manage pain, including OPANA®ER.

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review by FDA as of November 23, 2007." The FDA's letter also requested that Impax provide the notice and information required by 21 U.S.C. §§ 355(j)(2)(B)(i).

16. On December 13, 2007, Impax sent Penwest and Endo a notice stating that it had submitted ANDA No. 79-087 seeking approval to manufacture, use, or sell generic oxymorphone hydrochloride extended-release tablets prior to the expiration of the '933 and '456 patents (the "Impax Notice").

17. The Impax Notice advised Penwest and Endo that Impax's ANDA included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "paragraph IV certification") that, in Impax's opinion, the proposed manufacture, importation, use or sale of the generic oxymorphone hydrochloride extended-release tablets described in its ANDA would not infringe any claim of the '933 or '456 patents.

18. In the Impax Notice, Impax did not assert that either patent is invalid.

19. On January 25, 2008, Endo and Penwest filed a complaint against Impax in the District of Delaware alleging patent infringement of the '456 and '933 patents. In their complaint, Penwest and Endo asserted that Actavis's submission of an ANDA to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constituted infringement of the '456 and '933 patents under 35 U.S.C. § 271(e)(2)(A). This matter is Civil Action No. 08-057 (GMS) and is currently pending in this district.

20. On June 13, 2008, Impax sent Penwest and Endo another notice stating that it had submitted an amendment to ANDA No. 79-087 seeking approval to manufacture, use, or sell generic oxymorphone hydrochloride extended-release tablets at the 7.5 mg, 15 mg, and 30 mg strengths prior to the expiration of the '933 and '456 patents.

EXHIBIT U

Redacted in entirety

EXHIBIT V

Redacted in entirety

EXHIBIT W

Redacted in entirety

EXHIBIT X

Redacted in entirety

EXHIBIT Y

PUBLIC

Press Release

Impax Laboratories Receives Tentative FDA Approval for Generic Opana(R) ER 5, 7.5, 10, 15, 20, 30 and 40 mg Tablets

05/14/2010

HAYWARD, Calif., May 14, 2010 (BUSINESS WIRE) --**Impax Laboratories, Inc.(NASDAQ: IPXL)** today confirmed that the U.S. Food and Drug Administration (FDA) has granted tentative approval of the Company's Abbreviated New Drug Application (ANDA) for generic version of Opana(R) ER (oxymorphone hydrochloride) 5, 7.5, 10, 15, 20, 30 and 40 mg tablets. Endo Pharmaceuticals Inc. markets Opana(R) ER for the treatment of moderate to severe pain.

According to Wolters Kluwer Health, U.S. sales of Opana(R) ER tablets were approximately $241 million for the 12 months ended March 31, 2010.

About Impax Laboratories, Inc.

Impax Laboratories, Inc. is a technology based specialty pharmaceutical company applying its formulation expertise and drug delivery technology to the development of controlled-release and specialty generics in addition to the development of branded products. Impax markets its generic products through its Global Pharmaceuticals division and markets its branded products through the Impax Pharmaceuticals division. Additionally, where strategically appropriate, Impax has developed marketing partnerships to fully leverage its technology platform. Impax Laboratories is headquartered in Hayward, California, and has a full range of capabilities in its Hayward and Philadelphia facilities. For more information, please visit the Company's Web site at:www.impaxlabs.com.

"*Safe Harbor" statement under the Private Securities Litigation Reform Act of 1995:*

To the extent any statements made in this news release contain information that is not historical, these statements are forward-looking in nature and express the beliefs and expectations of management. Such statements are based on current expectations and involve a number of known and unknown risks and uncertainties that could cause the Company's future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Such risks and uncertainties include, but are not limited to, the effect of current economic conditions on the Company's industry, business, financial position, results of operations and market value of its common stock, the ability to maintain an effective system of internal control over financial reporting, fluctuations in revenues and operating income, reductions or loss of business with any significant customer, the impact of competitive pricing and products and regulatory actions on the Company's products, the ability to sustain profitability and positive cash flows, the ability to maintain sufficient capital to fund operations, any delays or unanticipated expenses in connection with the operation of the Taiwan facility, the ability to successfully develop and commercialize pharmaceutical products, the uncertainty of patent litigation, consumer acceptance and demand for new pharmaceutical products, the difficulty of predicting Food and Drug Administration filings and approvals, the inexperience of the Company in conducting clinical trials and submitting new drug applications, reliance on key alliance and collaboration agreements, the availability of raw materials, the ability to comply with legal and regulatory requirements governing the healthcare industry, the regulatory environment, exposure to product liability claims and other risks described in the Company's periodic reports filed with the Securities

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and Exchange Commission. Forward-looking statements speak only as to the date on which they are made, and Impax undertakes no obligation to update publicly or revise any forward-looking statement, regardless of whether new information becomes available, future developments occur or otherwise.

SOURCE: Impax Laboratories, Inc.

Impax Laboratories, Inc.
Mark Donohue, 215-933-3526
Sr. Director, Investor Relations and Corporate Communications
www.impaxlabs.com

EXHIBIT Z

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MINUTES OF PROCEEDINGS

NEWARK **DATE:** 6/3/10

JUDGE: **HAYDEN**

CASE: 09-831
09-836

COURT REPORTER: **Ralph Florio**

Deputy Clerk: **RoseMarie Guilloty**

Title of Case:

Endo v. Impax
Endo v. Sandoz, Inc.

APPEARANCES:

Marin Black, Esq for pltf
Robert Rhoad, Esq for pltf
Kevin Flannery, Esq for pltf
Ron Shulma Esq for defts
Michael Berta, Esq for defts
Jennifer Koh, Esq for defts
Kerry Mctigue, Esq for defts
Vincent Capuano, Esq for defts
Richard Ruzich, Esq for defts

Nature of proceedings:

Bench trial moved at 9:00 a.m.
Plaintiff calls witness Demir Bingol to the stand.
Witness sowrn.
Cross as to witness Bingol.
Redirect of witness Bingol.
Plaintiff calls witness Anthony Lowman to the stand.
Witness sworn.
Lunch recess from 1:00 until 2:00.
Plaintiff continued direct of witness Lowman.

Plaintiff's exhibits admitted.
Defendant's exhibits admitted.

Bench trial adj. @ 4:00 p.m. until 6/8/10 @ 9:00 a.m.

Time in court: 6:00

RoseMarie Guilloty
RoseMarie Guilloty, Deputy Clerk

cc: chambers

EXHIBIT AA

Redacted in entirety

EXHIBIT BB

Redacted in entirety

EXHIBIT CC

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

201655Orig1s000

Trade Name: OPANA, ER

Generic Name: Oxymorphone Hydrochloride Extended-Release Tablets, CII

Sponsor: Endo Pharmaceuticals, Inc.

Approval Date: 12/09/2011

Indications:

OPANA ER is an opioid agonist indicated for the relief of moderate to severe pain in patients requiring continuous around-the-clock opioid treatment for an extended period of time.
Not intended for use as an as needed analgesic. Not indicated in the immediate post-operative period or if the pain is mild or not expected to persist for an extended period of time.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

201655Orig1s000

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	**X**
Other Action Letters	**X**
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Summary Review	**X**
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Office Director Memo	
Cross Discipline Team Leader Review	**X**
Medical Review(s)	**X**
Chemistry Review(s)	**X**
Environmental Assessment	**X**
Pharmacology Review(s)	**X**
Statistical Review(s)	**X**
Microbiology Review(s)	**X**
Clinical Pharmacology/Biopharmaceutics Review(s)	**X**
Other Reviews	**X**
Risk Assessment and Risk Mitigation Review(s)	**X**
Proprietary Name Review(s)	**X**
Administrative/Correspondence Document(s)	**X**

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

201655Orig1s000

APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 201655

NDA APPROVAL

Endo Pharmaceuticals Inc.
100 Endo Boulevard
Chadds Ford, PA 19317

Attention: Tara Chapman, Pharm.D.
Director, Regulatory Affairs

Dear Dr. Chapman:

Please refer to your New Drug Application (NDA) dated July 7, 2010, received July 7, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for OPANA ER (oxymorphone hydrochloride) Extended-Release Tablets, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg.

We also refer to our approval letter dated December 9, 2011, which contained the following error: The statement granting an expiration dating period of (b) (4) months was incorrect.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain December 9, 2011, the date of the original approval letter.

We acknowledge receipt of your amendments dated July 23, August 27 and 30, September 9, 14, and 29, October 1, 6, 12, 13, and 27, November 4 and 12, and December, 6, 17, 27, 28, and 29, 2010, and January 3, 6, and 14, February 22, June 13, July 8, September 7 and 30, October 6, and November 9, 16, 21, and 30, 2011.

The June 13, 2011, submission constituted a complete response to our January 7, 2011, action letter.

This new drug application provides for the use of OPANA ER (oxymorphone hydrochloride) Extended-Release Tablets for the management of moderate to severe chronic pain in adults when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling text for the package insert and Medication Guide). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your November 9, 2011, submission containing final printed carton and container labels.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

On April 18, 2011, you were notified that in accordance with section 505-1 of the FDCA, we have determined that a risk evaluation and mitigation strategy (REMS) is necessary for certain long-acting and extended-release (LA/ER) opioid products, including OPANA ER (oxymorphone hydrochloride) Extended-Release Tablets, to ensure that the benefits of the drugs continue to outweigh the risks of adverse outcomes (addiction, unintentional overdose, and death) resulting from inappropriate prescribing, abuse, and misuse, and we notified you of the elements of the REMS that would be required. You were also notified that, in the interest of public health and to minimize the burden on the healthcare delivery system of having multiple unique REMS programs, a single, shared system should be used to implement the REMS for all members of the class.

While the class-wide REMS, including the single shared system, is being developed, your proposed interim REMS, submitted on November 21, 2011, and appended to this letter, is approved. This interim REMS consists of a Medication Guide, elements to assure safe use, and a timetable for submission of assessments of the REMS. We believe this interim REMS provides for management of the risks of adverse outcomes (addiction, unintentional overdose, and death) that is comparable to the REMS that we have determined is necessary for the class of LA/ER opioid products and is designed to ensure that the benefits of OPANA ER (oxymorphone hydrochloride) Extended-Release Tablets continue to outweigh its risks while the single shared system, class-wide REMS is being developed.

We expect you to be working with the Industry Working Group (IWG) to develop the class-wide REMS. Prior to the implementation of the class-wide REMS, we will notify you in writing and you will be required to submit a proposed modified REMS that conforms to the class-wide REMS. The assessment plan requirements for this REMS were also described in the April 18, 2011, letter, and in that letter, FDA strongly recommended that sponsors make provision in the single shared system for joint assessments of the effectiveness of the REMS.

Your interim REMS must be fully operational before you introduce OPANA ER (oxymorphone hydrochloride) Extended-Release Tablets into interstate commerce.

The interim REMS assessment plan should include, but is not limited to, the following:

1. An evaluation of patients' understanding of the serious risks of OPANA ER (oxymorphone hydrochloride) Extended-Release Tablets.

2. A report on periodic assessments of the distribution and dispensing of the Medication Guide in accordance with 21 CFR 208.24.

3. A report on failures to adhere to distribution and dispensing requirements, and corrective actions taken to address noncompliance.

4. An evaluation of healthcare providers' understanding of the serious risks of OPANA ER (oxymorphone hydrochloride) Extended-Release Tablets

5. An assessment of the extent to which the elements to assure safe use are meeting the goal or goals to mitigate a specific serious risk listed in the labeling of the drug, or whether the goal or goals or such elements should be modified.

6. Information on the status of any postapproval study or clinical trial required under section 505(o) or otherwise undertaken to investigate a safety issue. With respect to any such postapproval study, you must include the status of such study, including whether any difficulties completing the study have been encountered. With respect to any such postapproval clinical trial, you must include the status of such clinical trial, including whether enrollment has begun, the number of participants enrolled, the expected completion date, whether any difficulties completing the clinical trial have been encountered, and registration information with respect to requirements under subsections (i) and (j) of section 402 of the Public Health Service Act. You can satisfy these requirements in your REMS assessments by referring to relevant information included in the most recent annual report required under section 506B and 21 CFR 314.81(b)(2)(vii) and including any material or significant updates to the status information since the annual report was prepared. Failure to comply with the REMS assessments provisions in section 505-1(g) could result in enforcement action.

We remind you that section 505-1(f)(8) of FDCA prohibits holders of an approved covered application with elements to assure safe use from using any element to block or delay approval

of an application under section 505(b)(2) or (j). A violation of this provision in 505-1(f) could result in enforcement action.

We also remind you that, in addition to the assessments submitted according to the timetable included in the approved REMS, you must submit a REMS assessment and may propose a modification to the approved REMS when you submit a supplemental application for a new indication for use as described in section 505-1(g)(2)(A) of the FDCA.

An authorized generic drug under this NDA must have an approved REMS prior to marketing. Should you decide to market, sell, or distribute an authorized generic drug under this NDA, contact us to discuss what will be required in the authorized generic drug REMS submission. Prominently identify the submission containing the REMS assessments or proposed modifications with the following wording in bold capital letters at the top of the first page of the submission:

NDA 201655 REMS ASSESSMENT

NEW SUPPLEMENT FOR NDA 201655
PROPOSED REMS MODIFICATION
REMS ASSESSMENT

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA 201655
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

If you do not submit electronically, please send 5 copies of REMS-related submissions.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing,

Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

EXPIRATION DATING PERIOD

An expiration dating period of 36 months is granted for OPANA ER (oxymorphone hydrochloride) Extended-Release Tablets, stored at 25° C (77° F) with excursions permitted from 15° to 30°C (59°-86°F).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

In addition to the standard reporting requirements for an approved NDA, we request that you submit as 15-day expedited reports, all post-marketing and clinical trial cases of choking, gagging, sticking, and gastrointestinal obstruction, regardless of whether these reports are classified as serious or unexpected, and that you provide analyses of clinical trial and post-marketing reports of these adverse events of special interest in your periodic safety update reports.

If you have any questions, call Lisa Basham, M.S., Senior Regulatory Health Project Manager, at (301) 796-1175.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, M.D.
Director
Division of Anesthesia, Analgesia,
and Addiction Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURES:
Content of Labeling
Carton and Container Labeling
REMS

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

BOB A RAPPAPORT
12/09/2011

EXHIBIT DD

PUBLIC

News Release

Endo Completes Transition of OPANA® ER Franchise to New Formulation Designed to be Crush Resistant

CHADDS FORD, Pa., June 14, 2012 /PRNewswire/ -- Endo Health Solutions (Nasdaq: ENDP), today announced the completion of the company's transition of its OPANA ER franchise to the new formulation designed to be crush resistant. In connection with the completion of this transition, the U.S. Food and Drug Administration (FDA) has moved the old formulation of OPANA ER to the Orange Book Discontinued List.

"While the original formulation of OPANA ER was deemed by FDA to be safe and effective when taken according to the prescribing information, the original formulation was subject to both intentional and inadvertent abuse and misuse," said Dr. Ivan Gergel, chief scientific officer of Endo. "Patient safety is our top concern and addressing appropriate use of opioids is a responsibility that we take very seriously. We firmly believe that the new formulation of OPANA ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers."

As a result of the FDA placing OPANA ER (NDA 21-610) in the Orange Book Discontinued List, all strengths of the original formulation of OPANA ER are now on the Discontinued List. The OPANA ER (NDA 21-610) 7.5 mg and 15 mg dosage strengths were moved to the Discontinued List previously. The new formulation of OPANA ER designed to be crush resistant (under NDA 201655) remains on the approved prescription drug product list as it is the only currently available formulation.

About Endo

Endo Health Solutions Inc. (Endo) is a US-based diversified healthcare company that is redefining healthcare value by finding solutions for the unmet needs of patients along care pathways for pain management, pelvic health, urology, endocrinology and oncology. Through our operating companies: AMS, Endo Pharmaceuticals, HealthTronics and Qualitest, Endo is dedicated to improving care through a combination of branded products, generics, devices, technology and services that creates maximum value for patients, providers and payers alike. Learn more at www.endo.com.

Safe Harbor Statement

PUBLIC

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Statements including words such as "believes," "expects," "anticipates," "intends," "estimates," "plan," "will," "may," "look forward," "intend," "guidance," "future" or similar expressions are forward-looking statements. Because these statements reflect our current views, expectations and beliefs concerning future events, these forward-looking statements involve risks and uncertainties. Investors should note that many factors, as more fully described under the caption "Risk Factors" in our Form 10-K, Form 10-Q and Form 8-K filings with the Securities and Exchange Commission and as otherwise enumerated herein or therein, could affect our future financial results and could cause our actual results to differ materially from those expressed in forward-looking statements contained in our Annual Report on Form 10-K. The forward-looking statements in this press release are qualified by these risk factors. These are factors that, individually or in the aggregate, could cause our actual results to differ materially from expected and historical results. We assume no obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

SOURCE Endo Health Solutions Inc.

Investors/Media, Blaine Davis, +1-610-459-7158, Media, Kevin Wiggins, +1-610-459-7281, Investors, Jonathan Neely, +1-610-459-6645

EXHIBIT EE

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

(Mark One)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**
For the fiscal year ended December 31, 2012

Or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**
For the transition period from to

Commission file number: 001-15989

ENDO HEALTH SOLUTIONS INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**13-4022871**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
1400 Atwater Drive, Malvern, Pennsylvania	**19355**
(Address of Principal Executive Offices)	(Zip Code)

(Registrant's Telephone Number, Including Area Code): (484) 216-0000

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock of $0.01 par value	**The NASDAQ Global Select Market**

Securities registered pursuant to Section 12(g) of the Act: N/A

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.	Yes x No o
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act.	Yes o No x
Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Sections 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.	Yes x No o
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every interactive data file required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months.	Yes x No o
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.	x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act

Large Accelerated Filer	x	Accelerated Filer	o	Non-accelerated filer	o	Smaller reporting company	o

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).	Yes o No x

The aggregate market value of the voting common equity held by non-affiliates as of June 30, 2012 was $3,600,317,403 based on a closing sale price of $30.98 per share as reported on the NASDAQ Global Select Market on June 30, 2012. Shares of the registrant's common stock held by each officer and director and each beneficial owner of 10% or more of the outstanding common

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5,827,529, which covers the formulation of Lidoderm®. This patent is listed in the FDA's Orange Book and expires in October 2015. On June 29, 2012, EPI filed a lawsuit against Noven in the U.S. District Court for the District of Delaware. Because the suit was filed within the 45-day period under the Hatch-Waxman Act for filing a patent infringement action, we believe that it triggered an automatic 30-month stay of approval under the Act.

On May 24, 2012, EPI and Teikoku received a Paragraph IV Notice from TWi Pharmaceuticals, Inc. (TWi) advising of its filing of an ANDA for a generic version of Lidoderm® (lidocaine topical patch 5%). The Paragraph IV Notice refers to U.S. Patent Nos. 5,827,529 and 5,741,510, which cover the formulation of Lidoderm®. These patents are listed in the FDA's Orange Book and expire in October 2015 and March 2014, respectively. On July 5, 2012, EPI filed a lawsuit against TWi in the U.S. District Court for the District of Delaware. Because the suit was filed within the 45-day period under the Hatch-Waxman Act for filing a patent infringement action, we believe that it triggered an automatic 30-month stay of approval under the Act.

Endo intends, and has been advised by Teikoku that they too intend, to vigorously defend the intellectual property rights relating to Lidoderm® and to pursue all available remaining legal and regulatory avenues in defense of Lidoderm®, including enforcement of the product's intellectual property rights and approved labeling. However, there can be no assurance that we will be successful. If we are unsuccessful and any one of the above generic manufacturers is able to obtain FDA approval of its product, that generic manufacturer may be able to launch its generic version of Lidoderm® prior to the applicable patents' expirations in 2014 and 2015. Additionally, we cannot predict or determine the timing or outcome of ongoing litigation but will explore all options as appropriate in the best interests of the Company. In addition to the above litigation, it is possible that another generic manufacturer may also seek to launch a generic version of Lidoderm® and challenge the applicable patents.

Paragraph IV Certifications on Opana® ER

As previously reported, starting in December 2007 through December 2011, EPI received Paragraph IV Notices from various generic drug manufacturers, including Impax Laboratories, Inc. (Impax), Actavis South Atlantic LLC (Actavis), Sandoz, Inc. (Sandoz), Barr Laboratories, Inc. (Teva), Watson Laboratories, Inc. (Watson), Roxane Laboratories, Inc. (Roxane) and most recently, Ranbaxy Inc. (Ranbaxy) advising of the filing by each such company of an ANDA for a generic version of the non-crush resistant formulation of Opana® ER (oxymorphone hydrochloride extended-release tablets CII). To date, EPI settled all of the Paragraph IV litigation relating to the non-crush resistant formulation of Opana® ER. Under the terms of the settlements, each generic manufacturer agreed not to challenge the validity or enforceability of patents relating to the non-crush resistant formulation of Opana® ER. As a result, Actavis launched its generic non-crush resistant Opana® ER 7.5 and 15 mg tablets on July 15, 2011, and Impax launched its generic non-crush resistant Opana® ER 5, 10, 20, 30 and 40 mg tablets on January 2, 2013. We expect Sandoz, Teva, Watson, Roxane and Actavis to launch production and sale of all strengths of their respective versions of generic non-crush resistant Opana® ER during the third quarter of 2013. We evaluated Ranbaxy's Paragraph IV Notice and concluded that we will not sue Ranbaxy at this time. As a result, and because Ranbaxy filed a Paragraph III notice against two patents expiring September 9, 2013, we expect Ranbaxy to launch all strengths of its generic non-crush resistant Opana® ER on September 9, 2013.

On December 11, 2012, EPI filed a Complaint against Actavis South Atlantic LLC (Actavis) in the United States District Court for the District of New Jersey claiming false advertising and calling for Actavis to cease and desist promoting its non-crush resistant formulation of Opana® ER product as AB rated, or bioequivalent, to the crush-resistant formulation of Opana® ER. On February 5, 2013, Endo filed a Motion for Preliminary Injunction with the court requesting the court enjoin Actavis from further false advertising. That Motion is pending before the court.

Pursuant to the June 2010 Settlement and License Agreement (the Impax Settlement Agreement) with Impax, EPI agreed to provide a payment to Impax should prescription sales of the non-crush resistant formulation of Opana® ER, as defined in the Impax Settlement Agreement, fall below a predetermined contractual threshold in the quarter immediately prior to the date on which Impax was authorized to launch its generic version of the non-crush resistant formulation of Opana® ER, which occurred on January 2, 2013. During the first quarter of 2012, the Novartis shut-down of its Lincoln, Nebraska manufacturing facility and resulting lack of 2012 oxymorphone active pharmaceutical ingredient (API) quota granted by the DEA to Novartis caused EPI to attempt an accelerated launch of the crush-resistant formulation of Opana® ER. While significant uncertainties existed throughout the first quarter of 2012 about our ability to rapidly ramp up production of the formulation designed to be crush-resistant and produce finished goods at a new, untested manufacturing facility in a very short period of time, we were able to do so in March 2012. Accordingly, the Company recognized a liability under the Impax Settlement Agreement upon the Company's sale of the formulation designed to be crush-resistant, which occurred in March 2012. The total charge of $102.0 million was recorded in Cost of revenues in our 2012 Consolidated Financial Statements.

From September 21, 2012 through February 6, 2013, EPI and its partner Grünenthal received Paragraph IV Notices from each of Teva Pharmaceuticals USA, Inc. (Teva), Amneal Pharmaceuticals, LLC, Sandoz Inc., ThoRx Laboratories, Inc. (ThoRx), Par Pharmaceuticals (Par), Actavis South Atlantic LLC (Actavis), and Impax Pharmaceuticals (Impax), advising of the filing by each such company of an ANDA for a generic version of the formulation of Opana® ER designed to be crush-resistant. These Paragraph IV Notices refer to U.S. Patent Nos. 8,075,872, 8,114,383, 8,192,722, 7,851,482, 8,309,060, 8,309,122 and 8,329,216, which variously

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cover the formulation of Opana® ER, a highly pure version of the active pharmaceutical ingredient and the release profile of Opana® ER. EPI filed lawsuits against each of these filers in the US District Court for the Southern District of New York. Each lawsuit was filed within the 45-day deadline to invoke a 30-month stay of FDA approval pursuant to the Hatch-Waxman legislative scheme. EPI intends, and has been advised by Grünenthal that they too intend, to vigorously defend the intellectual property rights covering Opana® ER and to pursue all available legal and regulatory avenues in defense of Opana® ER, including enforcement of the product's intellectual property rights and approved labeling. However, there can be no assurance that we will be successful. If we are unsuccessful and Teva, Amneal, Sandoz, ThoRx, Par, Actavis or Impax is able to obtain FDA approval of its product, it may be able to launch a generic version of Opana® ER prior to the applicable patents' expirations in 2023 through 2029. Additionally, we cannot predict or determine the timing or outcome of this defense but will explore all options as appropriate in the best interests of the Company. In addition to the above litigation, it is possible that another generic manufacturer may also seek to launch a generic version of Opana® ER and challenge the applicable patents.

Paragraph IV Certification on Fortesta® Gel

On January 18, 2013, EPI and its licensor Strakan Limited received a notice from Watson advising of the filing by Watson of an ANDA for a generic version of Fortesta® (testosterone) Gel. On February 28, 2013, EPI filed a lawsuit against Watson in the U.S. District Court for the Eastern District of Texas, Marshall division. Because the suit was filed within the 45-day period under the Hatch-Waxman Act for filing a patent infringement action, we believe that it triggered an automatic 30-month stay of approval under the Act.

Endo intends to vigorously defend Fortesta® Gel and to pursue all available legal and regulatory avenues in defense of Fortesta® Gel, including enforcement of the product's intellectual property rights and approved labeling. However, there can be no assurance that we will be successful. If we are unsuccessful and Watson is able to obtain FDA approval of its product, Watson may be able to launch its generic version of Fortesta® Gel prior to the applicable patents' expirations in 2018. Additionally, we cannot predict or determine the timing or outcome of this litigation but will explore all options as appropriate in the best interests of the Company. In addition to the above litigation, it is possible that another generic manufacturer may also seek to launch a generic version of Fortesta® Gel and challenge the applicable patents.

Paragraph IV Certification on Frova®

As previously reported, in July 2011, EPI and its licensor, Vernalis Development Limited received a notice from Mylan Technologies Inc. (Mylan) advising of the filing by Mylan of an ANDA for a generic version of Frova® (frovatriptan succinate) 2.5 mg tablets. Mylan's notice included a Paragraph IV Notice with respect to U.S. Patent Nos. 5,464,864, 5,561,603, 5,637,611, 5,827,871 and 5,962,501, which cover Frova®. These patents are listed in the FDA's Orange Book and expire between 2013 and 2015. As a result of this Paragraph IV Notice, on August 16, 2011, EPI filed a lawsuit against Mylan in the U.S. District Court for the District of Delaware alleging infringement of U.S. Patent Nos. 5,464,864, 5,637,611 and 5,827,871. Because the suit was filed within the 45-day period under the Hatch-Waxman Act for filing a patent infringement action, we believe that it triggered an automatic 30-month stay of approval under the Act. On September 22, 2011, Mylan filed an Answer and Counterclaims, claiming the asserted patents are invalid or not infringed.

Endo intends to vigorously defend its intellectual property rights and to pursue all available legal and regulatory avenues in defense of Frova®, including enforcement of the product's intellectual property rights and approved labeling. However, there can be no assurance that we will be successful. If we are unsuccessful and Mylan is able to obtain FDA approval of its product, Mylan may be able to launch its generic version of Frova® prior to the applicable patents' expirations in 2014 and 2015. Additionally, we cannot predict or determine the timing or outcome of this litigation but will explore all options as appropriate in the best interests of the Company. In addition to the above litigation, it is possible that another generic manufacturer may also seek to launch a generic version of Frova® and challenge the applicable patents.

Other Legal Proceedings

In addition to the above proceedings, we are involved in, or have been involved in, arbitrations or various other legal proceedings that arise from the normal course of our business. We cannot predict the timing or outcome of these claims and other proceedings. Currently, we are not involved in any arbitration and/or other legal proceeding that we expect to have a material effect on our business, financial condition, results of operations and cash flows.

EXHIBIT FF

12 CIV 9261

PUBLIC

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

ENDO PHARMACEUTICALS INC., and GRÜNENTHAL GMBH,

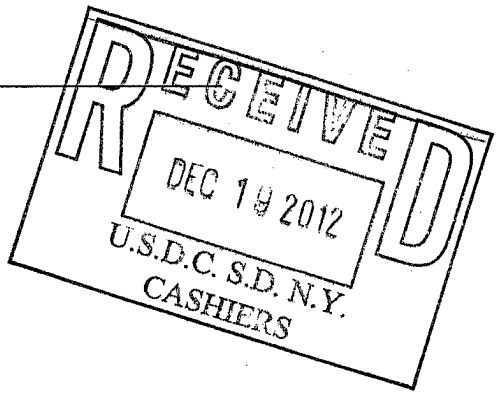
Plaintiffs,

v.

PAR PHARMACEUTICAL COMPANIES, INC., and PAR PHARMACEUTICAL, INC.,

Defendants.

C.A. No. _____



COMPLAINT

Plaintiffs Endo Pharmaceuticals Inc. ("Endo"), and Grünenthal GmbH ("Grünenthal") for their Complaint against defendants Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. (collectively "Par" or "Defendants"), allege as follows:

PARTIES

1. Plaintiff Endo is a Delaware corporation, having its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317. Endo is a specialty pharmaceuticals company engaged in the research, development, sale and marketing of prescription pharmaceuticals used, among other things, to treat and manage pain. Endo markets and distributes OPANA® ER, an innovative crush-resistant opioid tablet (alternatively referred to herein as "Opana ER CRF").

2. Plaintiff Grünenthal is a corporation organized and existing under the laws of Germany, having an address at 52078 Aachen, Zieglerstaβe 6, North Rhine-Westaphalia, Germany.

58. Par's commercial manufacture, offer for sale, or sale of its ANDA Products would infringe the '722 Patent under 35 U.S.C. § 271(a)-(c).

59. Any launch by Par of its ANDA Products before expiration of the '722 Patent would cause Endo to suffer immediate and irreparable harm.

60. Par was aware of the existence of the '722 Patent, as demonstrated by its reference to that patent in the Par Notice Letters, and was aware that the filing of its Paragraph IV Certification with respect to the '722 Patent would constitute infringement of the patent.

COUNT IV: INFRINGEMENT OF THE '122 PATENT

61. Endo incorporates each of paragraphs 1-42 above as if set forth fully herein.

62. The submission of Par's ANDA to FDA constitutes infringement of the '122 Patent under 35 U.S.C. § 271(e)(2)(A).

63. Par is seeking FDA approval to engage in the commercial manufacture, use, or sale of its ANDA Products before the expiration of the '122 Patent. If granted approval, Par intends to launch its ANDA Products before expiration of the '122 Patent.

64. Par's commercial manufacture, offer for sale, or sale of its ANDA Products would infringe the '122 Patent under 35 U.S.C. § 271(a)-(c).

65. Any launch by Par of its ANDA Products before expiration of the '122 Patent would cause Endo to suffer immediate and irreparable harm.

COUNT V: INFRINGEMENT OF THE '216 PATENT

66. Endo incorporates each of paragraphs 1-42 above as if set forth fully herein.

67. The submission of Par's ANDA to FDA constitutes infringement of the '216 Patent under 35 U.S.C. § 271(e)(2)(A).

68. Par is seeking FDA approval to engage in the commercial manufacture, use, or

sale of its ANDA Products before the expiration of the '216 Patent. If granted approval, Par intends to launch its ANDA Products before expiration of the '216 Patent.

69. Par's commercial manufacture, offer for sale, or sale of its ANDA Products would infringe the '216 Patent under 35 U.S.C. § 271(a)-(c).

70. Any launch by Par of its ANDA Products before expiration of the '122 Patent would cause Endo to suffer immediate and irreparable harm.

COUNT VI: INFRINGEMENT OF THE '060 PATENT

71. Plaintiffs incorporate each of paragraphs 1-42 above as if set forth fully herein.

72. The submission of Par's ANDA to FDA constitutes infringement of the '060 Patent under 35 U.S.C. § 271(e)(2)(A).

73. Par is seeking FDA approval to engage in the commercial manufacture, use, or sale of its ANDA Products before the expiration of the '060 Patent. If granted approval, Par intends to launch its ANDA Products before expiration of the '060 Patent.

74. Par's commercial manufacture, offer for sale, or sale of its ANDA Products would infringe the '060 Patent under 35 U.S.C. § 271(a)-(c).

75. Any launch by Par of its ANDA Products before expiration of the '060 Patent would cause Endo and Grünenthal to suffer immediate and irreparable harm.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Endo and Grünenthal respectfully request the following relief:

A. A judgment that Par has infringed the '482 Patent, and a declaration that Par's commercial manufacture, distribution, use, and sale of its ANDA Products would infringe the '482 Patent;

B. A declaration that the '482 Patent is valid and enforceable;

EXHIBIT GG

US008871779B2

(12) **United States Patent**
Buehler et al.

(10) **Patent No.: US 8,871,779 B2**
(45) **Date of Patent: Oct. 28, 2014**

(54) **PROCESS FOR PREPARING MORPHINAN-6-ONE PRODUCTS WITH LOW LEVELS OF α,β-UNSATURATED KETONE COMPOUNDS**

(75) Inventors: **Henry J. Buehler**, St. Louis, MO (US); **William E. Dummitt**, St. Louis, MO (US); **Anthony Mannino**, Maryland Heights, MO (US); **Dennis C. Aubuchon**, Arnold, MO (US); **Hong Gu**, Oak Park, CA (US)

(73) Assignee: **Mallinckrodt LLC**, Hazelwood, MO (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 996 days.

(21) Appl. No.: **11/915,606**

(22) PCT Filed: **Mar. 2, 2007**

(86) PCT No.: **PCT/US2007/005256**

§ 371 (c)(1),
(2), (4) Date: **Nov. 27, 2007**

(87) PCT Pub. No.: **WO2007/103105**

PCT Pub. Date: **Sep. 13, 2007**

(65) **Prior Publication Data**

US 2008/0312442 A1 Dec. 18, 2008

Related U.S. Application Data

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C07D 489/04	(2006.01)
C07D 489/08	(2006.01)

(52) **U.S. Cl.**

CPC ***C07D 489/08*** (2013.01)
USPC **514/282**; 546/45

(58) **Field of Classification Search**

USPC 546/45, 44; 514/282
See application file for complete search history.

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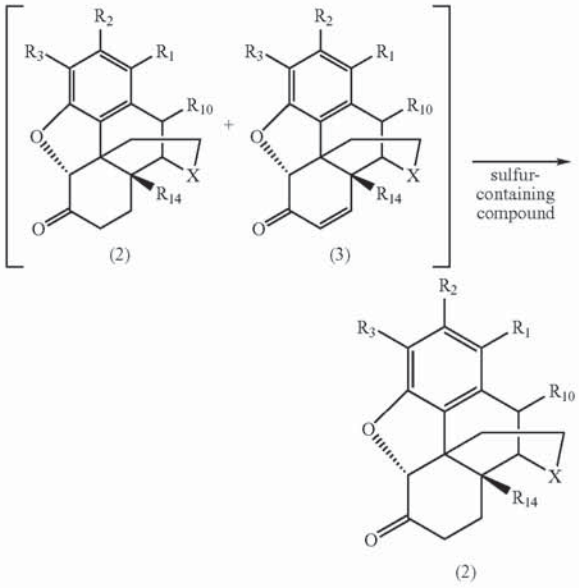
(57) **ABSTRACT**

The present invention generally relates to processes for preparing highly pure morphinan-6-one products. The processes involve reducing the concentration of α,β-unsaturated ketone compounds present as impurities in morphinan 6 one products or reaction mixtures including morphinan 6 one compounds by treatment with a sulfur-containing compound. (A)

(A)



6 Claims, No Drawings

EXHIBIT HH

Endo Pharms. Inc. v. Amneal Pharms., LLC

United States District Court for the District of Delaware

October 7, 2016, Decided; October 7, 2016, Filed

Civil Action No. 14-1382-RGA; Civil Action No. 14-1389-RGA

Reporter
224 F. Supp. 3d 368 *; 2016 U.S. Dist. LEXIS 140112 **

ENDO PHARMACEUTICALS INC. and MALLINCKRODT LLC, Plaintiffs, v. AMNEAL PHARMACEUTICALS, LLC and AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, Defendants.ENDO PHARMACEUTICALS INC. and MALLINCKRODT LLC, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. and BARR LABORATORIES, INC., Defendants.

Subsequent History: Request denied by Endo Pharms., Inc. v. Teva Pharms. USA, Inc., 2016 U.S. Dist. LEXIS 164926 (D. Del., Nov. 30, 2016)

Prior History: Purdue Pharma L.P. v. Teva Pharms., USA, Inc. (In re Oxycontin Antitrust Litig.), 994 F. Supp. 2d 367, 2014 U.S. Dist. LEXIS 5031 (S.D.N.Y., 2014)

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Judges: Richard G. Andrews, UNITED STATES DISTRICT JUDGE.

Opinion by: Richard G. Andrews

Opinion

[*372] /s/ Richard G. Andrews

ANDREWS, U.S. DISTRICT JUDGE:

Plaintiffs brought these patent infringement actions against Amneal Pharmaceuticals, LLC, Amneal Pharmaceuticals of New York, LLC (collectively, "Amneal"), Teva Pharmaceuticals USA, Inc., and Barr Laboratories, Inc. (collectively, "Teva") in 2014. (D.I. I).[1] On April 3, 2012, Amneal filed an Abbreviated New Drug Application ("ANDA"), seeking to engage in the commercial manufacture, use, and sale of generic versions of Endo's Opana ER CRF product.[2] (D.I. 130, Ex. 1 ¶ 14). Teva filed an ANDA on April 17, 2012, with amendments on May 4, 2012 and September 20, 2012, seeking to do the same. (*Id.* ¶ 16). Plaintiffs allege that these ANDAs infringe U.S. Patent No. 8,871,779 ("the

[1] Unless otherwise indicated, all docket citations, except those in the implied license section, are to C.A. No. 14-1382. In the section on implied license, docket citations are to C.A. No. 14-1389.

[2] "CRF" stands for "crush-resistant formulation." (Tr. 614:16-20).

'779 patent").

These cases concern two molecules. The first is 14-hydroxydihydromorphinone, [**3] also referred to as "oxymorphone" or "oxymorphone HCl."[3] The other is 14-hydroxymorphinone, also referred to as "oxymorphone ABUK." ABUK stands for alpha, beta-unsaturated ketone, an organic compound having a double bond between the ketone's alpha and beta carbons.

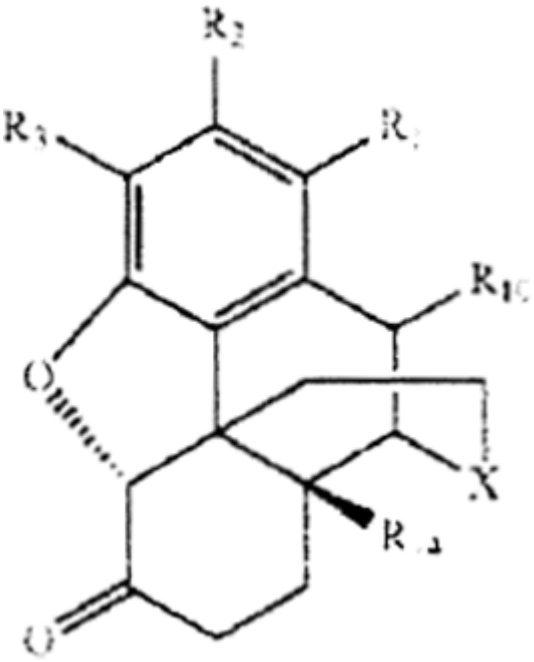
Oxymorphone HCl was first patented in 1955 and first approved by the FDA in 1959. (Trial Transcript ("Tr.") at 86:1-5, 11-14). Prior to 2002, manufacturers of oxymorphone HCl were aware of the presence of the impurity now known as oxymorphone ABUK. (Tr. at 229:9-230:4; *see also* JTX-23). During the period before 2002, manufacturers regularly sold oxymorphone HCl with oxymorphone ABUK levels in the range of hundreds of parts per million ("ppm"). (Tr. at 229:9-230:4). In 2002, the FDA informed Mallinckrodt and several other manufacturers that it was concerned about the levels of ABUK in certain products. (Tr. 217:9-218:22). The FDA informed Mallinckrodt that it intended to impose limits on the levels of ABUK, and that it might require limits as low as 0.001 percent (or 10 ppm) ABUK. (Tr. 110:19-111:21, 218:7-18). In 2004, the FDA mandated that opioid manufacturers lower the levels of ABUK in opioid pharmaceuticals to less than [**4] 10 ppm. (Tr. 199:10-201:20, 218:7-18). In these cases, oxymorphone HCl which contains less than 10 ppm of oxymorphone ABUK—and thus complies with FDA's mandate—is called "low-ABUK oxymorphone."

In 2005, Mallinckrodt succeeded in reaching the low ABUK levels mandated by the FDA for oxymorphone HCl. Mallinckrodt applied for a patent on its new low-ABUK oxymorphone product. The application ultimately issued as the '779 patent. The asserted claims of the '779 patent[4] are all composition claims directed to low-ABUK oxymorphone. (Tr. 88:22-89:8, 111:13-21; DTX-17 at 37:58-38:61).

[*373] Independent claim 1 of the '779 patent reads: [**5]

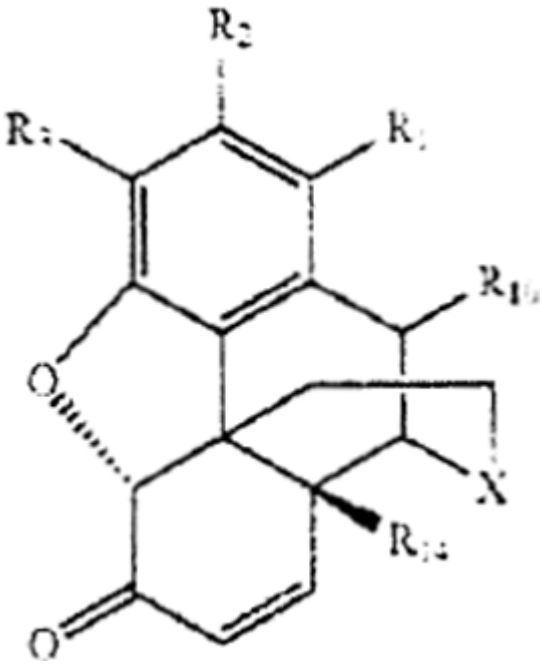
> A hydrochloride salt of oxymorphone comprising less than 0.001% of 14-hydroxymorphinone.

(DTX-17 at 37:58-59). Dependent claim 2 limits the level of 14-hydroxymorphinone to less than 0. 0005%. (*Id.* at 37:60-61). Dependent claim 3 claims a pharmaceutically acceptable form of the hydrochloride salt in claim 1. (*Id.* at 37:62-63). Independent claim 4 reads:

> A hydrochloride salt of a morphinan-6-one compound corresponding to Formula (2):
>
> 
>
> comprising less than 0.001% measured by HPLC of an α, β-unsaturated ketone compound corresponding to Formula (3):

[3] Oxymorphone and oxymorphone HCl are actually different compounds, in that the latter is a salt formed when chloride is added. In this opinion, however, they are used interchangeably, as the key distinction in this case is between oxymorphone ABUK and oxymorphone without the ABUK double bond.

[4] Plaintiffs assert that all six claims of the '779 patent are infringed.



[*374] wherein the morphinan-6-one compound is oxymorphone and wherein X is —N(R
17)—;
R
1 and R
2 are hydrogen;
R
3 is hydroxy;
R
10 is hydrogen;
R
14 is hydroxy; and
R
17 is methyl.

(*Id.* at 38:16-57). Dependent claim 5 limits the level of 14-hydroxymorphinone to 0.0005%. (*Id.* at 38:58-59). Dependent claim 6 claims a pharmaceutical formulation of the oxymorphone chloride in claim 4. (*Id.* at 38:60-61).

The Court held a bench trial on July 11-13, 2016. Both Amneal and Teva concede that their proposed products meet all the limitations of the '779 patent. (D.I. 150, Ex. 1 ¶¶ 18-20). Teva contends, however, that because it obtained an implied license from Mallinckrodt, it does not [**6] infringe. Both defendants argue that the '779 patent is invalid as obvious.

I. OBVIOUSNESS

A. Legal Standard

A patent claim is invalid as obvious under 35 U.S.C. § 103 "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; *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406-07, 127 S. Ct. 1727, 167 L. Ed. 2d 705 (2007). The determination of obviousness is a question of law with underlying factual findings. *See Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1359-60 (Fed. Cir. 2012). "The underlying factual inquiries include (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art; and (4) any relevant secondary considerations . . . ." *Western Union Co. v. MoneyGram Payment Sys., Inc.*, 626 F.3d 1361, 1370 (Fed. Cir. 2010) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 86 S. Ct. 684, 15 L. Ed. 2d 545 (1966)).

A court is required to consider secondary considerations, or objective indicia of nonobviousness, before reaching an obviousness determination, as a "check against hindsight bias." *See In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1078-79 (Fed. Cir. 2012). Relevant secondary considerations include commercial success, long felt but unsolved needs, failure of others, praise, unexpected results, and copying, among others. *Graham*, 383 U.S. at 17-18; *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 662-63 (Fed. Cir. 2000); *Tex. Instruments, Inc. v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 1178 (Fed. Cir. 1993).

A party asserting that a patent is invalid as obvious must [**7] "show by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings 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." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007). That "expectation of success need only be reasonable, not absolute." *Id.* at 1364. "Whether an ordinarily skilled artisan would have reasonably expected success . . . . is measured as of the date of the invention[] . . . ." *Amgen Inc. v. F. Hoffmann-La Roche, Ltd*, 580 F.3d 1340, 1362 (Fed. Cir. 2009).

B. Findings of Fact

1. The level of ordinary skill in the art is either (1) a person with a Ph.D. degree in [*375] medicinal

chemistry, organic chemistry or a related discipline, and at least a few years of experience in synthetic organic chemistry; or (2) a person with a lesser degree in one of those fields, but with commensurately greater experience.

2. Weiss and Chapman are prior art.

3. Neither Weiss nor Chapman teach a person of ordinary skill that catalytic hydrogenation could be used to create low-ABUK oxymorphone.

4. There was no simultaneous invention of low-ABUK oxymorphone.

5. Low-ABUK oxymorphone would not have been obvious to one of ordinary skill in the art.

C. Conclusions of Law

Defendants contend that the [**8] low-ABUK oxymorphone claimed in the '779 patent would have been obvious to one of ordinary skill in the art. Specifically, Defendants argue that an ordinary-skilled artisan would have had a reasonable expectation of success in using catalytic hydrogenation to convert oxymorphone ABUK to oxymorphone HCl, thereby lowering the level of oxymorphone ABUK to below 10 ppm. Defendants rely on Weiss, a paper published in 1957, to demonstrate that a person of ordinary skill would understand that hydrogenation could be used to convert oxymorphone ABUK to oxymorphone HCl. (JTX-23). Defendants also rely on Chapman, a 2005 patent application which claims priority to a provisional application filed on March 30, 2004. (DTX-97; DTX-137). Defendants argue that the real-world experiment described in Chapman "corroborates" the expectation of success instilled by Weiss.[5]

The parties generally agree that the person of ordinary skill to whom the '779 patent is directed is a person with "a Ph.D. degree in medicinal chemistry, organic chemistry or a related discipline, and at least a few years of experience in synthetic organic chemistry" or a person with a lesser degree in one of those fields, but with greater experience. (Tr. 361:2-15, 67:19-68:22; D.I. 143 at p. 9 n.3). Plaintiffs' expert, Dr. Davies, opined that the person of ordinary skill would "also need [experience with] process chemistry involving natural products or compounds of related complexity." (Tr. 361:15-22). I do not think this addition makes a difference. In determining obviousness, I considered the person of [**10] ordinary skill upon which the parties agreed.

i. Scope and Content of the Prior Art

1. Weiss

Weiss generally describes the process of hydrogenating oxymorphone ABUK, thereby converting it into oxymorphone HCl. Weiss does not provide the all of the reaction conditions required to reproduce the described reaction. (Tr. 174:11-175:6, 347:20-22, 388:24-389:14, 390:21-391:11; *see also* JTX-23 at 1507). Specifically, Weiss lacks details about hydrogen pressure, [*376] amount of acid, amount and composition of catalyst, and reaction time.[6] (*Id.*). It is undisputed that Weiss does not provide any information about the level of oxymorphone ABUK or other impurities remaining after hydrogenation. (Tr. 107:22-108:11, 380:11-15, 389:15-21; *see* also JTX-23 at p. 1507). Further, analytical methods available at the time of Weiss would only have been able to determine the remaining ABUK levels in the hundreds of ppm. (Tr. 145:18-22, 380:11-15). Between the publication of Weiss in 1957 and the date of invention in 2005, no other prior art reference mentioned oxymorphone ABUK. (Tr. 146:22-147:19).

2. Chapman

The Chapman reference is a United States patent application filed on March 30, 2005. The parties dispute whether the Chapman reference is prior art. Defendants

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[5] In post-trial briefing, Defendants also rely on U.S. Patent No. 7,851,482 ("the Dung reference"). (DTX-100; *see, e.g.*, D.I. 139 at 22). Plaintiffs have moved to strike all discussions of Dung. (D.I. 183). At trial, Defendants sought to move Dung into evidence. (Tr. 113:5-114:1). Plaintiffs objected on the grounds that Dr. Heathcock had provided "nothing substantive about the [**9] document" in his report. (Tr. 114:2-7). The Court admitted the document into evidence for the limited purpose of "show[ing] that it really exist[ed]." (Tr. 114:15-19). There was no testimony about Dung during trial. Thus, Plaintiff's arguments regarding Dung are completely unsubstantiated by the trial record. Further, they seek to use evidence admitted for one purpose for an entirely different purpose, in violation of Fed. R. Evid. 105. Plaintiffs' motion to strike (D.I 149; C.A. No. 14-1389, D.I. 183) is therefore GRANTED.

[6] The parties agree that Weiss lacks these parameters. Defendants' expert, Dr. Heathcock, opines that these could all be [**11] determined based on routine experimentation. (Tr. 213:3-215:23, 316:22-317:2). Dr. Heathcock stated that they were not recited because they were so simple. (Tr. 174:11-175:6).

argue that Chapman qualifies as 35 U.S.C. § 102(e) prior art. That section provides that an invention described in an application for a U.S. patent filed before the invention under review is prior art. Since § 102(e) requires that the application predate "the invention," a patentee may "swear behind" a potential § 102(e) reference. The dispute centers on the proper date of the invention for the '779 patent's claims, and whether Chapman is entitled to the filing date of an earlier provisional application. Specifically, while the parties agree that claims 1, 2, 4, and 5 of the '779 patent are entitled to a priority date of February 2, 2005, they disagree as to whether claims 3 and 6 are entitled to that date or the date of filing—March 2, 2007. (D.I. 139 at 13; D.I. 143 at pp. 13-14). Additionally, Plaintiffs argue that Defendants have not shown that Chapman is entitled to the filing date of the provisional [**12] application—March 30, 2004.

Since I conclude that the Chapman reference does not render obvious the claims of the '779 patent, I need not resolve these questions. I will accept that Chapman is valid § 102(e) prior art, and that the date of invention for all asserted claims is February 2, 2005.

Chapman does not discuss oxymorphone. Instead, Chapman describes a process for using hydrogenation to convert 14-hydroxycodeinone ("oxycodone ABUK") into oxycodone. Chapman uses a "double hydrogenation" process. (Tr. 382:12-384:3). This process involves an initial step of hydrogenating oxycodone ABUK, resulting in oxycodone which still contains relatively high levels of oxycodone ABUK. (Tr. 127:9-128:14, 382:12-383:6; DTX-97 at fig. 1, ¶ 13). Then, the oxycodone product from the first step is hydrogenated again under specific parameters, producing oxycodone with less than 25 ppm of oxycodone ABUK. (Tr. 127:9-128:14, 383:7-20; DTX-97 ¶ 20).[7]

iii. Comparing Prior Art and Claimed Subject Matter

Defendants' expert, Dr. Heathcock, opines that a hydrogenation action, like the one described in Weiss, carried out to its [*377] completion, would eventually result in a low concentration of the initial reactant—in this case oxymorphone ABUK. (Tr. 93:2-95:1, 96:9-99:14). Specifically, Dr. Heathcock testified that the driving force of hydrogenation would strongly propel the conversion of oxymorphone ABUK into oxymorphone. (Tr. 89:9-91:3). Dr. Heathcock stated that the prior art shows that the equilibrium constant[8] of a hydrogenation reaction is on the order of 10^{20}. (Tr. 94:3-98:15; DTX-114). Thus, according to Dr. Heathcock, if the hydrogenation reaction were carried out to completion—its equilibrium—the resulting mixture would contain 5 parts per million million million of oxymorphone ABUK, a level well below the 10 ppm required by the FDA. (Tr. 93:2-95:1, 96:9-99:14). In other words, according to Dr. Heathcock, if a person of skill in the art just ran a hydrogenation [**14] reaction for a sufficient amount of time, one would ultimately end up with low-ABUK oxymorphone. To support this conclusion, Dr. Heathcock relies on an illustration involving hydrogenating cyclohexene to cyclohexane. (Tr. 97:18-99:14). Dr. Heathcock refers to all of this as "basic chemistry." (Tr. 135:11-136:14, 137:8-12).

One problem with Dr. Heathcock's "basic chemistry" theory is that there is simply no indication, and certainly no experimental evidence, that the hydrogenation procedure described in Weiss could result in ABUK levels below 10 ppm.[9] At the time of the invention, it was "very unusual" and "very, very challenging" to remove impurities like ABUK to levels below 10 ppm. (Tr. 360:1-6, 370:23-371:8). These levels were described as "remarkable." (Tr. 401:22-403:8). Further, "[t]here are very few methods that will measure such low levels." (Tr. 371:4-5).

Dr. Heathcock's "basic chemistry" theory does not account for the complexities involved in reducing ABUK levels to below 10 ppm. Oxymorphone has numerous impurities, aside from the oxymorphone ABUK, the most

[7] Chapman also states that the process may reduce the levels of oxycodone ABUK to below 15 ppm, 10 ppm, or 5 ppm. (DTX-97 ¶ 16). Chapman, in an experiment called Example 2, states that two different analytical methods showed levels of oxycodone ABUK at less than 5 ppm. (Tr. 194:20-23; [**13] DTX-97 ¶¶ 189-90). In Example 3, Chapman stated that two different analytical methods showed levels of oxycodone ABUK at 5 ppm and 10 ppm, respectively. (Tr. 194:10-19; DTX-97 ¶¶ 197-98).

[8] An equilibrium constant is essentially the ratio of the concentrations of the products and reactants at equilibrium.

[9] To achieve low-ABUK oxymorphone, Mallinckrodt did not use hydrogenation. (Tr. 207:14-208:4, 211:24-213:2). Instead, Mallinckrodt used a process involving sodium bisulfite and sulfurous acid to achieve low-ABUK oxymorphone. [**15] (*Id.*). Additionally, while two other manufacturers, Noramco and Johnson Matthey, were successful in making low-ABUK oxymorphone, no evidence in the record explains how or when these companies succeeded in making it. (Tr. 237:3-238:4).

important of which, for purposes of this case, is oxymorphone diol. Oxymorphone diol, or 8,14-dihydroxy-7,8-dihydromorphinone, is formed when water is added to the oxymorphone ABUK. Since oxymorphone diol lacks the ABUK double bond, it, unlike oxymorphone ABUK, is not converted to oxymorphone upon hydrogenation. (Tr. 350:8-21, 351:14-24, 414:22-415:16). When the diol becomes dehydrated, it converts back into oxymorphone ABUK. (Tr. 414:15-415:11). According to Dr. Davies, this creates a problem. Generally, to create oxymorphone, one first begins with a poppy straw, which is converted into thebaine. (Tr. 152:23-153:14). Then, through an oxidizing process, the thebaine is converted into oxycodone ABUK, which is then hydrogenated to form oxycodone. (Tr. [**16] 154:5-155:10). Then, the oxycodone is O-demethylated to form oxymorphone. (Tr. 420:9-11). During oxidation, "you will produce [oxycodone] diol because you have water present with the Oxycodone ABUK." (Tr. 420:2-8). During O-demethylation, the oxycodone diol that formed will be converted in oxymorphone diol. (Tr. 420:9-421:15).

Oxymorphone diol will be converted into oxymorphone ABUK "under acid and [*378] heat." (Tr. 422:4-8; *see also* Tr. 414:15-415:11). When working-up[10] the reaction, "you filter the acidic reaction mixture." (Tr. 422:17-19). Then, during purification, "you do a crystallization which involves heating it in a solvent. . . .[,] [a]nd then you heat dry the product." (Tr. 422:19-22). In each stage of this process, the oxymorphone diol may regenerate the oxymorphone ABUK, even if the ABUK had previously been reduced to extremely low levels. (Tr. 422:17-423:2; *see also* 415:17-416:21, 424:24-430:20). Thus, the diol can act like a "reservoir" for regenerating oxymorphone ABUK. (Tr. 388:6-23, 415:2-11, 428:13-28). This was described at various times as the "reappearing ABUK." (*See, e.g.*, Tr. 170:2-7, 189:5-12).[11] This regeneration is significant, since the FDA requires, and the '779 patent claims, such [**17] low levels of oxymorphone ABUK.

Defendants argue that Weiss had removed the oxymorphone diol from his starting material for the hydrogenation reaction, and that it would therefore have no impact on the levels of the ABUK. Defendants rely on the statement in Weiss that "[t]he solid residue was kept at room temperature for about 24 hr. with 60 ml. acetone, which dissolved the [oxymorphone diol] present." (JTX-23 at p. 1506).

In response, Dr. Davies testified that "it's very hard to remove the [**18] Oxymorphone diol." (Tr. 416:20-21). Dr. Davies testified that the acetone wash described in Weiss—a process called trituration—would not "completely remove the compound you're trying to wash away." (Tr. 416:22-417:24). Since it is a "very crude technique," it could not be expected to completely remove the oxymorphone diol. (Tr. 417:14-418:4).

Thus, while a person of ordinary skill would reasonably expect the Weiss hydrogenation procedure to reduce the levels of oxymorphone ABUK, a person of ordinary skill would not reasonably expect that the Weiss hydrogenation procedure to lower ABUK levels below 10 ppm.

Defendants contend that Chapman "corroborates" the hydrogenation procedure described in Weiss. (Tr. 133:19-24; *see also* Tr. 136:5-14). The Chapman hydrogenation procedure differs from Weiss in some critical respects, however. Most importantly, Chapman describes the hydrogenation of oxycodone, rather than oxymorphone. (Tr. 186:9-187:13,382:2-11). While oxycodone and oxymorphone are both morphinan-6-ones that may form an ABUK, the evidence demonstrates that oxycodone and oxymorphone react in different ways. These differences are attributable to certain structural variations. Oxycodone [**19] and oxycodone ABUK contain anisole, a benzene ring with an OCH3 (methoxy) group attached. (Tr. 411:1-6). Oxymorphone and oxymorphone ABUK, on the other hand, contain phenol, a benzene ring with an OH (hydroxy) group attached. (*Id.*).

Two prior art references illustrate how these structural variations result in reactivity differences. A prior art patent from [*379] 1965, U.S. Patent No. 3,193,584 ("the '584 patent"), compares the hydrogenation of phenol with anisole. (PTX-90; Tr. 410:21-411:19). Table 1 of the '584 patent indicates that, under basic, neutral, and acidic conditions, phenol hydrogenates faster than anisole. (PTX-90; Tr. 411:1-19). This means that the six-

[10] "Work[-]up is the processing of a reaction product mixture in order to remove unwanted components such as solvents and inorganic materials that may be resulting from the reaction, and to obtain the intended products, normally the organic products." (Tr. 156:21-157:3).

[11] This "reappearing ABUK" problem occurred in Chapman, in the context of hydrogenating oxycodone ABUK to form oxycodone. In Example 5, oxycodone ABUK levels were undetectable before work-up, and after work-up, were measured at 11 ppm. (Tr. 426:9-427:21; DTX-97 ¶¶ 267-69). In Example 3, no oxycodone ABUK was detected after work-up, "but during the purification[,] . . . 5 or 10 ppm of ABUK have reappeared." (Tr. 427:18-428:23; DTX-97 ¶¶ 192-98).

membered ring to which the methoxy group or hydroxy group is attached, is reduced.[12] (Tr. 412:18-413:15). This reduction fundamentally changes the molecule; it ceases to be oxymorphone or oxycodone. (Tr. 413:16-414:4). The '584 patent indicates that this is more likely to occur in oxymorphone than in oxycodone. (Tr. 412:6-17, 413:8-414:14).

In Schmidhammer, [**20] a prior art paper published in 1990, a hydrogenation reaction was performed on two ABUK molecules with similar structures to oxycodone ABUK and oxymorphone ABUK. (PTX-79). When hydrogenating these two molecules, the anisole compound yielded 92%, while the phenol compound yielded 76%. (PTX-79; Tr. 407:2-410:5). In other words, the compound similar to oxycodone ABUK hydrogenated more efficiently than the compound similar to oxymorphone ABUK. (Tr. 409:1-410:1). Dr. Davies therefore opined that a person of ordinary skill is "less likely to succeed with [the] Chapman [process] on Oxymorphone ABUK than . . . on oxycodone ABUK." (Tr. 409:21-410:1).

Dr. Davies also explained that the higher amount of diol present in oxymorphone would lead an ordinary-skilled artisan to believe that hydrogenation of oxymorphone ABUK would be less effective than hydrogenation of oxycodone ABUK. Dr. Davies refers to oxymorphone diol as an ABUK precursor, since it is formed by adding water to the ABUK double bond, and can convert back into ABUK when dehydrated. (Tr. 414:15-415:8). Weiss explains that, in alkaline solution, oxymorphone ABUK is converted to oxymorphone diol "with unexpected ease." (JTX-23 at p. 1507; [**21] Tr. 168:4-10, 169:8-170:7). In other words, oxymorphone diol is "produced very, very easily from Oxymorphone ABUK." (Tr. 418:5-14). On the other hand, oxycodone ABUK hydrates to form oxycodone diol "much less readily than" oxymorphone ABUK hydrates to form oxmorphone diol. (JTX-23 at p. 1506; Tr. 170:8-171:2, 405:7-407:1). As explained previously, the oxymorphone diol "act[s] like a reservoir for regenerating ABUK." (Tr. 388:6-23, 428:13-28). Therefore, "ABUK precursors"—the oxymorphone diols—would "just. . . regenerate ABUK at the end of the day." (Tr. 436:5-16).

Weiss does not, on its own, disclose low-ABUK oxymorphone. (Tr. 380:6-15). That is, it does not teach that the hydrogenation procedure described would result in the low-ABUK oxymorphone claimed in the '779 patent. "Although published subject matter is 'prior art' for all that it discloses, in order to render a claimed apparatus or method obvious, the prior art must enable one skilled in the art to make and use the apparatus or method."[13] *In re Kumar*, 418 F.3d 1361, 1365 [*380] (Fed. Cir. 2005) (quoting *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989)); *see also In re Payne*, 606 F.2d 303, 314-15 (C.C.P.A. 1979). Since Weiss does not disclose low-ABUK oxymorphone, Defendants must "establish that a person of ordinary skill would have nonetheless been able to make [the claimed invention]." *Geo. M. Martin Co. v. Alliance Mach. Sys. Int'l LLC*, 618 F.3d 1294, 1303 (Fed. Cir. 2010); *see [**22] also Rockwell Int'l Corp. v. United States*, 147 F.3d 1358, 1365 (Fed. Cir. 1998). If the Weiss hydrogenation procedure would not actually produce low-ABUK oxymorphone, it cannot be said that the prior art enables those of skill in the art to make low-ABUK oxymorphone. While Dr. Heathcock opines that the hydrogenation would result in the claimed invention, Dr. Davies opines that an experiment would be required to verify that prediction. (Tr. 94:3-99:14, 389:22390:4). Dr. Heathcock did not run any experiments to confirm that a hydrogenation process would indeed result in low-ABUK oxymorphone. (Tr. 151:1-8, 174:4-10,390:5-391:11). Therefore, Defendants have failed to show that a person of ordinary skill in the art could make low-ABUK oxymorphone using hydrogenation.

Even if the Weiss hydrogenation procedure could produce low-ABUK oxymorphone, however, Defendants would still have much of their work ahead of them. The prior art must actually "suggest to one of ordinary skill in the art how to [make the claimed apparatus] with a reasonable likelihood of success." *Rockwell*, 147 F.3d at

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[12] In this context, a reduction occurs when each of the three double bonds in the six-membered ring is reduced to a single bond, resulting in an additional hydrogen atom bonding to each carbon atom in the ring. (*See* Tr. 412:18-413:19).

[13] "Under § 103,. . . a reference need not be enabled; it qualifies as a prior art, regardless, for whatever is disclosed therein." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1357 (Fed. Cir. 2003); *see also Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1578 (Fed. Cir. 1991) ("While a reference must enable someone to practice the invention in order to anticipate under § 102(b), a non-enabling reference may qualify as prior art for the purpose of determining obviousness under § 103."); *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989) ("Even if a reference discloses an inoperative device, it is prior art for all that it teaches."). Whether the prior art enables one skilled in the art to produce the [**23] claimed invention is, however, a different question.

1365. Neither Weiss, nor Chapman, disclose low-ABUK oxymorphone. Additionally, Defendants have not proven that the combination of those references would enable a person of ordinary skill to make low-ABUK oxymorphone with a reasonable expectation of success. *See Geo. M. Martin*, 618 F.3d at 1303; *Rockwell*, 147 F.3d at 1365. In fact, the Chapman inventors, when seeking to lower ABUK levels in oxycodone, found that a single hydrogenation reaction was insufficient to reach the desired ABUK levels. (Tr. 396:5-397:6; *see also* Tr. 32:2-384:3). "[T]here can be little better evidence negating an expectation of success than actual reports of failure." *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1354 (Fed. Cir. 2003). Although the Chapman inventors succeeded in creating low-ABUK oxycodone with a double hydrogenation process, due to the differences between oxycodone and oxymorphone, that would not suggest to a person having ordinary skill that the same process would have been effective [**24] in creating low-ABUK oxymorphone. (Tr. 403:2-13, 414:5-14). Thus, Defendants have not shown that a person of ordinary skill "would have had a reasonable expectation of success in" "achiev[ing] the claimed invention . . . ." *Pfizer*, 480 F.3d at 1361.

Defendants discuss, at length, the Federal Circuit's recent decision in *Purdue Pharma L.P. v. Epic Pharma., LLC*, 811 F.3d 1345 (Fed. Cir. 2016). To the extent the conclusions in *Purdue* are relevant to this case,[14] they do not suggest [*381] that low-ABUK oxymorphone would have been obvious to one of ordinary skill in the art. In *Purdue*, the patentee—in applications which continued from Chapman—claimed low-ABUK oxycodone. "The district court found that the prior art taught that oxidation of thebaine produced [oxycodone ABUK] and that it was well known in the art that [oxycodone ABUK] could be removed using hydrogenation." *Id.* at 1351. The patentee, in arguing for the patent's validity, argued that the discovery of the source of oxycodone ABUK—the 8α isomer of oxycodone diol—rendered its solution non-obvious. The Federal Circuit confirmed that the discovery of 8α as the source of the ABUK was not necessary to the claimed invention, which was directed to low-ABUK oxycodone as an end product. "One need not know that the [oxycodone ABUK] was derived from 8α" to know [**25] that it was obvious to use hydrogenation to remove the oxycodone ABUK. *Id.* at 1353.

I fail to see the relevance of *Purdue Pharma*. Purdue's validity position hinged on discovering the source of the oxycodone ABUK. Plaintiffs here make no analogous argument. Additionally, the Federal Circuit's conclusion that low-ABUK oxycodone was obvious does not command a conclusion that low-ABUK oxymorphone is obvious. As stated above, the evidence reveals significant differences between oxycodone and oxymorphone, such that an ordinary-skilled artisan would not reasonably expect that what had been successful with oxycodone would have been successful with oxymorphone.

I conclude that Defendnats have failed to make a *prima facie* showing that the '779 patent would have been obvious to one of ordinary skill in the art.

iv. Secondary Considerations

"[S]econdary considerations, when present, must be considered in determining obviousness." *Ruiz*, 234 F.3d at 667; *see also Cyclobenzaprine*, 676 F.3d at 1076 ("[E]vidence on these secondary considerations [**26] is to be taken into account *always*, not just when the decisionmaker remains in doubt after reviewing the art." (internal quotation marks omitted) (quoting *Cable Elec. Prods, v. Genmark, Inc.*, 770 F.2d 1015, 1026 (Fed. Cir. 1985))). Here, Plaintiff did not present any evidence on any secondary considerations. Defendants, however, argue that there is evidence of near-simultaneous invention by others in the industry. "Independently made, simultaneous inventions, made 'within a comparatively short space of time,' are persuasive evidence that the claimed apparatus 'was the product only of ordinary mechanical or engineering skill.'" *Geo. M. Martin Co. v. Alliance Mach. Sys. Int'l LLC*, 618 F.3d 1294, 1305 (Fed. Cir. 2010) (quoting *Concrete Appliances Co. v. Gomery*, 269 U.S. 177, 184, 46 S. Ct. 42, 70 L. Ed. 222, 1926 Dec. Comm'r Pat. 284(1925)).

Defendants assert that Chapman's invention of low-ABUK oxycodone through a process involving hydrogenation is a "near-simultaneous invention." (D.I. 139 at 35; DTX-97 ¶¶ 185-90). Since low-ABUK oxycodone is not low-ABUK oxymorphone, I do not think there is any evidence of simultaneous invention. Thus, there are no secondary considerations to be contemplated here.

[14] Defendants repeatedly cite to facts described in *Purdue*. This is improper. "The reports of [decisions] may be referred to as expositions of law upon the facts there disclosed, but they are not evidence of those facts in other cases." *Mendenhall v. Cedarapids, Inc.*, 5 F.3d 1557, 1570 (Fed. Cir. 1993) (alteration in original) (quoting *MacKay v. Easton*, 86 U.S. (19 Wall.) 619, 632, 22 L. Ed. 211 (1873)).

Having considered the scope and content of the prior art, the differences between the prior art and the claims at issue, and the level of ordinary skill in the art, I conclude that Defendants have not carried their burden of showing that "the differences between the [**27] subject matter sought to be patented and the prior art are such that the subject matter as a whole would [*382] have been obvious at the time the invention was made to a person having ordinary skill in the [pertinent] art." 35 U.S.C. § 103.

II. IMPLIED LICENSE

Teva concedes that its ANDA meets every limitation of the asserted claims of the '779 patent, but maintains, as an affirmative defense, that Plaintiffs' infringement claims are barred by its implied license defense. (D.I. 150 ¶ 16).

A. Legal Standard

"[A]n implied license, like an express license, is a defense to patent infringement." *Carborundum Co. v. Molten Metal Equip. Innovations, Inc.*, 72 F.3d 872, 878 (Fed. Cir. 1995). A license may be inferred based on "[a]ny language used by the owner of [a] patent, or any conduct on his part exhibited to another from which that other may properly infer that the owner consents to his use of the patent in making or using it, or selling it. . . ." *Wang Labs., Inc. v. Mitsubishi Elecs. Am., Inc.*, 103 F.3d 1571, 1580 (Fed. Cir. 1997) (quoting *De Forest Radio Tel. Co. v. United States*, 273 U.S. 236, 241, 47 S. Ct. 366, 71 L. Ed. 625, 63 Ct. Cl. 677 (1927)). The Federal Circuit has acknowledged that there are "various avenues to an implied license." *Id.* "[I]mplied licenses arise by acquiescence, by conduct, by equitable estoppel (estoppel in pais), or by legal estoppel." *Id.* "[J]udicially implied licenses are rare under any doctrine." *Id.* at 1581.

In *Wang Laboratories*, the Federal Circuit confirmed the existence of an implied license where:

> the jury necessarily [**28] found that (1) a relationship existed between [the parties], (2) within that relationship, [the patentee] granted to [the accused infringer] a right to use its . . . inventions, (3) [the patentee] received valuable consideration for that grant of right, (4) [the patentee] denied that [the accused infringer] had an implied license, and (5) [the patentee's] statements and conduct created the impression that [the patentee] consented to [the accused infringer] making, using, or selling [the] patented inventions . . . .

Id. at 1579. "Courts grant implied licenses to preclude patent holders from suing purchasers for infringement where, at the time of sale, the patentee led the purchaser to believe that his manufacture, use, or sale of the patented article was permissible." *Monsanto Co. v. Good*, 2003 U.S. Dist. LEXIS 27217, 2004 WL 1664013, at *7 (D.N.J. July 23, 2003). "A mere sale," however, "does not import a license except where the circumstances plainly indicate that the grant of a license should be inferred." *Bandag, Inc. v. AlBolser's Tire Stores, Inc.*, 750 F.2d 903, 925 (Fed. Cir. 1984). "[T]he alleged infringer . . . ha[s] the burden of establishing the existence of an implied license as an affirmative defense." *Carborundum*, 72 F.3d at 878. Whether an implied license exists, based on the underlying facts, is a question of law. *Anton/Bauer, Inc. v. PAG, Ltd.*, 329 F.3d 1343, 1348 (Fed. Cir. 2003).

B. Factual Background

Teva and Mallinckrodt, in 2008, entered into a supply [**29] agreement for the supply of non-low-ABUK oxymorphone to Teva. (D.I. 154 ¶ 7).[15] That agreement expired in 2009. (*Id.*). In late 2010 and early 2011, Teva purchased two batches of low-ABUK oxymorphone API[16] from Mallinckrodt pursuant [*383] to stand-alone purchase orders. (*Id.* ¶¶ 11-12). Those purchase orders were dated October 31,2010 and February 3, 2011, respectively. (*Id.*). Mallinckrodt shipped the requested quantities of low-ABUK oxymorphone API, and Teva paid Mallinckrodt the amount due. (*Id.* ¶¶ 13-14). Since those purchase orders, Teva has not purchased any low-ABUK oxymorphone API from Mallinckrodt. (*Id.* ¶ 16).

Mallinckrodt maintains [**30] a Drug Master File ("DMF") with the FDA, which contains confidential and proprietary information about its low-ABUK oxymorphone API. (D.I. 154 ¶ 17). This DMF is numbered 14502. (D.I. 154 ¶ 17). In February 2012, Teva requested a Letter of Authorization ("LOA") for

[15] For the implied license phase of the trial, the parties submitted a joint stipulation of facts. (D.I. 154). Since the underlying facts material to Teva's implied license defense are not in dispute, the stipulation is adopted as the Court's findings of fact.

[16] API means "active pharmaceutical ingredient." (D.I. 154 ¶ 1). Mallinckrodt is in the business of, among other things, manufacturing and selling API for use in pharmaceutical products. (*Id.*). Teva is in the business of, among other things, manufacturing and selling finished dosage forms which contain API. (*Id.* ¶ 3).

low-ABUK oxymorphone API from Mallinckrodt. (D.I. 154 ¶ 18). On March 8, 2012, Mallinckrodt sent a copy of an LOA for low-ABUK oxymorphone API to Teva. (D.I. 154 ¶ 20; DTX-501). This LOA allowed the FDA to review, in connection Teva's ANDA filing, the information contained in Mallinckrodt's DMF, without Mallinckrodt having to share that information with Teva. (Tr. 564:2-13; 694:1-695:2). In other words, the LOA provided a mechanism whereby Teva could cross-reference information about Mallinckrodt's low-ABUK oxymorphone API in its ANDA, without Mallinckrodt having to reveal that information to Teva. As explained by Teva's industry expert, Dr. Fabian, the LOA accomplished two things: (1) Mallinckrodt authorized Teva to incorporate by reference the information from its DMF into an ANDA, and (2) Mallinckrodt authorized the FDA to review its DMF when considering Teva's ANDA application. (Tr. 703:17-704:3). Mallinckrodt only knew [**31] that Teva sought to use DMF No. 14502 in a product; it did not know the particular product for which Teva sought the LOA. (Tr. 748:23-749:15).

On April 17, 2012, Teva submitted an ANDA to the FDA, requesting approval for its generic version of Endo's Crush-Resistant Formulation of Opana ER ("Teva CRF ANDA"). (D.I. 154 ¶ 22). Teva incorporated DMF No. 14502 into the Teva CRF ANDA. (*Id.* ¶ 24). Mallinckrodt is the only supplier of low-ABUK oxymorphone API referenced in the Teva CRF ANDA. (*Id.* ¶ 25). Teva has the ability, however, to amend its ANDA to qualify additional suppliers of low-ABUK oxymorphone API. (*Id.* ¶ 26).

In August 2012, Mallinckrodt and Teva began negotiating a supply agreement for low-ABUK oxymorphone API. (D.I. 154 ¶ 30). On August 3, 2012, Ayne Klein of Teva sent Stephanie Bucalo and Nick Litzsinger of Mallinckrodt a draft supply agreement via email. (*Id.* ¶ 31; JTX-300; JTX-301). Mr. Litzsinger, on September 5, 2012, emailed Ms. Klein a counter-proposal. (D.I. 154 ¶ 32; JTX-302; JTX-303). Teva did not respond with any further proposals. (D.I. 154 ¶ 33). Several months later, on or around November 29, 2012, Ms. Klein sent an email to Mr. Litzsinger which memorialized a [**32] discussion which had occurred the previous day. (*Id.* ¶ 34). In the email, Ms. Klein wrote: "3) Oxymorphone - we agreed we would complete Morphine supply agreement and then tackle the Oxymorphone." (*Id.* ¶ 34; DTX-542). The parties never reached an agreement for the supply of low-ABUK oxymorphone API. (D.I. 154 ¶ 36).

In 2012 and 2013, Mallinckrodt and Endo were parties to Patent Interference No. 105,893 in the PTO, which related to U.S. Patent Application No. 11/915,606—which issued as the '779 patent—and U.S. [*384] Patent No. 7,851,482 ("the '482 patent").[17] (*Id.* ¶ 38). On May 15, 2013, Endo filed a patent infringement lawsuit against Mallinckrodt, alleging that a Mallinckrodt ANDA filing infringed the '482 patent. (*Id.* 39). On December 16, 2013, Endo and Mallinckrodt settled the interference proceedings and the district court litigation, and entered into two license agreements. (*Id.* ¶ 41; JTX-3; PTX-10). Pursuant to the agreement settling the interference proceedings, Mallinckrodt granted Endo an exclusive license to the patent which ultimately issued as the '779 patent. (*Id.* ¶ 42; JTX-3). After settling with Endo, Mallinckrodt did not withdraw or modify the LOA it had issued to Teva. (*Id.* ¶¶ 47-51). Because of its agreement with Endo, Mallinckrodt is unwilling to sell low-ABUK [**33] oxymorphone API to Teva for use in the product described in the Teva CRF ANDA. (*Id.* ¶ 44). Mallinckrodt remains willing to sell low-ABUK oxymorphone API to Teva for use in an immediate release oxymorphone product. (*Id.* ¶ 45).

On November 7, 2014, less than two weeks after the issuance of the '779 patent, Endo and Mallinckrodt sued Teva for infringement of the '779 patent. (*Id.* ¶ 43).

D. Conclusions of Law

In a Hatch-Waxman case, a plaintiff's infringement claim is based on the accused infringer's future conduct, rather than past acts of infringement.[18] "The filing of an ANDA is considered an act of infringement under § 271(e)(2)(A), but this 'act' is merely a vehicle 'to create case or controversy jurisdiction to enable a court to promptly resolve' a dispute concerning infringement that will happen in the future." *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249 (Fed. Cir. 2000) (quoting *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562,1569 (Fed. Cir. 1997)). Thus, for an implied license defense to succeed, the accused infringer must demonstrate that the patentee consented to its use of the claimed invention in "the ANDA product that is likely to be sold following FDA approval." *Spectrum Pharms., Inc. v. Sandoz Inc.*, 802 F.3d 1326, 1336 (Fed. Cir. 2015). Here, Teva has failed to make such a showing.

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[17] Endo had previously acquired U.S. Patent No. 7,851,482 from Johnson Matthey. (*Id.* ¶ 40).

[18] Otherwise infringing acts, undertaken in connection with the development [**34] and submission of an ANDA, are immunized from liability. 35 U.S.C. § 271(e)(1).

Teva's implied license defense relates only to API which may be supplied by Mallinckrodt. (D.I. 175 at p. 3 n.2).[19] According to Teva, since Mallinckrodt is the only API supplier identified in the Teva CRT ANDA, the product that is likely to be sold—should Teva's ANDA be approved—will contain Mallinckrodt API. Put another way, Teva argues that, to the extent any infringing low-ABUK oxymorphone API ends up in its product, that API will come from Mallinckrodt. Based on Mallinckrodt's past conduct, Teva argues that it must be entitled—or, impliedly licensed—to use low-ABUK oxymorphone API that it receives from Mallinckrodt.[20] [*385] Under these circumstances, to succeed in an implied license defense, Teva must show that Mallinckrodt consented to Teva's use of the patented invention in the product likely to be sold. Under the facts here, there is no such license.

Teva's argument focuses on the 2010 and 2011 purchase orders, and the 2012 LOA. The 2010 and 2011 purchase orders concerned discrete, stand-alone purchases. (D.I. 154 ¶¶ 11-15; Tr. 602:18-605:11). On each, Teva included written terms and conditions. No evidence suggests that Mallinckrodt objected to these terms and conditions. (D.I. 154 ¶ 15). Each purchase order included an integration clause which provided that, "[e]xcept as expressly set forth in writing executed by [Teva], the terms and conditions set forth in this order constitute the entire agreement between the parties regarding the subject matter . . . ." (DTX-502; DTX-503). Thus, these terms and conditions constitute the entirety of the agreement with respect to each purchase order. Under the terms and conditions in each order, Mallinckrodt agreed "to exonerate, indemnify [**36] and hold harmless [Teva] from and against any and all liability . . . which may accrue to, or be sustained by [Teva] on account of any claim . . . brought against [Teva] . . . for . . . infringement of any patent. . . by reason of the manufacture of goods covered by this order . . . ." (DTX-502; DTX-503). By the terms of the purchase orders, Mallinckrodt granted Teva permission to use the low-ABUK oxymorphone API however it wished. As the terms and conditions of the purchase orders make clear, however, the scope of that permission does not extend beyond the "manufacture of goods covered by th[e] [purchase] order." (DTX-502; DTX-503). The only material covered by the terms and conditions is the low-ABUK oxymorphone API Teva actually purchased. No evidence suggests that, by selling low-ABUK oxymorphone API to Teva on two occasions, Mallinckrodt consented to Teva's commercial sale of products embodying the '779 patent through the use of low-ABUK oxymorphone API not covered by the purchase orders. The two purchases of low-ABUK oxymorphone API do not create an implied license.

Aside from the purchase orders, Teva relies heavily on the LOA issued by Mallinckrodt. An LOA is a regulatory document. In an LOA, [**37] a DMF holder grants an ANDA applicant "permission to incorporate their API into the ANDA." (Tr. 697:21-698:6). As conceded by Teva's expert, Dr. Fabian, these documents create no binding commercial obligations. (Tr. 706:4-707:5). Dr. Fabian testified that "the issue of successful or unsuccessful consummation of a Supply Agreement is a completely independent issue as to whether or not permissions have been granted based on actions of certain parties." (*Id.*). Further, Dr. Fabian testified that "there is no obligation to purchase [API] because an LOA has been received." (Tr. 698:19-699:6). Thus, while Mallinckrodt is the only supplier listed on the Teva CRF, it is not under any obligation to supply low-ABUK oxymorphone API to Teva. Similarly, no witness testified that the LOA itself confers a patent license.

Teva argues that because Mallinckrodt chose not to withdraw or modify the LOA, Mallinckrodt "suggested [to Teva] that it could file ANDA 204324 without being sued for infringing the '779 patent." (D.I. 175 at p. 10). This inference draws on a misapprehension about the significance of a LOA. Since a LOA places no binding obligation on Mallinckrodt, it would have no reason to withdraw the LOA. [**38] Additionally, leaving the LOA in place allows the FDA to review Teva's ANDA while Teva seeks to find, and qualify, additional suppliers of low-ABUK oxymorphone API. [*386] (Tr. 724:16-726:1). This is standard within the industry, as ANDA applicants seek to qualify multiple suppliers for pharmaceutical products. (Tr. 617:13-618:3, 699:8-22). Indeed, Dr. Fabian testified that, when an API supplier is asked for a LOA from a manufacturer, the API supplier "would have no reason to believe" that "they would be the primary

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[19] Teva concedes this and also acknowledges that "[n]o case or controversy exists today regarding whether the sale of a hypothetical future product that includes API purchased from a supplier other than Mallinckrodt would infringe the '779 patent." (*Id.*).

[20] There is some intuitive appeal to the argument [**35] that Mallinckrodt should not be able to sue a buyer for using the product it sold. In such a scenario, however, Teva would likely obtain a license not by virtue of Mallinckrodt's past conduct, but through the terms of a later transaction. The question here is whether the conduct hitherto undertaken by Mallinckrodt suffices to show that Mallinckrodt licensed the '779 patent.

supplier to the applicant." (Tr. 699:8-22). This is because "API suppliers realize that ANDA sponsors mitigate [their] risk . . . by including more than a single supplier in their AND A." (*Id.*) Thus, while an ANDA applicant might request an LOA so that it can eventually "market a dosage form on the market with [the DMF holder's] API in that dosage form," that is not the only possible scenario. (Tr. 698:2-18).

Teva has amassed considerable evidence for the unremarkable proposition that Teva could use the low-ABUK oxymorphone API supplied by Mallinckrodt in pursuing its ANDA. Mallinckrodt did not place any limits on the low-ABUK oxymorphone API Teva purchased in 2010 and 2011, and [**39] indeed, explicitly agreed to "exonerate, indemnify and hold harmless" Teva from any patent infringement liability. (DTX-502; DTX-503). Ms. Klein testified, based on the preceding facts, that Teva believed it was authorized to include Mallinckrodt's low-ABUK oxymorphone API in its ANDA. (Tr. 574:2-16). Additionally, to the extent Teva used the low-ABUK oxymorphone API for a purpose reasonably related to its ANDA, such activity is protected by § 271(e)(1). Mallinckrodt is not, however, suing Teva for using the low-ABUK oxymorphone API it previously supplied. Rather, Mallinckrodt is suing Teva for including low-ABUK oxymorphone API in the product that is likely to be sold in the future. Teva has not pointed to any evidence demonstrating that Mallinckrodt granted Teva a license to include low-ABUK oxymorphone API in the CRF product it ultimately sells. That is a fatal shortcoming.

In support of its theory of implied license, Teva introduced evidence about the way these sorts of interactions might ordinarily proceed between an entity like Teva and an entity like Mallinckrodt. Ms. Klein summarized the relevant process as follows: "You order a product. You test the product. You put it into your drug [**40] product towards the ultimate goal of submitting to FDA, having a review, having the product approved and selling it commercially. And the fact that somebody . . . sells you the API and gives you that Letter of Authorization, this is the process." (Tr. 574:7-16). Ms. Klein testified that she "never had anyone provide [her] with a letter of authorization, put them in the [ANDA] and then have them sue me for using their product." (Tr. 575:7-10). Mr. Litzsinger similarly testified that Mallinckrodt had never "given an LOA to a customer and then sued that customer for filing an ANDA that included the API related to that LOA." (Tr. 829:13-18). Dr. Fabian also stated that, in his experience, he had never "seen a case where . . . a DMF holder . . . provided [a] LOA to the ANDA applicant and then subsequently . . . sued them." (Tr. 729:4-22). I think this testimony suggests that, in the majority of circumstances, a party in Teva's shoes could expect to eventually enter into an API supply agreement with a party in Mallinckrodt's shoes. That did not happen here. Teva cannot pretend that it did in order to sustain an implied license defense. This is perhaps an unusual situation, but it is not [**41] one where an implied license arises. While Teva may have hoped that Mallinckrodt would eventually supply it low-ABUK oxymorphone API, despite Mallinckrodt's assertions for the last twenty months that it would not (D.I. 154 ¶ 44; Tr. 646:21-647:13), "an implied license cannot arise [*387] out of unilateral expectations or even reasonable hopes of one party." *Stickle v. Heublein, Inc.*, 716 F.2d 1550,1558 (Fed. Cir. 1983).

Teva briefly argues that its product may not contain low-ABUK oxymorphone after all. Plaintiff relies on the FDA's requirement that an opioid manufacturer must show either that (1) the drug contains less than 10 ppm of ABUK, or (2) that levels above that amount are not genotoxic. (D.I. 166 at pp. 13-14).[21] This argument fails for at least two reasons. First, the specification in the Teva CRF AND A limits the amount of oxymorphone ABUK to less than 10 ppm. (D.I. 154 ¶ 24). Second, Teva never raised this argument in the Final Pretrial Order, and it is therefore waived.

Teva argues that it has proven the five facts that the Federal Circuit found sufficient to create an implied license in *Wang Laboratories*. I disagree. In *Wang Laboratories* [**42] , the Federal Circuit concluded that the jury necessarily found that the patentee granted the accused infringer a right to use the claimed invention. *Wang Laboratories*, 103 F.3d at 1579. Here, as discussed above, Mallinckrodt only granted Teva the right to use the low-ABUK oxymorphone API which was the subject of the two purchase orders.

Additionally, in *Wang Laboratories*, the patentee had "received valuable consideration for [the] grant of [a] right [to use the claimed invention]." *Id.* Here, the only consideration paid to Mallinckrodt was the purchase price of the two stand-alone purchases. In short, Teva paid for two quantities of low-ABUK oxymorphone API; it did not pay for rights regarding future sales of low-ABUK oxymorphone API. Teva argues that Mallinckrodt received consideration for the LOA "in the form of

[21] This argument is premised on JTX-4, which was not admitted into evidence or supported by any testimony.

potential future sales of commercial quantities of [low-ABUK] [o]xymorphone API." (D.I. 166 at pp. 9-10). As Dr. Fabian testified, however, commercial supply is an issue entirely separate from a LOA authorization. (Tr. 706:4-707:5). Since a LOA does not create a binding commercial obligation, Mallinckrodt is under no obligation to sell any low-ABUK oxymorphone API to Teva. "[W]here the promisor may perform or not, solely on the [**43] condition of his whim, his promise will not serve as consideration." *Wallach v. Eaton Corp.*, 125 F. Supp. 3d 487, 493-94 (D. Del. 2015) (quotation marks omitted) (quoting 3 Samuel Williston & Richard A. Lord, *Williston on Contracts* § 7.7 (4th ed. 1992)), *appeal filed*, No. 15-3320 (3d Cir. Sept. 29, 2015).

I therefore conclude that Teva has failed to demonstrate the existence of an implied license.

III. CONCLUSION

Defendants failed to prove by clear and convincing evidence that any of the asserted claims of the '779 patent are invalid. Teva failed to prove its affirmative defense of implied license by a preponderance of the evidence.

Plaintiffs should submit an agreed upon form of final judgment within two weeks.

End of Document

EXHIBIT II

 KeyCite Yellow Flag - Negative Treatment
Amended in Part by Endo Pharmaceuticals Inc. v. Amneal Pharmaceuticals, LLC, S.D.N.Y., April 29, 2016

2015 WL 9459823
Only the Westlaw citation is currently available.
United States District Court,
S.D. New York.

Endo Pharmaceuticals Inc. and Grünenthal GmbH, Plaintiffs,
v.
Amneal Pharmaceuticals, LLC and Amneal Pharmaceuticals of New York, LLC, Defendants.
Endo Pharmaceuticals Inc. and Grünenthal GmbH, Plaintiffs,
v.
Teva Pharmaceuticals USA, Inc. and Barr Laboratories, Inc., Defendant.
Endo Pharmaceuticals Inc. and Grünenthal GmbH, Plaintiffs,
v.
Impax Laboratories, Inc. and Thorx Laboratories, Inc., Defendants.
Endo Pharmaceuticals Inc., Plaintiff,
v.
Actavis Inc. and Actavis South Atlantic LLC, Defendants.
Endo Pharmaceuticals Inc. and Grünenthal GmbH, Plaintiffs,
v.
Impax Laboratories, Inc., Defendants.
Endo Pharmaceuticals Inc. and Grünenthal GmbH, Plaintiffs,
v.
Actavis Inc, Actavis South Atlantic LLC, and Watson Pharmaceuticals, Inc., Defendants.
Endo Pharmaceuticals Inc., Plaintiff,
v.
Roxane Laboratories, Inc., Defendant.
Endo Pharmaceuticals Inc., Plaintiff,
v.
Sun Pharmaceutical Industries, Ltd., Defendant.

12 Civ. 8115 (TPG), 12 Civ. 8060 (TPG), 12 Civ. 8317 (TPG), 12 Civ. 8985 (TPG), 13 Civ. 435 (TPG), 13 Civ. 436 (TPG), 13 Civ. 3288 (TPG), 13 Civ. 4343 (TPG), 13 Civ. 8597 (TPG)
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Signed August 14, 2015
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Filed 08/18/2015

FINDINGS OF FACT AND CONCLUSIONS OF LAW

THOMAS P. GRIESA, U.S. District Judge

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April 24, 2015 marked the conclusion of a five-week bench trial for patent infringement. Plaintiffs Endo Pharmaceuticals Inc. ("Endo") and Grünenthal GmbH (Grünenthal) argue that defendants, all of which are generic drug manufacturers, infringe on patents covering Endo's branded painkiller OPANA® ER by selling or seeking approval to sell generic versions of the drug in either crushable or non-crushable formulations. Defendants argue that their generic products, as described in their Abbreviated New Drug Applications ("ANDAs"), do not and will not infringe the patents-in-suit, and that in any event those patents are invalid. Defendants also asserted other statutory and equitable defenses.

There are seven groups of defendants in these cases. Plaintiffs sued the defendants separately, but the cases were tried jointly upon mutual consent. The defendants are: Amneal Pharmaceuticals, LLC and Amneal Pharmaceuticals of New York, LLC (collectively, "Amneal"); Teva Pharmaceuticals USA, Inc. and Barr Laboratories, Inc. (collectively, "Teva"); Impax Laboratories, Inc. ("Impax"), ThoRx Laboratories, Inc. ("ThoRx") Actavis Inc., Actavis South Atlantic LLC, and Watson Pharmaceuticals, Inc. (collectively, "Actavis"); Roxane Laboratories, Inc. ("Roxane") and Sun Pharmaceutical Industries ("Sun Pharma.").

There are three patents-in-suit. Endo owns two of the patents, United States patent numbers 8,309,122 ("the '122 Patent") and 8,329,216 ("the '216 Patent"). These patents recite a controlled release formulation of the painkilling opioid oxymorphone suitable for twelve-hour dosing. Grünenthal owns the third patent, United States Patent Number 8,309,060 ("the '060 Patent"), which describes an invention for drug-tablets so hard that they are difficult to abuse through crushing and snorting, and which also accommodate other barriers to abuse.

The court concludes that defendants' generic products infringe or will infringe all but two of the asserted claims of the '122 and '216 patents, and that defendants have failed to satisfy their burden of showing those claims to be invalid. Because each of the defendants infringe the asserted claims of the '122 and '216 Patents, the court enters judgment in Endo's favor and enjoins defendants from selling the generic oxymorphone products described in their ANDAs. With regard to the '060 Patent, the court finds that certain defendants infringe each of the asserted claims, but concludes that defendants have satisfied their burden of showing those claims to be obvious in light of the prior art at the time of the invention. Thus, the asserted claims of the '060 Patent are invalid.

Background Findings of Fact

***3** Endo Pharmaceuticals Inc. was founded in 1997 as a "spinout" from the well-known DuPont Merck Pharmaceutical Company. Trial Tr. at 23:3–5. As a new drug company, Endo had considerable flexibility in deciding which new drug products to develop. *See id.* at 25–27. A number of potential projects were under consideration, including a project to explore developing a certain opioid, oxymorphone, into a controlled-release tablet. *See generally* Project Team Minutes (Feb. 12, 1998) (PTX–0157). Oxymorphone is a semisynthetic opioid created from manipulating morphine, which is derived from poppies. Trial Tr. at 180:7–10. In 1997, Endo sold oxymorphone in intravenous and suppository formulations. *Id.* at 179:24–25. Both of these formulations provided pain-relief to patients, but were not very profitable. *Id.* at 180:17–18. Thus, Endo was eager to see whether oxymorphone could be developed into a controlled release tablet which patients could take to manage chronic pain at twelve-hour intervals. *Id.* at 406:3–5. Endo believed that if such a product could be developed, it would capture a portion of the then-estimated $650 million market for opioid painkillers. *See* Alliance Committee Meeting Overheads (July 10, 1998) (PTX–0217 at 383).

Oxymorphone had been sold in tablet form between 1959 and 1971 as the branded-drug Numorphan. Trial Tr. at 180:3–4; 1458:7–9. It was pulled from the market in 1971 because of poor sales. Regulatory Background (PTX–0115 at 406). Like the intravenous and suppository formulations of oxymorphone, Numorphan had been an immediate-release drug. Trial Tr. at 1458:11–12. An immediate release drug, when swallowed or otherwise administered, releases almost all of its active ingredient within an hour. Trial Tr. at 176–177; *see also* '122 Patent at 3:20–30. In contrast, a controlled-release drug releases the active ingredient over many hours. *Id.* at 178:12–18. In 1997, when Endo began developing its new product, there had never been a controlled-release formulation of oxymorphone. Briefing Package to FDA (Apr. 6, 2000) (PTX–0223 at 428–31).

Developing oxymorphone into an effective controlled-release formulation presented a number of challenges. First among these was a relative lack of previous research into orally administered oxymorphone's pharmacokinetic effects, meaning the drug's impact on the human body. *Id.* at 177:3–4. At the time of Endo's development work for oxymorphone there were already two controlled-release opioid painkillers on the market, MS Contin and OxyContin. *Id.* at 204:8–20. Those products were controlled-release formulations of morphine and oxycodone, both of which had been studied extensively in human subjects in their immediate release formulations. *See id.* In contrast, only four studies had been conducted on the effects of orally administered oxymorphone in humans, and each of those had been completed before 1983. *Id.* at 201:9–12; *see also* Briefing Packet (PTX–0223 at 410). Thus, unlike with the development of MS Contin and OxyContin, Endo faced an almost total lack of pharmacokinetic data to use in developing controlled-release oxymorphone. Trial Tr. at 201–02.

This lack of pharmacokinetic data made it difficult for Endo's development team to predict in advance whether oxymorphone would be suitable in a controlled-release form. Oxymorphone in immediate-release form has an exceptionally low bioavailability of only about 10%. *Id.* at 194:9–11. This means that when ingested, 90% of the oxymorphone is metabolized by the liver and only 10% actually enters the bloodstream to provide pain relief. *Id.* This is starkly different from morphine and oxycodone, which exhibit bioavailability of 40% and 60–87% respectively. *See id.* at 2611:6; 2613:21–22. Oxymorphone's unusually low bioavailability in immediate release form raised doubts that it would work in a controlled release setting, where far less of the tablet is dissolved at any given time. *Id.* at 190:8–15.

Endo partnered with another company, Penwest Pharmaceuticals, to develop oxymorphone into a controlled-release tablet. Trial Tr. at 190. Penwest specialized in the development of pharmaceutical formulations. *Id.* It had invented a technology, called TIMERx, which used natural gums to slow the release of a drug's active ingredient over a period of many hours. *Id.* at 303:12– 17. With Penwest as partner, by 1998 Endo had developed tablets of controlled-release oxymorphone hydrochloride (which is oxymorphone in its salt-form). *See* Project Team Minutes (Feb. 12, 1998) (PTX–0157 at 423–24).

***4** Between 1998 and 2001, Endo tested its new formulation in both laboratory settings (*in vitro* testing) and in human subjects and patients (*in vivo* testing). *See* Project Team Minutes (Feb. 12, 1998) (PTX–0157 at 2) (discussing dissolution testing); *see also* Alliance Committee Meeting Minutes (May 2, 2001) (PTX–144) (discussing clinical studies). On October 15, 2001, Endo filed applications with the United States Patent and Trademark Office for patents covering its new controlled release oxymorphone product. *See* United States Patent 3,309,122 at 1 (PTX–0001 at 372); United States Patent 8,329,216 at 1 (PTX–0005 at 463). Shortly thereafter, in December of 2002, Endo filed a New Drug Application ("NDA") with the Food and Drug Administration for the branded drug OPANA® ER. Trial Tr. at 220:2–3.

An NDA is required to obtain regulatory approval to sell branded drugs in the United States. *Id.* at 597:6–11. The new-drug applicant must prove to the FDA, through extensive clinical testing, that the drug is both safe and effective. *Cf.* 21 U.S.C. § 355(b)(1). Moreover, the applicant must inform the FDA of the patents covering the new drug. *See id.* Upon approving the new drug for sale, the FDA will list all of the patents covering the product in a publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as the "Orange Book."

There is an expedited process when seeking FDA approval of a generic version of a branded drug. The generic manufacturer will file an Abbreviated New Drug

Application ("ANDA") with the FDA. This eliminates the need to conduct extensive clinical trials. The generic manufacturer need merely show that the generic drug has the same active ingredient as the branded-drug, and that the two products are bioequivalent. 21 U.S.C. § 355 (j). Moreover, the applicant must certify to the FDA that the patents listed in the Orange Book as covering the branded drug do not preclude approval of the generic drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii). One way of doing this is to certify that the patents are invalid, or that the proposed generic product would not infringe those patents. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). This type of certification is known as "Paragraph IV" certification. Once a generic manufacturer files a Paragraph IV certification, it must inform the patent holder of the filing. *Id.* This gives the patent holder a period of time in which to bring a lawsuit asserting the patents. *Id.* If the patent holder brings suit, FDA approval of the generic drug will be stayed for 30 months. 21 U.S.C. § 355(j)(5)(B)(iii).

As discussed, Endo filed its New Drug Application for OPANA® ER in December of 2002. Trial Tr. at 220. That NDA would not be approved until 2006, four years later. *Id.* at 185:20–22. In the meantime, Endo continued to perform development work on the OPANA® ER product. *Id.* at 220. Concerned about the public's abuse of prescription opioids, Endo began exploring ways to make OPANA® ER tamper resistant. *See id.* at 221:10–13. Project team meetings from this time reveal that Endo had considered a number of mechanisms for deterring abuse of OPANA® ER once it was approved by the FDA for sale, including the use of "antagonists," agents in the drug formulation that would block the effect of the opioid if the tablet were tampered with. *Id.*; *see also* PowerPoint Presentation "Opioid Abuse Deterrent (OAD) In–Depth Review" (Dec. 7, 2005) (PTX–0922 at 6). Endo also considered making its tablets difficult to crush, so that the drug would be difficult to sniff or inject. Trial Tr. at 221–22. However, these early efforts were unsuccessful. Trial Tr. at 222.

Things began to change in 2006. In that year, the FDA finally approved Endo's NDA for OPANA® ER. Trial Tr. at 794:18–21. Endo launched the product in August of 2006, and it began to be prescribed by physicians across the country. *See id.* However, Endo remained concerned about the growing abuse of prescription opioids. *Id.* at 796:15–20. Recreational drug abusers would crush OPANA® ER and other opioids and sniff the resulting powder to achieve a euphoric effect. *Id.* Therefore, Endo continued to seek partners for developing a crush-resistant version of the drug. *See* Trial Tr. at 797–98.

***5** Endo found such a partner in Grünenthal GmbH. Grünenthal had developed a process for creating tablet pills with an exceptionally high breaking strength, and also integrating other abuse-deterrent features. Trial Tr. at 1053:1–7. Following the launch of OPANA® ER, Endo sent a delegation to Grünenthal's offices in Germany. *Id.* at 1054:20–21. There, Grünenthal demonstrated that its technology could be used to create tablets that were exceptionally hard. *Id.* at 155. Moreover, Dr. Bartholomäus, one of the inventors of the technology, showed that the tablets were also effective in releasing the active ingredient of the drug for legitimate use. *Id.* at 1055:22–25. Impressed by this presentation, Endo eventually entered into a license agreement with Grünenthal to use its technology to develop a crush-resistant formulation of the recently-introduced OPANA® ER product. *Id.* at 1056:9–11; *see also* Development, License and Supply Agreement between Grünenthal GmbH and Endo Pharmaceuticals Inc. (Dec. 18, 2007) (PTX–0551).

After its launch in 2006, the original formulation of OPANA® ER became one of Endo's core products. Trial Tr. at 788:16–18. Net sales of the drug were $5 million in 2006, and by 2011 had grown to $384 million. Trial Tr. at 805:2025. The high sales of OPANA® ER in 2011 ($384 million) marked a dramatic increase from the previous year's sales of $240 million. *See id.* at 806–07. But sales in subsequent years tapered off, amounting to $198 million in 2014. *Id.* at 806:4.

Endo's crush-resistant formulation of OPANA® ER, which it had been developing with Grünenthal, was approved for sale in the United States at the end of 2011. *Id.* at 807:13. Endo launched the new, crush-resistant formulation of OPANA® ER (OPANA® ER CRF) in early 2012. Trial Tr. at 2021:24. Endo then discontinued the sale of the original, non-crush-resistant formulation of OPANA® ER.

In 2012, the Patent and Trademark Office awarded the three patents at issue in these cases. The '122 and '216

patents cover Endo's invention of a controlled release oxymorphone tablet. The '060 Patent covers Grünenthal's invention of a hard, crush-resistant tablet which also accommodates secondary barriers to abuse.

Defendants are generic drug manufacturers. Each has filed an Abbreviated New Drug Application with the FDA seeking approval to market generic versions of OPANA® ER in its crushable or non-crushable formulations. *See* Trial Tr. at 697:21; 1134; *see also* Summary Chart (PTX–3562) (listing the ANDA numbers for each defendant). Actavis and Sun Pharma sought FDA approval to market both crushable and crush-resistant generic versions of OPANA® ER. Trial Tr. at 599:18–21. Roxane sought approval solely for the crushable version. *See id.* at 600:4–6. Amneal, Teva, Impax, and ThoRx sought approval solely to manufacture crush-resistant generic products. *Id.* at 598:20–23 (referring to PX–4002.80). To date, the FDA has approved the crushable-product ANDAs filed by Actavis and Roxane, but only Actavis has brought its generic product to market. Trial Tr. at 600:3–7.

Between 2012 and 2013, plaintiffs filed lawsuits against each of the defendants for patent infringement. As many as seven patents have been asserted in this case at various times, involving scores of patent claims. However, as trial approached the parties mutually narrowed the number of patents and patent claims asserted. *See, e.g.,* Stipulation and Order Re U.S. Patent 7,851,482 (Doc. # 96 in 12–CV–8060). Moreover, on March 17, 2015, the court dismissed one of the patents from the case on collateral estoppel grounds. *See* Order of March 17, 2015 at 6. Thus, the bench trial involved only the '122, '216, and '060 patents.

Discussion

In an action for patent infringement, it is the plaintiff's burden to prove by a preponderance of the evidence that every limitation of the asserted patent claims is found in the accused device. *Siemens Med. Solutions USA, Inc. v. Saint–Gobain Ceramics & Plastics, Inc.,* 637 F.3d 1269, 1279 (Fed.Cir.2011); *Glaxo, Inc. v. Novopharm, Ltd.,* 110 F.3d 1562, 1565 (Fed.Cir.1997). "The preponderance of the evidence standard requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence...." *Bosies v. Benedict,* 27 F.3d 539, 542 (Fed.Cir.1994) (internal quotation marks and citations omitted).

***6** A defendant asserting the invalidity of the patents-in-suit carries a higher burden. The defendant must prove the patents' invalidity by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P'ship,* 131 S.Ct. 2238, 2242 (2011). "Clear and convincing evidence is such evidence that produces 'an abiding conviction that the truth of the factual contentions are highly probable.' " *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.,* 694 F.3d 1312, 1327 (Fed.Cir.2012) (*quoting Colorado v. New Mexico,* 467 U.S. 310, 316 (1984)).

A. Whether Defendants Infringe the Patents–in–Suit.

Determining patent infringement is a two-step process. First, the court must construe the asserted patent claims. *Markman v. Westview Instruments, Inc.,* 517 U.S. 370, 391 (1996). Second, the claims as construed must be compared to the accused device. *Carroll Touch, Inc. v. Electro Mech. Sys., Inc.,* 15 F.3d 1573, 1576 (Fed.Cir.1993). The accused device will infringe if it "embodies every limitation of the claim, either literally or by an equivalent." *Id.*

1. Step One: Construing the Asserted Claims.

The first step in the infringement analysis is to construe the asserted patent claims. The purpose of construing the patent claims is not to rewrite the patent, but to simply elaborate on "normally terse claim language" to aid in comprehension thereof. *Terlep v. Brinkmann Corp.,* 418 F.3d 1379, 1382 (Fed.Cir.2005). The words of a patent claim should generally be given their ordinary and customary meaning as would be understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.,* 415 F.3d 1303, 1313 (Fed.Cir.2005). The primary source of material in determining the claim's meaning is the intrinsic evidence, meaning the patent specification, the patent claims themselves, and the prosecution history of the patent. *Id.* at 1318. The patent specification may show that the inventor had ascribed meanings to certain words that those words do not ordinarily convey, and had acted as his own lexicographer. *Id.* at 136. In such a case, the inventor's definition will govern. *Id.* Likewise, the specification may also disavow the scope of a claim term, and such disavowal will also govern. *Id.* It is only after considering the intrinsic

evidence of the claim's meaning that the court may resort to extrinsic evidence, such as dictionaries and treatises, to aid in comprehension of the claim terms. *Vitronics Corp. v. Conceptronic, Inc.,* 90 F.3d 1576, 1584 n.6 (Fed.Cir.1996).

Patent claims generally fall into two broad categories: product claims and method claims. A product claim describes the invention of a physical product, such as a machine or pharmaceutical tablet. A method claim describes a series of steps, or process, constituting the claimed invention. In construing patent claims, courts "must generally take care to avoid reading [method] limitations into [product] claims ... because the process by which a product is made is irrelevant to the question of whether that product infringes a pure [product] claim." *Baldwin Graphic Sys., Inc. v. Siebert, Inc.,* 512 F.3d 1338, 1344 (Fed.Cir.2008). That being said, some patent claims describe a product by the process used to achieve it. *See Abbott Labs. v. Sandoz, Inc.,* 566 F.3d 1282, 1291 (Fed.Cir.2009). Such "product-by-process" claims should be read to require use of the claimed process. *Id.* at 1294.

***7** Claims may be either independent or dependent. 35 U.S.C. § 112(c). An independent claim stands alone. *Id.* In contrast, a dependent claim refers back to a previous independent claim. *Id.* To establish whether a claim is dependent upon another, the court examines if the new claim both refers to an earlier claim and further limits that referent. *Monsanto Co. v. Syngenta Seeds, Inc.,* 503 F.3d 1352, 1357 (Fed.Cir.2007). Significantly, a dependent claim must be construed to incorporate all of the limitations of the independent claim to which it refers. 35 U.S.C. § 112(d).

Pharmaceutical patent claims generally take one of several common forms. *See* Shashank Upadhye, Generic Pharmaceutical Patent and FDA Law §§ 1:9– 1:19. Inventors may choose to claim the active pharmaceutical ingredient ("API") itself, meaning the actual molecule at the root of the invention. *Id.* § 1:9. However, because many APIs cannot be used in their pure form, the inventor will claim the API in its salt-form. *Id.* § 1:10; *see also* Trial Tr. at 1457:6–7. Another type of pharmaceutical patent claim is the "release profile claim." *Id.* § 1:19. A release profile claim recites the amount of an API delivered from a drug at certain intervals. *Id.*

The first step in construing the claims asserted in this case is to define a person of ordinary skill in the art at the time of the inventions. At trial, plaintiffs and defendants provided similar definitions for a person of ordinary skill in the art. Defendants' expert, Dr. Umesh Banakar, testified that such a person would have "at least a master's degree or a doctorate in pharmaceutical sciences with experience in developing formulations, including controlled release formulations. If the individual had a lesser degree of training, such as a bachelor's degree, then he would need several more years of experience in the areas of pharmaceutical formulation development." Trial Tr. at 1502:13–20. Plaintiffs adopted this definition at multiple points during the proceedings, *see, e.g.,* Trial Tr. at 1692:13; 1937:2–6, and the court finds that it is a reasonable one. Thus, a person of ordinary skill in the art would possess the above-described qualifications and experience at the time of the inventions.

a. Construing the Asserted Claims of the '122 Patent.

The invention embodied in the '122 Patent is a controlled-release tablet of oxymorphone, effective in providing pain relief over a twelve-hour period. Endo asserts claims 2, 3, 19, and 20 of the '122 Patent against defendants. Claim 1, upon which Claim 2 depends, reads as follows:

> 1. An analgesically effective controlled release pharmaceutical composition with a twelve hour dosing interval in the form of a tablet, comprising oxymorphone or a pharmaceutically acceptable salt thereof as the sole active ingredient in the tablet, and a controlled release delivery system comprising at least one pharmaceutical excipient, wherein upon placement of the composition in an in vitro dissolution test comprising USP Paddle Method at 50 rpm in 500 ml media having a pH of 1.2 to 6.8 at 37° C., about 15% to about 50%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 1 hour in the test.

'122 Patent at 25:50–60.

The intrinsic evidence provides clarity as to how Claim 1 would read to a person of ordinary skill in the art at

the time of the invention. First, the claim calls for an "analgesically effective controlled release pharmaceutical composition .... in the form of a tablet." '122 Patent Claim 1. A "tablet" is a solid oral dosage form. *Id.* at 3:5. Analgesia is a dulling of the sensation of pain. *See* '122 Patent at 1:15–24. While the patent calls for analgesia, it does not encompass any pain relief regardless of how slight. *See id.* at 4:41–45. Rather, the patent calls for the *effective* dulling of pain. *See id.* at 25:50. The substance must provide pain relief at a level sufficient to treat patients suffering from chronic illnesses. *Id.* at 1:39–40. This means it must treat moderate, severe, or acute chronic pain. *Id.* at 44:43–46. Indeed, the specification defines how much oxymorphone is needed to enter the bloodstream for the dosage form to be considered "effective." *See id.* at 3:41–53. Thus, a person of ordinary skill in the art would read the terms "analgesically effective controlled release pharmaceutical composition .... in the form of a tablet" as: a tablet providing pain relief at therapeutically useful levels. *See id.* at 3:4–6.

***8** A "controlled release pharmaceutical composition" is a drug formulation that releases its active ingredient slowly. The specification explains the concept of controlled release drugs by comparison to immediate release drugs. *Id.* at 3:19– 33. An immediate release tablet, when dissolved in an environment akin to the human digestive system, releases more than 80% of its active ingredient within 30 minutes. *Id.* at 26. In contrast, a controlled release tablet generally lasts much longer, releasing no more than 80% of its active ingredient in 60 minutes. *See id.* at 3:30–34. Thus, a "controlled release pharmaceutical composition" is a drug formulation that releases its active ingredient slowly over time.

A "dosing interval" refers to length of time between doses of a drug. The specification explains that when a drug is taken by a patient, its effects wear off over time, requiring the patient to take another dose. *Id.* at 1:40–43. The length of time between doses, then, is the dosing interval. *See id.* Claim 1 of the '122 Patent calls for a "twelve hour dosing interval." *Id.* at 25:51. This means that the when a patient takes a dose, it will last for twelve hours before another dose is needed.

Claim 1 requires the tablet to be comprised of "oxymorphone or a pharmaceutically acceptable salt thereof as the sole active ingredient in the tablet." *Id.* at 25:53–54. Oxymorphone is an opioid analgesic. *Id.* at 1:25. Like many opioids, oxymorphone may be paired with a non-toxic salt for use in medicine. *Id.* at 4:56–62. A "pharmaceutically acceptable salt" of oxymorphone would by oxymorphone hydrochloride, or other salts formed by mixing oxymorphone with acids such as sulfuric acid, nitric acid, and others. *Id.* at 4:58–68. Thus, the patent requires a tablet containing oxymorphone or a salt of oxymorphone as the sole active ingredient.

Claim 1 also requires that the tablet comprise a "controlled release delivery system comprising at least one pharmaceutical excipient." *Id.* at 25:53–56. As discussed, "controlled release" means that a drug's active ingredient releases slowly over time. "Delivery system" refers to the vehicle used to provide the controlled release property. *See id.* at 5:48–62. Such systems include "osmotic pumps"; use of a coating of controlled release film; or use of a "controlled release matrix." *Id.* at 5–6. An "excipient" is a substance other than the active ingredient. *See id.* at 6:1–2. In the context of this claim, it is the excipient (not the oxymorphone) which provides the controlled-release delivery properties of the tablet. *Id.* at 25:54–55.

Claim 1 further provides that "upon placement of the composition in an in vitro dissolution test comprising USP Paddle Method at 50 rpm in 500 ml media having a pH of 1.2 to 6.8 at 37° C, about 15% to about 50%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 1 hour in the test." *Id.* at 55–60. "In vitro dissolution test" refers to laboratory testing, as opposed to human testing (*in vivo*), of the rate at which a substance dissolves. *See id.* at 3:34–42. "RPM" means revolutions per minute, and pH is a measure of acidity. *Id.* at 464:10–11; 469:1–2. The term "USP Paddle Method" is not defined in the specification. However, a person of ordinary skill in the art would know that "USP" stands for United States Pharmacopeia, a book describing standard formulation methods. Trial Tr. at 467:16–18.

The United States Pharmacopeia describes two dissolution testing methods relevant to this litigation, each of which uses a different dissolution testing apparatus. *See* The National Formulary, The United States Pharmacopeia (1995 ed.) (PTX–0909 at 1792). The first apparatus consists of vessel filled with a fluid. *Id.* at 1791. A metal rod with a basket attached is lowered into the vessel and spun. *Id.* Inside the basket is a tablet. *Id.* As the basket spins in the fluid, the tablet will dissolve. *Id.* This method of dissolution testing, using a basket-

apparatus, is known as the "basket method." *See* Figure 1 Below. *Id.* at 1792.

***9** Tabular or Graphical Material not displayable at this time.

The second apparatus is similar to the first apparatus. However, the second apparatus uses a "paddle," which is formed from a blade, as the stirring element. *Id.* In this method, the tablet is not contained within a basket, but rests at the bottom of the vessel. *Id.* As the paddle spins above the tablet, the tablet will dissolve. *See id.* This method of dissolution testing, using a paddle, is known as the "paddle method." See Figure 2 Below. *Id.*

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Thus, a person of ordinary skill in the art would understand the term "USP Paddle Method" as referring to a specific dissolution test described in the United States Pharmacopeia, one that uses a vessel filled with a fluid which is stirred by a blade-shaped paddle.

Finally, the remainder of Claim 1 describes the rate at which the tablet releases the active ingredient using the method described. This language is clear: "about 15% to about 50%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 1 hour in the test."

The release rate is further elaborated in claims 2 and 3 of the '122 Patent. Claim 2 provides that at four hours into the test, "about 45% to about 80%" of the oxymorphone is released. '122 Patent at 25:60–64. Claim 3 provides that at 10 hours into the test, "about 80%" of the oxymorphone is released. *Id.* at 25:65– 67.

In sum, Claim 1 of the '122 Patent would, to a person of ordinary skill in the art at the time of the invention, read as follows: "a controlled-release pharmaceutical tablet providing pain relief at therapeutically useful levels for twelve hours, consisting of oxymorphone (or its salt) as the sole active ingredient, and also consisting of a controlled-release delivery system made up of a non-oxymorphone substance that, when tested using the Paddle Method at 50 revolutions per minute in 500 ml of media of a certain acidity and temperature, releases about 15%–50% of the oxymorphone (or its salt) by about an hour into the test." Claim 2 would be read as providing that about 45%–80% of the oxymorphone will be released by about four hours into the test. Finally, Claim 3 provides that about 80% of the oxymorphone will be released by about ten hours into the test.

Endo also asserts Claim 20 of the '122 Patent against defendants. Claim 20 depends from Claim 18. Taken together, the two claims read:

> 18. A method of treating pain in a subject in need thereof, the method comprising administering to the subject the pharmaceutical composition of claim 1 comprising about 5 mg to about 80 mg of oxymorphone or pharmaceutically acceptable salt thereof.
>
> 20. The method of claim 18 wherein upon oral administration of the composition the oxymorphone $AUC_{(0-inf)}$ is no more than 20% higher when the composition is administered to the subject under fed as compared to fasted conditions.

'122 Patent at 26:54–58.

The construction of the term "administering" was hotly debated at trial. Defendants argued that as mere drug manufacturers, they do not actually administer tablet pills to subjects or patients, and thus cannot infringe the method claims of the '122 and '216 patents. *See, e.g.,* Trial Tr. at 611–13. While this argument presents issues of claim construction, it also implicates questions of infringement and indirect infringement, which will be dealt with in subsequent sections of this decision. *See infra* Part A(2)(a)(ii). As matter of claim construction, the meaning of the term "administering" would be readily apparent to a person of ordinary skill in the art upon reading the specification.

***10** The specification uses the term "administering" in two contexts. In the first context, "administering" is used synonymously with the unsupervised "taking" of the drug by patients in order to enjoy long periods of pain relief. *See, e.g.,* '122 Patent at 1:39–41; 4:41–48. In the second context, the term "administering" implies a clinical or laboratory setting, wherein an actor, such as a physician or scientist, gives, or more specifically *feeds,* tablet pills to a patient and then observes the results. *See, e.g., id.* at 20:53–55 (beginning on the morning of Day 3, the volunteers were administered a ... tablet every 12 hours....). Both of these contexts are relevant to claims 18 and 20 of the '122 Patent. Claim 18 recites

"a method of treating pain in a subject in need thereof, the method comprising *administering* to the subject the pharmaceutical composition of claim 1." *Id.* at 26:54–56. A person of ordinary skill in the art would understand the "administering" requirement to mean when the subject *takes* the tablet to treat his or her pain, and also when another actor *feeds* the tablet to the subject to treat his or her pain.

Claim 20 incorporates the method of "administering" the tablets described in claim 18, and then provides that "upon oral administration of the composition the oxymorphone $AUC_{(0-inf)}$ is no more than 20% higher when the composition is administered to the subject under fed as compared to fasted conditions." *Id.* at 28:1–5. Consistent with the claim construction above, "oral administration" means a subject's *taking* of the tablet by mouth, or the *feeding* of a tablet to a subject to be taken by mouth.

The term "AUC" means "area under the curve," and is a way to measure the concentration of a drug in the bloodstream for a stated period of time, as signified by the subscript within the parenthesis. *See id.* at 11:36–40. Thus, $AUC_{(0-inf)}$ means "area under the curve," or concentration of drug in the blood, from zero hours to infinity. *Id.* at 11:40–43. The terms "fed" and "fasted" refer to whether a person has eaten or not. *See id.* at 13:67–14:1 (describing that for a particular study, "fed" patients were those who had eaten a high-fat breakfast). Putting the above constructions together, Claim 20 of the '122 Patent reads as follows: "A method of treating pain in which the subject, upon taking or being fed the tablet orally, exhibits total blood concentration levels of oxymorphone no more than 20% higher after having eaten a meal as compared to having taken the tablet on an empty stomach."

The final asserted claim of the '122 Patent is Claim 19. Claim 19 reads as follows:

> 19. An analgesically effective controlled release pharmaceutical composition with a twelve hour dosing interval in the form of a tablet, comprising oxymorphone or pharmaceutically acceptable salt thereof as the sole active ingredient in the tablet and a controlled release delivery system comprising a hydrophilic material that forms a gel upon exposure to gastrointestinal fluid, wherein upon placement of the composition in an in vitro dissolution test comprising USP Paddle Method at 50 rpm in 500 ml media having a pH of 1.2 to 6.8 at 37° C., about 15% to about 50%, by weight, of the oxymorphone or salt thereof is released from the composition at about 1 hour in the test, about 45% to about 80%, by weight, of the oxymorphone or salt thereof is released from the composition at about 4 hours in the test, and at least about 80%, by weight, of the oxymorphone or salt thereof is released from the composition at about 10 hours in the test.

'122 Patent at 26:59–27:7. Most of Claim 19 simply restates limitations already recited in claims 1, 2, and 3 of the '122 Patent. Claim 19 differs, however, in that it provides that the controlled release delivering system comprises "a hydrophilic material that forms a gel upon exposure to gastrointestinal fluid." Id. at 26:63– 65. "Hydrophilic" is not defined in the specification, but a person of ordinary skill in the art would understand it to mean "water-loving," or something that absorbs water. Trial Tr. at 1475:13–15. Upon exposure to gastrointestinal fluid, the water-absorbing material forms a gel which releases oxymorphone slowly. See '122 Patent at 6:48–55. In sum, Claim 19 would read the same way as claims 1, 2, and 3 of the '122 Patent, but recites the additional limitation that the controlled release delivery system be comprised of a hydrophilic substance which forms a gel upon exposure to gastrointestinal fluid.

b. Construing the Asserted Claims of the '216 Patent.

***11** The '216 Patent is similar to the '122 Patent, and in fact contains the exact same specification. Consequently, where the two patents share certain language, a person of ordinary skill in the art would interpret that language the same way for both patents. Moreover, many of the asserted claims of the '216 Patent are repetitive, and repeat the same limitations in different combinations. For these

reasons, the court will construe terminology appearing in the '216 Patent claims in the first instance, but where terminology has already been construed, will generally apply the earlier construction. In all, Endo asserts sixteen claims from the '216 Patent, claims 1, 22, 40, 42, 50, 54, 57, 62, 64, 71, 73, 74, 78, 79, 80, and 82. Those claims, as well as seven independent claims incorporated therein by reference (claims 21, 38, 49, 55, 66, 72, and 77), are construed below.

Claim 1 of the '216 Patent reads as follows:

1. An oral controlled release oxymorphone formulation, comprising:

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

b. a hydrophilic material, wherein upon oral administration of the formulation to a subject in need of an analgesic effect:

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

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

(iii)the blood plasma levels of 6–OH oxymorphone and oxymorphone exhibit a ratio of area under the curve (AUC(0 to inf)) of blood plasma level versus time for 6–OH oxymorphone compared to oxymorphone in a range of about 0.5 to about 1.5;

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

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

'216 Patent at 26:35–55. A person of ordinary skill in the art would understand parts (a) and (b) of the claim as describing a formulation of oxymorphone or its salt combined with a hydrophilic substance. When that formulation is taken by or fed to a subject in need of pain relief, it will produce the effects described in subparts (i) thorough (v).

Subpart (i) states that the formulation "provides detectable blood plasma levels of 6–OH oxymorphone and oxymorphone." '216 Patent at 26:42–43. "Blood plasma level" refers to the amount of a substance in the bloodstream. *Cf. id.* at 2:8–14. 6–OH oxymorphone has a technical definition as "the analog of oxymorphone having an alcohol (hydroxy) moiety that replaces the carb oxy moiety found on oxymorphone at the 6–position." *Id.* at 2:65–3:2. While this is the definition a person of ordinary skill in the art would apply, it may be helpful to the reader to explain what 6–OH oxymorphone is in plain terms. At trial, a number of experts explained that 6–OH (or "six-hydroxy") oxymorphone is a byproduct produced when oxymorphone is metabolized in the human liver. *See, e.g.,* Trial Tr. at 592:2–6. This byproduct, known as a "metabolite," will have a measurable presence in the bloodstream. *See id.* at 592–93. Thus, subpart (i) of Claim 1 of the '216 Patent simply means that the formulation will provide detectable levels of the metabolite 6–hydroxy–oxymorphone and oxymorphone in the bloodstream.

Subparts (ii) through (v) of the claim define what those levels will be. Subpart (ii) explains that the blood levels of 6–hydroxy–oxymorphone and oxymorphone will "peak" within about 1 to about 8 hours after administration. '216 Patent at 26:44–46. At trial, there was some dispute among the experts as to what the term "peak" meant. *See* Trial Tr. at 1575:7–10. But such debate is academic in light of the specification. The specification refers to "peaks" of curves as drawn on charts. *See* '216 Patent at 12:58–67. Upon looking at the charts, one of ordinary skill in the art would immediately recognize a "peak" as occurring where blood concentration reaches a high-point before declining. See Figure 5 below.

***12** Tabular or Graphical Material not displayable at this time.

'216 Patent at "Sheet 5."

Subpart (iii) provides that "the blood plasma levels of 6–OH oxymorphone and oxymorphone exhibit a ratio of area under the curve (AUC(0 to inf)) of blood plasma level versus time for 6–OH oxymorphone compared to oxymorphone in a range of about 0.5 to about 1.5." '216 Patent at 26:47–51. This means that upon measuring the total amount of 6–hydroxy–oxymorphone (the metabolite) in the bloodstream over time, and comparing that amount to the total amount of oxymorphone in the bloodstream over time, there will be

between half to 50% more 6–hydroxy–oxymorphone in the bloodstream than oxymorphone in the bloodstream. Cf. id. at 3:51–53.

The final subparts of Claim 1 are clear. Subpart (iv) provides that the pain killing effect of the formulation will last about twelve hours; and subpart (v) provides that the blood plasma level of oxymorphone will exhibit two or three peaks, or high-points, within twelve hours of administration. *See id.* at 26:52–54. Claim 21 of the '216 Patent is similar to claims asserted in the '122 Patent. Claim 21 provides:

> 21. A pharmaceutical tablet prepared by:
>
> a. mixing oxymorphone or a pharmaceutically acceptable salt of oxymorphone and one or more controlled release excipients; and
>
> b. forming the tablet,
>
> wherein upon placement of the tablet in an in vitro dissolution test comprising USP Paddle Method at 50 rpm in 500 ml media having a pH of 1.2 to 6.8 at 37° C., about 15% to about 50%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 1 hour in the test; and wherein upon oral administration to a human subject the tablet alleviates pain for 12 to 24 hours.

'216 Patent at 28:10–22.

A person of ordinary skill in the art would understand part (a) of Claim 21 as describing a tablet made by mixing oxymorphone or its salt with a substance to slow release of the active ingredient. Part (b) calls for "forming" the tablet. "Forming" is not explicitly defined in the specification, but is used in contexts implying a meaning synonymous with "making." Indeed, the specification states that the invention "includes a method of making an oxymorphone controlled release ... form ... which comprises mixing the particles of oxymorphone ... with granules comprising the controlled release delivery system." *Id.* at 4:52–57. It then says that a preferred means of doing this is to "directly compress the mixture to form tablets." *Id.* This latter step, compression, is embodied in Claim 13. *See id.* at 27:38–39. But as used in Claim 21, the phrase "forming the tablet" simply means "making the tablet."

The remainder of Claim 21 would be understood as requiring that when tested using the Paddle Method at 50 revolutions per minute in 500 ml of media of a certain acidity and temperature, the tablet releases about 15%–50% of the oxymorphone (or its salt) by about an hour into the test, and that when taken by or fed to a human subject, the tablet will provide pain relief for 12 to 24 hours. *See id.* at 28:15–23.

***13** Claim 22 depends from Claim 21, and further describes the rate at which the dosage form will release the active ingredient over time. *Id.* at 28:23–27. The tablet will release about 45% to about 85% of the oxymorphone or its salt at about 4 hours in the test, and will release about 80% of the oxymorphone at about 10 hours into the test. *Id.*

Claim 38 is a method claim, and reads as follows:

> 38. A method for treating pain in a human subject in need of acute or chronic pain relief, comprising the steps of:
>
> (a) Providing a solid oral dosage form comprising about 5 mg to about 80 mg oxymorphone or a pharmaceutically acceptable salt thereof in a controlled release delivery system with a release rate profile designed to provide adequate blood plasma levels over at least 12 hours to provide sustained pain relief over this same period, wherein oxymorphone is the sole active ingredient, and wherein upon placement of the composition in an in vitro dissolution test comprising USP Paddle Method at 50 rpm in 500 ml media having a pH of 1.2 to 6.8 at 37°C., about 15% to about 50%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 1 hour in the test, about 45% to about 80%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 4 hours in the test, and at least about 80%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 10 hours in the test; and
>
> (b) administering a single dose of the dosage form to the subject, wherein the oxymorphone Cmax is at least 50% higher when the dosage form is administered to the subject under fed versus fasted conditions.

'216 Patent at 29:49–30:5.

Parts (a) and (b) of Claim 38 require the "providing" and "administering" of the dosage form to a person in need of acute or chronic pain relief. *Id.* Because the terms "providing" and "administering" are used separately in Claim 38, those terms, as a matter of construction, have distinct meanings. It has already been established that "administering" involves either the *taking* of a dosage form by the subject, *see, e.g.,* '216 Patent at 4:42–43 (discussing the taking of two or three doses daily to manage pain), or the *feeding* of a dosage form to the subject by another actor. *Id.* at 5:13–14. Such an actor might be a scientist who *feeds* tablets to subjects in conducting a study. *See, e.g.,* '216 Patent at 5:9–18.

Because "administration" involves the taking or feeding of the dosage form, it represents a terminal point in the process described in Claim 38. Since this is the termination of the process, then "making" the dosage form marks some distant beginning (although it is not a part of the actual method claim). The specification speaks of "making" the dosage form in terms of actually manufacturing it, or actually mixing oxymorphone or its salt with a controlled release delivery system. *See, e.g.,* '216 Patent at 4:51–58; 28:10–14.

"Providing" the dosage form, then, must come before administering in the method recited in Claim 38. The dosage form must first be made (manufactured), then provided to the subject, and then administered to subject. *Id.* at 29:50– 30:1–2. In this context, "providing" is synonymous with "making available." After the dosage form is manufactured, it is made available (provided) to a subject who takes it or has it fed to him by another person. Thus, the court construes the term "providing" as the "making available" of the dosage form described in the claims.

***14** The remainder of Claim 38 covers familiar ground. The claim requires, in subpart (a), the making available to subjects of a 5mg to 80mg controlled-release dosage form of oxymorphone or its salt, with a release rate "designed to provide" [1] sufficient blood levels to achieve pain relief over a 12 hour period, and that when tested using the Paddle Method at 50 revolutions per minute in 500 ml of media of a certain acidity and temperature, the oxymorphone will be released about 15%–50% at about one hour in the test, about 45%–80% at about fours in the test; and at least 80% at about 10 hours into the test. '216 Patent at 29:50–67. Subpart (b) of Claim 38 requires the taking or feeding of a single dose by or to a subject. *Id.* at 30:1–2.

Finally, Claim 38 requires that once the dose is provided and administered, "the oxymorphone Cmax is at least 50% higher when the dosage form is administered to the subject under fed versus fasted conditions." "Cmax" means the maximum observed concentration of a drug in the bloodstream. '216 Patent at 11:44. It measures concentration of the drug at its highest single point, and consequently is different than the measurement of "AUC," or area under the curve, which measures the concentration of the drug in the blood over a stated period of time. *See id.* at 11:40–43. Thus, this portion of the claim would be understood by a person of ordinary skill in the art as meaning "the maximum observed concentration of oxymorphone in the bloodstream is at least 50% percent higher when the dosage form is taken by (or fed to) a subject after having eaten a meal than it would be on an empty stomach."

Claim 40 of the '216 Patent depends from Claim 38, and recites the additional limitation that "the difference in the oxymorphone area under the curve AUC($_{O-inf}$) between fed and fasted conditions is less than 20%." *Id.* at 30:10– 12. As discussed above, this language would be understood by a person of ordinary skill in the art as meaning that, having taken the dosage form, the subject will exhibit total blood concentration levels of oxymorphone no more than 20% higher after having eaten a meal as compared to having taken the dosage form on an empty stomach.

Claim 42 also depends from claim 38, and reads as follows:

> 42. The method of claim 38 wherein upon oral administration of the dosage form to the subject under fed or fasting conditions:
>
> (i) the dosage form provides detectable blood plasma levels of 6–OH oxymorphone and oxymorphone;
>
> (ii) the blood plasma levels of 6–OH oxymorphone and oxymorphone peak within about 1 hour to about 8 hours after administration; and
>
> (iii)the blood plasma levels of 6–OH oxymorphone and oxymorphone exhibit a ratio of AUC($_{0\ to\ inf}$) of blood plasma level versus time for 6–OH oxymorphone

compared to oxymorphone in a range of about 0.5 to about 1.5.

Id. at 30:15–27. A person of ordinary skill in the art would understand part (i) of the claim to require that the dosage form provide detectable levels of 6–hydroxy–oxymorphone (the metabolite) and oxymorphone; and would understand part (ii) to require that the levels of both 6–hydroxy–oxymorphone and oxymorphone "peak," or reach a high-point, within 1 to 8 hours after the dosage form is taken. Finally, a person of ordinary skill in the art would understand part (iii) to require that the ratio of 6–hydroxy–oxymorphone to oxymorphone in the bloodstream will be between about 0.5 to 1.5.

Claims 49, 50, and 54 of the '216 Patent are composition claims with terms already construed in the preceding paragraphs of this decision. The claims read as follows:

***15** 49. An analgesically effective controlled release pharmaceutical composition for oral delivery, comprising:

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

(b) about 5 mg to about 80 mg of oxymorphone or a pharmaceutically acceptable salt of oxymorphone, wherein oxymorphone is the sole active ingredient,

wherein upon oral administration of a single dose of the composition to a human subject, the oxymorphone Cmax is at least 50% higher when the dose is administered to the subject under fed as compared to fasted conditions, and wherein upon placement of the composition in an in vitro dissolution test comprising USP Paddle Method at 50 rpm in 500 ml media having a pH of 1.2 to 6.8 at 37°C., about 15% to about 50%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 1 hour in the test.

50. The composition of claim 49 wherein upon oral administration thereof the oxymorphone $AUC_{(0-inf)}$ is no more than 20% higher when the dosage form is administered to the subject under fed as compared to fasted conditions.

54. The composition of claim 49 wherein about 45% to about 80%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 4 hours in the test, and at least about 80%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 10 hours in the test.

'216 Patent at 30:52–31:26.

Claim 49 would be understood by a person of ordinary skill in the art as describing a pharmaceutical composition of 5mg to 80mg of oxymorphone or its salt to be taken orally and which provides, in a controlled or "slow" fashion, pain relief at therapeutically useful levels over a twelve hour period. The maximum concentration of oxymorphone in the blood will be at least 50% higher when the dose is taken after eating a meal as opposed to on an empty stomach. The composition would, when tested using the Paddle Method at 50 revolutions per minute in 500 ml of media of a certain acidity and temperature, release about 15% to about 50% of the oxymorphone or its salt at about an hour into the test.

Claim 50 would be understood as stating the additional limitation that the composition of Claim 49, upon being administered, will produce total blood concentration levels of oxymorphone no more than 20% higher after having eaten a meal as compared to having taken the tablet on an empty stomach. Finally, Claim 54 would be understood to mean that the composition of Claim 49, upon being tested using the Paddle Method at 50 revolutions per minute and under certain other conditions, would release about 45% to about 80% of the oxymorphone at about 4 hours in the test, and would release about 80% of the oxymorphone or its salt at about 10 hours in the test.

Claim 55, 57, 62, 64, and 66 of the '216 Patent are also composition claims whose terms were construed in the previous sections of this decision. Together, those claims read as follows:

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

***16** a. a controlled release delivery system with a release rate profile designed to provide adequate blood plasma levels of oxymorphone and 6–

hydroxy–oxymorphone over at least 12 hours to provide sustained pain relief over this same period; and

b. about 5 mg to about 80 mg of oxymorphone or a pharmaceutically acceptable salt of oxymorphone, wherein oxymorphone is the sole active ingredient,

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

57. The composition of claim 55; wherein the composition is in the form of a tablet and wherein at least 27%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 1 hour in the test, at least 40%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 2 hours in the test, at least 50%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 3 hours in the test, at least 64%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 5 hours in the test, at least 70%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 6 hours in the test, at least 79%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 8 hours in the test, at least 85%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 10 hours in the test, and at least 89%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 12 hours in the test.

62. The composition of claim 55, wherein the composition is in the form of a tablet and wherein at least 70%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 6 hours in the test.

64. The composition of claim 55, wherein the composition is in the form of a tablet and wherein at least 85%, by weight, of the oxymorphone or salt thereof is released from the tablet at about 10 hours in the test.

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

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

b. about 5 mg to about 80 mg of oxymorphone or a pharmaceutically acceptable salt of oxymorphone, wherein oxymorphone is the sole active ingredient,

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

'216 Patent at 31:27–32:50.

Parts (a) and (b) of Claim 55 are nearly identical to Claim 49, except that part (a) contains the additional language: "a controlled release delivery system with a release rate profile designed to provide adequate blood plasma levels of *oxymorphone and 6–hydroxy–oxymorphone* over at least 12 hours to provide sustained pain relief over this same period." *Id.* at 31:29–34 (additional language in italics). A person of ordinary skill in the art would understand this language to mean a delivery system that releases the active ingredient slowly over time that provides adequate blood plasma levels of oxymorphone or 6–hydroxy–oxymorphone (the metabolite) over at least 12 hours to provide sustained pain relief over this same period.

***17** The remainder of Claim 55 would be understood to mean that upon testing the composition in the laboratory using the Paddle Method at 50 revolutions per minute in 500 ml of media of a certain acidity and temperature, the composition will release about 15% to about 50 of the oxymorphone or its salt at about one hour in the test.

Claim 57 depends from Claim 55, but recites narrower dissolution ranges when the composition is tested using the Paddle Method at 50 revolutions per minute in 500 ml of media of a certain acidity and temperature. *See* '216 Patent at 49–67. The claim provides that the oxymorphone or its salt will be released at the following rates: at least 27% at about 1 hour into the test; at least 40% at about 2 hours into the test; at least 50% at about 3 hours into the test; at least 64% at about 5 hours in the test, at least 70%

at about 6 hours in the test, at least 79% at about 8 hours in the test, at least 85% at about 10 hours in the test, and at least 89% at about 12 hours in the test. *Id.* at 31:52–67.

Claims 62 and 64 would be understood as simply restating, in individual fashion, two of the dissolution limitations already recited in Claim 57. *Compare id.* at 32:18–21 and 32:26–29 *with* 31:59–65. Specifically, Claim 62 requires that the composition of Claim 55 release at least 70% of the oxymorphone or its salt at about 6 hours into the test; and Claim 64 requires that the composition of Claim 55 release at least at least 85% of the oxymorphone or its salt at about 10 hours in the test.

Claim 66 is almost identical to Claim 55, except that part (a) of Claim 66 omits the language "of oxymorphone and 6–hydroxy–oxymorphone" contained in part (a) of Claim 55. *See* '216 Patent at 32:37–38. Additionally, Claim 66 provides that: "wherein upon oral administration of the composition to a human subject, the blood plasma levels of oxymorphone comprise one or more peaks." *Id.* at 32:48–50. As discussed above, a "peak" would be recognized by a person of ordinary skill in the art as occurring when blood concentration of oxymorphone reaches a high-point before declining. The last clause of Claim 66 would be understood, then, as requiring that blood plasma levels of oxymorphone reach one or more high-points after the composition is taken by or fed to a human subject.

Claim 71 depends from Claim 66, and provides that the composition be in tablet form, and release about 45% to about 80% of its oxymorphone or its salt at about 4 hours in the test, and at least about 80% of the oxymorphone or its salt at about 10 hours in the test. *See* '216 Patent at 33:8–14.

Claim 72 of the '216 Patent describes a composition of oxymorphone that uses a "controlled release matrix ... of a gelling agent which forms a gel upon exposure to gastrointestinal fluid." '216 Patent at 33:14–20. Claim 72 reads as follow:

> 72. A controlled release pharmaceutical composition comprising oxymorphone or a pharmaceutically acceptable salt thereof as the sole active ingredient and a controlled release matrix, comprising about 10% to about 75% (by total weight of the controlled release matrix) of a gelling agent which forms a gel upon exposure to gastrointestinal fluid;
>
> wherein upon placement of the composition in an in vitro dissolution test comprising USP paddle method at 50 rpm in 500 ml media having a pH of 1.2 to 6.8 at 37° C., about 15% to about 50%, by weight, of the oxymorphone or salt thereof is released from the composition after about 1 hour in the test.

***18** *Id.* at 33:14–26.

The specification explains that a "controlled release matrix" exists when oxymorphone is paired with a certain type of controlled release delivery system. *Id.* 6:48–51. That delivery system consists of a gelling agent. *Id.* at 6:52. The gelling agent is a hydrophilic material, such as xanthan gum, that gels when exposed to gastrointestinal fluid. *See id.* 6:7:12–15. Because the substance forms a gel upon exposure to gastrointestinal fluid, it releases the active ingredient, or oxymorphone, at a controlled rate rather than all at once. *See id.* at 6:50–53. Thus, a person of ordinary skill in the art would understand the terms "controlled release matrix ... comprising ... a gelling agent" to mean the pairing of oxymorphone or its salt with a controlled release delivery system consisting of a gelling agent, a hydrophilic material that forms a gel upon exposure to gastrointestinal fluid which releases the oxymorphone slowly.

The remainder of Claim 72 as provides that between about 10% to about 75% of the controlled release matrix will consist of the gelling agent. '216 Patent at 33:18–19. Moreover, upon being tested in the laboratory using the Paddle Method at 50 revolutions per minute in media of a certain acidity and temperature, about 15% to about 50% of the oxymorphone or its salt will be released at about 1 hour into the test. *Id.* at 33:20–26.

Claims 73 and 74 of the '216 Patent depend from Claim 72, and provide that the composition of Claim 72 will release about 45% to about 80% of the oxymorphone or its salt at about four hours in the dissolution test; and at least 80% of the oxymorphone or its salt after about 10 hours in the test. *See* '216 Patent at 33:27–37.

Claim 77 is an independent claim that brings together many of the limitations discussed earlier. Claim 77 reads as follows:

> 77. A controlled release pharmaceutical composition comprising oxymorphone or pharmaceutically acceptable salt thereof as the sole active ingredient, and a controlled release matrix comprising about 10% to about 75% (by total weight of the controlled release matrix) of a gelling agent which forms a gel upon exposure to gastrointestinal fluid;
>
> wherein upon placement of the composition in an in vitro dissolution test comprising USP paddle method at 50rpm in 500ml media having a pH of 1.2 to 6.8 at 37°C., about 15% to about 50%, by weight, of the oxymorphone or salt thereof is released from the composition after about 1 hour in the test, about 45% to about 80%, by weight, of the oxymorphone or salt thereof is released from the composition after about 4 hours in the test, and at least 80%, by weight, of the oxymorphone or salt thereof is released from the composition after about 10 hours in the test,
>
> wherein upon oral administration of a single dose of the composition to a human subject, the composition provides an oxymorphone Cmax of at least 50% higher when the dose is administered to the subject under fed as compared to fasted conditions and provides a difference in oxymorphone AUC(0–inf) of less than 20% higher when the dose is administered to the subject under fed as compared to fasted conditions.

***19** '216 Patent at 33:56–34:18.

Claim 77 would be understood by a person of ordinary skill in the art as reciting a pharmaceutical composition with oxymorphone or its salt as the active ingredient paired with a controlled-release matrix, which is a controlled-release delivery system consisting of about 10% to 75% of a gelling agent, a hydrophilic material that forms a gel upon exposure to gastrointestinal fluid. See '216 Patent at 33:56–67. Moreover, Claim 77 would be understood as requiring that the composition, upon being tested in the laboratory using the Paddle Method at 50 revolutions per minute in 500 ml of media of a certain acidity and temperature, will release about 15% to about 50% of the oxymorphone or its salt after about 1 hour in the test, about 45% to about 80% of the oxymorphone or its salt after about 4 hours in the test, and at least 80% of the oxymorphone or its salt after about 10 hours in the test. *Id.* at 34:1–11. Finally, Claim 77 would also be read as providing that upon the composition being taken by or fed to a human subject, the maximum observed concentration (Cmax) of oxymorphone in the bloodstream will be at least 50% percent higher after having eaten a meal than it would be on an empty stomach, and the total blood concentration levels of oxymorphone, as measured by area under the curve, will be no more than 20% higher after having eaten a meal as compared to having taken the tablet on an empty stomach. *Id.* at 34:11–18.

Claim 78 depends from Claim 77, and thus incorporates all of Claim 77's limitations. However, Claim 78 recites a number of additional limitations already construed for Claim 1. See '216 Patent at 26:40–55. To a person of ordinary skill in the art, Claim 78 would be read to mean: the composition of Claim 77 which, when taken by or fed to a subject in need of pain relief, will produce two or three peaks, or high-points, in blood oxymorphone levels within about the first twelve hours. Moreover, part (i) means that the formulation will provide detectable levels of the metabolite 6–hydroxy–oxymorphone and oxymorphone in the bloodstream. Part (ii) explains that the blood levels of 6–hydroxy–oxymorphone and oxymorphone will "peak," or reach a high-point, within about 1 to about 8 hours after administration. Part (iii) means that after the composition is taken, the total amount of 6–hydroxy–oxymorphone (the metabolite) in the bloodstream over time will be between half to 50% more than the total oxymorphone in the bloodstream. Finally, part (iv) provides that the pain relief will last at least twelve hours.

Claims 79 and 80 recite additional dissolution ranges for the composition of Claim 77. '216 Patent at 34:19–43. A person of ordinary skill in the art would understand the claims as providing that the composition of Claim 77 will release about 58% to about 66% of the oxymorphone or its salt after about 4 hours in the test; and will release about 85% to about 96% of the oxymorphone or its salt after about 10 hours in thetest. *id.*

***20** Claim 82 of the '216 Patent is a method claim reading as follows:

> 82. A method of treating pain in a subject in need thereof, the method comprising administering to the subject the pharmaceutical composition of claim 77 in an amount sufficient to provide the

> subject with about 5 mg to about 80 mg of oxymorphone or salt thereof.

'216 Patent at 34:56–60. A person of ordinary skill in the art would understand the claim as follows: a method of treating pain in a subject in need pain relief, by which the subject is fed or takes the composition described in Claim 77 in sufficient amounts as to provide 5mg to about 80mg of the oxymorphone or its salt to the subject.

c. Construing the Asserted Claims of the '060 Patent.

The '060 Patent is the product of co-plaintiff Grünenthal's efforts to invent a dosage form so hard that it is difficult to abuse by crushing, and which also accommodates secondary barriers to abuse. See '060 Patent at 2:26–62. Plaintiffs assert twelve claims of the '060 Patent, claims 1, 4, 9, 24, 25, 27, 29, 30, 31, 32, 33, and 34[2]. Those claims, as well as three independent claims incorporated therein (claims 22, 23, and 28), will be construed in the following paragraphs of this decision.

Claim 1 of the '060 Patent reads as follows:

> 1. An abuse-proofed, thermoformed dosage form comprising one or more active ingredients with abuse potential (A) optionally together with physiologically acceptable auxiliary substances (B), at least one synthetic or natural polymer (C), wherein the polymer (C) has a molecular weight of at least 0.5 million according to rheological measurements, and optionally at least one wax (D), wherein the dosage form exhibits a breaking strength of at least 500 N.

'060 Patent at 21:6–14.

At trial, the parties identified four areas of dispute regarding the construction of Claim 1 of the '060 Patent: (i) whether the term "abuse-proofed" requires a demonstrated elimination of abuse, or merely a reduction in the potential for abuse; (ii) whether the term "thermoformed" involves the subsequent application of heat; (iii) whether "breaking" involves requires separation of the dosage form into two or more pieces; and (iv) whether Claim 9 requires a separate viscosity increasing agent that forms a gel.

i. The Term "Abuse–Proofed" Means a Reduction in the Potential for Abuse.

Claim 1 recites "an abuse-proofed thermoformed dosage form." *Id.* at 21:6– 7. At trial, the parties suggested different readings of the term "abuse-proofed." Defendant Actavis argued that the term "abuse-proofed" means that the dosage form must achieve a demonstrated and significant elimination of abuse, and plaintiffs argued that "abuse-proofed" requires merely a reduction in the potential for abuse. *See, e.g.,* Trial Tr. at 1137:7–11; 2151–52.

Plaintiffs' construction of "abuse-proofed" is correct. The '060 Patent certainly aims to combat abuse of opioids, but the specification makes clear that it does not require a demonstrated elimination of abuse. The specification explains that opioids, because of their efficacy in treating pain, "also have abuse potential," meaning they can be "used by abusers to induce a state of ... euphoria," or a high. '060 Patent at 1:25–32. Abuse is possible when users grind opioid dosage forms in a mortar and sniff the resulting powder, or mix the powder with water to inject intravenously. *Id.* at 32–49. The purpose of the Grünenthal's invention was to "*complicate* or prevent the pulverization" of dosage forms to prevent abuse "simply by pulverization." *Id.* at 2:5–14. To this end, the Grünenthal patent recites a dosage form of exceptional hardness, so hard that "pulverization ... is considerably more difficult using conventional means" like a hammer, mortar and pestle, or mallet. *Id.* at 2:227–42. Moreover, the Grünenthal invention accommodates the inclusion of additional barriers to abuse, such as irritants to deter snorting, or the use of a "viscosity-increasing agent" to complicate injection. *Id.* at 6:35–54.

***21** This language does not require a demonstrated reduction of abuse, or even the elimination of the ability to crush the dosage form. Rather, it signifies to a person of ordinary skill in the art that the invention intends to *reduce the potential for abuse,* to make it potentially more difficult. *See id.* at 6:24–34. ("In the event of ... pulverization ... achieved by application of extreme force, the dosage forms ... may ... contain further agents which *complicate* or prevent abuse.") "*Id.* at 6:24–34." But this

does not require the showing of a demonstrated actual reduction in abuse.

A person of ordinary skill in the art, upon reading the specification, would understand the term "abuse-proofed" as requiring "a reduction in the potential for abuse."

ii. The Term "Thermoformed" Allows for the Subsequent Application of Heat.

At trial, the parties vigorously debated the meaning of the term "thermoformed." *See, e.g.,* Trial Tr. at 1138:5–9. There is general agreement that "thermoforming" is the creation of a dosage form by applying heat and pressure to mixtures of certain substances. *Id.* at 1250:21; 1339:22–25. First, the formulator mixes the active ingredient with a synthetic or natural polymer of high molecular weight, preferably a "thermoplastic" (heat-softening) polymer such as polyethylene oxide. '060 Patent at 11:13–14; 5:65–6:2. He may also include in the mixture "an auxiliary substance" intended to deter abuse in ways other than increasing hardness. *See id.* at 6:40–54; 11:15–19. Second, the mixture is formed by applying pressure to it, and by exposing it to heat at some point. This is where the parties disagree. Plaintiffs argue that the heat may be applied before, simultaneously to, or subsequently to the forming the tablet. Defendants argue that thermoforming does not encompass the subsequent application of heat.

The specification indicates that subsequent heat can be used to thermoform. *See id.* at 11:25–39 ("The resultant mixture is preferably formed directly by application of pressure to yield the dosage form according to the invention with preceding, simultaneous or subsequent exposure to heat."). Indeed, subsequent heat is discussed a total of five times in the patent, including in one of the patent claims *See* Claim 25; '060 Patent at 23:9. However, in an example using the subsequent application of heat, the specification inexplicably states that, "in direct tabletting with subsequent exposure to heat, the formed tablets are briefly heated at least to the softening temperature (glass transition temperature, melting temperature; sintering temperature) of component (C) and cooled again." '060 Patent at 11:33–36 (emphasis added). The use of the words "cooled again" is baffling. If the thermoforming process encompasses the subsequent application of heat, how can the tablets be "cooled again"? This would imply that the tablets had been heated and cooled at some previous point rather than subsequently. Indeed, as defendants point out, Trial Tr. at 1095:14– 15, none of the examples tested in the '060 Patent actually used the subsequent application of heat. See '060 Patent at 17–20.

The court concludes that the singular and baffling use of "cooled again" in column 11 of the '060 Patent would be insufficient to cause a person of ordinary skill in the art to exclude subsequent heat from his understanding of the term "thermoformed," given that the specification and one claim expressly allow for the subsequent application of heat.

Nor is there anything in the prosecution history of the '060 Patent to suggest the inventors had, at some point after filing the patent application, disclaimed a reading of thermoforming inclusive of the subsequent application of heat. At trial, defense counsel attempted to establish that Grünenthal had made statements to the Patent and Trademark Office removing subsequent heat from the definition of thermoforming. Trial Tr. at 1091:3–7. However, these statements were made in the prosecution of a different patent, not the '060 Patent. *See* November 27, 2006 Response to Office Action from Certified Prosecution History for U.S. Patent No. 8,114,383 (PTX–30B at 1). To the extent these statements are relevant to the '060 Patent, Grünenthal merely said "the inventive dosage forms exhibiting the desired properties may be obtained only if, during preparation of the dosage form, the components are exposed to a sufficient pressure at a sufficient temperature for a sufficient period of time." See November 27, 2006 Response to Office Action from Certified Prosecution History for U.S. Patent No. 8,114,383 (PTX–30B at 11) (emphasis added).

***22** As defendants suggest, "during preparation" could be read to mean "during an early" stage of the manufacturing process of the dosage form. However, when read in context, "preparation of the dosage form" does not refer to some early stage in the manufacturing process of the tablets, but to the manufacture of the tablets as a whole. *See id.* Thus, the statement to the PTO merely provided that during the manufacture of the dosage form, the components are exposed to heat. This squares completely with a definition of "thermoformed" encompassing the subsequent application of heat.

For these reasons, the court construes the terms "thermoformed dosage form" to mean "a dosage form created by applying pressure to a mixture of the active ingredient and high-molecular weight polymer and by applying the prior, simultaneous, or subsequent application of heat."

iii. The Term "Breaking" Means the Separation of the Dosage Form Into Two or More Pieces.

Claim 1 of the '060 Patent provides that the dosage form will "exhibit[ ] a breaking strength of at least 500 N." '060 Patent at 21:13–15. Breaking strength is the primary feature of invention. *See id.* at 2:26–30. The invention is intended to create dosage forms which are hard enough to withstand 500 newtons of force, a level of pressure so high that it would be exceedingly difficult to crush the dosage form using household tools. *Id.* at 2:38–42.

At trial, the parties advanced different constructions of the term "breaking." No party disputed that a dosage form may deform and still be unbroken. *See, e.g.,* Trial Tr. at 2173:3–5. But plaintiffs argued that in order for a dosage form to "break," it must separate into two or more pieces. Trial Tr. at 1177:8–9. Defendants argued that "breaking" occurs earlier, when the dosage form cracks or "fractures." *See, e.g.*, *id.* at 1178:5–10. These competing constructions are relevant to infringement–if defendants' tablets "break" before 500N of force is applied, then they do not infringe the hardness claims of the '060 Patent.

Defendants' construction is at odds with the specification. The specification contemplates scenarios where the tablets deform, but explains that deformation is not tantamount to breaking. *Id.* at 17:24–26. Moreover, defendants' construction overlooks large sections of the specification describing the invention as a means for preventing comminution or *pulverization* of the dosage form. This prevention of crushing (and by extension the prevention of snorting and injecting) is the dominant theme of the specification. *See id.* at 2:26–39. When a tablet is crushed, it separates into two or more pieces, and then hundreds of pieces, which can then be snorted and injected. Thus, to be abused, the tablet *must* separate into multiple pieces. *See* '060 Patent at 1:33–35. By the same token, to be abuse-proofed, the tablet resists separation into multiple pieces when exposed to mechanical forces below 500N. *Id.* at 2:37–42. Defendants' construction of "breaking" is inconsistent with this language. A tablet that is cracked or fractured, but not separated into multiple pieces, is useless to the abuser for snorting and injecting.

A person of ordinarily skill in the art, upon reading the specification, would understand that where it describes tablets with high breaking strength, it means tablets that will not separate into multiple pieces before 500N of force is applied. The court construes the limitation "exhibits a breaking strength of at least 500 N" to mean "only separates into two or more pieces when exposed to a force of at least 500 newtons."

***23** Some additional terms of Claim 1 were not disputed at trial, but require construction to be fully understood. An ingredient with "abuse potential" is one susceptible to abuse, especially opiates and opioids, which are misused to obtain a euphoric state. '060 Patent at 1:25–32. Where the claim calls for "physiologically acceptable auxiliary substances," a person of ordinary skill in the art would understand this to mean a substance intended to further reduce abuse. See '060 Patent at 6:30–35.

In light of the above considerations, the court construes Claim 1 to read as follows:

> "A dosage form that reduces the potential for abuse which is formed by applying pressure and heat (before, during, or after pressure being applied) and comprising one or more active ingredients with abuse potential (A) optionally together with physiologically acceptable auxiliary substances (B), at least one synthetic or natural polymer (C), wherein the polymer (C) has a molecular weight of at least 0.5 million according to rheological measurements, and optionally at least one wax (D), wherein the dosage form only separates into two or more pieces when exposed to a force of at least 500 newtons."

Plaintiffs also assert Claim 4 of the '060 Patent. Claim 4 depends from Claim 1, and reads as follows:

> 4. A dosage form according to claim 1, Wherein the polymer (C) is at least one polymer selected from the group consisting of polyethylene oxide, polymethylene oxide, polypropylene oxide, polyethylene, polypropylene, polyvinyl chloride, polycarbonate, polystyrene, polyacrylate, copolymers and the mixtures thereof.

'060 Patent at 21:19–24. This claim incorporates the limitations of Claim 1, but further recites that the polymer used be selected from a group of certain polymers including polyethylene oxide and others.

Claim 9 of the '060 Patent also depends from Claim 1, and reads as follows:

> 9. A dosage form according to claim 1, which additionally comprises at least one of the following components (a)-(f):
>
> (a) at least one substance which irritates the nasal passages and/or pharynx,
>
> (b) at least one viscosity-increasing agent, which, with the assistance of a necessary minimum quantity of an aqueous liquid, forms a gel with the extract obtained from the dosage form, which gel optionally remains visually distinguishable when introduced into a further quantity of an aqueous liquid,
>
> (c) at least one antagonist for the active ingredient or active ingredients with abuse potential,
>
> (d) at least one emetic,
>
> (e) at least one dye as an aversive agent,
>
> (f) at least one bitter substance.

'060 Patent 21:37–52. Essentially, Claim 9 recites a dosage form which, in addition to meeting the limitations of Claim 1, also consists of at least one of six other barriers to abuse. *See id.* at 6:24–34. A substance that irritates the nasal passages or pharynx (part (a)) is one that brings about a strongly unpleasant physical reaction when administered via the nose or throat. *Id.* at 7:13–19. An "antagonist" (part (c)) is a substance in the dosage form which is inert when the dosage form is taken properly, but which blocks the effects of the active ingredient when the dosage form is subverted. *Cf. id.* at 9:35–67; *see also* Trial Tr. at 985–86. An "emetic" (part (d)) is a substance that induces vomiting. A "dye as an aversive agent" (part (e)) is a dye of such brightness that it discourages abuse by injection into the vein. '060 Patent at 10:45–47. A "bitter substance" (part (f)) is one that impairs flavor to discourage oral and nasal abuse. *Id.* at 10:54–58.

iv. The Viscosity Increasing Agent Must Be Distinct From the Hardening Polymer.

***24** As discussed, Claim 9 describes six barriers to abuse beyond the hardening feature of Claim 1. Part (b) of Claim 9 provides that the dosage form will include "at least one viscosity-increasing agent, which, with the assistance of a necessary minimum quantity of an aqueous liquid, forms a gel with the extract obtained from the dosage form...." '060 Patent at 21:41–45.

The definition of "viscosity-increasing agent" was never seriously disputed at trial. [3] What was disputed, however, is whether the viscosity-increasing agent of Claim 9 must be distinct from the hardening polymer of Claim 1. *See, e.g.,* Trial Tr. at 1044. As discussed, Claim 1 of the '060 Patent requires the presence of a high-molecular weight polymer. *See* '060 Patent at 21:9–11. It is this polymer which strengthens the tablet. *Id.* at 5:54–58. However, Claim 9 recites *additional* abuse-deterrent features beyond mere hardness. *See id.* at 21:37–51. One of these additional barriers is the use of a viscosity-increasing agent that forms a gel. The purpose of the gel is simple. It makes a tablet that has been cut and mixed with water difficult to inject intravenously. *Id.* at 8:27–38. Plaintiff Grünenthal suggests that the hardening polymer of Claim 1 can also qualify as the viscosity increasing agent of Claim 9(b). Defendants argue the opposite, that the viscosity-increasing agent must be distinct from the hardening polymer.

Defendants have the correct reading of Claim 9. Claim 9 provides that the dosage form of Claim 1 will "*additionally* comprise[ ]" one of the six other abuse deterrent features, one of which is a viscosity-increasing agent. '060 Patent at 21:37–38 (emphasis added). A person of ordinary skill in the art, upon reading the words "additionally comprising," would understand that the viscosity increasing agent is distinct from (in

"addition" to) the hardening polymer of Claim 1. A contrary reading would render the words "additionally comprising" meaningless.

Defendants' construction is also supported by the specification examples. The specification lists six examples of dosage forms created according to the invention. Each of these dosage forms was subjected to various tests. The dosage forms in the first three examples contained no separate viscosity-increasing agent, but simply the hardening polymer polyethylene oxide. *See* '060 Patent at 17–18. These dosage forms were only tested for *hardness,* and were not tested for producing a gel. *Id.* On the other hand, the dosage forms from examples 4, 5, and 6 did contain a separate viscosity increasing agent, xanthan gum. *See* '060 Patent at 19–20. These dosage forms were tested for hardness *and* for their gelling properties. See '060 Patent at 19–20. Each of them, when cut into multiple pieces and mixed with water, formed a "highly viscous gel." E.g., id. at 20:19. The inventors' decision to test only the examples with a separate viscosity-increasing agent for gelling indicates their understanding that the hardening polymer would be distinct from the viscosity-increasing agent. This would be apparent to a person of ordinary skill in the art comparing examples 1–3 with examples 4–6.

***25** Thus, in light of the language of the claims and the examples of the specification, the court adopts defendants' construction of "viscosity-increasing agent" as requiring a substance distinct from the hardening polymer. The entirety of part (b) of Claim 9 would read as requiring a distinct viscosity-increasing agent which, with an aqueous liquid, forms a gel that preferably remains visible when introduced into a further quantity of aqueous liquid.

Claims 22 and 23 of the '060 Patent depend from Claim 1, and read as follows:

> 22. A dosage form according to claim 1, which comprises at least one active ingredient at least partially in controlled release form.
>
> 23. A dosage form according to claim 22, wherein each of the active ingredients with abuse potential (A) is present in a controlled release matrix.

'060 Patent at 22:59–64.

Upon reading the specification, a person of ordinary skill in the art would understand that a "controlled release" dosage form is one that releases its active ingredient slowly over time. *See* '060 patent at 45–49. A "controlled release matrix," as used in the '060 Patent, may consist of hydrophilic gel-forming materials which swell and release the active ingredient by diffusion. *Id.* at 17:20–25. The controlled release matrix may also consist of hydrophobic (water-hating) materials which release the active ingredient through pores in the matrix. *Id.* at 16:23–25.

Claim 24 depends from Claim 23, and reads as follows:

> 24. A dosage form according to claim 23, wherein component (C) and/or component (D) also serve as a controlled release matrix material.

'060 Patent at 22:65–67. This claim ultimately traces back to Claim 1, which, as discussed, has four components: (A), (B), (C), and (D). Claim 24 simply provides that the synthetic or natural polymer (C) and/or the optional wax (D) may also serve as the controlled release matrix material. *See* '060 Patent at 21:5–15; 22:65–67.

Claim 25 of the '060 Patent is a process claim. *See* '060 Patent at 23:1. Claim 27 is a product claim covering the dosage form obtained by the process according to Claim 25. *Id.* at 11–15. Together, claims 25 and 27 read as follows:

> 25. A process for the production of a dosage form according to claim 1, comprising:
>
> mixing components (A), (B), (C) and the optionally present component (D) and the optionally present components (a) to (f) to form a resultant mixture, and
>
> press-forming the resultant mixture, optionally after granulation, to yield the dosage form with preceding, simultaneous, or subsequent exposure to heat.
>
> 27. A dosage form obtainable by a process according to claim 25.

'060 Patent at 23:1–14. These claims are novel in that they refer to a process known as "press-forming." Press-forming means exactly what it sounds like: the dosage form is created by putting the mixture in a press, with heat applied before, during, or after pressure is applied in the press. See '060 Patent at 11:13– 19; 23:3–9. Thus, Claim 25 refers to a process of creating a dosage form using a

press and the application of heat; and Claim 27 refers to the actual dosage form created as a result of that process.

Claims 28 and 29 of the '060 Patent reads as follows:

> 28. A method of treating a therapeutic condition in a patient suffering therefrom, said method comprising administering to said patient a dosage form according to claim 1.
>
> 29. The method according to claim 28, wherein the therapeutic condition is pain.

'060 Patent at 23:13–19. The term "therapeutic condition" is not defined in the patent, but would be understood as meaning a condition requiring medical treatment. Thus, Claim 28 is construed as a method claim requiring the dosage form of Claim 1 to be administered to a patient suffering from a condition requiring medical treatment. Claim 29 is identical, except that it requires the condition requiring medical treatment to be pain. Id. at 23:17–19.

***26** Claims 30, 31, 32, and 33 depend from Claim 1. These claims read as follows:

> 30. A dosage form according to claim 1, wherein the polymer (C) is polyethylene oxide having a molecular weight of from 1–15 million g/mol.
>
> 31. A dosage form according to claim 1, wherein the one or more active ingredients with abuse potential (A) is/are selected from the group consisting of oxymorphone, oxycodone, tapentadol and the physiologically acceptable salts thereof.
>
> 32. A dosage form according to claim 31, which is in the form of a tablet.
>
> 33. A dosage form according to claim 1, wherein the content of polymer (C) is at least 60% by weight relative to the total weight of the dosage form.

'060 Patent at 23:18–24:10. Claim 30 simply repeats the dosage form of Claim 1, but provides that the polymer used will be polyethylene oxide ("PEO") with a molecular weight, or mass, of 1–15 million grams per mole. *See id.* 23:18–20. Similarly, Claim 31 requires that the active ingredient with abuse potential be oxymorphone, oxycodone, tapentadol or the salts thereof. *Id.* at 24:1–5. Claim 32 provides that the dosage form will be a tablet. Finally, Claim 33 provides that the polymer used in Claim 1 will comprise at least 60% of the total dosage form. *Id.* at 24:8–10.

Claim 34 of the '060 Patent also depends from Claim 1, and reads as follows:

> 34. A dosage form according to claim 1, which is in the form of a tablet, wherein the one or more active ingredients with abuse potential (A) is/are selected from the group consisting of oxymorphone, oxycodone, tapentadol and the physiologically acceptable salts thereof; Wherein the polymer (C) is polyethylene oxide having a molecular Weight of from 1-15 million g/mol:
>
> and wherein the content of polymer (C) is at least 30%[4] by Weight relative to the total weight of the dosage form.

'060 Patent at 24:11–19. This claim recites the dosage form according to Claim 1, but specifies that component (A) will be oxymorphone, oxycodone, or tapentadol or their salts; and that component (C) will be PEO with a mass of between 1–15 million grams per mole and will comprise 60% of the weight of the dosage form.

2. Step Two: Infringement.

Having construed the claims of the '122, '216, and '060 patents, the next step is to determine whether defendants' pharmaceutical products, if manufactured and sold,[5] would infringe on those claims.

Direct infringement exists if the defendants' product or methods, as described in their ANDAs, meet each and every element of the claims. *Sunovian Pharm., Inc. v. Teva Pharm. USA, Inc.*, 731 F.3d 1271, 1278 (Fed.Cir.2013). If the defendants' products or methods fail to meet an element of the claims asserted, they may still infringe under the "doctrine of equivalents" if the differences are insubstantial. *Pozen Inc. v. Par Pharm., Inc.*, 696 F.3d 1151, 1167 (Fed.Cir.2012). To determine if the differences are insubstantial, the court employs the "function, way, and result" test. The missing element is insubstantial if the accused product performs substantially the same *function,* in substantially the same *way,* and achieves substantially the same *result* as each claim limitation in the asserted patent. *Id.*

***27** Indirect infringement occurs where a defendant, rather than directly infringe the patent, induces another party to do so. *See* 35 U.S.C. § 271(b). A person infringes by inducement when he "actively and knowingly aid [s] and abet[s] another's direct infringement." *C.R. Bard, Inc. v. Advanced Cardiovascular Systems, Inc.,* 911 F.2d 670, 675 (Fed.Cir.1990). This requires a showing that the defendant knew of the patent, knowingly induced direct infringement of the patent by a third party, and did so with the specific intention that the third party directly infringe the patent. *Vita–Mix Corp. v. Basic Holding, Inc.,* 581 F.3d 1317, 1328 (Fed.Cir.2009); *DSU Medical Corp. v. JMS Co., Ltd.,* 471 F.3d 1293, 1306 (Fed.Cir.2006). In ANDA litigation, evidence of an intent to induce infringement of a method claim may be found if the defendant's proposed product label instructs users to perform the patented method. *See AstraZeneca LP v. Apotex, Inc.,* 633 F.3d 1042, 1060 (Fed.Cir.2010).

The requirement that the defendant induce a third party to *directly infringe* the patent raises difficulties with regard to method claims. A method claim consists of multiple steps. *Limelight Networks, Inc. v. Akamai Technologies, Inc.,* 134 S.Ct. 2111, 2117 (2014). Of course, if the defendant itself performs all of these steps, it will be responsible for direct infringement. Likewise, if the defendant induces a third party to perform all of these steps, that third party will have committed direct infringement, and the defendant will be liable for inducing that direct infringement. *Cf. id.* A more difficult scenario is presented where a defendant induces the third party to perform some, but not all, of the steps of the method claim. In such cases, how may the defendant be liable for inducing infringement of the method claim when all of the steps of the method claim have not been performed? The answer, as the Supreme Court recently decided in *Limelight,* is that there can be no indirect infringement unless the defendant induces the third party, a single actor, to perform all of the steps provided. *Id.* at 2119 ("[A] method patent is not directly infringed ... unless a single actor can be held responsible for the performance of all steps of the patent.").

Finally, a defendant may also commit contributory infringement. Contributory infringement occurs when a defendant makes a component he knows will be used by others to make an infringing product or to conduct an infringing method. See 35 U.S.C. § 271(c). To prove contributory infringement of a method claim, the plaintiff must show that: "there is direct infringement; the accused infringer [the defendant] had knowledge of the patent at issue; the component has no substantial non-infringing uses; and the component is a material part of the invention." *Fujitsu Ltd. v. Netgear Inc.,* 620 F.3d 1321, 1326 (Fed.Cir.2010) (internal numbering omitted).

a. Infringement With Regard to the '122 and '216 Patents.

As demonstrated in the claim construction section of this decision, Endo asserted an unusually large number of claims in these actions. Endo asserted four claims [6] with regard to the '122 Patent; and sixteen claims [7] with regard to the '216 Patent. This large number of claims is not as unwieldy as it may seem, however, because most of the claims repeat common elements. More significantly, defendants do not dispute infringement of most of the asserted claims. In stipulations dated March 27, 2015 and April 9, 2015, defendants agreed that their tablets "satisfy each limitation of each '122 and '216 patent claim asserted against them" except with regard to two issues: (i) whether their tablets satisfy the "food effect limitations" of the asserted claims; and (ii) whether defendants infringe the asserted method claims. *See* Stipulation and Order at 1, No. 12–CV–8060 (Mar. 27, 2015) (Dkt.# 152); *see also* Second Stipulation and Order at 1, No. 12–CV–8060 (Apr. 9, 2015) (Dkt.# 154).

i. Whether Defendants' Tablets Satisfy the Food Effect Limitations of the Asserted Claims of the '122 and '216 Patents.

***28** Defendants argue that their tablets do not satisfy the food effect limitations embodied in Claim 20 of the '122 Patent and claims 40, 42, 50, 54, 78, 80, and 82 of the '216 Patent. The "food effect" refers to a patient's physiological response to a drug after having eaten. For example, a patient who takes a drug with a pronounced food effect might experience much higher concentrations of the active ingredient if he has recently eaten. *See* Trial. Tr. at 298. Part of the invention claimed by Endo is a dosage form that addresses this "food effect," keeping the concentration of oxymorphone in the bloodstream at an acceptably constant rate regardless of whether a patient has eaten or has fasted. *See id.* at 299–300. Defendants argue that their tablets would not or do not infringe on the several food effect limitations of the '122 and '216 Patents.

Defendants infringe the food effect limitations of the '122 and '216 Patent if their tablets, upon being administered to a patient, produce the following effects: (1) the maximum observed concentration (Cmax) of oxymorphone in the bloodstream is at least 50% percent higher after having eaten a meal than it would be on an empty stomach; and (2) the subject exhibits total blood concentration levels (AUC(0–inf)) levels of oxymorphone no more than 20% higher after having eaten a meal as compared to having taken the dosage form on an empty stomach.

At trial, Endo's expert on infringement, Dr. Reza Fassihi, testified that the defendants' submissions to the FDA prove that their drug products infringe or will infringe on the food effect limitations of the '122 and '216 Patents. Trial Tr. at 637:6. Dr. Fassihi explained that in order to obtain approval to sell a branded or generic drug, the FDA requires an applicant to demonstrate the drug's food effect, if any. *Id.* at 641. In the case of a new branded drug, the applicant performs food-effect studies, which measure the effect of the drug in groups of human subjects who have been fed or who have fasted. *See id.* at 638:10–19. The resulting data will demonstrate to the FDA whether a food effect exists. On the other hand, a generic drug applicant seeking FDA approval is not required to perform new food effect studies. *Id.* at 641. Rather, the generic manufacturer may submit to the FDA information showing that their proposed drug will have the same effects as the branded drug. *Id.* This is the course each of the defendants chose. Based on the information defendants provided to the FDA, Dr. Fassihi concluded that their generic products infringe or will infringe on the food effect limitations of the asserted patent claims.

In reaching his conclusion, Dr. Fassihi relied heavily on defendants' "package inserts." A package insert is included with the drug, and provides information to patients and doctors on how to correctly take and prescribe the tablets. *Id.* at 643:15–20. Defendants' package inserts expressly state that their products satisfy the AUC and Cmax limitations of the '122 and '216 patents. *See, e.g.,* Actavis CRF Package Insert (PTX–2436 at 21) ("Cmax was increased by approximately 50% in fed subjects compared to fasted subjects.... The AUC was unchanged in one study and increased by approximately 18% in the other study in fed subjects."); *see also* Roxane Package Insert (PTX–3070 at 4). Each of defendants' package inserts contains this information. Trial Tr. at 647:16–18 ("Every defendant has the same feed-effect information and package insert for the pills that they have made.").

Dr. Fassihi also relied on defendants' statements to the FDA that their proposed generic drugs are bioequivalent to Endo's branded drugs. *See* Trial Tr. at 717. Each defendant conducted bioequivalence studies to show that their drug does not differ significantly from Endo's branded drugs. *See, e.g.,* Actavis Bioequivalence Study (PTX–2385). This is important because Endo, in drafting the '122 and '216 Patents, recited limitations reflecting their extensive clinical and laboratory testing of dosage forms that would become OPANA® ER. Indeed, the asserted claims of the patents, including the food effect claims, are drawn around studies Endo performed during the testing and development of the branded product. *See* Trial Tr. at 482. For example, one of Endo's studies, highlighted in the specifications of the patents, showed an oxymorphone peak concentration level (Cmax) 58% higher under fed conditions as compared to fasted conditions. *See, e.g.,* '216 Patent at 17:43–46. The relevant patent claim, then, called for a Cmax greater than 50% under fed conditions as compared to fasted conditions. *See, e.g.,* '216 Patent at 30:3–5.

***29** Dr. Fassihi reasoned that defendants, by demonstrating to the FDA that their products are bioequivalent to OPANA® ER and OPANA® ER CRF, also demonstrated that their products exhibit the same food effects as those branded drugs. Trial Tr. at 717. The court finds him to be persuasive in explaining this inference. The bioequivalence of the products described in defendants' ANDAs indicates that those products will exhibit the same pharmacokinetic properties as Endo's branded drug, the effects of which are embodied in relevant claims of '122 and '216 Patents.[8] Trial Tr. at 716. The court need not rely solely on this inference, however. As discussed, Dr. Fassihi referred to defendants' package inserts in reaching his conclusions on infringement. He also considered defendants' product labels, dissolution test data, requests for bio-waivers, approval letters, and other evidence. See Trial Tr. at 654–55.

On cross-examination, defendants argued that Dr. Fassihi should have performed his own food effect studies of defendants' products to determine infringement, rather than rely on their submissions to the FDA. Trial Tr.

at 722– 724. Having heard Dr. Fassihi's testimony, the court concludes that such independent testing was unnecessary. Dr. Fassihi's review of Defendant's ANDA submissions, including defendants' package labels and other documentation, revealed sufficient evidence of infringement to meet plaintiffs' burden. To require plaintiffs to perform independent clinical testing of each of defendants products would put them to a burden beyond a preponderance of the evidence.

The court concludes, upon hearing the credible testimony of Dr. Fassihi, and upon reviewing the documents he relied on, that it is more likely than not that defendants' generic drug products, as described in their ANDAs, would satisfy the food effect limitations of the asserted claims of the '122 and '216 patents.

ii. Whether Defendants Infringe the Asserted Method Claims of the '122 and '216 Patents.

Defendants argue that they do not infringe the asserted method claims of the '122 and '216 Patents. With regard to direct infringement, defendants argue that they do not directly infringe the claims because they simply make and sell tablets and do not actually administer them to patients. *See* Trial Tr. at 613:18 ("We just manufacture pills ... we don't ever administer the pill to the patient."). With regard to indirect infringement, defendants argue that: (1) their product labels do not instruct subjects to take the tablets under fed *and* fasted conditions, thus defendants do not induce infringement of the method claims that have food effect components; and (2) no single person performs all of the steps of the asserted method claims, and since there is no direct infringement by any single person, there can be no indirect infringement Trial. Tr. at 530:12– 13 (referring to the Supreme Court's decision in *Limelight Networks, Inc. v. Akamai Technologies, Inc.,* 134 S.Ct. 2111 (2014)).

Defendants are correct in that they, as drug manufacturers, do not directly infringe the asserted method claims of '122 and '216 Patents. Defendants do not feed tablets to patients or subjects, and thus do not "administer" them as required in Claim 20 of the '122 Patent, as required in part (b) of Claim 38 of the '216 Patent (and the asserted claims, claims 40 and 42, that depend from it), and as required by Claim 82 of the '216 Patent. Thus, defendants cannot be liable for direct infringement.

With regard to indirect infringement, defendants are incorrect to argue that they must instruct patients to take their tablets under fed and fasted conditions.

***30** Defendants have submitted to the FDA proposed product labels for their generic oxymorphone products. *See* Trial Tr. at 517:1–4. These product labels instruct patients to take the generic tablets on an empty stomach. *See, e.g.,* DTX 3542 at 2244. At trial, defendants' expert on non-infringement, Dr. Timothy Deer, testified that in prescribing generic oxymorphone tablets to patients, he and his colleagues are careful to instruct them according to the product labels. Trial Tr. at 517:1–14. Thus, defendants argue that since their labels do not instruct patients to take the tablets under fed conditions, they do not induce infringement of the "food effect" portions of the asserted method claims.

This argument relies on an unsupported reading of the asserted method claims. The most complicated of the method claims, claims 40 and 42 of the '216 Patent (both of which depend from Claim 38), consist of two parts and require that the tablets be provided to the subject, and then administered to that subject.[9] *See* '216 Patent at 29:49–30:40 ("A method for treating pain in a human subject ... comprising the steps of: (a) providing a solid oral dosage form ... and (b) administering a single does ... to the subject...."). The claims then go further, stating that the composition that was administered, *upon being tested,* will exhibit certain *in vitro* and *in vivo* characteristics. *See, e.g., id.* at 29:51–67. ("Wherein upon placement of the composition in an *in vitro* dissolution test comprising ...."). Similarly, Claim 20 of the '122 provides that upon oral administration of the tablet, the subject will exhibit higher blood concentrations of oxymorphone if he has eaten than if he had taken the tablet on an empty stomach. '122 Patent at 1–5.

This language indicates that it is not necessary to the completion of the methods that the tablet be taken under fed *and* fasted conditions. Rather, the methods are completed once the tablets are administered. Once the tablets are administered, the subject will exhibit different pharmacokinetic effects depending on whether he has eaten or fasted. *See, e.g.,* '216 Patent at 15–28; *see also* '122 Patent at 1–5. It is the taking of the qualifying tablet (one

that will produce the claimed pharmacokinetic effects) that constitutes the method claimed. Once a patient administers the qualifying tablet, he directly infringes the method claims.

Thus, it is not necessary for defendants to instruct subjects to take the tablets under fed *and* fasted conditions. By instructing subjects to take the tablets at all, defendants assure that patients will complete the methods asserted in the '122 and '216 patents. Once patients have followed defendants' instructions and infringed the method claims, their blood will exhibit certain pharmacokinetic characteristics. *See, e.g.,* '216 Patent at 30:18–19 ("the dosage form provides detectable levels of 6–OH oxymorphone and oxymorphone."). Those characteristics will be different if the patient has recently eaten. But the method performed–the administration of the tablet–will be the same.

This puts to rest defendants' argument regarding instruction, but the court must still resolve the question of whether a single actor performs all of the steps of the asserted method claims. As discussed, the Supreme Court has recognized that indirect infringement of a method claims requires proof of *direct infringement* by some third party. *Limelight,* 134 S.Ct. at 2117. But there can be no direct infringement by a third party unless that party has itself performed all of the required steps of the asserted method. *Id.* Thus, indirect infringement requires proof, by a preponderance of the evidence, that defendants induce a single party to perform all of the steps of the asserted method claims.

***31** There is clear indirect infringement with regard to claims 20 of the '122 Patent and 82 of the '216 Patent. The methods recited in these claims is merely the administration of the dosage form to the subject. Defendants, through their product labels, instruct subjects to take qualifying generic oxymorphone tablets. *See, e.g.,* DTX–3542, DTX–3523; DTX–3563. In doing so, they demonstrate a specific intention to induce infringement. *See DSU Med. Cor. v. JMS Co.,* 471 F.3d 1293, 1306 (Fed.Cir.2006). The subjects then perform all of the steps of the methods recited in those claims, because they "administer," or take orally, defendants' tablets. *See* '122 Patent at 26:54–56, 28:1–5; '216 Patent at 34:56– 60. Once the method is completed, the subjects' blood will exhibit certain concentrations of oxymorphone depending on whether they have eaten or have fasted. '122 Patent at 28:1–5. Thus, there is clear indirect infringement of claims 20 of the '122 Patent and 82 of the '216 Patent.

It is a closer question as to whether a single party performs all of the steps of claims 40 and 42 of the '216 Patent. As discussed, these claims require the tablet to be provided *and* administered to subjects. Dr. Deer, testified that multiple parties perform these two steps. As a prescribing physician, he performs the first step, providing the tablets, by making them available to patients. Trial. Tr. at 522:15–25. This step is also performed when a pharmacy fills the prescription. *Id.* at 523:1–19. The second step, "administration," occurs when the patient takes the pill orally. Thus, according to Dr. Deer, up to three parties are involved in performing the methods recited in claims 40 and 42 of the '216 Patent. Trial Tr. at 524:6–9 ("[A]t least three people are involved in this process, a physician, a pharmacy, and a patient."). This would indicate that there can be no indirect infringement because no single party can be liable for direct infringement.

On the other hand, Endo's expert on infringement, Dr. Fassihi explained that physicians and nurses in a hospital setting often perform both the "provide" and "administer" steps by directly giving patients tablets to swallow. *See* Trial Tr. at 656–57. This would imply that there is indirect infringement, since defendants induce a single party to perform the entire method claimed.

The court finds Dr. Deer to be more persuasive on this question. Defendants, through their product labels, instruct physicians to prescribe tablets to patients. By writing prescriptions for the tablets, physicians perform the first step of the methods recited in claims 38, 40, and 42 of the '216 Patent by making tablets available to patients. However, in the majority of cases, it is the patient who performs the second step and administers the tablet at home to treat chronic pain. While there may be isolated settings where physicians physically insert tablets into patients' mouths, *see* Trial Tr. at 657:1–7, plaintiffs did not provide the court with sufficient evidence to find that this happens with any degree of regularity. Thus, plaintiffs have not shown that it is probable that a single actor performs all of the steps of the methods recited in claims 40 and 42 of the '216 Patent, and there is no direct infringement of those claims. Since there is no direct infringement, defendants cannot be liable for indirect infringement of claims 40 and 42.

For similar reasons, contributory infringement is also unavailing with regard to claims 40 and 42 of the '216 Patent. While Endo has satisfied most of the elements of its contributory infringement claim (by showing no-substantial non-infringing use; knowledge, and materiality); *see* Trial Tr. at 668, it did not show that there is direct infringement of the methods recited in claims 40 and 42. Again, Endo has not submitted sufficient evidence showing that any third party directly infringes the method of claims 40 and 42 of the '216 Patent by both "providing" and "administering" the dosage form to subjects. Thus, without direct infringement, there can be no contributory infringement. *Aro Mfg. Co. v. Convertible Top Replacement Co.,* 377 U.S. 476, 483 (1964) ("There can be no contributory infringement in the absence of a direct infringement.").

***32** The court makes the following conclusions with regard to infringement of the '122 and '216 patents. The court concludes that plaintiffs have satisfied their burden in showing that defendants' generic drug products, as described in their ANDAs, infringe the food effect limitations of the asserted claims. The court concludes that defendants indirectly infringe method claims 20 of the '122 Patent and 82 of the '216 Patent. However, the court concludes that plaintiffs have failed to satisfy their burden and show indirect infringement of claims 40 and 42 of the '216 Patent. Thus, defendants infringe all of the asserted claims except those two. [10]

b. Infringement With Regard to the '060 Patent.

Grünenthal presented evidence of infringement of the '060 Patent against Actavis, Impax, ThoRx and Teva.

As discussed above, the '060 Patent is the product of Grünenthal's efforts to produce a tablet so hard that it is resistant to abuse through crushing, and which also accommodates other barriers to abuse. As with the '122 and '216 patents, plaintiffs have asserted an unusually large number of claims of the '060 patent. However, determining infringement of these claims is straightforward, involving five issues. These issues are whether defendants' tablets: (i) are abuse-proofed; (ii) are "thermoformed"; (iii) have a breaking strength of at least 500 newtons; (iv) have a "viscosity-increasing agent" which "forms a gel" with the extract obtained from the dosage form; and (v) whether plaintiffs have shown infringement of the remainder of the asserted claims.

i. Whether Defendants' Tablets Are Abuse-Proofed.

Claim 1 of the '060 Patent describes a dosage form that is "abuse-proofed." *See* '060 Patent at 21:6. The portions of the trial dealing with this limitation focused primarily on issues of claim construction, specifically, whether "abuse-proofed" requires a demonstrated elimination of abuse, or whether it simply requires a reduction in the potential for abuse. *See, e.g.,* Trial Tr. at 1137:7–11. As the court determined in the claim construction section of this decision, a person of ordinary skill in the art would understand the term "abuse-proofed" as merely requiring a reduction in the potential for abuse. *See supra* Part A(1)(c)(i).

***33** At trial, defendant Actavis was the only party to dispute whether its tablets are "abuse-proofed." Trial Tr. at 1137:4. During his direct testimony, defendants' expert on non-infringement, Dr. Muzzio, stated that the issue regarding "abuse-proofed" was not that it required a complete eradication of all abuse, but that it required some factual showing that a tablet achieves a significant elimination of abuse. Trial Tr. at 2151–52. Dr. Muzzio testified that plaintiffs have failed to show that defendants' tablets actually cause a significant elimination of abuse, and thus have failed to meet their burden in showing infringement. *Id.*

Plaintiffs have met and exceeded their burden of showing that defendants' tablets reduce the potential for abuse. As will be discussed below, plaintiffs' expert, Dr. Stanley Davis, tested defendants' generic products and showed that they exhibit an exceptionally high breaking strength. *See infra* Part A(2)(b)(iii). Dr. Davis explained that the hardness of defendants' tablets reduces their potential for abuse by making it more difficult to grind the dosage form into a powder suitable for snorting and injecting. Trial Tr. at 1150:18–22. This is not mere speculation. Indeed, in Actavis's submissions to the FDA, it repeatedly refers to its generic product as "crush-resistant." *See, e.g.,* PTX 2369 [11] . at 3970. When Actavis tested its tablets using a mortar and pestle, they flattened into a "pancake" shape but did not crumble into a powder. *Id.* ("Both crushed tablets resembled a pancake.").

In the court's view, it is absurd to argue that a crush-resistant tablet fails to reduce the potential for abuse to some extent. Of course, a drug abuser who fails to crush a hard tablet may take other efforts to subvert the tamper-resistant properties of the drug. *See, e.g.,* Letter from the FDA to Robert Bart (May 10, 2014) at 5 (DTX 5032) ("[E]xtended-release features can be compromised ... when subjected to other forms of manipulation...."). But this does nothing to diminish the fact that the tablet reduces the potential for abuse of the dosage form by crushing.

A crush-resistant tablet reduces the potential for abuse through crushing, and is thus "abuse-proofed." Having heard the testimony of Dr. Davis, *see infra* Part A(2)(b)(iii), and Dr. Muzzio, and upon reviewing the exhibits they relied on, the court is satisfied that defendants' generic products are "abuse-proofed" as required by Claim 1 of the '060 Patent.

ii. Whether Defendants' Tablets are Thermoformed.

Each of the asserted claims of the '060 Patent require a "thermoformed dosage form." *See, e.g.,* '060 Patent at 21:6. As determined in the claim construction section of this decision, a "thermoformed dosage form" is a "dosage form created by applying pressure to a mixture of the active ingredient and high-molecular weight polymer and applying the prior, simultaneous, or subsequent application of heat." *See supra* Part A(1)(c)(ii).

Defendants' ANDAs describe the process used in manufacturing their generic oxymorphone tablets. Defendant Actavis uses a fixed-speed blender to mix oxymorphone hydrochloride with the hardening polymer. See Trial Tr. at 1170, *see also* PTX–2372[12] at 24645. It then compresses the mixture in a rotary tablet press with a force feeder. PTX–2372 at 24645. Actavis cures the mixture by applying 65–72°C of heat. *Id.* at 24649. [redacted text] PTX–2766 at 0389; PTX–3413 at 0415. Teva's manufacturing process involves first blending the ingredients, and then compressing the mixture in a tablet press. *See* PTX–3257 at 0399. Teva then heats the compressed mixture for 15–90 minutes, and coats them. *See* PTX–3257 at 0399.

***34** The court concludes that because thermoforming encompasses manufacturing processes involving the subsequent application of heat, each of the defendants' tablets are "thermoformed" as required by Claim 1 of the '060 Patent.

iii. Whether Defendants' Tablets Have a Breaking Strength of at Least 500N.

Defendants argue that their generic oxymorphone tablets do not have a breaking strength of at least 500N, and therefore do not infringe any of the asserted claims of the '060 Patent. *See, e.g.,* Trial. Tr. at 151–53.

As discussed in the claim construction portion of this decision, a tablet is "broken" when it separates into two or more pieces. *See supra* Part A(1)(c)(iii). Thus, to satisfy its burden on infringement, Grünenthal must prove by a preponderance of the evidence that defendants' tablets are unbroken, or not separated into two or more pieces, when subjected to a pressure of at least 500N.

Dr. Davis tested each of defendants' tablets to determine whether they broke when subjected to pressures of at least 500N. *See* Trial Tr. at 1185. He used a sophisticated protocol in doing so. Using a calibrated Instron testing device, Dr. Davis took ten of each dosage strength of defendants' tablets and applied 503 newtons of force to them. *See* Trial Tr. at 1279:9–11. After being squeezed by the Instron testing device, Dr. Davis's assistant removed the tablets and placed them onto a "data form," or a sheet of paper with labels identifying the tablets. *Trial Tr.* at 1191–92. Dr. Davis then took photographs of all of the tablets. Upon studying these photographs, Dr. Davis observed that while some of the tablets had deformed, none of them had broken into two or more pieces. Trial Tr. at 1192:22–24.

Dr. Davis also created "compression curves" of defendants' tablets, showing the extent to which the tablets compressed, or flattened, when subjected to pressures between zero and 504 newtons. *See, e.g.,* PTX 2567. Based on his observations, Dr. Davis concluded that defendants' tablets are sufficiently hard as to infringe the breaking strength limitation of Claim 1 of the '060 Patent. Trial Tr. at 1194.

Dr. Muzzio reviewed Dr. Davis's photographs, and with regard to defendant Actavis, concluded that some of the tablets had, in fact, separated into two or more pieces upon being tested at 503N. Trial Tr. at 2122:2–3 ("If

anything, these pictures show broken tablets. You see dust and pieces falling off."). Dr. Muzzio also reviewed Dr. Davis's compression curves. Trial Tr. at 2122–23. He interpreted the compression curves as showing that that defendants' tablets "break" before 500N because at some point they continue to flatten without requiring the application of additional force. *See* Trial Tr. at 2123:9–19.

Defendants also argued that rather than simply rely on Dr. Davis's photographs of the tablets, those tablets should have been brought to court so the court could make the factual determination of whether they are broken. *See* Letter from Charles Weiss to the Court at 2 (Feb. 25, 2015); No. 13–CV–436 (ECF # 75). The court initially agreed, stating "It would be helpful to the court, as the finder of fact, for the tablets to be available at trial if needed in either party's presentation." Order of Mar. 19, 2015, No. 13–CV–436 (ECF # 118). However, as trial approached, Grünenthal found it impossible to secure release of the tablets from the facility in which they were stored, given that they are a controlled substance. *See* Letter from Jennifer Roscetti to the Court at 3 (Mar. 9, 2015), No. 13–CV–436 (ECF # 94) ("Actavis feigns ignorance as to the legal burdens of handling and transporting a Schedule II controlled substance pursuant to the Controlled Substances Act...."). Given Grünenthal's concerns, the court settled on an intermediate solution, allowing Actavis to travel to Grünenthal's expert's testing facility in Pennsylvania to make its own inspection of the tablets. *See* Trial Tr. at 229–230. The court then instructed Grünenthal that it need not produce the actual tablets at trial. Trial Tr. at 230:3–5 ("If you can [produce the tablets], fine. If you can't [produce them], we'll do without.").

***35** In the end, having heard the testimony of Dr. Davis and Dr. Muzzio, and having examined photographs of the tablets taken both when they were tested and on the eve of trial,[13] the court finds that defendants' tablets, in every dosage strength, remain unbroken when subjected to 503 newtons of force. *See, e.g.,* (PTX 2554); (PTX 2593); (PTX–2700); and (PTX–2661). It is true that two of the Actavis 30mg tablets tested showed significant deformation, and exhibited large fractures, in Dr. Davis's photographs. See PTX2569 at 0063. Similarly, a photograph of one of the tested Teva tablets, the 10mg tablet, shows a flake separated from the dosage form. See PTX 2667 at 0036. But these are the results of just three tests. Each dosage strength was in fact tested ten times. Thus, even though a photograph of one Teva's 10mg shows a flake, the other nine photographs of Teva's 10mg tablet show completely unbroken tablets. See PTX 2667 at 0036. The same is true of eight out of ten Actavis 30mg tablets, which show no hint of separating into two or more pieces. See PTX2569 at 0063. Given that each tablet was tested ten times, and that the overwhelming majority of tests indicated no hint of separating into two or more pieces, the court finds it probable that the Actavis 30mg tablets and Teva 10mg tablets have a breaking strength of more than 500N. The same is true regarding the other dosage strengths. Dr. Davis's photographs prove, by a preponderance of the evidence, that these tablets remain unbroken at pressures above 500N. Thus, the court concludes that defendants infringe the breaking strength limitation of the '060 Patent.

iv. Whether Defendants' Products Have a Separate Viscosity–Increasing Agent Which Forms a Gel With the Extract From the Dosage Form.

Claim 9 of the '060 Patent takes the dosage form described in Claim 1 and incorporates additional barriers to abuse beyond hardness, such as the use of an emetic, a nose/throat irritant, a dye, a "viscosity increasing agent," et cetera. See '060 Patent at 21:37–52. Of these additional barriers to abuse, the only one that could possibly be found in defendants' products is the "viscosity-increasing agent," which when exposed to an aqueous liquid "forms a gel with the extract obtained." Trial Tr. at 149; '216 Patent at 21:41–46 (Claim 9 part (b)). The purpose of this additional barrier is to complicate abuse by injection. A drug abuser, upon attempting to dissolve a subverted tablet in a liquid, will discover that it forms a gel that is difficult to inject by needle. See Trial Tr. at 987.

As discussed in the claim construction section of this decision, the '060 Patent would be read by a person of ordinary skill in the art as requiring the viscosity-increasing agent to be distinct from the hardening polymer. *See supra* Part A(1)(c)(iv). Thus, Grünenthal must show that defendants' tablets, beyond having a hardening polymer, use some other substance, such as xanthan gum, to provide increased viscosity. It fails in this burden with regard to each of the four defendants. Neither Actavis, Impax, ThoRx, nor Teva[14] have been shown to include a distinct viscosity-increasing agent, such as xanthan gum, in their generic products.

While defendants' products do not contain a separate viscosity-increasing agent, the court nonetheless concludes that defendants infringe part (b) of Claim 9 pursuant to the doctrine of equivalents. Each of defendants' tablets, as discussed, contain polyethylene oxide ("PEO"), At trial, Dr. Davis explained that the PEO in defendants' tablets performs substantially the same function, in the same way, and achieves the same result as the xanthan gum in Endo's tablets. Trial Tr. at 1203.

***36** The PEO in defendants' tablets makes it more difficult for abusers to prepare defendants' tablets for intravenous injection. This is because the PEO, aside from providing hardness, also functions to increase viscosity of the extract when exposed to water. See Trial Tr. at 1203–04. It does this in the same way as the xanthan gum in plaintiffs' products, by mixing with the aqueous liquid. Trial Tr. at 1204:2–6. It also achieves the same result as the xanthan gum in Endo's tablets. When defendants' tablets are milled and placed in a spoon containing water, the PEO forms a "slimy stick paste" that cannot be poured from the spoon. See Trial Tr. at 1204:19–21; see also Actavis Introduction to Overall Quality Summary (PTX–2367 [15] at 23622). Thus, the PEO in defendants' tablets, by performing the same function in the same way as a separate viscosity-increasing agent, and by achieving the same result, infringes part (b) of Claim 9 of the '060 Patent.

At trial, defendants argued that their products do not "form a gel" as required by the remainder of part (b) of Claim 9 of the '060 Patent. However, defendants' own submissions to the FDA, and Dr. Davis's testing of their tablets, show otherwise. As discussed, Actavis reported to the FDA that its milled tablets formed a "slimy sticky paste" when combined with water in a spoon. (PTX–2367 at 23622). In the court's view, there is no significant difference between a "slimy sticky paste" and a "gel." The court need not rely on semantics, however, to resolve whether defendants' tablets "form a gel." Dr. Davis, in testing defendants' tablets, assessed each of them for whether they formed a gel when milled and placed in a vial of water. *See* Trial Tr. at 1359–60. The results of these tests, captured in photographs, speak for themselves. Each of defendants' tablets form a thick and unmistakable gel when milled and placed in water. *See, e.g.,* PTX–2577 (showing the results of "gel testing" Actavis's 7.5mg tablet).

Grünenthal has satisfied its burden and shown by a preponderance of the evidence that defendants' tablets infringe Claim 9 of the '060 Patent. Although their tablets do not contain a distinct viscosity-increasing agent as required by the claim, the PEO in their tablets satisfies the limitation under the doctrine of equivalents. Moreover, each of defendants' tablets forms a gel as required by the claim.

v. Whether Defendants Infringe The Remaining Limitations of the Asserted Claims.

Having resolved the issues disputed at trial, the remainder of the infringement inquiry is straightforward. Grünenthal has proved by a preponderance of the evidence that defendants infringe the asserted composition and method claims of the '060 Patent.

With regard to Claim 1, defendants' tablets are, as discussed, "abuse-proofed thermoformed dosage forms." Because defendants' products contain the opioid oxymorphone, they indisputably have an "active ingredient with abuse potential" as required by the claim. *See* '060 Patent at 21:6–7. Moreover, the hardening polymer used in defendants' tablets, polyethylene oxide, satisfies part (C) of the claim. *Id.* at 21. Finally, as discussed above, defendants' tablets satisfy the final limitation of the claim because they exhibit a breaking strength of at least 500N. Thus, defendants products infringe Claim 1 of the '060 Patent.

Because defendants' tablets use polyethylene oxide as the hardening polymer, they infringe Claim 4 of the '060 Patent. *See* '060 Patent at 19:20–23 ("wherein the polymer is at least one polymer selected from the group consisting of polyethylene oxide...."). Since the tablets are in a controlled release form, and because the PEO in them serves as the controlled release matrix material, defendants infringe on Claim 24 of the '060 Patent. Moreover, defendants' tablets satisfy the limitations of claims 25 and 27 because they are made by mixing the components of Claim 1, press-forming that mixture, and then subsequently exposing it to heat. *See, e.g.,* Trial Tr. at 2548; *see also* '060 Patent at 23:1–12; DTX–2192 at 1236. Defendants induce infringement of the method recited in Claim 29 by instructing patients to administer the tablets to treat pain. *See, e.g.,* PTX–2352. Defendants' tablets infringe Claim 30 because their hardening polymer,

Polyox (the commercial version of polyethylene oxide) has a molecular weight above one million grams per mole. Trial Tr. at 1202:4–5. Defendants' products satisfy claims 31 and 32 because they use oxymorphone as the active ingredient, and the dosage form is a tablet. They satisfy Claim 33 because the polyethylene oxide in their tablet comprises more than 60% of the dosage form by weight. *See, e.g.,* PTX–2589 at 10; PTX–2657 at 12. Likewise, each of the defendants except for Teva, against whom it is not asserted, infringe Claim 34 of the '060 Patent because the content of their hardening polymer, polyethylene oxide, is at least 60% by weight relative to the dosage form.

***37** The court concludes that plaintiffs have satisfied their burden and shown by a preponderance of the evidence that Actavis, Impax, ThoRx, and Teva infringe claims 1, 4, 9, 24, 25, 27, 29, 30, 31, 32, 33, and 34[16] of the '060 Patent.

B. Whether the Patents–in–Suit are Invalid.

An invention is only patentable if it is novel. *See* 35 U.S.C. § 101. An invention is novel if there is no substantially identical matter disclosed by a piece of prior art. *See* 35 U.S.C. § 102(a). It goes without saying that an invention is not novel, and is therefore not patentable, if it simply recites a law of nature, natural phenomenon, or abstract idea. *Alice Corp. Pty. v. CLS Bank Int'l,* 134 S.Ct. 2347, 2354 (2014). If an invention touches on natural phenomena, to be patentable it must provide additional elements such that the practice of the invention amounts to more than the practice of the natural phenomenon. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.,* 132 S.Ct. 1289 (2012). In addition to being novel, an invention must also be useful. *See* 35 U.S.C. § 101. An invention is "useful" if it confers substantial utility to society, meaning it provides some practical benefit to the public. *See Brenner v. Manson,* 383 U.S. 519, 534– 35 (1966); *In re Fisher,* 421 F.3d 1365, 1371 (Fed.Cir.2005).

Once awarded, a patent is presumed to be valid. 35 U.S.C. § 282(a). In an action for patent infringement the defendant, regardless of whether it asserts non-infringement of the claims, may argue that the patent itself is invalid. 35 U.S.C. § 282(b). The defendant carries a heavy burden in this regard. It must prove the patent's invalidity by clear and convincing evidence, *Microsoft Cor. v. i4i Ltd. P'ship,* 131 S.Ct. 2238, 2242–43 (2011), meaning evidence that instills in the court an "abiding conviction" that the patent's invalidity is highly probable. *ActiveVideo Networks, Inc. v. Verizon Communications, Inc.,* 694 F.3d 1312, 1327 (Fed.Cir.2012).

Generally speaking, a defendant may prove the invalidity of a patent by showing that it is anticipated by a single prior art reference; or would have been obvious to a person of ordinary skill in the art at the time of the invention. *See* 35 U.S.C. §§ 102, 103. A patent will also be invalid if, more than a year before the patent application was filed, the invention was both ready for patenting and the subject of a commercial offer for sale, *Pfaff v. Wells Elecs., Inc.,* 525 U.S. 55, 67 (1998); or if the patent fails to provide a sufficient written description of the invention, fails to enable use of the invention, or is indefinite. *See* 35 U.S.C. § 112(a).

Anticipation requires that a single prior art reference disclose every element of the claimed invention. *Schering Corp. v. Geneva Pharm.,* 339 F.3d 1373, 1377 (Fed.Cir.2003). If the prior art reference fails to disclose a feature of the invention, it will only anticipate the invention if the "missing characteristic is necessarily present, or inherent, in the single anticipating reference." *Id.*

To establish obviousness, a defendant "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, 706–07 (Fed.Cir.2012). In determining whether a patent claim is obvious, the court will consider "the scope and content of the prior art; the level of ordinary skill in the art; the differences between the claimed invention and the prior art; and evidence of secondary factors, also known as objective indicia of nonobviousness." *Unigene Labs., Inc. v. Apotex, Inc.,* 655 F.3d 1352, 1360 (Fed.Cir.2011) (citing *Graham v. John Deere Co.,* 383 U.S. 1, 17–18 (1966)) (internal numbering omitted). Objective indicia of non-obviousness include the commercial success of the invention, the invention's satisfaction of a long-felt but unmet need, the failure of others to solve the problem at hand, and the copying of the invention by others. *Graham,* 383 U.S. at 17.

***38** As mentioned, a patent will be invalid if the invention was both "ready for patenting" and the subject of a commercial offer for sale more than one year before the patent application was filed. *See* 35 U.S.C. § 102(b); *Pfaff,* 525 U.S. at 67. This is known as the "on-sale bar." An invention is "ready for patenting" if it has been reduced to practice, meaning actually made, or if it has been sufficiently described or depicted in drawings by the inventor to enable a person skilled in the art to make the invention. *See In re Omeprazole Patent Litig.,* 536 F.3d 1361, 1373 (Fed.Cir.2008). A commercial offer for sale occurs where the invention is marketed commercially. *Pfaff,* 525 U.S. at 67. This includes both actual sales of the invention and offers to sell the invention. *Hamilton Beach Brands, Inc. v. Sunbeam Products, Inc.,* 726 F.3d 1370, 1374 (Fed.Cir.2013). However, a commercial sale does not occur where the transaction is for experimental purposes. *Pfaff,* 525 U.S. at 67. The transaction will be for experimental purposes if represents a " 'bona fide effort to bring the invention to perfection, or to ascertain whether it will answer the purpose intended,' " rather than represent an effort to earn profits. *Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.,* 488 F.3d 982, 998 (Fed.Cir.2007) (*quoting City of Elizabeth v. Am. Nicholson Pavement Co.*, 97 U.S. 126, 136 (1877)).

A patent must also meet the requirements of 35 U.S.C. § 112, which requires the specification to contain a sufficient description of the invention, to enable make and use of the invention, and to be sufficiently definite. *See* 35 U.S.C. § 112(a)–(b). A specification has a sufficient written description if it "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date" of the patent application. *Hynix Semiconductor Inc. v. Rambus Inc.,* 645 F.3d 1336, 1351 (Fed.Cir.2011). The enablement requirement is satisfied if the specification allows a person of ordinary skill in the art to make and use the invention without undue experimentation. 35 U.S.C. § 112(a); *Cephalon, Inc. v. Watson Pharm., Inc.,* 707 F.3d 1330, 1336 (Fed.Cir.2013). Finally, "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." *Nautilus, Inc. v. Biosig Instruments, Inc.,* 134 S. Ct. 2120, 2124 (2014).

1. Whether the Asserted Claims of the '122 and '216 Patents are Invalid.

Defendants argue that the asserted claims of the '122 and '216 patents are invalid for three reasons. First, they argue that the patents are invalid as obvious in light of the prior art at the time of the invention, October 15, 2001. Second, they argue that the '122 and '216 patents are invalid under the on-sale bar because they were ready for patenting and the subject of a commercial offer for sale more than a year before the patent applications were filed. Third, they argue that the patents fail to satisfy the written description, enablement, and definiteness requirements of 35 U.S.C. § 112.

a. Whether Endo's Invention Would Have Been Obvious to a Person of Ordinary Skill in the Art.

Defendants argue that Endo's invention, embodied in the asserted claims of the '122 and '216 patents, would have been obvious to a person of ordinary skill in the art at the time the patent applications were filed. There was general consensus at trial regarding the definition of a person of ordinary skill in the art in 2001. The parties agreed that such a person would have "at least a master's degree or a doctorate in pharmaceutical sciences with experience in developing formulations, including controlled release formulations. If the individual had a lesser degree of training, such as a bachelor's degree, then he would need several more years of experience in the areas of pharmaceutical formulation development." Trial Tr. at 1502:13–20.

***39** This is where the parties' consensus ended. In all, the parties highlight four areas in dispute regarding the obviousness/non-obviousness of Endo's invention [17]: (i) whether there was a motivation to select oxymorphone for use in a controlled-release delivery system; (ii) whether the prior art discloses the dissolution ranges claimed in the '122 and '216 patents; (iii) whether the pharmacokinetic limitations of the patent claims are obvious or otherwise invalid; and (iv) whether secondary factors indicate the invention's non-obviousness.

i. Whether There Was a Motivation to Select Oxymorphone For Use in a Controlled Release Setting.

The first area of dispute with regard to obviousness of the '122 and '216 patents is whether an ordinarily skilled artisan would be motivated to select oxymorphone for use in a controlled release setting.

Oxymorphone was known at the time of the invention. At trial, Dr. Banakar explained that opioids, as a family of molecules, have long been known in the art for their analgesic effect. See Trial Tr. at 1460. Oxymorphone specifically was known, and in fact had been approved and marketed under the branded name Numorphan between 1959 and 1971. Trial Tr. at 2623:17–21. Numorphan would be known to a person of ordinary skill in the art in 2001 because it had been included in the Physician's Desk Reference as early as 1969. See Physician's Desk Reference, Twenty–Third Edition (1969) at 698 (DTX–2890) (describing "Numorphan (oxymorphone) hydrochloride [as] a semisynethetic narcotic ... indicated for all instances of pain ... [administered] Orally ... every 4 to 6 hours."). But while Numorphan was known in the art, it was also understood to be an immediate-release drug, to be taken every four to six hours. Trial Tr. at 1458:13–15. Endo had also been selling oxymorphone in intravenous and suppository forms, both of which are immediate release formulations. *See* Trial Tr. at 247–48, 450:7–9.

Although oxymorphone was known for use in immediate release form, it had never been integrated into a controlled release setting. This is not surprising given the state of the art in 2001.

Controlled release platforms were themselves known to persons of ordinary skill in the art at the time. Trial Tr. at 1474–75. For example, a patent awarded in 1997, Number 5,662,933 (the "Baichwal Reference") taught the use of the TIMERx system, the same system Endo licensed from Penwest, with a "wide variety" of active ingredients, including the analgesics aspirin, codeine, morphine, dihydromorphone, and oxycodone. *See* Baichwal Reference at 8:29– 30 (DTX–3559). Moreover, the 1999 Physician's Desk Reference listed two controlled release opioid tablets, MS Contin and OxyContin, both of which used hydrophilic delivery systems. *See* Physician's Desk Reference at 2556, 2569–79, Fifty–Third Edition (1999) (DTX 2870 and DTX 2961); *see also* Trial Tr. at 1476. However, while these pieces of art taught the integration of some opioids in a controlled release setting, they were silent in regard to integrating *oxymorphone* into a controlled release setting.

The teaching of the prior art indicates that selecting oxymorphone for use in a controlled release setting would have been counterintuitive because of its exceptionally low bioavailability. As plaintiffs' expert Dr. Salomon Stavchansky testified, bioavailability refers to the amount of drug that survives metabolism in the liver and gut and enters the bloodstream, where it will be available to provide a therapeutic effect. *See* Trial Tr. at 2608–09. The 2000 Physician's Desk Reference reported the bioavailability of oxycodone at 60–87% and morphine at 40%. *See* Physician' Desk Reference at 2527, 2537, 54th Edition (2000) (PTX–404 and PTX–0532). Hydromorphone had a bioavailability of between 20% and 60% depending on the source. *Compare* Sarhill *et al.*, *Hydromorphone: pharmacology and clinical applications in cancer patients* at 86 (2000) (DX–3157) *with* Ritschel and Kearns, *Handbook of Basic Pharmacokinetics* at 491 (5th ed. 1998) (PTX–509). Oxymorphone had a reported bioavailability of just 10%. *See* Gordon *et al.,* Opioid Equianalgesic Calculations, 2 J. Palliative Med at 212 (1999) (PTX–117).

***40** The art available in 2001 taught that bioavailability is a significant, even crucial, factor in evaluating a drug's suitability for placement in a controlled release vehicle. *See* U.S. Patent Number 5,958,452 (the "Oshlack Reference") at 2:47–50 (DTX–3560) ("[D]issolution time and ... bioavailability ... are two of the most significant fundamental characteristics for consideration when evaluating sustained-release compositions."). This is because bioavailability was suspected to influence a drug's inter-subject variability, meaning the differences in its clinical effect among a group of patients. *See* Hellriegel et al., *Interpatient variability is related to the extent of absorption,* 60 Clinical Pharmac. & Therap. at 604 (1996) (PTX–461) ("Our results clearly show a significant relationship between the absolute bioavailability of an oral dosage form and its intersubject ... variation"). The lower a drug's bioavailability, the more likely the drug will be to produce variations in clinical effect among a group of patients. *Id.*; *see also* Trial Tr. at 26:20–24. This effect on intersubject variability was suspected to be more pronounced given other influences, including a patient's

food consumption and amount of restedness. *See* William H. Barr, *Bioavailability of Oral Solid Dosage Forms and Clinical Response to Drug Therapy* at 58–59 (1973) (PTX–412).

As a result of its exceptionally low bioavailability, oxymorphone was considered by those skilled in the art to be a poor candidate for controlled-release treatment. Indeed, in an article in the Journal of Pharmaceutical Sciences, a group of authors explained that oxymorphone is ideally suited for delivery through the skin since it "is not very effective orally." *See* Aungst *et al.*, *Transdermal Oxymorphone Formulation Development and Methods for Evaluating Flux and Lag Times for Two Skin Permeation–Enhancing Vehicles,* 79 J. Pharmac. Sciences at 1072 (PTX–410). Moreover, the art taught that because drugs like oxymorphone are almost wholly metabolized upon first passing through the liver, the only way to increase the amount of drug that survives to the bloodstream is to use an exceptionally large dose from the beginning, potentially "risking toxicity." Read *et al.*, *Gastrointestinal Dynamics and Pharmacology for the Optimum Design of Controlled–Release Oral Dosage Forms,* 4 CRC Critical Reviews in Therap. Drug Carrier Systems 221, 240 (PTX–505).

Controlled release delivery systems were suspected of actually reducing certain drugs' bioavailability due to a phenomenon known as "saturable first pass metabolism." Trial Tr. at 2640. Some drugs, when administered in immediate release form, "saturate" or exhaust the liver's metabolizing enzymes, allowing the remainder of the drug to enter the bloodstream unopposed. *See* Welling & Dobrinska, *Dosing Considerations and Bioavailability Assessment of Controlled Drug Delivery Systems* at 258 (1986) (PTX–526). Controlled release drugs, because they release the active ingredient slowly, may never "saturate" the liver's defensive enzymes, and will thus be blocked far more efficiently than their immediate release counterpart. *Id.*; *see also* Mordenti and Williams, *Controlled Release Drug Delivery: Pharmacodynamic Consequences* at 208–09 (1988) (PTX–491) ("controlled release formulations have less of a tendency to produce saturable first pass metabolism...."). To a person of ordinary skill in the art, the saturable first pass phenomenon would have, at least to some degree, cautioned against selecting oxymorphone, a low-bioavailability opioid, for controlled-release treatment.

The notion that low-bioavailability drugs were considered unsuitable for extended-release formulation is reinforced by the fact that, until Endo's development of OPANA® ER, there were remarkably few such examples. At trial, Endo and its experts repeatedly emphasized that at the time of its invention, OPANA® ER was the lowest-bioavailability drug, by a wide margin, ever formulated into a controlled-release setting. *See, e.g.,* Trial Tr. at 2655–56, *see also* Plaintiff's Opening Statement Slide Deck at 001.92 ("Why Oxymorphone? ... Lower bioavailability than any prior controlled release formulation."). During cross-examination of Endo's expert Dr. Stavchansky, defendants revealed that another low-bioavailability drug, oxybutynin (bioavailability of 6%), had previously been developed into a controlled release formulation. See Trial Tr. 2779. But in the court's view, this merely served to underscore, rather than diminish, the fact that low bioavailability drugs were remarkably rare in controlled-release settings. Dr. Stavchansky's unmistakable surprise upon being confronted with Oxybutynin's low bioavailability, and its total absence from the expert reports of both sides, impressed on the court that low-bioavailability drugs were, at the time of the invention, perceived as unsuited for development into controlled release forms.

***41** Defendants argue that, rather than teach away from the selection of oxymorphone, the prior art actually discloses its use in the type of controlled-release setting embodied in the '122 and '216 patents. The first of these pieces of prior art is an application for an international patent application filed in 2000. See PCT International Publication No. WO 01–09661 A2 (the "Maloney Reference") (DTX–3561). The second piece of prior art is United States Patent Number 5,958,452 (the "Oshlack Reference") (DTX–3560).

The Maloney Reference describes a sustained-release formulation for opioid compounds that avoids the need for certain product features hitherto common in sustained release formulations. See Maloney Reference at 8. In describing this invention, Maloney clearly discloses the type of controlled-release matrix delivery systems asserted in Claim 1 of the '122 Patent and claims '72 and '77 of the '216 Patent. See Maloney Reference at 6–7, 9. However, the Maloney reference claims as its invention "an improved formulation for the sustained release of *oxycodone,*" not oxymorphone. *Id.* at 7 (emphasis added). Indeed, each of the many examples provided in

the Maloney Reference deal exclusively with oxycodone hydrochloride, *id.* at 15–17, a completely different opiate from that embodied in the '122 and '216 patents.

The Maloney Reference does mention the use of oxymorphone. However, it does so by sheer overinclusion, by simply listing dozens of molecules and purporting to cover them as part of the invention. First, Maloney discloses controlled release dosage forms combined with an "opioid compound." *Id.* at 8. This opioid compound is defined to preferably include *all* opioid analgesics, meaning the "diverse group of drugs ... that displays opium or morphine-like properties." *Id.* at 9. Maloney then goes further, providing a list of 65 molecules considered to be opioid analgesics. *Id.*; *see also* Trial Tr. at 1671. This list includes oxymorphone. Maloney at 9. It also includes heroin, opium, and fentanyl. *Id.*

The court finds it difficult to believe that a person of ordinary skill in the art, upon reading Maloney, would understand oxymorphone to be suitable for a controlled release setting. Maloney's vast listing of molecules, inclusion of heroin, opium, and fentanyl, raises doubts as to whether that list would be taken seriously as indicating suitability for controlled release treatment. *See* Trial Tr. at 1671; *see also* Maloney at 8–9 ("Preferably the opioid compound included in the formulation is an opioid analgesic.... Opioid analgesics include ... heroin ... opium ... etc...."). Indeed, fentanyl was widely understood as only suitable for transdermal, not oral, delivery. Trial Tr. at 1672. In all, Maloney mentions oxymorphone four times. *See* Maloney Reference at 9, 13, 26, 28. However, in each instance where oxymorphone is mentioned, it is situated among dozens of molecules, such as fentanyl, whose suitability for inclusion in a controlled-release setting is not established in the reference. *Id.*

Maloney is also silent as to the dosing interval of the invention. A primary feature of Endo's invention, embodied in the first claims of both the '122 and '216 patents, is that Endo's tablet will be suitable for a 12 hour dosing interval, meaning the patient will only have to take the tablet twice per day. *See* '122 Patent at 25:50–53; '216 Patent at 26:52–53. Maloney does provide dissolution data for oxycodone hydrochloride, but for reasons that will be discussed below, this data was measured using methods that would not give any indication of the *in vitro* dissolution rate of oxymorphone, which Endo was the first to measure and which it claimed in its patents. *See* Maloney Reference at 21. A person of ordinary skill in the art, upon reading Maloney, would have no understanding of the dosing interval of controlled-release oxymorphone.

***42** The Oshlack Reference shares the Maloney Reference's deficiencies, and adds its own. The Oshlack reference describes using "melt extrusion technology" to produce sustained-release dosage forms, where such technology had previously been used only for immediate release formulation. Oshlack Reference at 1:10–15. Like Maloney, Oshlack discloses the use of "sustained-release matrix pharmaceutical formulations." *Id.* However, it only discloses the use of hydrophobic delivery systems, not hydrophilic systems. Oshlack Reference at 3:39–49; 6:44. In describing suitable active ingredients, Oshlack includes opioid analgesics, but like Maloney, simply lists 72 molecules as covered without regard as to whether they would actually be suitable for use in a controlled release setting. *Id.* at 8–39. Indeed, Oshlack includes heroin, opium, and fentanyl as suitable opioid analgesics. *Id.* But just as with Maloney, it is doubtful that these active ingredients would be understood as capable of being housed in a controlled release delivery system. *See also* Trial Tr. at 1671–72 ("There is no controlled release oral formulation of fentanyl available, but there is a controlled release dermal formulation which is applied on the skin.").

While Oshlack contains examples providing dissolution data for certain active ingredients, it only does so for chlorpheniramine, morphine, oxycodone, hydromorphone, dilaudid, tramadol, and stearyl alcohol. Oshlack Reference at 14–25. It does not list a single example using oxymorphone. This is notable because, as discussed, oxymorphone has a much lower bioavailability than any of the opioids listed as examples. Beside listing oxymorphone among other potential active ingredients, *see, e.g.,* Oshlack at 7:37–38, Oshlack simply gives no indication, to a person of ordinary skill in the art, that the opioid could actually be integrated into a controlled release setting, much less a setting providing a 12 hour dosing interval.

The court is persuaded by the expert testimony that the art taught away from the selection of oxymorphone for use in a controlled release setting because of its exceptionally low bioavailability. Defendants failed to show that a person of ordinary skill in the art would, upon reading the Maloney, Oshlack, and other prior art references, be motivated to

select oxymorphone for development into a controlled release formulation.

ii. Whether the Prior Art Discloses the Claimed Dissolution Rates.

As discussed above, the prior art in 2001 taught away from the selection of oxymorphone for use in a controlled release setting. But even if an artisan were motivated to select oxymorphone, a key feature of Endo's invention is the pairing of oxymorphone with a controlled-release delivery system which releases the active ingredient at a specified rate. See, e.g., '122 Patent 25:55–60. Three of the four claims asserted from the '122 Patent contain dissolution limitations. See claims 2, 3, and 19; '122 Patent at 25–28. Likewise, nineteen of the twenty asserted claims from the '216 Patent recite (directly or by reference) dissolution limitations. See claims 22, 40 and 42, [18] 50, 54, 57, 62, 64, 71, 73, 74, 78, 79, 80, 82. '216 Patent at 26–34. Thus, crucial to defendants' assertion of obviousness is whether the prior art discloses to a person of ordinary skill the dissolution ranges recited in the '122 and '216 patents.

This creates two problems for defendants' obviousness argument. First, each of the prior art references relied on by defendants discloses the dissolution profile of a drug with an active ingredient other than oxymorphone. See Oshlack Reference at 18–19 (oxycodone); Baichwal Reference at 15:32–40 (albuterol); Maloney Reference at 23 (oxycodone). Second, most of the prior art references defendants relied on used different methods to test dissolution than that used in the '122 and '216 patents. *Compare* Maloney Reference at 23 (using the USP Basket Method at 100 revolutions per minute) *with* '122 Patent at 26:65–68 (using the USP Paddle Method at 50 revolutions per minute).

***43** To demonstrate the obviousness of Endo's dissolution claims, it was incumbent on defendants to show two things at trial: (1) that a person of ordinary skill, upon reading the prior art, would understand oxymorphone to be interchangeable with other active ingredients in a controlled release delivery system; and (2) that the results of the dissolution testing methods used in the prior art could be read to indicate the results of the dissolution testing methods used in the Endo patents.

1. A Person of Ordinary Skill in the Art Would Not Understand Oxymorphone to Be Interchangeable With Other Active Ingredients in the TIMERx System.

At trial, Dr. Banakar testified that the TIMERx system Endo licensed from Penwest was essentially "plug and play," meaning that one could take Penwest's controlled-release delivery system and easily insert various suitable active ingredients. Trial Tr. at 1516:21–22. ("Now they plug and play, they changed the drug and put another drug and provide the system that I am looking for."). Referring to Penwest's 1997 filing with the Securities and Exchange Commission, Dr. Banakar noted that various drug substances had been paired with TIMERx, including the heart drug Nifedipine and, pursuant to Endo's development work, oxymorphone. Trial Tr. at 1519:7–25. In Dr. Banakar's opinion, different active ingredients may be readily interchanged in the TIMERx system. Trial Tr. at 1522– 23 ("Baichwal discloses ... the TIMERx platform using gums. Baichwal also discloses analgesics which could be put into these gums to get controlled release formulations for morphine.... A person of ordinary skill in the art would be able to develop a controlled release formulation for oxymorphone using the same technology as Baichwal discussed."). Thus, in his view a person of ordinary skill in the art, upon learning that other molecules had been paired with TIMERx, would find it obvious to do the same with oxymorphone.

Plaintiffs' expert on non-obviousness, Dr. Stavchansky, disagreed with Dr. Banakar's characterization of the TIMERx technology as a "plug and play" system. *See* Trial. Tr. at 2680:4–5. Dr. Stavchansky noted that different opioid molecules have different pharmacokinetic effects, and the fact that one opioid has been integrated into a controlled release setting does not indicate similar success for a different opioid. *Id.* at 2681. It is only upon testing the new opioid in the controlled-release setting under both laboratory conditions and in live subjects that one can assess its compatibility with the TIMERx system. *See id.* To support this opinion, Dr. Stavchansky compared two controlled release drugs marketed by Purdue Pharma, MS Contin (morphine) and OxyContin (oxycodone), and discovered that even though both use the same controlled-release technology, they exhibit significantly different formulations. Trial Tr. at 2686– 88. This indicates that it is no simple matter to "plug" a new active ingredient into a previously used delivery system.

The court finds Dr. Stavchansky to be more persuasive than Dr. Banakar on this issue. The court is not persuaded that controlled release systems, including TIMERx, would be understood by artisans as simply "plug and play." This is because, as Dr. Stavchansky testified, each controlled release drug is independently formulated and tested. A person of ordinary skill in the art, upon learning that one opioid had been developed into a controlled release formulation, would not find it obvious to do the same with oxymorphone.

2. Dissolution Profiles Measured Using the USP Basket Method and Paddle Method at 100rpm Were Not Known to Teach Dissolution Profiles Measured Using the USP Paddle Method at 50rpm.

***44** Even if the court were to accept defendants' argument regarding the interchangeability of oxymorphone and other active ingredients in controlled release systems such as TIMERx, the prior art would still fail to teach Endo's claimed dissolution ranges. Since OPANA® ER was the first drug to integrate oxymorphone into a controlled release setting, all of the prior art references disclose the dissolution rates of *other* controlled release drugs such as albuterol and oxycodone. *See, e.g.,* Baichwal Reference at 14:36–41 (showing dissolution for albuterol, a non-opioid). The person of ordinary skill in the art would have to assume that the disclosed dissolution rate of drugs such as albuterol and oxycodone would somehow be indicative of the dissolution rate Endo claimed for controlled-release oxymorphone.

But even if the artisan were to make this assumption, which the court is not convinced is reasonable, he would have to appreciate some way to correlate the dissolution profiles of the non-oxymorphone controlled release drug to the dissolution profile of controlled-release oxymorphone. This presents a significant challenge to defendants' obviousness argument, because most of the prior art references measured dissolution using different testing methods than what Endo used in its dissolution claims.

The Endo patents express the dissolution profile for controlled-release oxymorphone using the USP Paddle Method at 50rpm. See '122 Patent at 25:57. Where, for example, the Endo patents say that a tablet releases 45% to 80% of the active ingredient within four hours, they mean four hours after being placed in a vessel containing 500ml of medium that is agitated by the spinning of paddle-shaped blades at fifty revolutions per minute. See supra Part A(1)(a).

Most of the prior art references defendants rely on measured dissolution in a different way. The Maloney Reference measured dissolution of controlled-release oxycodone using the USP Basket Method at 100rpm. See Maloney Reference at 23. The same is true of another reference, United States Patent Number 5,549,912 (the " '912 Patent"). See '912 Patent at 2:20–25 (DTX–0042). The Oshlack Reference measured dissolution using the Paddle Method, but did so at twice the speed as Endo, 100 revolutions per minute, and in nearly twice the aqueous buffer (900ml compared to Endo's 500ml of media). See Oshlack Reference at 11:66.

While Maloney and Oshlack measured dissolution differently than Endo, some of their dissolution ranges coincide with those claimed for oxymorphone in the '122 and '216 patents. For example, the Maloney Reference shows that certain oxycodone hydrochloride tablets will be 25% dissolved at one hour. Id. The Oshlack Reference shows dissolution of 12.5% to 42.5% at one hour. See Oshlack Reference at 12:24–27. Both are similar to the dissolution range Endo claimed for oxymorphone, 15% to 50% at one hour. *See* '122 Patent at 25:57–60.

But to accept that Oshlack, Maloney, and the '912 Patent taught the dissolution ranges claimed in the '122 and '216 patents, the court would have to accept that a person of ordinary skill in the art would understand some correlation between results obtained using the Paddle and Basket methods at different speeds.

Dr. Banakar suggested that two pieces of art, the Hanson Reference and the Madden Reference, taught such a relationship between the two methods. Trial Tr. at 1551–52. The "Hanson Reference" is a handbook on dissolution testing published in 1991. *See* William A. Hanson, *Handbook of Dissolution Testing* (2d Ed.1991) (DTX–3556). It provides that "for general purposes when not otherwise specified–rates of 50 rpm for the paddle and 100 rpm for the basket are recommended and have proved to be *roughly equivalent* to one another in producing dissolution." *Id.* at 36 (emphasis added).

Similarly, in a 1998 report presented to the American Association of Pharmaceutical Scientists, a group of authors observed that the four USP dissolution testing methods, including the Paddle and Basket Methods, produce similar dissolution profiles "regardless of the degree of agitation...." *See* Madden *et al., Impact of Apparatus Type and Hydrodynamics on the Release of a Highly Soluble Drug From a Hydrophilic Matrix Tablet* (the "Madden Reference") (DTX–0069 at 9956).

***45** However, a significant body of other art showed no such relationship. A textbook published in 1999 stated that:

> "the use of various testing methods makes it even more difficult to interpret dissolution results because there is no simple correlation among dissolution results obtained with various methods. For many drug products, the dissolution rates are higher with the paddle method.... No simple correlation can be made for dissolution results obtained with different methods."

Shargel and Yu, *Applied Biopharmaceutics & Pharmacokinetics* at 145 (1999) (PTX 637) (the "Shargel Reference"). Similarly, a book written by defendants' own expert, Dr. Banakar, stated that the dissolution testing device used is one of six factors influencing dissolution rate. *See* Umesh Banakar, *Pharmaceutical Dissolution Testing* at 133–34 (PTX–411) (the "Banakar Reference"). Finally, an article published in 1978, the Hardwidge Reference, taught that different dissolution testing methods produce different results depending on the speed of agitation. *See* E.A. Hardwidge *et al., Comparison of Operation Characteristics of Different Dissolution Testing Systems,* 67 J. Pharmaceutical Sciences 1732 (1978) (PTX–0458) (the "Hardwidge Reference"). Hardwidge shows that the Paddle Method at 100rpms produces significantly faster dissolution over time than the Paddle Method at 50rpm. *See* Hardwidge Reference Fig. 1. Moreover, when dissolution is tested for the Paddle and Basket Methods at the same speed of agitation, the Paddle Method will produce faster dissolution results. *Compare id.* Fig. 1 *with id.* Fig. 2.

Even accepting, without approving, defendants' argument that a person of ordinary skill in the art would understand the dissolution profiles for the controlled release formulation of one molecule as teaching the dissolution profile for the controlled release formulation of a wholly different molecule,[19] the court remains unpersuaded that the art in 2001 taught the interchangeability of the USP Paddle Method and USP Basket Method at different speeds. At most the Hanson Reference merely provided that the two methods were "roughly equivalent in producing dissolution." This would be woefully insufficient instruction to a person of ordinary skill in the art, and would provide no way to infer some correlation between dissolution results obtained using the different methods. Rather than teach the equivalency of the various USP testing methods, a significant body prior art, including the Shargel, Banakar, and Hardwidge references, taught that dissolution results from one testing method were non-interchangeable with results obtained from a different testing method.

***46** The court concludes that defendants have failed to show disclosure in the art of the dissolution limitations claimed in the '122 and '216 patents. The court is unpersuaded that a person of ordinary skill in the art would understand oxymorphone to be interchangeable with oxycodone, morphine, and albuterol in a controlled release setting, nor is it clear that he would understand dissolution values for those drugs as indicating the dissolution profile of controlled-release oxymorphone. Even if a person of ordinary skill in the art made this assumption, the dissolution data provided in prior art would not predict or indicate Endo's claimed ranges because it was obtained using different testing methods. Because there was no way to equate the results obtained from the different testing methods, a person of ordinary skill in the art would not have been able to extrapolate from the prior art the dissolution limitations claimed in the '122 and '216 patents.

iii. Whether the Claimed Pharmacokinetic Limitations are Obvious or Otherwise Invalid.

In addition to the dissolution limitations discussed above, the '122 and '216 patents also recite pharmacokinetic limitations, or limitations describing how Endo's tablets will affect the human body once ingested. The pharmacokinetic limitations of the patents can be grouped into four broad categories: "analgesic effect" limitations (providing that the tablet will provide pain

relief for a certain period of time); "food effect" limitations (limitations describing blood concentration levels after having eaten a meal as opposed to having fasted); metabolite limitations (limitations stating that ingesting the tablets will produce the metabolite 6–OH oxymorphone); and peak plasma level limitations (limitations describing when and how often patients' blood will exhibit peak concentrations of oxymorphone). *See, e.g.,* '216 Patent at 26:35–55; *see also supra* parts (A)(1)(a)–(b).

Defendants challenged the validity of the asserted pharmacokinetic limitations at trial, arguing that: (1) some of the asserted pharmacokinetic limitations are the result of natural phenomena and therefore not patentable; (2) even if those pharmacokinetic limitations are patentable, they were nonetheless obvious in light of the prior art; and (3) the claimed pharmacokinetic limitations could have been predicted by a convolution analysis. The court will address each of these arguments in turn.

1. The Claimed Pharmacokinetic Limitations Do Not Merely Recite Natural Phenomena.

Defendants argue that some of the pharmacokinetic limitations claimed in the '122 and '216 patents merely capture natural phenomena and are therefore ineligible for patent protection. *See* Trial Tr. at 177:6.

Many of the asserted claims capture what are known as "food effects," meaning they provide that concentrations of oxymorphone or its metabolite in the bloodstream will vary to a certain extent depending on whether a patient has eaten or fasted. For example, claims 20 of the '122 Patent and 40 of the '216 Patent provide that total blood concentrations of oxymorphone (AUC(0–*inf*)) will be no more than 20% higher when the tablet is taken after having eaten a meal as opposed to having fasted; and that maximum observed concentrations of oxymorphone (Cmax) will be no more than 50% higher after having eaten. *See* '122 Patent at 26:54–58; '216 Patent at 30:10–12 (depending from Claim 38).

Other limitations of the patents describe "peaks," or highpoints, of oxymorphone concentration in the blood occurring within one to eight hours, and then recurring once or twice more within twelve hours. *See, e.g.,* '216 Patent at 26:35–55. Finally, some of the claims provide that the formulation will provide detectable levels of oxymorphone and its metabolite 6–OH oxymorphone, and in certain ratios. *See id.*

At trial, Dr. Banakar testified that the food effect, peak concentration, and "detectable level" limitations of the '122 and '216 patents are the result of the body's natural processes, and would be exhibited whenever oxymorphone is administered to human subjects. *See, e.g.,* Trial Tr. at 1571:17–24. With regard to the food effect limitations, Dr. Banakar testified that Endo merely administered controlled-release oxymorphone to subjects and then claimed the resulting blood concentrations. Trial Tr. at 1572:7–11. For example, Dr. Banakar claimed that Endo performed a food effect study in subjects which showed total blood concentration (AUC) of oxymorphone to be 18% higher after having eaten a meal as compared to having fasted, and simply recited as a claim limitation AUC values of not greater than 20%. Trial Tr. at 1572. Endo purportedly used a similar strategy in reciting the claim limitations for maximum observed concentrations of oxymorphone (Cmax). *Id.*

***47** At trial, defendants' expert failed to cite any reference for the proposition that the food effect limitations merely capture natural phenomena, other than opining to that effect. *See* Trial Tr. at 1501:21–25, 1571:13–16. Dr. Banakar offered no other support for his view that the pharmacokinetic limitations are the result of the body's natural processes. Of course, the court gives considerable weight to Dr. Banakar's opinion given his clear expertise in the field. But the court finds his testimony to be undermined by the fact that oxymorphone, when administered in an immediate release formulation, produces a total blood concentration (AUC) of 30% under fed conditions. Trial Tr. at 484:6–9; '122 Patent at 10:18–20. This is considerably higher than the food effect of controlled release oxymorphone, which when taken under fed conditions produces total blood concentration (AUC) of 20%. Trial Tr. at 486:9–14. If the food effect of oxymorphone was merely a result of natural processes, then one would expect the same total blood concentration (AUC) after eating for both the immediate release and controlled release formulations. This is not the case. Rather, it appears that formulating oxymorphone into a controlled-release setting curbs the pronounced food effects exhibited by immediate release oxymorphone, reducing them to more tolerable levels. *Cf.* Trial Tr. at

487–88. It is the inventive dosage form, and not merely the body's metabolism, that provides the significant reduction in food effects claimed in the Endo patents.

The invention has an equally significant effect on the number of peaks in oxymorphone blood concentration levels. When immediate release oxymorphone is ingested, the subject's blood exhibits a single dramatic peak in blood concentration levels occurring in the first four hours, and a second, much smaller peak occurring at about twelve hours. *See* '122 Patent at Fig. 5. When controlled-release oxymorphone is ingested, the subject's blood exhibits three moderate peaks in blood concentration levels over about twelve hours. *Id.* The highest peak occurs within eight hours. *Id.* Endo claimed these multiple-peak and highest-peak effects as limitations in the '216 Patent. *See, e.g.,* '216 Patent cls. 1, 78.

At trial, Dr. Banakar opined that the "multiple" peaks exhibited by controlled release oxymorphone were the result of a natural process known as "enterohepatic recirculation." Enterohepatic recirculation means that once ingested, oxymorphone is circulated between the intestine, liver, and bile duct multiple times, resulting in multiple peaks in blood concentration levels. See Trial Tr. at 1495. Indeed, in correspondence Endo submitted to the FDA in 2002, Endo explained that "the presence of multiple peaks ... suggests the presence of enterohepatic recycling...." Study of Human Pharmacokinetics and Bioavailability Data (Nov. 14, 2002) (DTX–1444 at 4173). Thus, it is Dr. Banakar's opinion that the multiple-peak limitations of the asserted claims merely describe the natural phenomena of enterohepatic recirculation of oxymorphone.

Dr. Banakar's observation appears sound, but the conclusion he draws is not. The "multiple peaks" that occur following administration of controlled release oxymorphone are of course the result of the body's natural processes. It could be no other way. But Endo's patents do not pretend to claim the natural process of enterohepatic recirculation. Rather, the Endo patents claim a dosage form for oxymorphone that provides an analgesic effect over twelve hours, *see* '122 Patent at 25:50–52, and which causes multiple peaks in blood concentration levels (and ensuing continued analgesic effectiveness) during that same period. '216 Patent at 34:20–24. Similarly, Endo claimed that that blood levels will peak within 8 hours of administration, *id.* cl. 1, as opposed to within 4 hours as would be expected with immediate release oxymorphone.

These pharmacokinetic effects *are only possible* because the dosage form, the invention itself, slows the release of oxymorphone to such a degree that: (1) peak blood concentration of oxymorphone occurs later (within 1–8 hours) than with immediate release oxymorphone (within 1–4 hours); and (2) the body has multiple opportunities to recirculate the opioid through the bile duct, liver and intestines, producing multiple high-points in blood concentration levels. This multiple peaking is not possible with immediate release oxymorphone because the drug simply does not remain concentrated in the body long enough to be circulated multiple times and produce multiple peaks. Thus, the peak limitations of the '216 Patent do not merely recite natural processes, but instead recite the unnatural result of the body's prolonged exposure to oxymorphone, made possible only because of the inventiveness of the dosage form.

***48** Dr. Banakar also challenged the metabolite limitations of the asserted claims. As discussed in the claim construction section of this decision, the asserted claims of the '216 Patent contain limitations stating that the formulation will "provide[ ] detectable blood plasma levels of 6–OH oxymorphone [the metabolite] and oxymorphone," and that ratio of 6–hydroxy–oxymorphone [the metabolite] to oxymorphone in the bloodstream will be between about 0.5 to 1.5. *See, e.g.,* '216 Patent cls. 1, 42, 62 and 64 (incorporating Claim 55). Dr. Banakar argued that these limitations merely recite the inevitable–that once oxymorphone is administered to a patient, that patient's blood will invariably exhibit detectable levels of oxymorphone *and* its metabolite, and always within the ratio claimed. *See* Trial Tr. at 1594:20–23. Thus, Dr. Banakar asserts that the metabolite limitations merely record natural processes. *Id.* at 1594–95.

Again, the court believes that Dr. Banakar's conclusion is unsound. It goes without saying that the liver's ability to metabolize substances is a natural process. But Endo did not attempt to patent the operation of the human liver, much less the operation of the liver on a natural substance. Rather, Endo patented the myriad of pharmacokinetic effects that occur when a subject ingests the inventive formulation of the semi-synthetic opioid oxymorphone in a controlled-release delivery system. These effects do not

occur in the absence of the controlled-release dosage form constituting the invention, and are therefore not natural phenomena.

2. The Pharmacokinetic Limitations Were Not Otherwise Disclosed in the Prior Art.

Defendants argue that even if the pharmacokinetic limitations are not invalid as claiming natural phenomena, they are nonetheless disclosed in the prior art. Defendants assert numerous pieces of prior art to this effect: the Maloney Reference, the Oshlack Reference, the Baichwal Reference, the '912 Patent, the Penwest Reference, and an article published in 2000 in the journal "Cancer Control." *See* James F. Cleary, *Cancer Pain Management,* 7 Cancer Control 120 (Mar.2000) (DTX–1951) (the "Cleary Reference"). The court must determine whether these references teach the pharmacokinetic characteristics for oxymorphone claimed in the '122 and '216 patents.

The first pharmacokinetic limitation of the asserted claims is that the dosage form containing oxymorphone or its salt will prove analgesically effective, meaning provide a painkilling effect, for twelve hours. *See* '122 Patent at cl. 1; '216 Patent cl. 1(iv); *see also supra* Part A(1)(a)–(b).

None of the prior art references taught the analgesic effectiveness of oxymorphone over a twelve-hour period. Maloney taught the analgesic effectiveness of a different molecule, oxycodone, but gave no indication of oxycodone's dosing interval. *See generally* Maloney Reference. Maloney did list the *in vitro* dissolution rate for oxycodone over twelve hours, *id.* at Table 2, and from this it is possible that a person of ordinary skill in the art could infer that oxycodone would have sustained analgesic effects given that much of the drug remained undissolved during that period. But this does not indicate the dosing interval of sustained release oxymorphone.

The same is true of the other prior art references, which show dissolution, and in some instances sustained analgesia, for molecules other than oxymorphone. *See* Oshlack Reference at 14–25 (chlorpheniramine, morphine, oxycodone, hydromorphone, dilaudid, tramadol, and stearyl alcohol); Baichwal Reference Figs. 1–3 (showing both dissolution and pharmacokinetic profiles over twelve hours for the albuterol); '912 Patent Figs. 1–5 (showing analgesic effect and blood plasma concentrations over twelve hours of oxycodone); Webster Reference at 3 (morphine sulfate). The Cleary Reference, published in 2000, indicated that oxymorphone is "currently under development in sustained-release formulation[ ]" but gives absolutely no indication of dosing interval or twelve-hour efficacy. *See* Cleary Reference at 126.

***49** In short, none of the prior art asserted would give any indication to a person of ordinary skill that *oxymorphone,* as opposed to some other substance, could be developed into a controlled-release formulation providing effective analgesia over a twelve-hour period.

Nor did any of the prior art references disclose the claimed food effects. In fact, defendants made no attempt at trial to show some teaching in the prior art of the food effects of controlled-release oxymorphone. Instead, they merely asserted that those effects were natural processes. And while immediate release oxymorphone's significant food effect is now known, it does not appear to have been known before 2001. *See, e.g.,* Physician's Desk Reference, Twenty–Third Edition (1969) at 698 (DTX–2890) (failing to indicate whether immediate release oxymorphone should be taken under fed or fasted conditions). Furthermore, there was no disclosure in the art that developing oxymorphone into a controlled release formulation would actually improve on immediate release oxymorphone's food effect as measured by AUC, *see supra* Part B(1)(a)(iii)(1), or predict the difference in AUC and Cmax values claimed for fed and fasted conditions. *See, e.g.,* '122 Patent cl. 20.

The prior art also failed to teach the multiple peaks in blood concentration levels exhibited by controlled-release oxymorphone. At trial, Dr. Banakar testified that the prior art showed multiple-peaking for controlled release morphine and hydromorphone. *See* Trial Tr. at 1576–77. An article published in 1980 shows multiple peaks in controlled release morphine over a twelve hour period. *See* Leslie *et al., Controlled Release Morphine Sulfate Tablets–A Study in Normal Volunteers,* 9 Br. J. Clin. Pharmac. 531, 534 (1980) (DTX–2816). Likewise, a patent issued in 1991 shows peaks in blood concentration levels of controlled release hydromorphone over twenty-four hours. *See* United States Paten 4,990,341 (the "Goldie Reference") at 8:20–30. But these sources did not indicate whether *oxymorphone,* when housed in a controlled release setting, would exhibit multiple peaks.

The fact that two controlled-release opioids exhibit multiple peaks does not indicate that a wholly different controlled-release opioid will also exhibit multiple peaks. A defense expert, Dr. Mayersohn, baldly testified that "it is well established for a lot of opioids that you see multiple peaks," Trial Tr. at 1740:19– 20, but he gave no indication of which of the nearly 70 opioids were known to do so in 2001. Unless a significant portion of all opioids were known to exhibit multiple peaks when developed into a controlled release formulation–something defendants did not come close to establishing at trial–there would be no reason for a person of ordinary skill in the art to think that oxymorphone would exhibit multiple peaks when developed into a controlled-release formulation. And while Endo certainly knew that oxymorphone in immediate release formulation exhibited dual peaks, *see* '216 Patent at Fig. 5, such information was not shown to be available to the public. Defendants simply failed to show how the known multiple-peaking of two controlled release opioids indicated multiple peaking for controlled-release oxymorphone.

***50** Finally, defendants did not provide prior art disclosing the metabolite limitations of the Endo patents. At trial, defendants were quick to note that it was known that oxymorphone, when metabolized by the liver, produced detectable levels of 6–OH oxymorphone. *See* Trial Tr. at 1591. But where Endo claimed as a limitation "detectable blood plasma levels of 6–OH–oxymorphone and oxymorphone," it did so only in the conjunctive sense along with four other limitations for the metabolite. *See* '216 Patent cl 1(i)-(v). Thus, while it was known that oxymorphone when metabolized produced 6–OH oxymorphone, *see* Cone *et al., Oxymorphone Metabolism and Urinary Excretion in Human, Rat, Guinea Pig, Rabbit, and Dog,* 11 Drug Metabolism and Disposition 446, 446 (DTX–3554), the prior art taught neither the ratio of oxymorphone to its metabolite, nor the timing of peak metabolite levels, as required by the asserted claims. *See* '216 Patent cl. 1(ii)-(iii).

3. Defendants' Convolution Analysis is Irrelevant Because it Relied on Data Not Found in the Prior Art.

In an effort to show the obviousness of the pharmacokinetic effects claimed in the '122 and '216 patents, defendants called a professor of pharmaceutical sciences, Dr. Michael Mayersohn, to testify that a person of ordinary skill in the art in 2001 could use a technique known as "convolution analysis" to predict the pharmacokinetic properties of controlled-release oxymorphone. Trial Tr. at 1706, 1713. The convolution analysis is a three-step process involving: (1) taking the "known" pharmacokinetic properties of immediate release oxymorphone; (2) taking the dissolution profile of known extended release opioids such as morphine; and (3) using computer modeling to combine the first and second steps and predict the pharmacokinetic properties of controlled-release oxymorphone. *See* Trial Tr. at 1721–23.

Dr. Mayersohn's convolution analysis was flawed from the outset because in 2001 there was no publicly available source disclosing the pharmacokinetic properties of immediate release oxymorphone. At trial, Endo's former chief scientific officer, Dr. David Lee, testified that when Endo began developing oxymorphone into a controlled release formulation, there was a lack of published research on immediate release oxymorphone's pharmacokinetic properties. *See* Trial Tr. at 202. Although the FDA had approved oxymorphone for sale as the branded drug Numorphan in 1959, it did not at that time require efficacy data. *Id.* at 203:2. In fact, in 2001 there had been only four published studies on oral oxymorphone. *See* Briefing Packet (PTX–0223 at 410). Endo's project development team realized that oxymorphone was for all intents and purposes a "pharmacologic enigma." Trial Tr. at 203:11.

It was Endo's own development team that, beginning in 1998, performed the studies needed to measure immediate-release oxymorphone's pharmacokinetic effects. *See, e.g.,* EN3202 Project Team Minutes (6/26/98) (PTX–173 at 342627) (discussing the results of an eight-subject pilot pharmacokinetic study). It was only after Endo had studied the pharmacokinetic properties of immediate release oxymorphone that it could take the next step, and begin developing controlled release oxymorphone. *See* Trial Tr. at 197–99.

All of Endo's studies on immediate-release oxymorphone's pharmacokinetic effects were confidential, and as defendants' own expert testified, "not available in the literature." Trial Tr. at 1741:10–11; *see also* Excerpt from Endo Study EN3203–001 (DTX–1069A). But when Dr. Mayersohn performed his convolution analysis, he used Endo's information as a starting point. *See* Trial Tr.

at 1758:1–4 ("Q. The study ... which you relied on for oxymorphone pharmacokinetic profile data is an Endo study, right? A. Yes, sir."). His only alternative would have been to conduct his own pharmacokinetic study, which he suggested could have been done by enlisting "six to perhaps ten human subjects." Trial Tr. 1741:18–19.

***51** The court finds Dr. Mayersohn's testimony to be unpersuasive. Regardless of whether convolution analysis can be used to predict the pharmacokinetic effects of a new controlled release drug, it requires as its starting point pharmacokinetic data for the immediate release formulation. In performing his convolution analysis, Dr. Mayersohn used Endo's own pharmacokinetic data, information that would be unavailable to the public in 2001, and which simply does not constitute "prior art." Dr. Mayersohn's suggestion that an ordinarily skilled artisan could perform his own study to obtain such data misses the point. The fact is that there was no published source in 2001 disclosing the relevant pharmacokinetic properties of immediate release oxymorphone. Therefore, a person of ordinary skill in the art would have lacked the information necessary to perform a convolution analysis predicting the pharmacokinetic properties of controlled-release oxymorphone.

iv. Whether Secondary Considerations Indicate the Non–Obviousness of the Invention.

The final factor in the obviousness inquiry asks the court to consider objective indicia of non-obviousness, including the commercial success of the invention, the invention's satisfaction of a long-felt but unmet need, the failure of others to solve the problem at hand, and the copying of the invention by others. *Graham v. John Deere Co.,* 383 U.S. 1, 17 (1966).

Endo was persuasive in demonstrating the commercial success of its OPANA® ER products, and in relating the success of those products to the claims of the '122 and '216 patents. Endo's expert on commercial success, economist Dr. Gregory Bell, demonstrated that once OPANA® ER launched in 2006, it gained wide acceptance among physicians, going from zero prescriptions before launch to 350,000 prescriptions in 2011. Trial Tr. at 1994:1–2. During the same period, gross sales of OPANA® ER increased by a corresponding amount, from zero dollars in 2006 to well over $150 million in 2011. See PTX–0336 (showing IMS sales data by month). OPANA® ER achieved this growth despite facing competition from other long-acting opioids, including branded and generic morphine, methadone, and oxycodone. Trial Tr. at 1990–91. Since its launch in 2012, OPANA® ER CRF has experienced consistent sales, despite the entry of Actavis's generic tablets on the market. *Id.* at 1995.

In cross-examining Dr. Bell, defendants attempted to establish that OPANA's commercial success was more the result of aggressive advertising and rebate programs than the drug's inherent properties. Trial Tr. at 2046–48. But Dr. Bell demonstrated, to the court's satisfaction, a clear nexus between the asserted claims of the '122 and '216 patents and the market success of the branded product. As discussed at length in the preceding sections of this decision, key features of the invention include its twelve-hour dosing interval and analgesic effectiveness over the same period. When physicians were asked why they were prescribing OPANA® ER, they overwhelmingly attributed their decision to clinical properties such as the drug's ability to provide "effective pain relief," "good side effect profile" and "long duration of action." See Trial Tr. at 2012–13, *see also* PX4010.15 (showing the results of a physician survey). Physicians also cited other reasons attributable to the invention, including better tolerability and greater pain relief. *See* PX4010.15. Thus, the court is satisfied that OPANA® ER has achieved commercial success, and that there is a nexus between that success and the asserted claims of the '122 and '216 patents.

The court is also persuaded that the invention satisfied a long-felt but unmet need in the marketplace. Endo's expert on long-felt need, Dr. Edgar Ross, testified that the medical community had long sought additional tools to effectively combat chronic pain. *See* Trial Tr. at 935–37. At the time of the invention, there were numerous immediate release opioids on the market, but these had a short duration and often involved inconvenient routes of administration, such as intravenous and transdermal delivery. Trial Tr. at 941– 42. Three controlled release opioids, morphine, methadone, and oxycodone, were on the market, but exhibited negative effect in some patients, including causing nausea and vomiting, poor interaction with other drugs, and diminished analgesic potency in patients unable to produce certain enzymes. Trial Tr. at 949–50. Overuse of the existing opioids could also

result in increased tolerance, requiring physicians to either increase the dose, risking toxicity, or alternatively switch patients to a different opioid (opioid rotation). Trial Tr. at 952. The introduction of a new controlled-release opioid, oxymorphone, fulfilled the need for a drug with less side effects than those currently on the market, and the need for an additional option for use in opioid rotation. *Id.* at 952–53.

***52** Others had failed to develop oxymorphone into a controlled release setting before Endo, but have since copied that work. Endo developed OPANA® ER between 1997 and 2001, and launched it in 2006. Trial Tr. at 794:18–21. It was undisputed at trial that no entity had developed oxymorphone in an extended release formulation before then. It was only after OPANA® ER had demonstrated years of significant growth in sales and prescriptions that other companies decided to develop their own sustained-release oxymorphone products. See Trial Tr. at 1994:1–2. Indeed, the instant litigation involves attempts by generic drug manufacturers to do exactly that.

OPANA® ER experienced significant commercial success in the years following its launch despite the existence of branded and generic opioid competition. There was a clear need for an additional opioid for use in opioid rotation, as well as one that would be better tolerated by patients ill-disposed to morphine, methadone, and oxycodone. Finally, it is undisputed that no other entity had developed controlled-release oxymorphone before Endo, and that others only did so years after the drug's commercial success had been established. These secondary considerations indicate that the invention was non-obvious.

b. Whether the On–Sale Bar Applies.

Defendants argue that the '122 and '216 patents are invalid because the invention was ready for patenting and the subject of a commercial offer for sale more than a year before the patent applications were filed on October 15, 2001.

At trial, defendants' expert on the on-sale bar, Dr. Anthony Palmieri, testified that all of the dissolution and pharmacokinetic studies necessary to achieve the claimed invention were performed before August of 2000. *See* Trial Tr. at 2307. Dr. Palmieri showed that for one dosage strength (20mg), OPANA® ER's formulation was determined as early as July of 1998. Trial Tr. at 2283. Moreover, Endo had completed a study on the *in vitro* dissolution rate of the tablets by October of that year. *See* EN3202 Formulation Development Report Part A EN3202 (PTX–0149 at 0634). Studies showing the dissolution and pharmacokinetic characteristics of the drug were performed by March of 2000. *See, e.g.,* Trial Tr. at 2290:16–18.

Finally, Dr. Palmieri testified that Endo knew the twelve-hour analgesic effect of its product by August of 2000. Trial Tr. at 2307. To support this assertion, Dr. Palmieri pointed to minutes from an August meeting between Endo and Penwest discussing the *"preliminary* results" from a study, study fifteen, showing that "EN3202 [OPANA] is an effective analgesic." *See* EN3202 Alliance Committee Meeting Minutes (Aug. 21, 2000) (PTX–589 at 7886–87) (emphasis in original). These "preliminary results" were again discussed at a meeting of Endo's Project Team in September of 2000. *See* EN2302 Project Team Meeting Minutes at 1 (Sept. 14, 2000) (PTX–345) ("preliminary results are positive ... EN3202 is an effective analgesic.").

Endo's expert, Dr. Edgar Ross, disputed the notion that the invention was ready for patenting before October 15, 2000. He explained that even though many of the studies on OPANA® ER (project name EN3202) had been completed before then, only the preliminary reports were available for some of them. Trial Tr. at 2816. Dr. Ross explained that preliminary reports cannot be completely trusted until the data from the study is carefully scrutinized and memorialized in a final report. Trial Tr. at 2816. In the interim, results may change significantly if errors are discovered. *Id.*

The final report for study fifteen, which defendants suggested was completed in August of 2000, was not in fact issued until June 19, 2001. *See generally* Final Clinical Study Report, Double–Blind, Placebo Controlled ... Comparison of the Efficacy and Safety of Controlled Release Oxymorphone.... (PTX–271). A final report for a study measuring controlled oxymorphone's "steady state" blood concentration levels was not issued until August 14, 2001. *See* A Randomized, Two–Period Crossover Trial Comparing the Single–Dose and Multiple–Dose (Steady State) Pharmacokinetics and Bioavailability of

Numorphan CR and Numorphan IR Tablets Phase I (PTX–281).

***53** The evidence does not demonstrate that the invention was ready for patenting more than a year before the applications were filed. As discussed in the claim construction section of this decision, a primary feature of the invention is that the dosage form will be "analgesically effective" for twelve hours, meaning it provides pain relief for that period. *See supra* Part A(1)(a). The invention could not be reduced to practice until the inventors were certain that it would provide the claimed analgesic effect. While preliminary reports indicated OPANA® ER's analgesic effectiveness, those results were not sufficiently trustworthy until the study data had been fully scrutinized. In the end, a mere two months separated the finalization of study nine, and just four months separated the finalization of study fifteen, from the filing of the '122 and '216 patent applications. Thus, the court concludes that the invention was not ready for patenting before the "critical date."

Furthermore, the invention was not the subject of a commercial offer for sale before October 15, 2000. In June of 2000, Endo entered into a "Development and Clinical Supply Agreement" with drug manufacturer Novartis Consumer Health Inc. *See* Development and Clinical Supply Agreement at 1 (June 1, 2000) (PTX–347). The stated purpose of this agreement was for Novartis to manufacture tablets for Endo [redacted text] *Id.* This was not a commercial offer for sale. To the extent a supply agreement could even be considered a "sale," the transaction was clearly experimental in nature, not commercial. *Id.* Because an NDA filing requires demonstrating to the FDA a drug's safety and efficacy, the "sale" of tablets for [redacted text] will involve human and laboratory testing, clearly an experimental purpose. Indeed, the agreement explicitly assumes that [redacted text] Since the Development and Supply Agreement involved a sale for [redacted text], the court concludes that it was experimental in nature.

Because the invention was not ready for patenting nor the subject of a commercial offer for sale before October 15, 2000, the on-sale bar does not apply.

c. Whether the '122 and '216 Patents Satisfy the Requirements of 35 U.S.C. § 112.

Defendants argue that the '122 and '216 Patents fail to satisfy the definiteness, enablement, and written description requirements of 35 U.S.C. § 112(a).

With regard to definiteness, the court concludes that the claims give adequate notice of the metes and bounds of the invention. As discussed, there was some debate at trial over the definition of "peaks" at trial. The court viewed this debate as one primarily of construction, but it could be argued that the Endo patents' call for multiple "peaks," and to a lesser extent "detectable blood plasma levels," *see, e.g.,* '216 Patent at 26:35–55, would leave a skilled artisan in some doubt as to how those limitations could be satisfied. But as discussed, the definition of the term "peak" would be readily apparent to a person of ordinary skill in the art upon reading the specification. *See supra* Part A(1)(b). Moreover, the specification provides that the studies described in the patents were performed using "standard FDA procedures such as those employed in producing results for use in a new drug application." '216 Patent at 3:63–65. From this, an ordinarily skilled artisan would have known how to detect blood plasma levels of oxymorphone.

With regard to written description and enablement, the court concludes that the patents would reasonably convey to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date, and that such artisans would be able to make and use the invention without undue experimentation. Each of the features recited in the patent claims, such as an "oral controlled release oxymorphone formulation" of "about 5mg to about 80mg of oxymorphone" finds adequate, even abundant, support in the specification. *Compare* '216 Patent cl. 1 with '216 Patent at 4:37–40. Moreover, the patent specifications are replete with examples of dosage forms satisfying each of the claimed limitations. *See, e.g.,* '216 Patent at 13–14. For example, the specification describes the administration to subjects of tablets containing 20mg of controlled-release oxymorphone, '216 Patent at 13:59–61, which were then shown to produce dissolution and pharmacokinetic characteristics within the ranges claimed. *Id.* at 14:59–15:20. The specifications also give detailed descriptions of the *in vitro* and *in vivo* testing methods employed in

developing the tablets. *Id.* at 3–4. A person of ordinary skill in the art, upon reading the specifications, would be convinced that Endo possessed the invention claimed, and could also use the specification to develop his own tablets constituting the invention.

***54** At trial, defendants' expert on indefiniteness, Dr. Arthur Kibbe, testified that certain of the asserted dissolution claims are overbroad. Trial Tr. at 1884– 85. To wit, the specification shows the *in vitro* dissolution rate of three different formulations of OPANA® ER. *See* '122 Patent Table 4. The slowest-dissolving tablet had dissolved 27.8% after the first hour, and the fastest-dissolving tablet had dissolved 32.3% after the first hour. *Id.* However, when Endo wrote its dissolution claims, it recited a broader dissolution range of 15%–50% at one hour. *See, e.g.,* '122 Patent cl. 19. It recited similarly broad ranges at the four and ten hour marks. *See* Trial Tr. at 1891:5–13. In Dr. Kibbe's view, these broad ranges indicate that the claims are insufficiently described in the specification. *See* Trial Tr. at 1879.

Defendants have not persuasively shown that the dissolution claims are so broad as to fail to inform an artisan that Endo possessed the invention claimed. A person of ordinary skill in the art, upon reading the dissolution ranges, would understand that the inventors had chosen ranges encompassing the invention, and also allowing for variations. Indeed, had the claims been more restrictively drawn they would have invited infringement. If, for example, Endo had claimed a dissolution range at the first hour of 27%–33%, generic manufacturers could escape infringement by formulating a tablet that dissolves at 26% percent at one hour, or that dissolves at 34% at one hour. The ordinarily skilled artisan, upon reading broader claims, would understand them to encompass the invention as claimed and possessed by the inventor.

The court concludes that the asserted claims, including the dissolution claims, would convey to those skilled in the art the metes and bounds of the invention and that Endo possessed the invention as claimed. Moreover an artisan, upon reading the claims and specifications, would be able to formulate his own controlled-release oxymorphone tablets. Thus, the '122 and '216 patents satisfy the written description, enablement, and definiteness requirements of 35 U.S.C. § 112.

Conclusion Regarding the Validity of the '122 and '216 Patents

Defendants have failed to show, by clear and convincing evidence, that the '122 and '216 patents are invalid. Defendants did not assert that the patents are anticipated. With regard to obviousness, the art revealed no motivation to select oxymorphone for use in a controlled-release formulation, and it failed to disclose the matters recited in the asserted claims. Even if an artisan were somehow motivated to select oxymorphone for use in a controlled release setting, he would have no reasonable expectation of success in doing so given the failure of the art to disclose the pharmacokinetic and dissolution characteristics. Moreover, secondary considerations strongly indicate the invention's non-obviousness. Because defendants' other defenses are without merit, the court concludes that they have failed to carry their burden and have not shown, by clear and convincing evidence, that the '122 and '216 patents are invalid.

2. Whether the Asserted Claims of the '060 Patent are Invalid.

Defendants also challenge the validity of the final patent-in-suit, the '060 Patent. Abuse-deterrence is the primary feature of the invention embodied in the '060 Patent, and is achieved through the tablet's exceptional hardness and its ability to accommodate secondary barriers. As discussed, Endo licensed the '060 Patent from co-plaintiff Grünenthal in order to develop OPANA® ER into a crush-resistant formulation. Endo and Grünenthal now assert infringement of the '060 Patent by those defendants seeking approval to market crush-resistant oxymorphone tablets. Crucial to the instant litigation, then, is whether defendants have carried their burden in showing the '060 Patent to be invalid.

***55** The '060 Patent reflects research and development performed by Grünenthal and its former head of pharmaceutic development, Dr. Johannes Bartholomäus. Grünenthal began exploring abuse-deterrent technologies in response to the growth in the abuse of prescription opioids, including the widespread abuse of OxyContin in the United States. See Trial Tr. at 984. Early on, Dr. Bartholomäus tested a number of ideas for combatting

tablet abuse, including the use of antagonists which block the action of the opiate in the body. See Trial Tr. at 989:22–24; 993:3–5. However, Grünenthal found each of these solutions to be inadequate.

In November of 2002, Dr. Bartholomäus gave a presentation suggesting the company explore other ways to combat abuse, such as making the tablets harder. See Trial Tr. at 999–1000. He suggested using PEO to "increase [the] mechanical resistance of tablets." Presentation at 19 (Nov. 11, 2002) (PTX–2199). After the presentation, Dr. Bartholomäus put this idea to work in the laboratory, making tablets solely out of compressed PEO. Trial Tr. at 1006. Those tablets proved to be exceptionally strong and resistant to crushing. Trial Tr. at 1007. However, the strength of the tablets evaporated when Dr. Bartholomäus added an opiate to them. *Id.* Adding the opiate seemed to "destroy" the hardness conferred by the PEO. *Id.*

Dr. Bartholomäus went on to conduct further experiments on mixtures of PEO and opiates. Eventually, he realized that by heating the mixture and forming it using a die and punches, he could create an opioid/PEO tablet of exceptional hardness. Trial Tr. at 1008–10. Not only was the tablet exceptionally hard, able to withstand 500N of pressure, it also dissolved in conditions mimicking the human body, releasing the opioid. Trial Tr. at 1011:11–15. Upon showing this to his managers, Dr. Bartholomäus set out to develop a process to mass produce the tablets. Trial Tr. at 1015:21–22. Over the next year, he and another inventor, Dr. Elisabeth Arkenau, did just that. Trial Tr. at 1016:14–16. Their work ultimately resulted in the '060 Patent.

Defendants argue that the '060 Patent is invalid for three reasons: (a) previous decisions of this court have a collateral effect establishing the invalidity of the asserted claims; (b) a prior art reference known as the McGinity Application anticipates the asserted claims; and (c) the asserted claims would have been obvious to a person of ordinary skill in the art at the time of the invention. The court will address each of these arguments in turn.

a. The Collateral Effect of This Court's Prior Decisions.

Defendants argue that a prior case in this court preclusively establishes that a piece of prior art known as the McGinity Application anticipates the asserted claims of the '060 Patent.

The "McGinity Application" is a patent application filed in 1997 by James McGinity and others to the World Intellectual Property Organization. *See* International Patent Application Publication WO 97/49384 (DTX–0098 at 2408) (the "McGinity Application"). The McGinity Application teaches the creation of controlled-release drugs using hot-melt extrusion. *Id.* at 11. Hot melt extrusion occurs in three steps consisting of combining a powdered-therapeutic compound with PEO and other optional components; and placing the mixture in an "extruder hopper" which is heated to a temperature that will melt or soften the PEO. The softened mixture then exits the extruder through a die; and still warm, is shaped, molded, chopped, cut, or tableted into the desired physical form. *Id.* at 11:28–30.

In addition to asserting the '060 Patent in this litigation, Grünenthal had also initially asserted two other patents, United States patent numbers 8,114,383 (the " '383 Patent") and 8,192,722 (the " '722 Patent"). Grünenthal's assertion of the '383 Patent was significant because it had asserted that same patent in a different case before this court involving the prescription drug OxyContin. In 2014, following a month-long bench trial, Judge Stein issued a decision concluding that the asserted claims of the '383 Patent were invalid as anticipated by the McGinity Application. *See In re OxyContin Antitrust Litig.,* 994 F.Supp.2d 367, 424 (S.D.N.Y.2014).

***56** In light of Judge Stein's decision, defendants in these actions filed a motion for partial summary judgment, arguing that the decision precluded Grünenthal from litigating the asserted claims of the '060, '383, and '722 patents here. *See* Dkt. No. 70, *Endo Pharmaceuticals Inc. et al v. Actavis Inc. et al.,* No. 13–CV–00436. The undersigned agreed in part, recognizing that Judge Stein had expressly invalidated (as anticipated by McGinity) four of the five asserted claims of the '383 Patent, and that his decision precluded litigation of those claims here. *See* Opinion of March 17, 2015 at 4 (Dkt. # 117 in Case 13–cv–00436) (the "March 17th Opinion"). The court also recognized a collateral effect with regard to the final asserted claim of the '383 Patent. *See id.* at 5. However, the court held that there was no collateral effect with regard to the '060 Patent because that patent was never asserted before Judge Stein and, more importantly, recited

limitations concerning abuse-deterrence absent from the adjudicated claims of the '383 Patent. *Id.* at 6–7.

Although the undersigned had rejected their collateral estoppel theory with regard to the '060 Patent, defendants continued to press the argument at trial, arguing that the similarities between the '383 Patent and the '060 Patent are so pronounced as to require a preclusive effect. *See* Trial Tr. at 135–36. *See also* Side By Side Comparison (DX–9001).

The court finds no need to revise its holding regarding the OxyContin decision's lack of a preclusive effect on the asserted claims of the '060 Patent. As the undersigned noted in the March 17th Opinion, there are "intriguing similarities" between the '383 and '060 patents. However, the '060 Patent has a crucial difference: it describes an *abuse-proofed* dosage form. *See* '060 Patent Claim 1. All of the asserted claims of the '060 Patent share this limitation. *See* '060 Patent cls. 4, 9, 24, 25, 27, 29, 30, 31, 32, 33, and 34 (all depending from Claim 1 or from claims themselves depending therefrom). Moreover, Claim 9 of the '060 Patent recites six additional barriers to abuse. '060 Patent at 21:37–51. In contrast, the asserted claims of the '383 Patent made no mention of abuse-proofing, nor did they recite additional barriers to abuse. *See* '383 Patent at 21–22. Thus, Judge Stein made no findings or conclusions as to whether an "abuse-proofed" dosage form would be invalid in light of the prior art, either through anticipation or obviousness. Consequently, the undersigned will not revise the holding that Judge Stein's decision regarding the '383 Patent does not preclude litigation of the asserted claims of the '060 Patent here.

b. Whether the Asserted Claims Are Anticipated by the McGinity Application.

Defendants argue that the McGinity Application anticipates the asserted claims of the '060 Patent. A prior art reference anticipates–and invalidates–the asserted claims only if it expressly or inherently discloses each of the invention's claimed elements. *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1377 (Fed.Cir.2003). The primary element of the asserted claims of the '060 Patent is that the tablets will be "abuse-proofed," *see* '060 Patent cl. 1, meaning they reduce the potential for abuse, by among other things exhibiting exceptional hardness. *See supra* Part (A)(1)(c)(i).

The McGinity Application is silent regarding abuse reduction. It describes the process of hot-melt extrusion, but does not say whether the process could produce abuse-proofed dosage forms or even dosage forms of unusual strength. Indeed, the words "abuse," "crush," "hardness," "breaking," "strength," "newtons," "snort," "inject," "insufflate," etc ... are wholly absent from the McGinity Application. Thus, the McGinity Application, while teaching a process for creating controlled-release tablets using hot-melt extrusion, fails to expressly disclose abuse-proofing.

***57** In order to show anticipation, then, it was incumbent on defendants to prove at trial that abuse-proofing is inherent to tablets made pursuant to the McGinity Application. To this end, Defendants' expert on invalidity, Dr. Fernando Muzzio, testified that any tablet made using the process described in the McGinity Application would be "abuse-proofed" because it would be exceptionally hard. *See* Trial Tr. at 2164–65. Dr. Muzzio tested this theory in the laboratory. He read the experiments disclosed in the McGinity Application and made tablets replicating those experiments. Trial Tr. at 2168. He then inserted his "McGinity tablets" into an Instron testing devise and determined their breaking strength. *Id.* None of the tested tablets broke when subjected to pressures above 500N. See Excerpt of the Final Muzzio Report at 36, (DTX–5119A). Indeed, video presented at trial showed that the McGinity tablets remained entirely whole. Thus, Dr. Muzzio concluded that tablets made pursuant to the McGinity Application are inevitably hard, and thus inevitably resistant to abuse through crushing.

The court is not persuaded that the McGinity Application inherently discloses abuse-proofing. In order to have an "abuse-proofed tablet," the tablet must contain an ingredient that is known to have abuse potential, such as the oxymorphone in plaintiffs' tablets. Indeed, McGinity discloses that the invention can be used with analgesics. See McGinity Application at 8:20–35. Some analgesics, notably opioids, were known to have abuse potential. But in creating his tablets, Dr. Muzzio did not use an opioid or any other active ingredient with abuse potential. Rather, Dr. Muzzio created his McGinity tablets using the cancer drug chlorpheniramine maleate ("CPM"). Trial Tr. at 2496:3; see also Expert Report of Fernando J. Muzzio, Ph.D. Ex. B at 2 (DTX–5119A) ("All of the formulations to be tested in this work are composed

of ... Chlorpheniramine Maleate."). Chlorpheniramine maleate, as Dr. Muzzio conceded at trial, is not known to have abuse potential. Trial Tr. at 2200:22–23.

The court can only speculate as to why Dr. Muzzio, in attempting to show that the practice of the McGinity Application would inevitably result in abuse-proofed tablets, chose to use an active ingredient that is not prone to abuse. Perhaps he felt confined to the active ingredient actually used in McGinity's examples. See McGinity Application at 19 (using CPM). But as Dr. Bartholomäus's early experiments with PEO showed, the introduction of a novel ingredient can dramatically alter PEO's hardness-conferring properties. Trial Tr. at 1006–07 ("I saw from this that mixing and adding this opiate ... with this polyethylene oxide, this PEO, does destroy any properties that PEO might have to form a high crushing strength tablet."). This is confirmed by McGinity, which expressly teaches that "particular combinations of therapeutic compound and PEO (of given molecular weight) will result in various formulations each possessing its particular combination of properties." McGinity Application at 3:15–17.

If Dr. Muzzio wished to establish that McGinity tablets are inevitably abuse-proofed because of their hardness, he should have used an active ingredient known to have abuse potential, such as an analgesic. Because he did not do so, he merely succeeded in showing that hot-melt extrusion of PEO and chlorpheniramine maleate ("CPM") will result in hard, even astoundingly hard, tablets. See Muzzio Report at 35 (DTX–5119a) (showing breaking strengths between 2,000 and 4,500 newtons). But such tablets cannot be said to be abuse-proofed because they have no ingredient with abuse-potential.

Moreover, the McGinity application is silent with regard to the type of additional barriers to abuse contained in Claim 9 of the '060 Patent. See '060 Patent at 21:37–51. It does not disclose irritants, viscosity increasing agents, antagonists, emetics, dyes, or bitter substances as required by the claim.

Dr. Muzzio's tests clearly demonstrate that the process taught in the McGinity Application, the hot-melt-extrusion of PEO and a therapeutic compound, will result in exceptionally hard tablets, and this demonstration is significant to the court's obviousness analysis. But given Dr. Muzzio's decision to use an active ingredient without abuse potential, the court feels that defendants fall slightly short of carrying their burden in showing anticipation.

***58** Defendants have not persuasively shown that McGinity inherently discloses abuse-proofing, and neither have they shown that McGinity discloses the additional barriers to abuse recited in Claim 9. Thus, the court concludes that defendants have not carried their burden in showing that the McGinity Application anticipates the asserted claims of the '060 Patent.

c. Whether the Asserted Claims of the '060 Patent Would Have Been Obvious to a Person of Ordinary Skill in the Art at the Time of the Invention.

The next step in determining whether the '060 Patent is invalid is to consider whether the asserted claims of the '060 Patent would have been obvious, in light of the prior art, to an ordinarily skilled artisan in 2003.[20] At trial, the parties identified three areas in dispute regarding the obviousness of the invention: (i) whether there was a motivation in the prior art to develop unusually hard tablets as a means of reducing the abuse of opioids; (ii) whether the prior art discloses the limitations of the asserted claims of the '060 Patent; and (iii) whether secondary considerations indicate the invention's non-obviousness.

i. Whether There Was a Motivation to Make Unusually Hard Tablets as a Means of Reducing Opioid Abuse.

Defendants argue that there was a motivation in the art to make unusually hard tablets as a means of reducing opioid abuse. *See* Trial Tr. at 2187–88. Defendants rely on three patents to support this assertion: United States Patent Number 7,968,119 (the " '119 Patent"); United States Patent Number 6,696,088 (the " '088 Patent"); and United States Patent Number 7,33,182 (the " '182 Patent"). The applications for each of these patents were filed before 2003. Defendants also rely on a body of art from 2002 related to the branded stimulant Concerta.

The '119 Patent shows knowledge in the art of the abuse of narcotics, including opioids and oxymorphone, through crushing and other means. It describes the invention of a "tamper proof system for delivery of narcotics." *See* '119 Patent at 1: 15–18 (DTX–161). It describes combining

an active ingredient with an antagonist. *Id.* at 3–4. When the drug is taken properly, the active ingredient will provide the desired effect long before the antagonist is activated. *Id.* at 4:1–9. However, when the dosage form is tampered with, through "adulteration, distillation, or *pulverization,*" the antagonist will be activated and block the euphoric effect of the drug. *Id.* at 4:50–64 (emphasis added). At the same time, tampering will "induc[e] a bowel movement in the subject" resulting in "rapid detoxification." *Id.* at 3–4.

The '088 and '182 patents also show knowledge in the art of opioid abuse through crushing. The '088 Patent, like the '119 Patent, uses an antagonist that only activates once the dosage form is "tampered with" by "crushing" or "shearing." '088 Patent at 7:38–40. Similarly, the '182 Patent suggests using an antagonist, as well as aversive agents (an irritant), to reduce tampering of the dosage form through crushing, shearing, grinding, and dissolving. *See* '182 Patent at 4:55–59.

These pieces of art show that there was knowledge of opioid abuse through crushing, and thus show some motivation to solve that problem. However, they do not show a motivation to select hardness as the solution. To the contrary, the '119, '088, and '182 patents taught away from selecting hardness as an abuse-deterrent feature because their antagonists are released when the dosage form is pulverized, sheared, crushed or ground. *See, e.g.,* 119 Patent at 3–4. To a person of ordinary skill in the art, patents teaching the use of crush-activated antagonists to deter abuse would not also teach crush-resistance (hardness) as a feature to deter abuse.

***59** Defendants are more persuasive in arguing that the prior art surrounding the branded drug Concerta taught the use of exceptional hardness to deter drug abuse. Trial Tr. at 2189. Concerta is a branded stimulant used in the treatment of Attention–Deficit/Hyperactivity Disorder. *See* Letter to the Editor of the Journal of the American Academy of Child & Adolescent Psychiatry (2002) (DTX–84 at 0759). It uses a technology, OROS, to deter abuse. An OROS tablet is designed to act as an "osmotic pump." Trial Tr. at 2517:8–9. The outside layer of the tablet consists of a semi-permeable membrane that absorbs water, allowing the inside contents of the tablet (containing the active ingredient and PEO) to be dissolved and slowly pushed out through a hole at the top of the tablet. Trial Tr. at 2522.

Four pieces of prior art in 2002 indicated that Concerta was known to be hard, and also known to deter abuse through crushing. A magazine article stated that Concerta is "difficult to abuse because ... in [its] time-release form, [it] can't be chopped and snorted." Craig Donnelly, MD., ADHD Medications Past and Future, 22 *Behavioral Health Management* 28, 29 (2002) (DTX–2554). An article in the Sacramento Bee newspaper stated that Concerta's manufacturer, McNeil, had "released a fact sheet stating that Concerta is hard to abuse because it is difficult to crush." Dorsey Griffith, *Potential New ADHD Drug Creating Lots of Big Hopes,* Sacramento Bee (Oct. 30, 2002) (DTX–82 at 0754). An article in Child & Adolescent Psychiatry indicated that Concerta is "resistant to diversion (cannot be ground up or snorted), [and] is well suited for treatment of adolescents." Greenhill *et al.*, *Practice Parameter for the Use of Stimulant Medications in the Treatment of Children, Adolescents, and Adults,* 41 J. Am. Acad. Child Adolescent Psychiatry (Feb.2002) (DTX–80 at 0745). Finally, a letter to the editor in the same journal indicated that the ingredient in the "Concerta tablet is very difficult ... to crush if the tablet is chewed accidentally." Ciccone, P. E., *Attempted Abuse of Concerta,* Letters to the Editor, J. Am. Acad. Child Adolescent Psychiatry, 41:7 (July 2002) (DTX–100). This significant body of art shows knowledge of hardness as a feature to deter abuse through crushing.

Plaintiffs' experts dispute Concerta's teaching. Dr. Bartholomäus testified that he knew of the OROS technology (the tablet technology used in Concerta) in 2002, but didn't believe OROS tablets to be crush-resistant because his team "bought some OROS from the U.S. market, took it to Germany, worked on it, and we could crush it. So it didn't solve the problem of crushing." Trial Tr. at 1000:21–23. Similarly, Dr. Davis testified that OROS was easily subverted by peeling off the outer membrane, "like the skin of an orange," and that once the outer membrane is removed the tablet becomes "quite soft." Trial Tr. at 2519: 11–13; 2520:4.

Plaintiffs have not persuasively countered defendants' assertion that the body of art surrounding Concerta would indicate hardness as a means of deterring abuse. The fact that Dr. Bartholomäus knew of OROS in 2002, and was motivated to test its hardness with a mortar and pestle, indicates that other ordinarily skilled artisans would also be motivated to explore exceptional hardness as an abuse-

deterrent feature. Both his and Dr. Davis's observation that OROS is easily subverted by peeling is irrelevant as to whether a motivation to develop hard tablets was taught by the prior art.

The art surrounding antagonist-based tablets demonstrated a motivation to solve the problem of crushing prescription drugs. The Concerta art made the same observation, and also indicated the use of hardness as a solution. While Concerta's active ingredient was a stimulant, an ordinarily skilled artisan would readily understand it to teach the abuse-deterring value of hardness for other active ingredients, including opioids. Thus, the court is persuaded that there was a motivation in the art to solve the crushing of opioids by making tablets of exceptional hardness.

ii. Whether the Prior Art Discloses the Limitations of the Asserted Claims of the '060 Patent.

***60** At trial, the parties disputed whether the prior art discloses: (1) an abuse-proofed thermoformed dosage form; comprising (2) one or more active ingredients with abuse potential and (3) at least one synthetic or natural polymer with a weight of at least 0.5 million according to rheological measurements; and more specifically the polymer polyethylene oxide; and (4) which exhibits a breaking strength of 500N; and (5) the six additional barriers to abuse recited in Claim 9 of the '060 Patent.

1. The Prior Art Discloses Thermoforming and Abuse Proofing.

The McGinity Application discloses thermoforming. As discussed in the claim construction section of this opinion, a thermoformed dosage form is one created by applying pressure to a mixture of an active ingredient and a high molecular weight polymer and exposing the mixture to the prior, simultaneous, or subsequent application of heat. *See supra* Part A(1)(c)(ii). The McGinity Application describes a dramatically similar process, hot melt extrusion, involving mixing a therapeutic compound with high molecular weight PEO, placing the mixture into an extruder which is heated, and then pushing that mixture through a die. *See* McGinity Application at 11:18–33. These two processes are so similar that at trial, experts for both sides referred to hot-melt extrusion as a type of thermoforming. *E.g.,* Trial Tr. at 1083:25–1084:2 ("Now hot melt extrusion is a type of thermoformed dosage form, yes? [BANAKAR] A. In general, yes ...."). Because hot-melt-extrusion shares the key features of thermoforming, the court concludes that the McGinity Application discloses a "thermoformed dosage form" as required by the asserted claims.

Regarding "abuse-proofing," there is a substantial body of prior art showing that the use of PEO and hot melt extrusion will result in tablets of unusual hardness, thus reducing the potential for abuse by crushing. PEO's strengthening properties were certainly known. A patent awarded in 1992 provided that "it is preferred to increase the hardness of the excipient by adding a small amount of polyethylene oxide (PEO) having a molecular weight from about 100,000 to about 500,000 daltons. The high molecular weight polyethylene oxide contributes strength to the molded dosage form and reduces brittleness." *See* United States Patent 5,139,790 at 5:19–28 (DTX–75). Likewise, a journal article showed that compressed tablets containing PEO in various proportions exhibits a breaking strength up to 255N, *see* L. Maggi *et al.*, *Dissolution Behaviour of Hydrophilic Matrix Tablets Containing Two Different Polyethylene Oxides (Peos) For The Controlled Release Of A Water Soluble Drug,* 23 Biomaterials 23: 1113, 1119 (2002) (DTX–76), which is above the known breaking strength of regular tablets (100N–200N). *See* Trial Tr. at Trial Tr. at 1024:13–14; 2528:24.

Hot melt extrusion was also known to increase the strength of tablets. A dissertation published in 1999 by Feng Zhang, co-inventor on the McGinity Application, provided that "hot-melt extrudate is anticipated to possess a higher physical strength ... than tablets prepared by ... direct compression." Zhang, Feng, *HotMelt Extrusion as a Novel Technology to Prepare SustainedRelease Dosage Forms* at 69 (DTX–170). Similarly, an article co-authored by Zhang and McGinity in 2001 provides that "When compared with traditional [melt granulation] HME [hot melt extrusion] produced harder tablets." Liu *et al.*, *Properties of Lipophilic Matrix Tablets Containing Phenylpropanolamine Hydrochloride Prepared by Hot–Melt Extrusion,* 52 European J. of Pharmaceutics and Biopharmaceutics 181, 190 (2001) (DTX–141). Indeed, four other pieces of prior art disclose hot-melt-extrusion's value in creating hard tablets. *See* (DTX–139), (DTX–137); (DTX–153); (DTX–164).

***61** The court is persuaded that a person of ordinary skill in the art would understand that a thermoformed tablet containing PEO would be unusually hard. An unusually hard tablet is more difficult to crush than a softer tablet, and thus would reduce the potential for abuse by crushing. Thus, the prior art discloses "an abuse-proofed thermoformed dosage form as required by Claim 1 and the dependent claims of the '060 Patent."

2. The McGinity Application Discloses Active Ingredients With Abuse Potential.

The McGinity Application also discloses active ingredients with abuse potential, including opioids. The invention calls for the mixture of PEO and a "therapeutic compound." McGinity Application at 2:25–29. It defines "therapeutic compounds" to include a host of substances, including valium (diazepam). *Id.* at 8. As Dr. Davis conceded at trial, valium is known to be addictive. Trial Tr. at 2556:2–5.

McGinity also lists analgesics as suitable therapeutic compounds. McGinity Application at 8:20. In 2002, it was well understood that opioids are analgesics. *See, e.g.,* Remington's Pharmaceutical Sciences 17 at 1103–05 (1985) (DTX–3201) (describing oxymorphone hydrochloride as one of several semisynthetic opiate analgesics); *see also* Goodman *et al.*, *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 491 (1985) (DTX–2781) ("The opioids are employed primarily as analgesics...."). A person of ordinary skill in the art, upon reading McGinity's disclosure of analgesics, would understand that analgesics include the known opioids, including oxycodone and oxymorphone. Thus, the McGinity Application discloses active ingredients with abuse potential, such as valium and opioids such as oxycodone and oxymorphone. Consequently, the McGinity Application discloses the relevant portions of Claim 1 of the '060 Patent ("one or more active ingredients with abuse potential"), and the relevant portions of claims 31 and 34 of the '060 Patent, which specify oxycodone and oxymorphone. *See* '060 Patent at 24:3–5; 13–15.

3. The McGinity Application Discloses the Polymer Limitations of the Asserted Claims.

The McGinity Application also discloses the various limitations of the asserted claims relating to the polymer used. McGinity discussed the use of high-molecular weight (1,000,000 – 10,000,000) PEO for use in hot melt extrusion, and actually tested numerous examples of tablets using such high-molecular weight PEO. *See* McGinity Application at 5:3–4; 19:11–34 (listing molecular weights of 1 million and 7 million). Thus, McGinity discloses the relevant limitations of claims 1, 4, and 30 of the '060 Patent, which require: (1) "at least one synthetic or natural polymer with a weight of at least 0.5 million;" that (4) the polymer be selected from the "group consisting of polyethylene oxide;" and (30) that "the ... polyethylene oxide have a molecular weight of from 1–15 million." See '060 Patent at 21:7–10, 19–24; 23:19–20. Because most of the McGinity's tablets used PEO in proportions greater than 60% by weight, see McGinity Application at 19:15–33 (listing percentages of weight between 54% and 94%), it also discloses the substance of Claim 33 of the '060 Patent. See '060 Patent at 24:7–10 ("wherein the content of the polymer is at least 30% [corrected to 60%] by weight relative to the total weight of the dosage form."). Finally, because McGinity provided that "the therapeutic compound may be ... suspended in the polymer matrix of the formulation," see McGinity Application at 8:6–7, it discloses the substance of Claim 24 of the '060 Patent, which provides that the polymer "also serve [s] as a controlled release matrix material." See '060 Patent at 22:65–7.

4. The McGinity Application Discloses Breaking Strength in Excess of 500N.

***62** While Dr. Muzzio's recreation of the McGinity Application failed to inherently disclose abuse-proofing in the anticipation context (because he failed to use an ingredient with abuse potential), see supra Part B(2)(b), his tests succeeded in showing that McGinity inherently discloses breaking strengths above 500N. Indeed, Dr. Muzzio created hundreds of tablets according to the McGinity Application's examples, and each of these tablets exhibited a breaking strength well above 2000N. See Muzzio Report at 34–36 (DTX–5119A). At trial, plaintiffs raised various criticisms of Dr. Muzzio's methods, see, e.g., Trial Tr. at 2219 (noting that Dr. Muzzio had failed to record torque values), but the court finds these criticisms to be outweighed by the sheer breadth and thoroughness of his testing. Thus, the court

is persuaded that the McGinity Application inherently discloses breaking strengths in excess of 500N as required Claim 1 of the '060 Patent. See '060 Patent at 21:12–13.

5. The Prior Art Discloses the Additional Barriers to Abuse Recited in Claim 9 of the '060 Patent.

Claim 9 of the '060 Patent recites six additional barriers to abuse to be incorporated into the dosage form. See '060 Patent at 21:37–51. These are: an irritant, a viscosity-increasing agent which forms a gel with the extract from the dosage form, an antagonist, an emetic (vomiting agent), a dye, and a bitter substance. See '060 Patent at 21:38–51. Each of these additional barriers to abuse is disclosed in the prior art.

Irritants were disclosed in a number of references, including a patent application filed in 2002 which described creating a dosage form incorporating an antagonist and "an irritant in an effective amount to impart an irritating sensation to an abuser upon administration of the dosage form after tampering." See Abstract, United States Patent No. 7,332,182 (DTX–160). The reference expressly discloses the irritant capsaicin, the active ingredient in peppers. Id. at 6:59. The specification of the '060 Patent discusses the use of peppers and other "capsaicinoids" as irritants. See '060 Patent at 8:10. Thus, the court concludes that the prior art discloses the use of irritants described in Claim 9 part (a) of the '060 Patent.

The prior art also discloses the use of viscosity increasing agents. As discussed in the claim construction section of this opinion, a "viscosity increasing agent" is a substance, distinct from the hardening polymer, which increases the thickness of the dosage form extract by forming a gel when exposed to a liquid, such gel optionally remaining visually distinguishable. *See supra* Part(A)(1)(c)(iv). At trial, Dr. Muzzio explained that the McGinity Application discloses several substances that are known to be viscosity increasing agents, such as guar gum and alginic acid. Trial. Tr. at 2178:14–18; *see also* McGinity Application 13:27–30 (listing guar gum and alginic acid as "disintegrating agents"). This is important because Guar gum was later listed in the '060 Patent as being a viscosity-increasing agent. '060 Patent at 9:7. Thus, McGinity discloses distinct viscosity-increasing agents as required by Claim 9.

Antagonists, emetics, dyes, and bitter substances were well known in the art. The '119, '088, and '182 patent applications, each filed before 2003, all describe the use of antagonists to deter abuse of prescription drugs. *See supra* Part (B)(2)(c)(i). Emetics, like the syrup of ipecac, were commercially available, as were dyes and bitter substances. *See* Trial Tr. at 1105–06.

The court is persuaded that each of the additional barriers to abuse recited in Claim 9 of the '060 Patent were disclosed in the prior art. Moreover, once an artisan had set out to create an abuse-proofed tablet, it would have been obvious to integrate one or more of these additional barriers along with the feature of unusual hardness as required by the claim. *See* '060 Patent at 21:37. Indeed, much of the prior art used a multiple-barrier approach, integrating two or more features, such as the use of an antagonist and irritant, to prevent abuse. *See, e.g.,* '182 Patent at 2:67–33 (DTX–161)

***63** Thus, the court concludes that the prior art discloses the substance of Claim 9 of the '060 Patent. Likewise, claims 25, 26, and 27, which also incorporate additional barriers to abuse, were also disclosed. To the extent those claims recite "press-forming" and a "melt process" as additional limitation, those limitations were disclosed by the McGinity Application, which teaches "compression molding" and hot-melt extrusion. *See* McGinity Application at 11:8.

The court concludes that each limitation of the asserted claims of the '060 Patent was disclosed in the prior art. The McGinity Application, while insufficient to anticipate the invention, nonetheless discloses many of its components. The remainder of the components were disclosed by other references.

iii. Whether Secondary Considerations Indicate the Non–Obviousness of the '060 Patent.

The final step in the obviousness analysis requires consideration of objective indicia of non-obviousness, such as the commercial success of the invention, the invention's satisfaction of a long-felt but unmet need, the failure of others to solve the problem at hand, and the copying of the invention by others. (*Graham v. John Deere Co.,* 383 U.S. 1, 17 (1966)).

The commercial success of the invention indicates its non-obviousness. At trial, Dr. Alexander Kraus, explained that Grünenthal has successfully licensed its crush-resistance technology to branded-drug manufactures Johnson & Johnson, Purdue Pharma, and Endo, for use in their flagship opioid products. Trial Tr. at 1380. The revenue from these licenses is significant. Revenues earned from reaching certain development milestones with these companies total 116 million euros. Id. at 1391. In addition, these companies have paid Grünenthal royalties totaling 312 million euros. Id. In all, Grünenthal has earned 428 million euros, or $556 million, from licensing its crush-resistant technology to American branded-drug manufacturers. Trial Tr. at 1392:5–10. Thus, Grünenthal has enjoyed clear and indisputable commercial success for its product. This success is directly related to the asserted claims, because each of the license agreements involved developing abuse-deterrent dosage forms, and abuse-deterrence is the primary feature of the asserted claims of the '060 Patent. See Trial Tr. at 1385– 88.

However, there does not appear to have been a long-felt need for the invention. Dr. Bartholomäus testified that Grünenthal began exploring abuse deterrence to confront the crisis of OxyContin abuse in the United States. Trial Tr. at 984:15–19. Dr. Lee testified that OxyContin only achieved widespread use "in the late '90's." Trial Tr. at 236:5–7. And it didn't become widely abused until the early 2000's. See Trial Tr. at 2840:10–24. Thus, there was at most only a few years separating the rise of OxyContin abuse and Grünenthal's invention.

Moreover, Grünenthal's evidence of skepticism and industry acclaim is unpersuasive. As evidence of skepticism, Grünenthal's experts testified that the company was met with incredulity when it first set out to sell its technology. See, e.g., Trial Tr. at 2542–43 ("[W]hen he [Bartholomäus] first began describing his invention, people were skeptical. His colleagues at Grünenthal were skeptical, people from Purdue or from Endo who were interested in the technology were skeptical...."). Members of the industry doubted that a tablet as hard as Grünenthal's could actually release the active ingredient. *Id.* at 2543. Grünenthal offered similar "evidence" of industry acclaim. Trial Tr. at 2545. ("The potential licensees, when they visited Grünenthal and saw the technology and saw not just the hardness but the release data, were indeed impressed. And I think a couple of the people said this is the best technology we have seen so far to date."). In the court's view, this evidence is too anecdotal to be useful. Grünenthal failed to provide tangible evidence that its invention was met with anything more than passing incredulity, and its only evidence of industry acclaim is secondhand and underwhelming.

Conclusion Regarding the Validity of the '060 Patent

***64** Defendants have shown, by clear and convincing evidence, that the asserted claims of the '060 Patent would have been obvious to a person of ordinary skill in the art at the time of the invention. The art in 2002 demonstrated a clear motivation to solve the problem of prescription opioid abuse, including abuse that requires, as a first step, the crushing and pulverization of the dosage form. The art surrounding the branded drug Concerta showed a motivation to make a tablet unusually hard as a means of deterring abuse through crushing and snorting.

In light of this motivation, a skilled artisan would have been led to the prior art teaching the hardness-conferring properties of both hot-melt extrusion and polyethylene oxide. This art included the McGinity Application, which discloses the hot-melt extrusion of PEO with therapeutic compounds, a process identical, in all crucial respects, to thermoforming. The McGinity Application also discloses many of the '060 Patent's other salient features, including active ingredients with abuse potential, the relevant polymer limitations, and a breaking strength above 500N. These disclosures are supplemented by art describing all of the secondary barriers to abuse recited in Claim 9 of the '060 Patent.

The commercial success of the invention favors Grünenthal, but there was no significant showing of skepticism and acclaim. And even if all the secondary factors favored Grünenthal, the court would nonetheless rule in defendants' favor given their strong showing of obviousness over the prior art.

In the end, the court finds that Grünenthal's invention was obvious when made. Defendants have satisfied their burden and shown, by clear and convincing evidence, that the asserted claims of the '060 Patent are invalid. [21]

C. Roxane's Unclean Hands Defense.

Roxane Laboratories, Inc. asserts unclean hands as an equitable defense to Endo's claims. Roxane argues that Endo, in order to settle an earlier patent infringement case, agreed to not oppose Roxane's launch of its generic oxymorphone product after a certain date. Roxane claims that after the settlement of the earlier case was complete, Endo took a number of steps to perpetually stall the launch of its generic product. Roxane argues that these actions amount to inequitable conduct which preclude Endo from obtaining an injunction from this court.

The United States courts are courts of law and equity. U.S. Const. art. III § 2. As courts of equity, district courts are closed to those "tainted with inequitableness or bad faith relative to the matter" in which they seek relief. *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.,* 324 U.S. 806, 814 (1945). Otherwise, they would risk becoming "abettors of iniquity," giving judicial sanction to those who have acted deceitfully and unfairly to gain an advantage. *See Keystone Driller Co. v. Gen. Excavator Co.,* 290 U.S. 240, 245 (1933).

***65** In 2009, Roxane filed an abbreviated new drug application to sell a generic version of OPANA® ER. At the time, Endo had three patents in the Orange Book listed as covering the branded drug: the '933 Patent, the '456 Patent, and the '250 Patent. Endo sued Roxane for patent infringement (the "First Action"). However, the litigation was eventually settled pursuant to a Settlement and License Agreement. [redacted text]

Two years before Roxane and Endo settled the First Action, Roxane had entered into a supply agreement with Johnson Matthey Inc. ("JMI") whereby JMI agreed to supply Roxane oxymorphone hydrochloride, the active ingredient in Roxane's planned generic product. See Supply Agreement Sched. A (DTX–2221). After the Supply Agreement was executed, JMI was awarded a patent, Number 7,851,482, concerning a new, low toxicity formulation of oxymorphone hydrochloride (the " '482 Patent"). [redacted text]

[redacted text] JMI sold the '482 Patent to Endo pursuant to a Patent Purchase Agreement. See Patent Purchase Agreement (DTX–2209).

[redacted text]

In 2012, Endo was awarded two new patents, the '122 and '216 patents, which cover its branded-oxymorphone product. In May of 2013, Endo filed the instant lawsuit against Roxane for patent infringement, asserting both its newly won patents (the '122 and '216 Patents) and the patent it had purchased from Johnson Matthey (the '482 Patent). See Compl. ¶¶ 18–25. As trial on these patents approached, Endo stopped asserting the '482 Patent. Thus, only the '122 and '216 patents were litigated at trial. Endo has also filed a third lawsuit against Roxane in the District of Delaware, asserting infringement of another patent.

Having reviewed Endo and Roxane's evidence *in camera,* the court concludes that Endo has not acted inequitably in this case. Roxane's unclean hands defense is less complicated than it seems, and amounts to this: [redacted text] but (2) after the settlement was finalized, Endo took a number of steps, [redacted text] and filing two new lawsuits, in order to perpetually prevent Roxane from entering the market.

[redacted text]

The court infers no inequitable motive surrounding Endo's purchase of the '482 Patent from JMI. [redacted text]

[redacted text] Finally, Endo stopped asserting the '482 Patent in this case. Thus, the court see no relationship between Endo and JMI's actions and the matters asserted at trial.

Finally, the court sees no inequity arising from Endo's assertive litigation strategy. At trial, Endo's witnesses explained that OPANA® ER is Endo's flagship product. The entry of generic competition represents an existential threat to the company. To confront this, Endo is clearly entitled to assert its patents. Congress, of course, has created mechanisms for generic manufacturers, like Roxane, to challenge those patents. But generic manufacturers are sophisticated entities, and upon settling litigation regarding one patent are perfectly capable of insisting that the settlement cover future patent issuances. There is nothing inequitable about a company, like Endo, asserting wholly different patents when they issue or are otherwise acquired.

Conclusion

For the reasons given above, the court concludes that defendants' generic products, as described in their ANDAs, infringe all but two of the asserted claims of the '122 and '216 patents, and that defendants have failed to satisfy their burden of showing those claims to be invalid. The court concludes that defendants infringe the asserted claims of the '060 Patent, but that they have satisfied their burden and shown those claims to be invalid.

***66** The court enters judgment in Endo's favor and enjoins defendants from making or selling their generic products prior to the expiration of the '122 and '216 patents. Moreover, the court orders that the effective date of approval of defendants' ANDAs shall be no sooner than the expiration date of the '122 and '216 patents. *See* 35 U.S.C. § 271(e)(4).

Because defendant Actavis is already on the market with its generic product, it shall have sixty days from the date of this decision to comply. The court reserves decision on whether to award additional relief, including damages against defendant Actavis, pending further briefing from the parties.

Endo's recently filed motion to strike Amneal's obviousness defense in case number 12–CV–8115 is moot. The clerk of court is directed to resolve all pending motions in the above captioned cases.

SO ORDERED.

All Citations

Not Reported in F.Supp.3d, 2015 WL 9459823

Footnotes

1 The parties agree that “designed to provide” means simply “that provides,” and does not require a specific intention. *See* Second Stipulation and Order (Apr. 9, 2015) ¶¶ 1–2.

2 Claim 34 is not asserted against Teva.

3 While not disputed, the specification leaves no doubt as to the meaning of “viscosity-increasing agent.” The specification explains that drug-abusers often attempt to subvert controlled-release drugs by crushing them and then mixing the resulting powder in a liquid which can be injected into the veins using a hypodermic needle. '060 Patent at 8:27–38. A viscosity increasing agent is a substance that increases the thickness of the dosage form extract by forming a gel when exposed to a liquid. *See id.* at 8:39–45. A “gel” is simply an area of thicker consistency in the mixture of the extract and the surrounding aqueous liquid, one that preferably remains visually distinguishable. *See, e.g.,* '060 Patent at 8:19–27.

4 This value, 30%, was later corrected to read 60%.

5 Defendant Actavis is already to market with its generic product.

6 Claims 2, 3, 19, and 20.

7 Claims 1, 22, 40, 42, 50, 54, 57, 62, 64, 71, 73, 74, 78, 79, 80, 82 (not all claims asserted against all defendants).

8 Another of Endo's experts, Dr. Stephen Ogenstad, used statistical methods to show that Endo's product, OPANA® ER in both crushable and non-crushable formulations, actually satisfies the limitations of the asserted claims. See Trial Tr. at 2089–92.

9 The other asserted method claims, Claim 20 of the '122 Patent and Claim 82 of the '216 Patent, do not require that the tablet first be “provided” to the subject. *See, e.g.,* '216 Patent at 34:56– 60. They merely require administration of the tablet. *Id.*

10 To be specific, through their stipulations and the court's findings, each of the defendants infringes claims 2, 3, 19, and 20 of the '122 Patent. Through their stipulations and the court's findings, the following conclusions apply with regard to the '216 Patent. Defendant Actavis, in case No. 13–cv–436, is liable for infringement of claims 1, 22, 50, 54, 57, 62, 64, 71, 73, 74, 78, 80, and 82 of the '216 Patent. Defendant Amneal, in case No. 12–cv–8115, is liable for infringement of claims 1, 22, 50, 54, 62, 64, 71, 73, 74, 78, 80, and 82 of the '216 Patent. Defendant ThoRx, in case No. 12–cv–8317, is liable for infringement of claims 1, 22, 50, 54, 57, 62, 64, 71, 73, 74, 78, 80, and 82 of the '216 Patent. Defendant Impax, in case No. 13–cv–435, is liable for infringement of claims 1, 22, 50, 54, 57, 62, 64, and 71 of the '216 Patent. Defendant Teva, in case No. 12–cv–8060, is liable for infringement of claims 1, 22, 50, 54, 62, 64, 71, 73, 74, 78, 79, 80 and 82 of the '216 Patent. Defendant Sun Pharmaceuticals, in case No. 13–cv–8597, is liable for infringement of claims 1, 22, 50, 54, 57, 62, 64, 71, 73, 74, 78, 79, 80, and 82 of the '216 Patent. Defendant Actavis, in case No. 12–cv–8985, is liable for infringement of claims 1, 22, 50, 54, 57, 62, 64, 71, 73, 74, 78, 80, and 82 of the '216 Patent. Defendant Roxane, in

case No. 13–cv–3288, is liable for infringement of claims 1, 22, 50, 54, 57, 62, 64, 71, 73, 74, 78, 79, 80, and 82 of the '216 Patent. Defendant Sun Pharma, in case No. 13–cv–4343, is liable for infringement of claims 1, 22, 50, 54, 57, 62, 64, 71, 73, 74, 78, 79, 80, and 82 of the '216 Patent.

11 Actavis objects to the admission of this exhibit, claiming it was "never discussed by any witness." That objection is overruled. Plaintiffs' expert, Dr. Davis, relied on the exhibit during his direct testimony. *See* Trial Tr. at 1209, and the court rules that it is relevant and not otherwise inadmissible. *See* Fed.R.Evid. 402.

12 Actavis objects to the admission of this exhibit, claiming it was "never discussed by any witness." That objection is overruled. Plaintiffs' expert, Dr. Davis, relied on the exhibit during his direct testimony. *See* Trial Tr. at 1169, and the court rules that it is relevant and not otherwise inadmissible. *See* Fed.R.Evid. 402.

13 Defendants note that upon visiting the Emerson Testing Facility during trial, the tablet pills were in far worse condition than when originally tested. *See* Trial Tr. at 1295–98. Moreover, the tablets had been covered in scotch tape. Trial Tr. at 1298:2–6. Defendants argue that Grünenthal, by covering the tablets with scotch tape after testing them, obscured the fact that they separated into multiple pieces after being tested. *Id.* at 1299:1–4. The court draws no such conclusions from Grünenthal's post-testing conduct. It is not surprising that the tablets, having been stored for a year, would be in a different condition than when initially tested. Moreover, Grünenthal's decision to cover the tablets with tape prior to storing them was reasonable given that testing was complete.

14 Defendant Teva did not dispute whether its product has a separate viscosity increasing agent. Trial Tr. at 1202:18–20. Nonetheless, it is Grünenthal's burden, as plaintiff, to show that Teva's drug infringes the asserted claims. Grünenthal has not shown that Teva's product contains a viscosity-increasing agent distinct from polyethylene oxide. *See* PX–5002.215; *see also* PTX 2657 at 5.

15 Actavis objects to the admission of this exhibit, claiming it was "never discussed by any witness." That objection is overruled. Plaintiffs' expert, Dr. Davis, relied on the exhibit during his direct testimony. See Trial Tr. at 1169, and the court rules that it is relevant and not otherwise inadmissible. See Fed.R.Evid. 402

16 Plaintiffs did not assert Claim 34 of the '060 Patent against Teva, so the court makes not findings or conclusion as to whether Teva infringes that claim.

17 Endo stipulated to the disclosure in the art of hydrophilic and hydrophobic materials, gelling agents, matrix formation, and other disclosures. See Stipulation and Order at 2–3, No. 12–CV–8060 (Mar. 27, 2015) (Dkt.# 152).

18 Although mentioned here, the court makes no conclusions regarding the validity of claims 40 and 42 of the '216 Patent because defendants do not infringe those two claims.

19 The court is willing to accept this assumption only to a certain point. Two prior art references use the Paddle Method at 50rpm but nonetheless fail to disclose the claimed ranges for other reasons. The Baichwal Reference shows the dissolution profile of albuterol, which isn't an opioid. *See* Baichwal Reference at 14:36–41 (using the Paddle Method at 50rpm). The court is unwilling, given the defendants' high burden, to go so far as to accept that the dissolution of a non-opioid would indicate to an artisan the dissolution of oxymorphone. A 1999 article shows the dissolution profile of an opioid, morphine sulfate, measured using the Paddle Method at 50rpm. *See* Webster *et al.*, *In Vitro Studies on the Release of Morphine Sulfate From Compounded Slow–Release Morphine–Sulfate Capsules* at 3, Int'l J. Pharmaceutical Compounding (1999) (the "Webster Reference") (DTX–0028). But while morphine is an opioid, the article provides dissolution values falling outside of those later claimed by Endo for oxymorphone. *Compare* Webster Reference at Fig. 2 (showing dissolution of morphine sulfate of 80% at four hours) *with* '216 Patent at 34:3640 (showing dissolution of oxymorphone of 58–66% at four hours).

20 As a divisional application of the '383 Patent, the '060 Patent is entitled to that patent's filing date for obviousness purposes. See 35 U.S.C. § 120.

21 Defendants also argue that the asserted claims of the '060 Patent are invalid for lack of enablement, lack of written description, and indefiniteness. The court disagrees. The patents would teach a skilled artisan how to practice the full scope of the invention without undue experimentation, and would also convey that Grünenthal possessed the entirety of the claimed invention. Thus, the claims are not invalid for lack of enablement and written description. Regarding indefiniteness, the court concludes that each of the asserted claims, including Claim 9 of the '060 Patent, is sufficiently defined to convey the metes and bounds of the invention. Thus, defendants' Section 112 arguments are without merit.

EXHIBIT JJ

PUBLIC

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

NOTICE OF DOCKETING

15-2021 - Endo Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.

Date of docketing: September 15, 2015

Appeal from: United States District Court for the Southern District of New York case no. **1:12-cv-08060-TPG-GWG** (1:12-cv-08115-TPG-GWG, 1:12-cv-08317-TPG-GWG, 1:13-cv-00435-TPG-GWG, 1:13-cv-00436-TPG-GWG, 1:13-cv-04343-TPG)

Appellant(s): Grunenthal Gmbh

Critical dates include:

- Date of docketing. See Fed. Cir. R. 12.
- Entry of appearance. (*Due within 14 days of the date of docketing*.) See Fed. Cir. R. 47.3.
- Certificate of interest. (*Due within 14 days of the date of docketing*.) See Fed. Cir. R. 47.4.
- Docketing Statement. (*Due within 14 days of the date of docketing, or within 30 days if the United States or its officer or agency is a party in the appeal*.) [Only in cases where all parties are represented by counsel. See the en banc order dated September 18, 2006, and guidelines available at www.cafc.uscourts.gov.]
- Requests for extensions of time. See Fed. Cir. R. 26 and 27. **N.B. Delayed requests are not favored by the court**.
- Briefs. See Fed. Cir. R. 31. **N.B. You will not receive a separate briefing schedule from the Clerk's Office**. However, in a case involving an appellant, a cross-appellant, and an appellee, a special briefing schedule is used. The appellant's opening brief is due within 60 days of the date of docketing. The cross-appellant's opening brief is due within 40 days of filing of the appellant's opening brief. The appellee's brief is due within 40 days of filing of the cross-appellant's brief. The appellant's response/reply brief is due within 40 days of filing of the appellee's brief. The cross-appellant's reply brief is due within 14 days of filing of the appellant's response/reply brief. The joint appendix is due within 10 days of filing of the cross-appellant's reply brief.
- Settlement discussions. See Fed. Cir. R. 33.
- **ORAL ARGUMENT SCHEDULE CONFLICTS:** Counsel should advise the clerk in writing within 30 days once briefing is completed of potential scheduling conflicts or as soon as they are known and should not wait until an actual conflict arises. Once scheduled, a case will not be postponed except on motion showing **compelling reasons**. See Practice Note following Fed. Cir. R. 34.

The official caption is reflected on the electronic docket under the listing of the parties and counsel. Counsel may download the Rules of Practice and required forms from www.cafc.uscourts.gov.

Daniel E. O'Toole
Clerk of Court

cc: United States District Court for the Southern District of New York
Martin J. Black
Elizabeth Holland
Basil J. Lewris

EXHIBIT KK

Endo Pharms., Inc. v. Actavis Inc.

United States District Court for the District of Delaware

November 17, 2015, Decided; November 17, 2015, Filed

Civil Action No. 14-1381-RGA

Reporter
2015 U.S. Dist. LEXIS 155034 *; 2015 WL 7253674

ENDO PHARMACEUTICALS INC. and MALLINCKRODT LLC, Plaintiffs, v. ACTAVIS INC. and ACTAVIS SOUTH ATLANTIC LLC, Defendants.

Prior History: Endo Pharms., Inc. v. Actavis Inc., 2015 U.S. Dist. LEXIS 127104 (D. Del., Sept. 23, 2015)

Counsel: [*1] For Endo Pharmaceuticals Inc., Plaintiff: Jack B. Blumenfeld, LEAD ATTORNEY, Morris, Nichols, Arsht & Tunnell LLP, Wilmington, DE; Blake B. Greene, Joseph J. Gribbin, Julie Latsko, Sharon K. Gagliardi, PRO HAC VICE.

For Mallinckrodt LLC, Plaintiff: Jack B. Blumenfeld, LEAD ATTORNEY, Morris, Nichols, Arsht & Tunnell LLP, Wilmington, DE.

For Actavis Inc., Actavis South Atlantic LLC, Defendants: Adam Wyatt Poff, Robert M. Vrana, Young, Conaway, Stargatt & Taylor LLP, Wilmington, DE.

Judges: Richard G Andrews, United States District Judge.

Opinion by: Richard G Andrews

Opinion

ORDER ADOPTING REPORT AND RECOMMENDATION

The United States Magistrate Judge made a Report and Recommendation dated September 23, 2015. (D.I. 51). Plaintiffs filed objections (D.I. 56), to which Defendants responded. (D.I. 63). My review of these objections is *de novo.* FED. R. CIV. P. 72(b)(3).

The Magistrate Judge recommended that Defendants' Motion to Dismiss Counts I, III and IV of Plaintiffs' Complaint (D.I. 11) be granted. (D.I. 51 at 19). Specifically, the Magistrate Judge concluded that U.S. Patent No. 8,808,737 (the "'737 patent") was facially invalid under 35 U.S.C. § 101, because it is directed to patent-ineligible subject matter. (*Id.* at 1). Because this conclusion would invalidate the patent, the Magistrate Judge did not [*2] address Defendants' additional argument that Plaintiffs alleged insufficient facts to support a claim for induced infringement under 35 U.S.C. § 271(b). (*Id.* at 18).

Plaintiffs first argue that the Magistrate Judge erred in finding that the claimed method was directed to a law of nature, because it "is instead directed to a new and useful process (the altered treatment regimen) that provides a practical, tangible benefit (relief of pain) in a particular patient population." (D.I. 56 at 6). Second, Plaintiffs argue that the Magistrate Judge's reliance on the similarities between the '737 patent's representative claim and the claim involved in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 182 L. Ed. 2d 321 (2012), was in error because the claim at issue in *Mayo* did not require that anyone act upon or apply the method in a tangible way, while claim 1 of the '737 patent actually requires that the lower dose be administered. (*Id.* at 7-8). Third, Plaintiffs contend that the Magistrate Judge failed to apply the Federal Circuit's decision in *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011), which "distinguished between a pharmaceutical patent claim that is merely directed to a natural law itself, and a claim (like the method-of-treatment claims at issue here) that applies that natural law in a new and useful away." (*Id.* at 9). Fourth, relying on the District of Maryland's [*3] decision in *Classen*—upon remand after the Supreme Court decided *Mayo*—Plaintiffs criticize the Magistrate Judge's statement that "nor is the relationship between renal impairment and this drug unknown." (D.I. 51 at 16-17). Specifically, Plaintiffs contend that this relationship was not previously known, by reiterating that the patentee's discovery was that "the bioavailability of controlled released oxymorphone is affected by renal function or that renally impaired patients could or should be treated safely and effectively by administering to them a reduced [] dosage of controlled release oxymorphone." (D.I. 56 at 11). Lastly, Plaintiffs make a

policy argument, seizing upon dicta from *Mayo*, that the reasoning employed by the Magistrate Judge's Report and Recommendation would in effect invalidate all pharmaceutical method-of-treatment patents using an existing, well-known compound. (*Id.* at 13).

Defendants respond by arguing that the specification of the '737 patent, and Plaintiffs' briefing, essentially admit that the claims are directed to a natural law, namely that "the bioavailability of oxymorphone is increased in patients with renal impairment." (D.I. 63 at 6). Defendants provide a side-by-side comparison [*4] of the claim limitations at issue in *Mayo* and those of Claim 1 of the '737 patent, arguing that the Supreme Court's *Mayo* analysis—and the Magistrate Judge's reliance upon it—is directly on point. (*Id.* at 7-8). Defendants also point out that the Federal Circuit's *Classen* decision predated *Mayo. (Id.* at 9). They argue that the principle from *Classen* upon which Plaintiffs rely was effectively overruled by the Supreme Court in *Mayo*, as it rejected the argument that the mere "inclusion of an application step" rendered otherwise non-patentable subject matter patentable. (*Id.*). Lastly, in rebutting Plaintiffs' policy argument, Defendants argue that the Magistrate Judge's Report and Recommendation "stands only for the unremarkable proposition that one cannot observe the way the body metabolizes an old drug used for an old purpose, and seek to patent the use of that knowledge." (*Id.* at 11).

The Magistrate Judge applied the two-step framework set forth by the Supreme Court in *Mayo* and *Alice Corp. Pty. Ltd. v. CLS Bank Intern.*, 134 S. Ct. 2347, 189 L. Ed. 2d 296 (2014). (D.I. 51 at 9-10). This framework requires the Court 1) to determine whether the claims are directed to a patent-ineligible concept—such as a law of nature, natural phenomenon, or abstract idea—and, if they are, 2) to determine whether there is an "inventive [*5] concept... sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself." *Alice*, 134 S. Ct. at 2355 (internal quotation marks and alterations omitted). In applying this framework, the bulk of the Magistrate Judge's Report and Recommendation emphasized the factual similarity between representative Claim 1 of the '737 patent and the representative claim at issue in the Supreme Court's *Mayo* decision. (D.I. 51 at 10-16). Because the claim limitations at issue in *Mayo* do in fact mirror the analogous limitations of Claim 1 of the '737 patent, I think it was correct for the Magistrate Judge to do so.

In order to highlight why the *Mayo* comparison is apt, below is a summary of the Supreme Court's reasoning in *Mayo*:

> Beyond picking out the relevant audience, namely those who administer doses of thiopurine drugs, the claim simply tells doctors to: (1) measure (somehow) the current level of the relevant metabolite, (2) use particular (unpatentable) laws of nature (which the claim sets forth) to calculate the current toxicity/inefficacy limits, and (3) reconsider the drug dosage in light of the law. These instructions add nothing specific to the laws of nature other than what is [*6] well-understood, routine, conventional activity, previously engaged in by those in the field. And since they are steps that must be taken in order to apply the laws in question, the effect is simply to tell doctors to apply the law somehow when treating their patients.

Mayo, 132 S. Ct. at 1299-1300. Here, the '737 patent similarly tells doctors to take an existing pharmaceutical compound for treating pain and 1) measure the creatinine clearance rate of the patient using an existing method, 2) use an unpatentable law of nature to assess the bioavailability of oxymorphone in light of the patient's creatinine clearance rate, 3) reconsider drug dosage in light of the law, and 4) administer that dosage.[1] (D.I. 1-1 at 42). Much like in *Mayo*, the claims of the '737 patent essentially state the discovery of a natural law and "simply [] tell doctors to apply the law somehow when treating their patients." *Mayo*, 132 S. Ct. at 1300. Accordingly, I agree with the Magistrate Judge's more thorough analysis of this issue. Nevertheless, I will briefly address Plaintiffs' objections.

Plaintiffs' argument that the '737 patent does not claim a law [*7] of a nature, but instead "a new and useful process," is thoroughly unconvincing. As the Magistrate Judge points out, Plaintiffs essentially admitted in their briefing that the '737 patent claims a natural law as its invention. (D.I. 18 at 20 ("[I]t is true that the claimed inventions relate to the unexpected discovery that the bioavailability of oxymorphone is increased in patients with renal impairment. ...")). The abstract of the '737 patent describes a method of treating pain by giving a patient an oxymorphone dosage form—which the specification refers to as a method "widely used in the treatment of acute and chronic pain"—and merely adds "informing the patient or prescribing physician that the

[1] I address further below Plaintiffs' argument that this administering step is the inventive leap that differentiates the '737 patent from the claim in *Mayo.*

bioavailability of oxymorphone is increased in patients with renal impairment." (D.I. 1-1 at 2, 19). After reviewing the '737 patent and the parties' arguments, I agree with the Magistrate Judge's conclusion that the subject matter of the invention is "the connection between the severity of renal impairment and the bioavailability of oxymorphone,"or, in other words, the reaction of the human body of a renally impaired individual to oxymorphone, which is unquestionably a natural law. (D.I. 51 at 13).

Second, I am not convinced [*8] that the distinction Plaintiffs raise between the claim language in *Mayo* and the '737 patent renders the Magistrate Judge's comparison between the two inapt. Below is a side-by-side comparison of the language Plaintiffs highlight:

Go to table1

The slight difference in phrasing is immaterial, because neither formulation provides any sort of "inventive concept" to suggest that more than just the natural law is being claimed. *See Alice*, 134 S. Ct. at 2355.[2] As the Supreme Court expressly stated in *Mayo*, "to transform an unpatentable law of nature into a patent-eligible *application* of such law, one must do more than simply state the law of nature while adding the words 'apply it.'" *Mayo*, 132 S. Ct. at 1294 (emphasis in original) (citation omitted). Accordingly, Plaintiffs' objections to the Magistrate Judge's *Mayo* comparison are without merit.

Third, in light of the Supreme Court's 2012 admonition in *Mayo* that a claim must do more than simply state the law of nature while adding the words "apply it," it is difficult to conceive how *Classen*, a 2011 Federal Circuit case, still holds any precedential value, at least with regard to the proposition for which Plaintiffs offer it. Plaintiffs' reliance on *Classen* amounts to an assertion that a mandatory application step is sufficiently transformative to save claims that are otherwise unpatentable under § 101. (D.I. 56 at 9-10). The Supreme Court clearly stated in *Mayo* that this is not the case.[3] Accordingly, I have little trouble rejecting Plaintiffs' arguments based on *Classen*.

Fourth, Plaintiffs' *Classen*-related objections make much of arguing that there is no factual basis in the specification [*10] for the Magistrate Judge's statement that: "nor is the relationship between renal impairment and this drug unknown." (D.I. 56 at 11 (quoting D.I. 51 at 16-17)). Because this statement is not essential to the decision, I decline to further address it.[4]

Lastly, I disagree with Plaintiffs' policy argument that the Magistrate Judge's reasoning is so far-reaching that it would invalidate all pharmaceutical method-of-treatment patents that employ an existing pharmaceutical compound. Patentees can still avoid invalidation under § 101 by demonstrating an inventive leap beyond merely claiming a law of nature. [*11] Plaintiffs here claimed a widely-used, well-known method of treating pain. The only new aspect of the '737 patent was to tell doctors to adjust the dosage of oxymorphone based upon their discovery of a natural law—namely, how the bodies of individuals with renal deficiencies process the drug. No creative steps or inventive leaps aside from the discovery of a natural law are contemplated here. The patent merely tells doctors to apply the natural law. Accordingly, this case is hardly the poster child for a policy argument on the wide-ranging implications of a § 101 rejection of a pharmaceutical method patent.

Thus, Plaintiffs' objections are **OVERRULED** and the Report and Recommendation (D.I. 51) is **ADOPTED**. Accordingly, Defendant's Motion to Dismiss Counts I, III and IV of Plaintiffs' Complaint (D.I. 11) is **GRANTED**.

It is SO ORDERED this 17 day of November, 2015.

/s/ Richard G Andrews

United States District Judge

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[2] In any event, the claim language in *Mayo* undoubtedly contemplates that the stated method is ultimately applied when it refers [*9] to "the amount of said drug subsequently administered to said subject." *Mayo*, 132 S. Ct. at 1295, 1299-1300 ("And since they are steps that must be taken in order to apply the laws in question, *the effect is simply to tell doctors to apply the law* somehow when treating their patients." (emphasis added)).

[3] In fact, it is difficult to square Plaintiffs' argument with any of the Supreme Court's § 101 jurisprudence since *Classen* was decided in 2011.

[4] In attempting to argue this point, however, Plaintiffs contend that the specification does not in fact disclose that it was previously "known that the bioavailability of controlled release oxymorphone is affected by renal function ... ." (D.I. 56 at 11). Plaintiffs' emphasis on the fact that this relationship between renal function and the effectiveness of oxymorphone was a new discovery, however, only adds support to the Court's understanding that Plaintiffs merely discovered a natural law (the way the human body reacts to a specific drug) and sought to patent the application of that natural law.

Table1 (Return to related document text**)**

"indicates a need to [increase/decrease] the amount of said drug subsequently administered to said subject" *Mayo*, 132 S.Ct. at 1295.	"orally administering to said patient, in dependence on which creatinine clearance rate is found, a lower dosage of the dosage form to provide pain relief' (D.I. 1-1 at 42).

Table1 (Return to related document text**)**

EXHIBIT LL

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

NOTICE OF DOCKETING

17-1887 - Endo Pharmaceuticals Inc. v. Actavis LLC

Date of docketing: April 7, 2017

Appeal from: United States District Court for the District of Delaware case no. 1:14-cv-01381-RGA

Appellant: Endo Pharmaceuticals Inc.

Critical dates include:

- Date of docketing. See Fed. Cir. R. 12.
- Entry of appearance. (*Due within 14 days of the date of docketing*.) See Fed. Cir. R. 47.3.
- Certificate of interest. (*Due within 14 days of the date of docketing*.) See Fed. Cir. R. 47.4.
- Docketing Statement. (*Due within 14 days of the date of docketing or within 30 days if the United States or its officer or agency is a party in the appeal*.) [Only in cases where all parties are represented by counsel. See Fed. Cir. R. 33.1 and the mediation guidelines available at www.cafc.uscourts.gov.]
- Requests for extensions of time. See Fed. Cir. R. 26 and 27. **N.B. Delayed requests are not favored by the court**.
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- **ORAL ARGUMENT SCHEDULE CONFLICTS:** Counsel should advise the clerk in writing within 30 days once briefing is completed of potential scheduling conflicts or as soon as they are known and should not wait until an actual conflict arises. Once scheduled, a case will not be postponed except on motion showing **compelling reasons**. See Practice Note following Fed. Cir. R. 34.

The official caption is reflected on the electronic docket under the listing of the parties and counsel. The Rules of Practice and required forms are available at www.cafc.uscourts.gov.

Peter R. Marksteiner
Clerk of Court

cc: United States District Court for the District of Delaware
Jack B. Blumenfeld
Adam Wyatt Poff

EXHIBIT MM

PUBLIC

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

NOTICE OF DOCKETING

17-1094 - Endo Pharmaceuticals Inc. v. Amneal Pharmaceuticals LLC

Date of docketing: October 24, 2016

Appeal from: United States District Court for the District of Delaware case no. 1:14-cv-01382-RGA

Appellant(s): Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals of New York LLC

Critical dates include:

- Date of docketing. See Fed. Cir. R. 12.
- Entry of appearance. (*Due within 14 days of the date of docketing*.) See Fed. Cir. R. 47.3.
- Certificate of interest. (*Due within 14 days of the date of docketing*.) See Fed. Cir. R. 47.4.
- Docketing Statement. (*Due within 14 days of the date of docketing or within 30 days if the United States or its officer or agency is a party in the appeal*.) [Only in cases where all parties are represented by counsel. See Fed. Cir. R. 33.1 and the mediation guidelines available at www.cafc.uscourts.gov.]
- Requests for extensions of time. See Fed. Cir. R. 26 and 27. **N.B. Delayed requests are not favored by the court**.
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- Settlement discussions. See Fed. Cir. R. 33.
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The official caption is reflected on the electronic docket under the listing of the parties and counsel. The Rules of Practice and required forms are available at www.cafc.uscourts.gov.

Peter R. Marksteiner
Clerk of Court

cc: United States District Court for the District of Delaware
Jack B. Blumenfeld
Mary B. Matterer

EXHIBIT NN

US008309060B2

(12) United States Patent

Bartholomaus et al.

(10) Patent No.: US 8,309,060 B2

(45) Date of Patent: *Nov. 13, 2012

(54) **ABUSE-PROOFED DOSAGE FORM**

(75) Inventors: **Johannes Bartholomaus**, Aachen (DE); **Heinrich Kugelmann**, Aachen (DE); **Elisabeth Arkenau-Marić**, Köln (DE)

(73) Assignee: **Grunenthal GmbH**, Aachen (DE)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **13/346,257**

(22) Filed: **Jan. 9, 2012**

(65) **Prior Publication Data**

US 2012/0107250 A1 May 3, 2012

Related U.S. Application Data

(62) Division of application No. 10/718,112, filed on Nov. 20, 2003, now Pat. No. 8,114,383.

(30) **Foreign Application Priority Data**

Aug. 6, 2003 (DE) 103 36 400

(51) **Int. Cl.**
A61K 49/00 (2006.01)

(52) **U.S. Cl.** **424/10.1**; 424/10.4

(58) **Field of Classification Search** 424/10.1
See application file for complete search history.

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Primary Examiner — Michael G Hartley

Assistant Examiner — Melissa Perreira

(74) *Attorney, Agent, or Firm* — Norris McLaughlin & Marcus, P.A.

(57) **ABSTRACT**

An abuse-proofed, thermoformed dosage form containing, in addition to one or more active ingredients with abuse potential optionally together with physiologically acceptable auxiliary substances, at least one synthetic or natural polymer with a breaking strength of at least 500 N and to a process for the production thereof.

34 Claims, No Drawings

EXHIBIT OO

US008309122B2

(12) **United States Patent**
Kao et al.

(10) **Patent No.: US 8,309,122 B2**
(45) **Date of Patent: *Nov. 13, 2012**

(54) **OXYMORPHONE CONTROLLED RELEASE FORMULATIONS**

(75) Inventors: **Huai-Hung Kao**, Syosset, NY (US); **Anand R. Baichwal**, Wappingers Falls, NY (US); **Troy McCall**, Smyma, GA (US); **David Lee**, Chadds Ford, PA (US)

(73) Assignee: **Endo Pharmaceuticals Inc.**, Chadds Ford, PA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1344 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **11/680,432**

(22) Filed: **Feb. 28, 2007**

(65) **Prior Publication Data**

US 2007/0134328 A1 Jun. 14, 2007

Related U.S. Application Data

(63) Continuation of application No. 10/190,192, filed on Jul. 3, 2002.

(60) Provisional application No. 60/303,357, filed on Jul. 6, 2001, provisional application No. 60/329,432, filed on Oct. 15, 2001, provisional application No. 60/329,444, filed on Oct. 15, 2001, provisional application No. 60/329,445, filed on Oct. 15, 2001.

(51) **Int. Cl.**

A61K 9/22	(2006.01)
A61K 9/34	(2006.01)
A61K 9/36	(2006.01)

(52) **U.S. Cl.** **424/464**; 424/468; 424/470; 424/479; 424/481; 424/482; 424/486

(58) **Field of Classification Search** ..... None
See application file for complete search history.

(56) **References Cited**

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4,464,376	A	8/1984	Sunshine et al.
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(Continued)

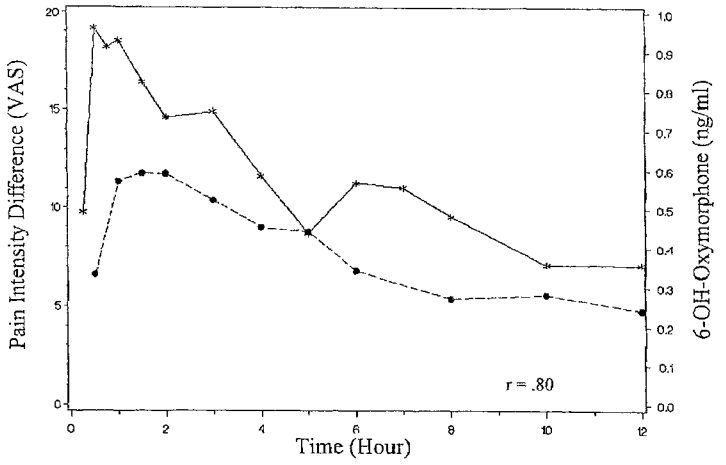
Primary Examiner — Lakshmi Channavajjala
(74) *Attorney, Agent, or Firm* — Mayer Brown LLP

(57) **ABSTRACT**

The invention pertains to a method of relieving pain by administering a controlled release pharmaceutical tablet containing oxymorphone which produces a mean minimum blood plasma level 12 to 24 hours after dosing, as well as the tablet producing the sustained pain relief.

20 Claims, 10 Drawing Sheets

PK Profile for 6-OH-Oxymorphone with PID Scores



* Pain Intensity Difference • 6-OH-Oxymorphone Plasma Concentrations

EXHIBIT PP

US008329216B2

(12) United States Patent

Kao et al.

(10) Patent No.: US 8,329,216 B2

(45) Date of Patent: *Dec. 11, 2012

(54) **OXYMORPHONE CONTROLLED RELEASE FORMULATIONS**

(75) Inventors: **Haui-Hung Kao**, Syosset, NY (US); **Anand R. Baichwal**, Wappingers Falls, NY (US); **Troy McCall**, Smyrna, GA (US); **David Lee**, Chadds, PA (US)

(73) Assignee: **Endo Pharmaceuticals Inc.**, Chadds Ford, PA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1192 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **11/427,438**

(22) Filed: **Jun. 29, 2006**

(65) **Prior Publication Data**

US 2007/0098794 A1 May 3, 2007

Related U.S. Application Data

(63) Continuation of application No. 10/190,192, filed on Jul. 3, 2002.

(60) Provisional application No. 60/329,445, filed on Oct. 15, 2001, provisional application No. 60/329,432, filed on Oct. 15, 2001, provisional application No. 60/303,357, filed on Jul. 6, 2001, provisional application No. 60/329,444, filed on Oct. 15, 2001.

(51) **Int. Cl.**

A61K 9/22	(2006.01)
A61K 9/34	(2006.01)
A61K 9/36	(2006.01)

(52) **U.S. Cl.** **424/464**; 424/468; 424/470; 424/479; 424/481; 424/482; 424/486

(58) **Field of Classification Search** ..... None

See application file for complete search history.

(56) **References Cited**

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3,393,197	A	7/1968	Pachter et al.
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3,980,766	A	9/1976	Shaw et al.
4,070,494	A	1/1978	Hoffmeister et al.
4,366,159	A	12/1982	Magruder
4,457,933	A	7/1984	Gordon et al.
4,464,376	A	8/1984	Sunshine et al.
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(Continued)

Primary Examiner — Lakshmi Channavajjala

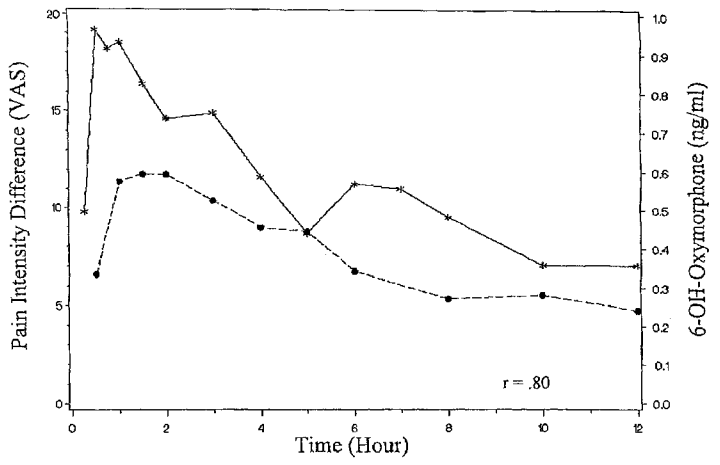
(74) *Attorney, Agent, or Firm* — Mayer Brown LLP

(57) **ABSTRACT**

The invention pertains to a method of relieving pain by administering a controlled release pharmaceutical tablet containing oxymorphone which produces a mean minimum blood plasma level 12 to 24 hours after dosing, as well as the tablet producing the sustained pain relief.

82 Claims, 10 Drawing Sheets

PK Profile for 6-OH-Oxymorphone with PID Scores



* Pain Intensity Difference • 6-OH-Oxymorphone Plasma Concentrations

EXHIBIT QQ

US008808737B2

(12) **United States Patent**
Ahdieh

(10) **Patent No.: US 8,808,737 B2**
(45) **Date of Patent: Aug. 19, 2014**

(54) **METHOD OF TREATING PAIN UTILIZING CONTROLLED RELEASE OXYMORPHONE PHARMACEUTICAL COMPOSITIONS AND INSTRUCTION ON DOSING FOR RENAL IMPAIRMENT**

(75) Inventor: **Harry Ahdieh**, Lincoln University, PA (US)

(73) Assignee: **Endo Pharmaceuticals Inc.**, Malvern, PA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **12/716,973**

(22) Filed: **Mar. 3, 2010**

(65) **Prior Publication Data**

US 2010/0151027 A1 Jun. 17, 2010

Related U.S. Application Data

(63) Continuation of application No. 11/766,740, filed on Jun. 21, 2007, now abandoned.

(51) **Int. Cl.**

A61K 9/20	(2006.01)
A61K 9/14	(2006.01)
A61K 31/44	(2006.01)

(52) **U.S. Cl.**
USPC **424/464**; 424/484; 514/282

(58) **Field of Classification Search**
USPC 424/464, 484; 514/282
See application file for complete search history.

(56) **References Cited**

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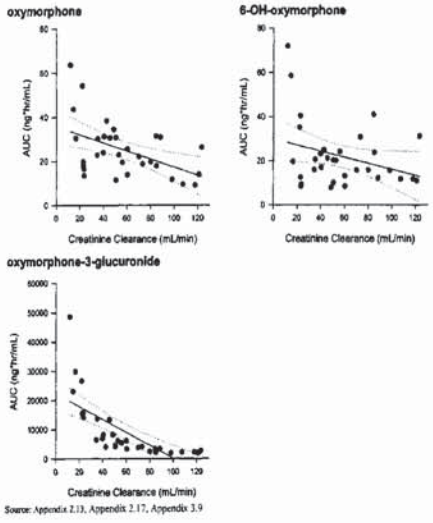
Primary Examiner — Aradhana Sasan
(74) *Attorney, Agent, or Firm* — Mayer Brown LLP

(57) **ABSTRACT**

The invention pertains to a method of using oxymorphone in the treatment of pain by providing a patient with an oxymorphone dosage form and informing the patient or prescribing physician that the bioavailability of oxymorphone is increased in patients with renal impairment.

6 Claims, 16 Drawing Sheets



Notice of Electronic Service

I hereby certify that on August 10, 2017, I filed an electronic copy of the foregoing Complaint Counsel's Motion for Partial Summary Decision (Public), with:

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