UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re: OXYCONTIN ANTITRUST LITIGATION	04 Md. 1603 (SHS)
PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., RHODES TECHNOLOGIES, and GRÜNENTHAL GMBH, Plaintiffs, -against- AMNEAL PHARMACEUTICALS, LLC, Defendant.	This document relates to: 11 Civ. 8153 (SHS)
PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., and RHODES TECHNOLOGIES, Plaintiffs, -against- EPIC PHARMA, LLC, Defendant.	13 Civ. 683 (SHS)
PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., RHODES TECHNOLOGIES, BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM, and GRÜNENTHAL GMBH, Plaintiffs, -against- IMPAX LABORATORIES, INC., Defendant.	11 Civ. 2400 (SHS)

PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., RHODES TECHNOLOGIES, BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM, and GRÜNENTHAL GMBH, Plaintiffs, -against- PAR PHARMACEUTICAL, INC., Defendant.	11 Civ. 2038 (SHS)
PURDUE PHARMA L.P and GRÜNENTHAL GMBH, Plaintiffs, -against- PAR PHARMACEUTICAL, INC., Defendant.	12 Civ. 5615 (SHS)
PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., RHODES TECHNOLOGIES, BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM, and GRÜNENTHAL GMBH, Plaintiffs, -against- SANDOZ INC., Defendant.	11 Civ. 4694 (SHS) 12 Civ. 897 (SHS)

PURDUE PHARMA L.P. and GRÜNENTHAL GMBH, Plaintiffs, -against- SANDOZ INC., Defendant.	12 Civ. 5082 (SHS) 12 Civ. 7582 (SHS)
PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., RHODES TECHNOLOGIES, and GRÜNENTHAL GMBH, Plaintiffs, -against- TEVA PHARMACEUTICALS, USA, INC., Defendant.	11 Civ. 2037 (SHS)
PURDUE PHARMA L.P. and GRÜNENTHAL GMBH, Plaintiffs, -against- TEVA PHARMACEUTICALS, USA, INC., Defendant.	12 Civ. 5083 (SHS)

CLAIM CONSTRUCTION OPINION & ORDER

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

This Hatch-Waxman Act litigation concerns the brand-name drug OxyContin, which is manufactured and sold by plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., and Rhodes Technologies (collectively, "Purdue"). Defendants—Amneal Pharmaceuticals, LLC; Epic Pharma, LLC; Impax Laboratories, Inc.; Par Pharmaceutical, Inc.; Sandoz Inc.; and Teva Pharmaceuticals, USA, Inc.—have filed Abbreviated New Drug Applications ("ANDAs") seeking to sell generic versions of OxyContin. Plaintiffs contend that defendants' ANDAs infringe six patents that claim the OxyContin formulation currently sold in the United States. Purdue, as well as plaintiffs the Board of Regents of the University of Texas System and Grünenthal GmbH (collectively with Purdue, "plaintiffs"), developed these patents to address two undesirable features of the original formulation of OxyContin. First, original OxyContin contained significant levels of 14-hydroxycodeinone, which belongs to a class of compounds known as ABUKs—alpha, beta unsaturated ketones—that may be genotoxic or carcinogenic. Second, original OxyContin tablets were often abused by snorting or injecting crushed or dissolved tablets.

The six patents that address these issues fall into two groups. Three are the "Abuse-Proof Patents":

- U.S. Patent No. 6,488,963 ("'963 Patent") (Rabenstein Decl., Ex. A)
- U.S. Patent No. 7,763,314 ("'314 Patent") (Rabenstein Decl., Ex. B)
- U.S. Patent No. 8,114,383 ("'383 Patent") (Rabenstein Decl., Ex. C)

And the other three are the "Low-ABUK Patents":

- U.S. Patent No. 7,674,799 ("'799 Patent") (PTX 2)[1]
- U.S. Patent No. 7,674,800 ("'800 Patent") (PTX 3)

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[1] The parties have incorporated the record of the trial held in *Purdue Pharma, L.P., et al. v. Ranbaxy, Inc., et al.*, No. 10 Civ. 3734, into this claim-construction proceeding. (Pls.' Opening Br. at 31 n.7; Defs.' Opening Br. at 3 n.3.)

- U.S. Patent No. 7,683,072 ("'072 Patent") (PTX 4)

On July 15, 2013, the Court held a consolidated *Markman* hearing to construe the disputed portions of the claims at issue in each of the patents listed above. This opinion and order is the result.

I. General Legal Standard

"[T]he claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quotation marks omitted). "The words of a claim are generally given their ordinary and customary meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Medtronic Inc. v. Boston Scientific Corp.*, 695 F.3d 1266, 1275 (Fed. Cir. 2012) (quotation marks and alterations omitted). "Claims, however, must be construed in light of the appropriate context in which the claim term is used." *Aventis Pharm. Inc. v. Amino Chems. Ltd.*, 715 F.3d 1363, 1373 (Fed. Cir. 2013). That context includes the specification, which "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (quotation marks omitted). "The prosecution history too, as part of the intrinsic record, has an important role in claim construction by supplying context to the claim language." *Aventis*, 715 F.3d at 1373.

The Court will set aside the rule that claim terms receive their ordinary and customary meaning in just two circumstances: "1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution." *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, No. 2012-1567, 2013 WL 3836240, at *7 (Fed. Cir. July 26, 2013) (quotation marks omitted). "A disclaimer must be clear and unmistakable, and unclear prosecution history cannot be used to limit claims." *Cordis Corp. v. Boston Scientific Corp.*, 561 F.3d 1319, 1329 (Fed. Cir. 2009) (quotation marks omitted).

With these legal principles in mind, the Court addresses the disputed claims, first in the Abuse-Proof Patents, then in the Low-ABUK Patents.

II. THE ABUSE-PROOF PATENTS

A. Background

The FDA first approved the sale of OxyContin tablets in 1995. *See* Determination that the OXYCONTIN (Oxycodone Hydrochloride) Drug Products Covered by New Drug Application 20-553 Were Withdrawn from Sale for Reasons of Safety or Effectiveness, 78 Fed. Reg. 23,273, 23,273 (Apr. 18, 2013) [hereinafter "FDA Determination"]. In approximately 2000, Purdue began receiving reports that its original OxyContin tablets were being abused. (Rabenstein Decl., Ex. 1 at 46.) The vast majority of abuse consisted of users swallowing too many pills. (*Id.* at 46.) Some abusers, however, were crushing the tablets and then either snorting them or, after dissolving the crushed tablets in a small amount of liquid, injecting them intravenously. (*Id.* at 44–46.)

As a result of these reports, Purdue began to take steps to make its tablets resistant to abuse. (*Id.* at 47, 49.) Purdue's early efforts centered on combining OxyContin's active pharmaceutical ingredient ("API") with other agents to block the effects of snorting or injecting the drug. (*Id.* at 49–52.) These avenues turned out to be dead ends. (*Id.* at 73; Rabenstein Decl., Ex. 4 at 0265164.)

Purdue thus began to look for third-party solutions to reduce abuse. In mid-2004, Purdue representatives visited the offices of Grünenthal in Germany for a demonstration of a prototype abuse-deterrent tablet. (Rabenstein Decl., Ex. 5 at PRF2704014–15.) The prototype tablet was very hard and difficult to crush. (*Id.* at PRF2704015.) The tablet also contained hydrogel, which made the tablet difficult to dissolve in water. (*Id.*) And if snorted, the hydrogel would "cause significant nasal discomfort, similar to nasal congestion from a cold or flu." (*Id.*) By November 2004, Purdue believed that Grünenthal's tablet "appear[ed] to be superior" to "all of the non-agonist abuse resistant technologies" that Purdue knew about. (Rabenstein Decl., Ex. 6 at PRF2699737.) Purdue and Grünenthal began negotiations about a possible licensing agreement in late 2004 and early 2005. (Rabenstein Decl., Ex. 7 at 178, 182.)

Also in 2004–2005, Purdue had an in-house team working on crush-resistant tablets. (Rabenstein Decl., Ex. 8 at 43–44.) In November 2005, scientists at Purdue experimented with tablet formulations that included a

high-molecular-weight form of polyethylene oxide ("PEO") as one of the components. (Rabenstein Decl., Ex. 8 at 78–79, 154; Rabenstein Decl., Ex. 20.) Purdue scientists found that if tablets containing PEO were put through a "curing step" of melting the tablet then cooling it, the resulting tablet became exceptionally hard. (Rabenstein Decl., Ex. 8 at 208.) Purdue scientists also found that if the tablets containing PEO were crushed and then mixed with water, the mixture formed a gel-like substance. (Rabenstein Decl., Ex. 8 at 403.)

Purdue's development of the PEO-based tablet led them to file New Drug Application ("NDA") 22-272, an updated version of the original OxyContin. Original OxyContin was the subject of NDA 20-553. The FDA approved NDA 22-272 in April 2010. *See* FDA Determination, 78 Fed. Reg. at 23,273. The drug that references NDA 22-272, so-called "Reformulated OxyContin," is now the only form of OxyContin that Purdue sells in the United States. (Rabenstein Decl., Ex. 14 at 40–41.)

Once Purdue was committed to moving forward with the PEO-based tablets, Purdue entered into licensing agreements with Grünenthal (Rabenstein Decl., Ex. 7 at 192) and the University of Texas System. *E.g.*, *Purdue Pharma L.P. v. Sandoz Inc.*, No. 12 Civ. 897, Dkt. No. 1 ¶ 15. Those two entities had applied for and received the three Abuse-Proof Patents in suit.

B. Construction of the Disputed Claims in the '963 Patent

The '963 Patent is a product of the research of Dr. James McGinty, a professor at the University of Texas at Austin, and one of his then-graduate students, Fen Zhang. McGinty and Zhang were researching whether high-molecular-weight PEO tablets could be made using a heat-based system. The particular method they explored was known as "hot-melt extrusion." Several steps went into McGinty and Zhang's hot-melt extrusion process. First, a powdered form of a therapeutic compound was mixed with high-molecular-weight PEO. '963 Patent at 8:8–11. This mixture was then placed into a machine called an extruder. *Id.* at 8:17–19. The mixture then passed through the heated area of the extruder at a temperature sufficient to melt or soften the PEO. *Id.* at 8:19–22. The softened mixture exited the extruder through a die, after which the mixture could be sliced into tablets. *Id.* at 8:22–28, 13:10–11.

Only two of the '963 Patent's six claims are at issue in this litigation. Plaintiffs assert that defendants' ANDAs infringe claim 6, which depends from claim 1. These two claims recite:

> 1. A non-film controlled release pharmaceutical formulation comprising an effective amount of a therapeutic compound and a high molecular weight poly(ethylene oxide), wherein the poly(ethylene oxide) has a molecular weight of about 1,000,000 to about 10,000,000 Daltons, and wherein the poly(ethylene oxide) and the therapeutic compound comprise a ratio of poly(ethylene oxide) to therapeutic compound of from about 99.99:.01 weight percent to about 50:50 weight percent.
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> 6. The non-film controlled release pharmaceutical formulation of claim 1 wherein said formulation is prepared by a process of hot-melt extrusion.

'963 Patent at 14:26–34, 51–53. The parties dispute the meaning of just two terms, both of them in claim 1. First, the parties contest the meaning of the term "non-film controlled release pharmaceutical formulation." Second, the parties dispute the meaning of the weight-ratio term of claim 1.

1. *The final formulation cannot be a film or comprised of layered films*

The parties first dispute the meaning of the preamble of claim 1: "non-film controlled release pharmaceutical formulation . . . ." All agree that this preamble limits the claims. (Pls.' Opening Br. at 10 n.4.) The dispute centers on the scope of the term "non-film." Defendants argue that this term means that the claimed formulation cannot, in its final form, be a film. Plaintiffs contend that the term "non-film" is broader (and thus that the claims are narrower). According to them, "non-film" means that the final formulation is not a film or made of films.

The term "non-film" is not defined in the claims, and the specification discusses it only briefly. In the "Field of the Invention" section of the '963 Patent, the inventors recite that the invention relates to PEO-based formulations "that are not film-like preparations." '963 Patent at 1:13. The use of the term "film-like" suggests that the invention excludes a broader class of final formulations than simple films. In addition, none of the

examples discloses a preparation in which the final formulation is made of films.

Neither the inventors nor the Examiner discussed the non-film term in any detail during prosecution. However, prior art cited to the Examiner demonstrates that, to those skilled in the art, the term "film" has both a broad and a narrow definition. *See ArcelorMittal France v. AK Steel Corp.*, 700 F.3d 1314, 1321–22 (Fed. Cir. 2012) ("[W]hen an inventor's understanding of a claim term is expressed in the prior art, it can be evidence of how those skilled in the art would have understood that term at the time of the invention." (quotation marks and citations omitted)). In particular, the inventors cited U.S. Patent No. Re. 33,093, known as "Schiraldi," which teaches a "controlled-releasing medicament-containing preparation for intra-oral use." (Rabenstein Decl., Ex. G at 7101, 1:12–14.) The principal form of the invention was "a very thin extruded thermoplastic film (which can be in single layer or laminated multi-layer form)." (*Id.* at 1:15–17.) The Schiraldi patent goes on to claim such a "single or multi-layered thin film." (*Id.* at 7105, 9:41–42.) "Mooney," another piece of prior art cited during prosecution (*id.* at 7195), also discloses formulations made of multiple layers extruded one onto the other. (*Id.* at 7206.) Mooney labels these preparations "multilayered films." (*Id.*) Mooney and Schiraldi thus make clear that the term "film" can be used to mean (and is used in the art to mean) alternatively: (1) single-layer films, or (2) the broader category of films, which encompasses single and multi-layered films.

The parties have also presented the Court with extrinsic sources—not cited in the '963 Patent or during prosecution—that shed some light on the meaning of "film." One article, known as "Apicella," teaches PEO-based "tablets" made by layering films. *See* A. Apicella et al., *Poly(ethylene oxide) (PEO) and different molecular weight PEO blends monolithic devices for drug release*, 24 Biomaterials 83, 83, 86 (1993) (Rabenstein Resp. Decl., Ex. 7). Specifically, Apicella teaches preparing polymer films containing an API, layering these films, then compression molding the layers at 75° C "to form sheets from which were cut circular tablets." *Id.* at 86. In other words, Apicella made a formulation comprised of layered films and called that formulation a "tablet." At the same time, however, Apicella never

explicitly states that its tablet does not also fall within the broader meaning of the term "film."

Plaintiffs point to an article known as "Kim" that characterized Apicella as teaching that "drug release from un-cross-linked low molecular weight PEO of MW = 0.6×10^6 (laminated films) ensures a constant release rate by achieving synchronized gel thickness." Cherng-ju Kim, *Drug Release from Compressed Hydrophilic POLYOX-WSR Tablets*, 84 J. Pharm. Sci. 303, 303 (1995) (Rabenstein Resp. Decl., Ex. 8). The parenthetical makes clear that Kim understood Apicella to teach "laminated films."

In light of all the available evidence, the Court concludes that one skilled in the art would read "non-film" to mean "not a film or comprised of layered films."[2] The prior art cited during prosecution make clear that film has both a broad and a narrow meaning. Layered films—even layered films that are heated—fall within the broader meaning of "film." And the use of the term "film-like" in the specification of the '963 Patent conclusively demonstrates that when the inventors claimed the term "non-film," they meant the broader meaning of that term. Since "film," as that word is used in claim 1, encompasses layered films, then the term "non-film" cannot encompass them. The ambiguous extrinsic evidence cannot overcome what is clear from the specification and cited prior art. As such, the Court will read the term "A non-film controlled release pharmaceutical formulation . . ." as "A controlled release pharmaceutical formulation, which, in its final form, is not a film or comprised of layered films . . . ."

2. *The final formulation must contain at least 50% PEO by weight*

The parties next dispute the weight-ratio term of claim 1, which provides that the PEO and API in the formulation shall "comprise a ratio of [PEO] to [API] of from about 99.99:.01 weight percent to about 50:50

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[2] The inclusion of the "Rippie" reference in the '963 Patent demonstrates that the inventors did not mean to exclude formulations in which a film was merely used at some intermediate step. *See* '963 Patent at 14:2; E.G. Rippie & J.R. Johnson, *Regulation of Dissolution Rate by Pellet Geometry*, 58 J. Pharm. Sci. 428, 429 (1969) (Prutzman Decl., Ex. 18).

weight percent." The parties agree that this term requires that the PEO and API be present in the final formulation in a ratio, by weight, of about 99.99:.01 to about 50:50. They disagree whether this term requires that the final formulation contain some minimum amount of PEO, measured by weight. Plaintiffs argue that the weight-ratio term specifies that the formulation comprises at least 50% PEO by weight. (Pls.' & Defs.' Proposed Constructions for Claim Terms at 1; Hearing Tr. 19.) Defendants assert that the plain meaning of the term contains no such limitation.

The Court agrees that a skilled artisan would not ordinarily understand the weight-ratio term to limit the amount of PEO in the final formulation. However, during prosecution, the inventors clearly and explicitly limited their invention to a final formulation in which PEO comprises at least 50% by weight.

a. The Inventors Limited Their Invention During Prosecution

As originally filed in March 1999, the application for the '963 Patent contained two claims (3 and 10) that specified a ratio of PEO to therapeutic compound. (Rabenstein Decl., Ex. G at 6907–08.) Claim 3 specified that the PEO and therapeutic compound would "comprise a ratio of from about 99.99:01 [sic] % wt. to about 80:20 % wt." (*Id.* at 6907.) Claim 10 specified that the PEO and therapeutic compound would be included in the formulation "in a ratio of about 99.99:0.01 to about 80:20% wt." (*Id.* at 6908.)

In May 2000, the Examiner rejected all of the proposed claims. Among other reasons, the Examiner rejected claims 1–18 as anticipated by U.S. Patent No. 4,629,621, referred to as "Snipes '621," which teaches formulations containing high-molecular-weight PEO in amounts up to 2%. (*Id.* at 7097.) The Examiner did not simply reject the claims, he gave the inventors a roadmap for overcoming this objection: "Applicants may overcome Snipes '621," he noted, "by specifying % PEO *with respect to the total composition*." (*Id.* (emphasis added).)

The inventors responded in October 2000. In their updated application, the inventors cancelled claims 3 and 10—the claims with the PEO ratios—and transposed the ratio term into amended claims 1 and 9. (*Id.* at 7111–13.) Although the inventors changed the placement of the ratio terms, they did not change their language—amended claims 1 and 9 contained

identical language to original claims 3 and 10, respectively. The inventors explained these amendments as follows: "The Examiner has recommended the specification of the percent [PEO] to distinguish the compositions over Snipes '621. Applicants have incorporated language in the amended claims that provide further definition of the formulation." (*Id.* at 7115.)

In January 2001, however, the Examiner once again rejected all of the proposed claims, including amended claims 1 and 9. (*Id.* at 7139–40.) This time, the Examiner stated that claims 1 and 9 were rejected as anticipated by U.S. Patent No. 4,764,378, known as "Keith." (*Id.* at 7141.) Keith, similar to Snipes '621, taught a composition comprising less than 50% high-molecular-weight PEO. (*Id.*)

In April 2001, the inventors submitted their final amendment. Claim 9 was left unchanged, but the inventors did alter claim 1 in two ways. First, the inventors replaced the term "% wt." with "weight percent," and second they also replaced the term "80:20" with "50:50." (*Id.* at 7150.) The inventors explained why the newly amended claim 1 was not anticipated by either Keith or Snipes '621. (*Id.* at 7147–48.) In Keith, PEO in amounts from 1% to 40% was given as one possible polymer to "'adjust the matrix'" of the formulation. (*Id.* at 7147.) By contrast, "[i]n the amended Claims to the present invention, *the percentage of PEO is never less than 50%.*" (*Id.* (emphasis added).) The inventors further argued that, "[s]imilarly, *Snipes* '621 teaches the use of PEO up to 2%, while *the present invention never contains less than 50%, as amended in this Response.*" (*Id.* at 7148 (emphasis added).)

The April 2001 amendment was successful. In August of that year, the Examiner allowed claim 1, with the amended term "weight percent" and its amended ratio of "50:50." (*Id.* at 7151–52.) But the Examiner again rejected claim 9—the claim whose language had not changed since the original application. (*Id.*)

The prosecution history clearly demonstrates that the inventors disclaimed embodiments of the '963 Patent that contain less than 50% PEO in the final formulation. The Examiner suggested that the inventors make this precise change to overcome Snipes '621 and the inventors complied in two ways. First, they amended the language of claim 1 to replace "% wt." with "weight percent" and the term "80:20" with "50:50." Second, they

explained this amendment as confirming that "the present invention never contains less than 50% [PEO], as amended in this Response." These direct responses to the Examiner's direct request constitute a "clear and unmistakable disavowal of scope" on the part of the inventors. *Purdue Pharma L.P. v. Endo Pharm. Inc.*, 438 F.3d 1123, 1136 (Fed. Cir. 2006); *see Regents of Univ. of Cal. v. Dakocytomation Cal., Inc.*, 517 F.3d 1364, 1373 (Fed. Cir. 2008); *Norian Corp. v. Stryker Corp.*, 432 F.3d 1356, 1362 (Fed. Cir. 2005). Defendants argue that the inventors' statements were not clear enough to constitute prosecution disclaimer. But it would be difficult for the inventors to speak more clearly than "the present invention never contains less than 50% [PEO], as amended in this Response." This statement is as clear, if not clearer, than other statements made during prosecution that the Federal Circuit has held to constitute a disclaimer. *See, e.g., ERBE Elektromedizin GmbH v. Canady Tech. LLC*, 629 F.3d 1278, 1285–86 (Fed. Cir. 2010); *Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1376–77 (Fed. Cir. 2008).

Defendants also assert that the inventors' statement does not refer to the amount of PEO in the final formulation. In order to accept this reading, however, the Court must blind itself to the uncontested fact that the Examiner himself requested that the inventors specify the "% PEO *with respect to the total composition*." (Rabenstein Decl., Ex. G at 7097 (emphasis added).) Moreover, the inventors clearly stated that the "*invention* never contains less than 50%" PEO. As all parties agree, the invention is a "non-film controlled release pharmaceutical formulation"—in other words, a final formulation. Defendants' arguments fail to dislodge the inventors' clear prosecution disclaimer.

b. The Intrinsic Evidence Does Not Overcome the Prosecution Disclaimer

The text of the '963 Patent does not change the impact of the inventors' clear prosecution disclaimer. In fact, plaintiffs find a good deal of support there. The claimed invention in the '963 Patent is a "controlled release pharmaceutical formulation." '963 Patent at 14:26–27. The specification makes clear that the amount of PEO in the final formulation greatly affects the tablet's controlled release properties. As the inventors stated, "[t]he amount of PEO used in the formulation will depend upon . . . [the] desired

release profile [among] other such reasons." '963 Patent at 3:57–65. Figure 1 teaches that altering the molecular weight of the PEO "affects the release profile of the formulation." '963 Patent at 4:13. The "Field of the Invention" section emphasizes that "[t]he present invention relates to the field of [PEO] based hot-melt extrudable pharmaceutical formulations . . . ." '963 Patent at 1:10–12. These portions from the specification strongly suggest that the final formulation must contain a minimum amount of PEO in order for the formulation to have the claimed controlled release properties. Further, none of the embodiments of the invention set forth in the specification contains less than 50% PEO in the formulation as a whole. Indeed, the smallest amount of PEO in any of the examples is 54% and the median amount of PEO is 81%. '963 Patent at 13:30–45.

Defendants, however, urge that the Court's construction impermissibly limits too many other portions of the '963 Patent. For example, claim 2 claims the formulation of claim 1 with the addition of a plasticizer. '963 Patent at 14:35–36. With three ingredients, the final formulation cannot at the same time have at least 50% PEO and have the ratio of PEO to API be 50:50. Defendants are correct that claim 2 does not claim the full scope of claim 1's weight-ratio range, because an exact 50:50 ratio is unavailable. They are incorrect, however, that this limitation presents a conflict. "It does not follow that because" claim 1 encompasses at least 50% PEO and a PEO to API ratio of at least 50:50, "its dependent claims must also be broad enough to encompass" both of these embodiments. *Am. Piledriving Equip., Inc. v. Geoquip, Inc.*, 637 F.3d 1324, 1335 (Fed. Cir. 2011). Dependent claim 2 need not cover the entirety of claim 1's ratio term.

Defendants also point to two portions of the '963 Patent that indicate that formulations with less than 50% PEO would still be covered by the asserted claims. The weight-ratio term from claim 1 claims ratios from "about 99.99:.01 to *about* 50:50," and one portion of the specification states: "When present, the relative amount of plasticizer used may be expressed by the ratio high molecular weight PEO % wt.:plasticizer % wt., and will generally fall in the range of about 100:0 to about 60:40. The amount of plasticizer will generally not exceed the amount of PEO." '963 Patent at 5:24–28. These passages suggest that some embodiments would contain less than 50% PEO yet still be contemplated by claim 1 and the

specification. But these isolated passages must be read in the context of the clear and unmistakable prosecution disclaimer. *See Solvay S.A. v. Honeywell Int'l, Inc.*, 622 F.3d 1367, 1385 (Fed. Cir. 2010). That explicit disclaimer mandates the Court's conclusion.

In the end, the specification and other claims do not alter the fact that the inventors disclaimed final formulations with less than 50% PEO. The Court will therefore construe the term "wherein the poly(ethylene oxide) and the therapeutic compound comprise a ratio of poly(ethylene oxide) to therapeutic compound of from about 99.99:.01 weight percent to about 50:50 weight percent" to read "wherein the poly(ethylene oxide) and the therapeutic compound comprise a ratio, by weight, of poly(ethylene oxide) to therapeutic compound of from about 99.99:.01 to about 50:50, with the poly(ethylene oxide) comprising at least 50% of the formulation."

* * *

The Court therefore construes claim 1 to read as follows:

> 1. A controlled release pharmaceutical formulation, which is not a film or comprised of layered films, comprising an effective amount of a therapeutic compound and a high molecular weight poly(ethylene oxide), wherein the poly(ethylene oxide) has a molecular weight of about 1,000,000 to about 10,000,000 Daltons, and wherein the poly(ethylene oxide) and the therapeutic compound comprise a ratio, by weight, of poly(ethylene oxide) to therapeutic compound of from about 99.99:.01 to about 50:50, with the poly(ethylene oxide) comprising at least 50% of the formulation.

C. Construction of the Disputed Claims in the '314 Patent

In the early 2000s, once reports of abuse of opioid drugs became common, researchers at Grünenthal began investigating ways to deter abusers from injecting intravenously the API from oral tablets. (Davies Decl. ¶ 39.) Johannes Bartholomäus and Henrich Kugelmann developed a product in which a "solid dosage form" would include a "viscosity-increasing agent." '314 Patent at 1:8–11. If the solid dosage form were crushed and mixed with liquid, the combination would form a gel that would "remain[] visually distinguishable even after being introduced into a further quantity of aqueous liquid" and passing through a syringe. *Id.* at

1:14–16. This result was intended to have two effects. First, the resulting gel, with its "turbid appearance, [would] provide[] the potential abuser with an additional optical warning and discourage[] him/her from administering the gel parenterally." *Id.* at 6:6–9. Second, if the abuser is not put off by the turbid appearance, "[i]ntravenous administration of such an extract would most probably result in obstruction of blood vessels, associated with serious embolism or even death of the abuser." *Id.* at 2:31–33.

The '314 Patent contains 12 claims, but the only claims in issue are independent claim 1 and dependent claims 2, 6, and 9. Of these, the parties only dispute terms from claim 1, which reads as follows:

> 1. A parenteral abuse-proofed solid dosage form for oral administration, comprising, in addition to one or more active ingredients with potential for abuse selected from the group consisting of opiates, opioids, tranquillizers, stimulants and narcotics, at least one viscosity-increasing agent in a quantity equal to or greater than 5 mg per dosage form and such that an aqueous extract obtained from the dosage form with 10 ml of water at 25° C. forms a gel which can still pass through a needle having a diameter of 0.9 mm and remains visually distinguishable when introduced by a needle into a further quantity of an aqueous liquid.

'314 Patent at 11:66–12:31. Two terms are at issue in this opinion. First, the parties dispute the meaning of "parenteral abuse-proofed." (Parenteral refers to any way of getting a substance into one's body other than orally.) Second, the parties contest the proper meaning of the term "visually distinguishable" or "remains visually distinguishable."[3]

1. *"Parenteral abuse-proofed" means "reduced potential for parenteral abuse"*

The preamble of claim 1 recites: "[a] parenteral abuse-proofed solid dosage form for oral administration." Once again, the parties agree that

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[3] Defendants also argue that the claims at issue in the '314 Patent are indefinite, and thus invalid. *See* 35 U.S.C. § 112(b). The Court declines to rule on this issue prior to trial.

this preamble limits the claim. (Pls.' Opening Br. at 10 n.4.) The parties disagree on the meaning of the term "parenteral abuse-proofed." Plaintiffs assert that this term means "reduced potential for parenteral abuse," while defendants claim that it means "preventing parenteral abuse under any circumstances." (Pls.' Opening Br. at 19; Defs.' Opening Br. at 33.) The Court agrees with plaintiffs' interpretation.

The Court begins with the plain meaning of the term. Defendants urge that the plain meaning unambiguously favors their interpretation. They point to Webster's dictionary, which defines the suffix "-proof" as "sometimes distinguished from *resistant*" (D'Amore Decl., Ex. 20), and "bulletproof" as "impenetrable to bullets." (D'Amore Decl., Ex. 21.) A bulletproof jacket, defendants argue, may not stop all bullets however large they might be, but it guarantees protection against *some* bullets. (Hearing Tr. 52.) Similarly, they assert that "parenteral abuse-proofed" does not connote that the claimed formulation will prevent any and all abuse—but it does claim that the invention will stop parenteral abuse.

"[J]udges may 'rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents.'" *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 429 F.3d 1364, 1375 (Fed. Cir. 2005) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1322–23 (Fed. Cir. 2005)) (quotation marks omitted). In this case, defendants' dictionaries do not unambiguously support their position. The Webster's reference explicitly states that the suffix -proof is only *sometimes* distinguished from resistant. But even if the dictionary definition were clear and unambiguous, the intrinsic evidence of the '314 Patent shows that one skilled in the art would not understand "abuse-proofed" in the manner defendants suggest. The inventors made clear in the specification that the object of the invention "has been achieved by the provision of the solid dosage form according to the invention with *at least reduced potential* for parenteral abuse . . . ." '314 Patent at 1:66–2:1 (emphasis added). "At least reduced potential for parenteral abuse" is a far cry from preventing all parenteral abuse.

The inventors' discussion of the prior art during prosecution also reveals that one skilled in the art would not read "abuse-proofed" as strictly as defendants suggest. In response to one of the Examiner's many rejections of the '314 Patent, the inventors commented that the "abuse-

proofing" of two pieces of prior art "proceed[] on a fundamentally different principle." (PRF0007668.) But neither of these pieces of prior art—international patent application WO 99/32120, known as "Palermo," and U.S. Patent No. 4,070,494 ("'494 Patent")—teaches abuse-proofing in the manner defendants suggest. Palermo claims a "method of *reducing* the abuse potential of an oral dosage form of an opioid analgesic," WO 99/32120 at 1, 42 (emphasis added), and the '494 Patent teaches improvements to "*inhibit or prevent* the abuse of the agent through parenteral injection." '494 Patent at 1:18–20 (emphasis added). Moreover, when the inventors distinguished Palermo to the Examiner, they did so by comparing their invention with the particular method Palermo employed to achieve its abuse-reducing potential. (PRF0007629–30; PRF0007665–68; PRF0007710.) The inventors never distinguished Palermo on the basis that it did not teach "abuse-proofing" as defendants interpret that term.

The Court therefore concludes that one skilled in the art would understand "abuse-proofed" to mean a "reduced potential for abuse."

2. ***The patentees defined "visually distinguishable"***

Claim 1 of the '314 Patent provides that the gel formed by mixing the claimed dosage form with water "remains visually distinguishable when introduced by a needle into a further quantity of an aqueous liquid." The parties dispute what the "remains visually distinguishable" term means.

"In construing the terms of a patent, the court must [] examine the specification to determine whether the patentee used the claim term consistent with its ordinary meaning or acted as his own lexicographer in defining the term." *Glaxo Grp. Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1346 (Fed. Cir. 2004). If the patentee does act as his own lexicographer, the definition provided "offers practically incontrovertible directions about claim meaning." *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1288 (Fed. Cir. 2009) (en banc). Put another way, "[i]f the special meaning of claim language [provided by the patentee] is reasonably clear and precise, the court's role in claim construction is to pronounce that meaning as the acquired meaning of the word used in the claim." Herbert F. Schwartz & Robert J. Goldman, Patent Law & Practice 153 (7th ed. 2011).

As plaintiffs admit, "the inventors explicitly defined 'visually distinguishable' in the specification." (Pls.' Opening Br. at 20.) Defendants

agree. (Defs.' Opening Br. at 20.) The portion of the specification that defines "visually distinguishable" reads:

> For the purposes of the present invention, visually distinguishable means that the active ingredient-containing gel formed by extraction from the dosage form with the assistance of a necessary minimum quantity of aqueous liquid, when introduced with a hypodermic needle with a diameter of 0.9 mm into a further quantity of aqueous liquid at 37° C., remains substantially insoluble and cohesive and cannot straightforwardly be dispersed in such a manner that it can safely be administered parenterally, in particular intravenously. The material preferably remains visually distinguishable for at least one minute, preferably for at least 10 min.
>
> The increase in viscosity of the gel with the assistance of the selected viscosity-increasing agent means that, although this has been rendered more difficult, the gel may still be passed through a needle or injected. It also means that when the resultant extract or gel is introduced at 37° C. into a further quantity of aqueous liquid, for example also by injection into blood, a largely cohesive thread is initially obtained which, while it may be broken up into smaller fragments by mechanical action, it cannot be dispersed or even dissolved in such a manner that it may safely be administered parenterally, in particular intravenously.

'314 Patent at 2:9–30. The Court must employ the definition supplied by the inventors.

Plaintiffs, however, take the position that even though the patentees acted as their own lexicographers, the Court should read into this definition additional glosses from the patent's examples. Specifically, plaintiffs suggest deleting the term "largely cohesive thread" (that forms when the gel extract is injected into the further quantity of liquid) and replacing it with "thread or thread-like fragments." (Pls.' Resp. Br. at 20.) Plaintiffs also suggest importing a requirement that the "broken up" threads be visible to the naked eye, and that the "mechanical action" be narrowed to mean "stirred." (*Id.* at 20.) Ultimately, plaintiffs "don't want to be litigating the question of the adverbs" contained in the patentees' own definition of "visually distinguishable." (Hearing Tr. 46.)

Plaintiffs simply ask the Court to do an end run around the patentees' own definition. Once the inventor acts as his own lexicographer, that definition overrules the traditional tools of claim construction. *See 3M Innovative Props. Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1374 (Fed. Cir. 2003). The scattered references to "thread-like fragments" in the '314 Patent's examples do not overcome the "practically incontrovertible directions" of the patentees' own definition. *Abbott Labs.*, 566 F.3d at 1288. Because the patentees set out their own definition, their "lexicography governs." *Phillips*, 415 F.3d at 1316.[4]

* * *

For these reasons, the Court construes claim 1 of the '314 Patent to read as follows:

> 1. A solid dosage form for oral administration with reduced potential for parenteral abuse, comprising, in addition to one or more active ingredients with potential for abuse selected from the group consisting of opiates, opioids, tranquillizers, stimulants and narcotics, at least one viscosity-increasing agent in a quantity equal to or greater than 5 mg per dosage form and such that an aqueous extract obtained from the dosage form with 10 ml of water at 25° C. forms a gel which can still pass through a needle having a diameter of 0.9 mm and, when introduced by such a needle into a further quantity of an aqueous liquid at 37° C., a largely cohesive thread is initially obtained which, while it may be broken up into smaller fragments by mechanical action, remains substantially insoluble and cohesive and cannot straightforwardly be dispersed in such a manner that it can safely be administered parenterally, in particular intravenously.

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[4] At oral argument, plaintiffs cautioned the Court against adopting a construction of "visually distinguishable" that defendants argued was indefinite. (Hearing Tr. 62.) But defendants argue that this term is indefinite based on allegedly missing steps in the visually distinguishable test. (Defs.' Opening Br. at 28.) Plaintiffs' proffered construction simply glosses some of the words in the patentees' own definition—it does not address the issue of the allegedly missing steps. (Pls.' Opening Br. at 20–23.) Thus, even if the Court adopted plaintiffs' proposed construction, that decision would not resolve defendants' indefiniteness argument.

D. Construction of the Disputed Claims in the '383 Patent

In the early 2000s, scientists at Grünenthal investigated whether they could make a tablet that would be difficult to crush—a first step before the drug can be snorted by an abuser—but at the same time be able to release the tablet's API when swallowed whole. '383 Patent at 1:16–39, 1:64–2:6; Davies Decl. ¶¶ 53–54. Three Grünenthal scientists—Johannes Bartholomäus, Heinrich Kugelmann, and Elisabeth Arkenau-Marić—succeeded in developing a tablet with a breaking strength of 500 Newtons, more than double a person's average chewing force. (Davies Decl. ¶¶ 53–55.) The claimed invention achieved this goal by including a polymer in the tablet formulation and exposing that formulation to heat and pressure. '383 Patent at 21:2–14.

Plaintiffs allege that defendants' ANDAs infringe five of the '383 Patent's nine claims: independent claim 1 and dependent claims 2, 5, 7, and 8. The parties, though, only dispute the meaning of two terms in claim 1. That claim recites:

> 1. A thermoformed dosage form comprising:
>
> i) one or more active ingredients with abuse potential (A) selected from the group consisting of opiates and opioids,
>
> ii) optionally physiologically acceptable auxiliary substances (B),
>
> iii) at least 30% by weight of polyalkylene oxide (C) having a molecular weight of 1-15 million according to rheological measurements, and
>
> iv) optionally at least one wax (D),
>
> wherein said dosage form has a breaking strength of at least 500 N and wherein the active ingredient with abuse potential (A) is present in a controlled release matrix of component (C).

Id. at 21:2–22:14. The two terms in dispute are "thermoformed dosage form" and "breaking strength of at least 500 N."

1. *"Thermoformed dosage form" means pressure with preceding or simultaneous application of heat*

The preamble of independent claim 1 claims a "thermoformed dosage form."[5] The parties agree that "thermoforming" encompasses formulations made by applying pressure with preceding or simultaneous application of heat. They disagree whether thermoforming can also encompass the application of pressure with *subsequent* heat—plaintiffs claim that it does, defendants disagree. The Court holds that the term "thermoform" does not include subsequent heat.

The Court begins with the claims of the '383 Patent, but the claims do not settle the parties' dispute. Plaintiffs do not assert that thermoforming bears a plain, ordinary meaning among those skilled in the art. Defendants, though, argue that thermoforming does have such a meaning—one that excludes subsequent heat. In support, defendants cite numerous general purpose and technical dictionaries and treatises. (Amiji Decl., Exs. D–H.) These extrinsic sources "'can shed useful light on the relevant art,' [but] this court considers such evidence 'less significant than the intrinsic record in determining the legally operative meaning of claim language.'" *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1362 (Fed. Cir. 2008) (quoting *Phillips*, 415 F.3d at 1317). At a minimum, defendants' dictionaries do establish that plaintiffs' proposed definition would be an outlier among these other lay and specialized meanings.

While claim 1 does not define "thermoformed," dependent claim 5 appears to provide some context. Claim 5 claims a process for producing the dosage form of claim 1, involving "mixing" the components specified in claim 1, "and, optionally after granulation, press-forming the mixture with preceding, simultaneous, or subsequent exposure to heat." '383 Patent at 22:6–8. Plaintiffs point out that dependent claim 5 must fit within the scope of claim 1. Plaintiffs are correct, *see Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n.9 (Fed. Cir. 1989), but this does not end the analysis. Even if "thermoform" does not encompass subsequent heat, claim 1 does not exclude dosage forms that include a subsequent heating step—provided that the dosage form was already "thermoformed." The

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[5] The parties again agree that the preamble limits claim 1. (Defs.' Opening Br. at 41 n.17.)

preamble of claim 1 is linked to the substantive claim language by the open-ended term "comprising." *See, e.g., In re Skvorecz*, 580 F.3d 1262, 1267 (Fed. Cir. 2009). Therefore, a dosage form that is thermoformed according to defendants' construction can still undergo a subsequent heating step and fit within the confines of claim 1. Claim 5 merely spells out this possibility.[6]

The Court next turns to the specification of the '383 Patent. The inventors did not take the opportunity in the specification to act as their own lexicographer, but the specification is replete with examples of thermoforming. None of the numbered examples discloses a method that involves a subsequent application of heat—every one of them utilizes pressure with either simultaneous or preceding heat. In fact, the specification discusses subsequent applications of heat only once, in column 11:

> 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. The mixture may, for example, be formed into tablets by direct tabletting. In direct tabletting with simultaneous exposure to heat, the tabletting tool, i.e. bottom punch, top punch and die are briefly heated at least to the softening temperature of the polymer (C) and pressed together. *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.*

'383 Patent at 11:16–28 (emphasis added). Plaintiffs naturally cite this passage and urge that any definition of thermoforming that excludes subsequent heat would exclude this preferred embodiment of the invention. Plaintiffs once again correctly state the law, *see SynQor, Inc. v. Artesyn Techs., Inc.*, 709 F.3d 1365, 1378–79 (Fed. Cir. 2013), but misconstrue the patent.

The disclosed method of direct tableting with subsequent heat makes clear that after the formed tablets are heated, they are "cooled *again*." The

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[6] Defendants claim that the entire press-forming step of claim 5 is optional. They are incorrect. The term "optionally" in claim 5 modifies "after granulation."

emphasized word means what it says—the tablets formed by this method had already been cooled, meaning they had already been heated. In other words, the tablets had already been thermoformed before they were subjected to subsequent heat.

Plaintiffs belittle this point, but do nothing to reduce its impact. They argue that defendants' reliance on the word "again" is nothing more than an attempt to summon up a "hidden previous heating step." (Pls.' Resp. Br. at 27 n.21.) Plaintiffs, though, have no better explanation for the word. They contend that "cooled again" means that the tablet is cooled to its original temperature. (*See id.*) But this reading simply deletes the word "again," or else has it modify something other than the verb "are . . . cooled."

Finally, the Court turns to the prosecution history. During prosecution, the inventors did not discuss the precise term "thermoform." The inventors did, however, repeatedly stress to the Examiner the importance to their invention of simultaneous pressure and heat. For example, in response to the Examiner's first rejection of all proposed claims, the inventors emphasized that "[t]he 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." (PRF0008744 (emphasis added).) The inventors repeated this point word-for-word in response to the Examiner's second rejection. (PRF0008828.)

Plaintiffs counter that even when the inventors stressed the simultaneous application of heat and pressure, they still cited portions of the application that discussed subsequent heating. This ambiguity may militate against a finding of prosecution disclaimer, but it does not detract from the thrust of the inventors' representations to the Examiner. Pressure and heat, applied together, were the crucial elements of the invention.

The claims and specification make clear that if the formulation is subjected to heat after it has already been pressed, that formulation must have already been "thermoformed." Pressure and prior or simultaneous heat are simply the essence of the claimed invention, as the inventors repeatedly stressed to the Examiner. Read in the complete context of the claims, the specification, and the prosecution history, it is plain that a

person of ordinary skill in the art would understand "[a] thermoformed dosage form" to mean "a dosage form that is formed by the application of pressure to the components with the simultaneous or preceding application of heat."[7]

2. *"Breaking strength" means "breaking strength"*

The parties also appear to contest the meaning of the term "a breaking strength of at least 500 N" from claim 1. But on closer inspection, there is no conflict at all. The parties agree that plastic deformation—i.e., squashing—does not constitute "breaking." (Defs.' Resp. Br. at 29.) Plaintiffs also urge that chipping of the color coating would not constitute "breaking." The Court agrees—the product that has "a breaking strength of at least 500 N" is the thermoformed dosage form. No construction of the term "breaking strength" is required.

* * *

For these reasons, the Court will construe claim 1 to read as follows:

> 1. A dosage form that is formed by the application of pressure to the components with the simultaneous or preceding application of heat comprising:
>
> i) one or more active ingredients with abuse potential (A) selected from the group consisting of opiates and opioids,
>
> ii) optionally physiologically acceptable auxiliary substances (B),
>
> iii) at least 30% by weight of polyalkylene oxide (C) having a molecular weight of 1-15 million according to rheological measurements, and
>
> iv) optionally at least one wax (D),
>
> wherein said dosage form has a breaking strength of at least 500 N and wherein the active ingredient with abuse potential (A) is present in a controlled release matrix of component (C).

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[7] This reasoning also compels the Court to conclude that claim 1 is not a product-by-process claim. The thermoforming of the claimed invention imparts structural characteristics to the final dosage form. *See Hazani v. U.S. Int'l Trade Comm'n*, 126 F.3d 1473, 1479 (Fed. Cir. 1997); *In re Garnero*, 412 F.2d 276, 279 (C.C.P.A. 1969).

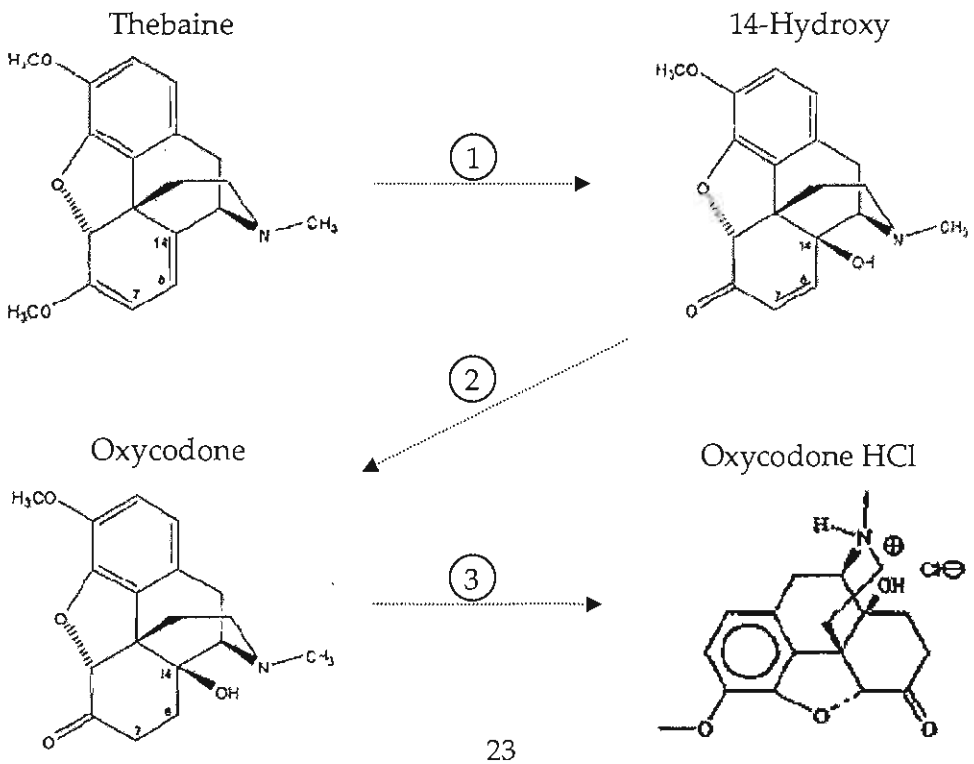
III. THE LOW-ABUK PATENTS

A. Background

1. *Purdue's development of low-ABUK oxycodone*

In 2004, the FDA mandated that manufacturers of oxycodone API—including Purdue and its subsidiary Rhodes—provide information about the impurity 14-hydroxycodeinone ("14-hydroxy"). Among other things, the FDA directed Rhodes to either (1) provide evidence that the level of 14-hydroxy in Rhodes's oxycodone API was safe or (2) lower the level of 14-hydroxy in Rhodes's oxycodone API to less than 10 ppm. (PTX 266.)

By the fall of 2004, Rhodes had developed a method to reduce the amount of 14-hydroxy and submitted an amendment to its drug master file to the FDA. (Kelly Tr. 517–18.) Rhodes's ability to rapidly achieve the FDA's 14-hydroxy purity standard reflected laboratory work undertaken years before the FDA mandate. Rhodes had previously developed a three-step process to synthesize oxycodone from thebaine: (1) Rhodes oxidized thebaine to form 14-hydroxy; (2) Rhodes hydrogenated 14-hydroxy to form oxycodone; and (3) Rhodes added hydrochloric acid to form oxycodone hydrochloride. (Shamblen Tr. 80; Kupper Tr. 124–25.)



In 2001 and 2002, scientists at Rhodes attempted to control levels of 14-hydroxy in the oxycodone API by ensuring that "the hydrogenation reaction from [14-hydroxy] [to] oxycodone free base was run to completion." (Kupper Tr. 129.) After this extended hydrogenation—step two of the method for synthesizing oxycodone—scientists were unable to detect 14-hydroxy in the free base. But after step three—transforming the oxycodone free base into oxycodone hydrochloride—Rhodes's scientists discovered that the 14-hydroxy had returned. (Kupper Tr. 135, 137–38.)

The scientists at Rhodes did not know at first why the 14-hydroxy had reappeared. In a report written in late 2002, though, Rhodes research scientist Lonn Rider hypothesized that the 14-hydroxy present in the API formed due to the dehydration of two impurities, 8α, 14-dihydroxy-7,8-dihydrocodeinone ("8α") and 8β, 14-dihydroxy-7,8-dihydrocodeinone ("8β"). (Kupper Tr. 139–41.) 8α and 8β are diastereomers of 8,14-dihydroxy-7,8-dihydrocodeinone ("8,14-dihydroxy"). As diastereomers, 8α and 8β are two forms of 8,14-dihydroxy: "[t]hey have the same atoms connected to other atoms but they differ in the[] three-dimensional arrangement of the atoms." (Heathcock Tr. 1144; *see also Chapman v. Casner*, 315 F. App'x 294, 295–96 (Fed. Cir. 2009) (discussing 8,14-dihydroxy's stereoisomers).)

Rider's focus on 8,14-dihydroxy reflected two reactions that occur within the Rhodes synthesis process. One, during the first step in the synthesis process, thebaine molecules convert into 14-hydroxy molecules by oxidation. While this reaction principally yields 14-hydroxy, it also produces "several overoxidation products [] in small amounts," including 8,14-dihydroxy. (Kupper Tr. 140.) Two, Rhodes and Rider knew that 8,14-dihydroxy could undergo acid-catalyzed dehydration to form 14-hydroxy. (Heathcock Tr. 1141–42.) Rhodes suspected that the addition of acid at the third manufacturing step was converting the 8,14-dihydroxy to 14-hydroxy. (Kupper Tr. 138.)

After additional experimentation, Rhodes scientists concluded that 8α was the source of the reappearing 14-hydroxy. They then began to consider "methods for controlling the levels of 14-[hydroxy] in oxycodone hydrochloride based on this knowledge." (Rider Tr. 219.) After considering several alternatives, Rhodes "decided that the best course of action . . . would be another hydrogenation step to remove the 14-

[hydroxy] . . . ." (Kupper Tr. 151; Rider Tr. 221.) This second hydrogenation step did not, however, exactly replicate the first. The first, original, hydrogenation step used water and formic acid to produce a formate salt, which was "converted to the free base by an addition of a base of sodium hydroxide." (Rider Tr. 298; Kupper Tr. 151–52.) The newly added second hydrogenation was performed after the free base had been converted to oxycodone hydrochloride. (Rider Tr. 299.) The second hydrogenation converted 14-hydroxy into oxycodone but did not react with previously formed oxycodone hydrochloride. (Rider Tr. 300–01.)

With this method in hand, Rhodes sought approval from the FDA and patent protection for their new method.

2. *Purdue obtains the '799, '800, and '072 Patents*

Purdue and Rhodes attempted to patent their work on low-ABUK oxycodone. This effort concluded in March 2010 when Purdue secured the three Low-ABUK Patents:

- U.S. Patent No. 7,674,799
- U.S. Patent No. 7,674,800
- U.S. Patent No. 7,683,072

Broadly speaking, the '800 Patent claims "a process for preparing an oxycodone salt substantially free of 14-[hydroxy]." '800 Patent at 34:22–23. The '072 Patent claims low-ABUK oxycodone hydrochloride API. '072 Patent at 34:57–60. The '799 Patent claims an "oral dosage form" of low-ABUK oxycodone hydrochloride. '799 Patent at 34:54.

The '799, '800, and '072 Patents continue from an earlier application, No. 11/391,897 ("Chapman application"). The Chapman application continues from the March 30, 2005 application No. 11/093,626, which issued as U.S. Patent No. 7,129,248. The '799 Patent continued as Serial No. 11/653,531 and was issued on March 9, 2010. The '800 Patent continued as Serial No. 11/729,741 and issued on March 9, 2010. The '072 Patent continued as Serial No. 11/653,529 and issued on March 23, 2010.

The Patent Office initially rejected as obvious a number of asserted claims of the patents as they were then drafted. The Examiner paid particular attention to one prior art reference, Chiu, which disclosed a

process for preparing a low-ABUK oxycodone crude base. (PTX 10 at P1052803–04; PTX 11 at P1034148–49; PTX 12 at P1045523–24; DTX 741.) The Examiner also questioned the nonobviousness of the patents on the grounds that 8,14-dihydroxy had been disclosed in the art. Accordingly, the Examiner directed the inventors to explain why prior art regarding 8β did not render obvious claims relating to 8α: "unless applicants provide some unexpected results of 8,14-dihydroxy[] with trans hydroxyl groups as compared to 8,14-dihydroxy[] with cis hydroxyl groups, it would have been obvious to one skilled in the art to prepare Oxycodone salt with reduced amount of 14-hydroxy[] with reasonable expectation of success." (PTX 11 at P1035381–82; Heathcock Tr. 1143.)

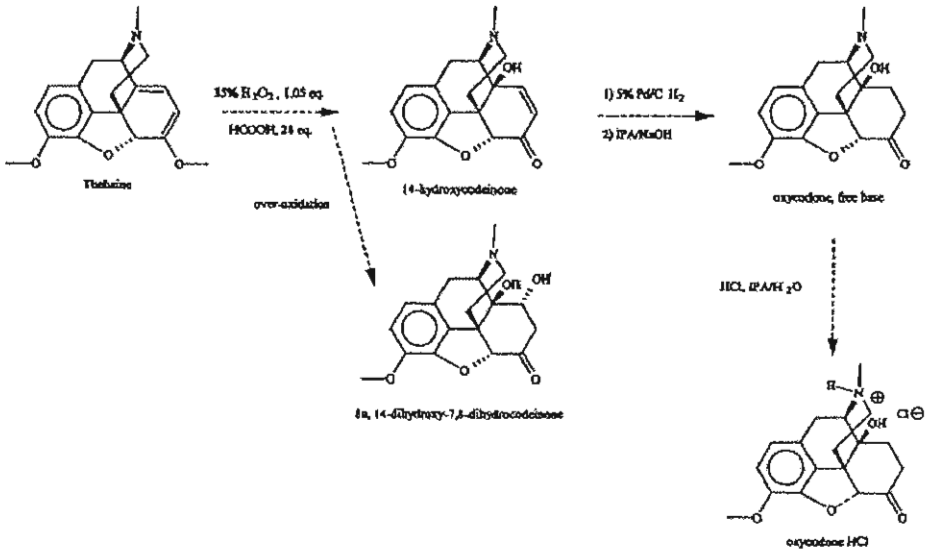
Purdue's response distinguished the prior art based on stereochemistry and the process steps involved in the Chiu reference. As to the stereochemistry, Purdue submitted the declaration of Steven Baldwin, Ph.D., to demonstrate the "unexpected results" of 8α to the Patent Office. Baldwin stated that 8α and 8β are "different compounds and have surprisingly different properties (e.g., reactivities)." (PTX 11 at P1035678; Heathcock Tr. 1143.) As to the Chiu reference, Purdue explained that the prior art reference concerned 14-hydroxy in oxycodone base, not 14-hydroxy that "would reappear during hydrochloride salt formation." (PTX 10 at P1052961–62; Crimmins Tr. 799–800.)

Purdue prevailed. The Examiner approved the patents, in part "due to [Purdue's] persuasive arguments and declaration by Dr. Baldwin." (PTX 10 at P1059552.)

a. The common specification

The '799, '800, and '072 Patents have substantially identical specifications but differ in the nature of the claims. Figure 1 depicts a scheme to synthesize oxycodone hydrochloride from thebaine.

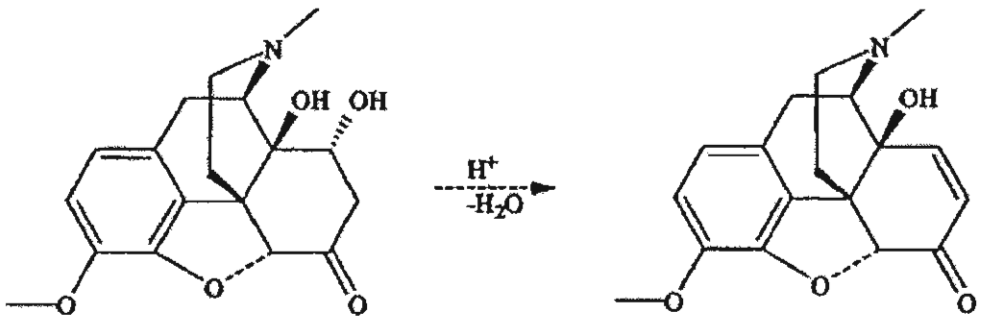
Figure 1



First, thebaine is oxidized to form 14-hydroxy. Second, 14-hydroxy is hydrogenated to form oxycodone free base. Third, the oxycodone free base is acidified to form oxycodone hydrochloride. In addition, Figure 1 depicts the formation of 8α as a result of the overoxidation of thebaine. (Wuest Tr. 554–55, 1253–54.)

Figure 2 depicts the conversion of 8α into 14-hydroxy as a result of dehydration in the presence of acid. *E.g.*, '800 Patent at 6:18–19; Wuest Tr. 1254.

Figure 2



8a,14-dihydroxy-7,8-dihydrocodeinone

14-hydroxycodeinone

The specification states that "[t]he term 8,14-dihydroxy-7,8-dihydrocodeinone includes either 8α,14-dihydroxy-7,8-dihydrocodeinone; or 8β,14-dihydroxy-7,8-dihydrocodeinone or can include a mixture of both compounds." *E.g.*, '800 Patent at 5:54–57.

The description recites the chemical structure of 8α and the nature of the reaction that produces it. For example, the specification states that 8,14-dihydroxy converts to 14-hydroxy "during salt formation reactions known in the art." '800 Patent at 8:4–11. The patents' written description does not explicitly identify conditions that transform 8α, but not 8β, into 14-hydroxy. (*E.g.*, Rider Tr. 278.) The specification also does not disclose a pH range at which 8α will not form. (Rider Tr. 278–79; Wuest Tr. 1330–31.) But Example 3 of the specification demonstrates conditions that suffice to convert 8α into 14-hydroxy. (Wuest Tr. 1258.) Wuest further explained that a skilled artisan "would understand that the 8β compound is essentially inert under [the] conditions [of Example 3] and would not undergo this acid-induced transformation." (Wuest Tr. 1258.) The specification includes no method for detecting 8α. (Kupper Tr. 191; Wuest Tr. 1324–25.)

B. Construction of the Disputed Claims in the Low-ABUK Patents

Purdue has asserted that defendants' ANDAs infringe claims 3 and 19 of the '799 Patent; claims 30–34 and 76–79 of the '800 Patent; and claims 1, 4, and 5 of the '072 Patent. The parties contest the meaning of various claim terms of each patent. Those disputes fit roughly into the following groups:

1) Whether terms of each claim require the presence of 14-hydroxy in the final oxycodone salt
2) Whether the process claims of the '800 Patent encompass processes that involve intermediate salt-formation steps that use salts other than oxycodone hydrochloride
3) Whether the '799 and '072 Patents require 8α to be present in the synthesis process and, if so, whether some portion of it must convert to 14-hydroxy at the final salt formation step
4) Whether the '799 and '072 Patents contain process limitations

5) Whether the presence of 14-hydroxy and 8α must be at "detectable levels"

The Court considers each issue below.

1. *All patents: 14-hydroxy must be present in the final salt*

Defendants urge the Court to construe the '800 Patent (claims 1 & 57), the '072 Patent (claim 1), and the '799 Patent (claim 3) as requiring 14-hydroxy in the final oxycodone salt. The Court adopts this construction.

Purdue does not seriously contest that an infringing product must have some 14-hydroxy present in the final oxycodone salt. After all, if a product had no 14-hydroxy whatsoever, it would have no 14-hydroxy derived from 8α as required by the claims. (Crimmins Tr. 803.) The specification supports this reading because it contains no embodiment where the level of 14-hydroxy is described as zero. To the contrary, Example 6 recites an analytical method "to determine the amount of codeinone and 14-[hydroxy] present." '799 Patent at 31:16–18. Therefore, the Court does not accept that a skilled artisan would understand the phrase "a portion of the [14-hydroxy]" to encompass the absence of 14-hydroxy.[8]

2. *'800 Patent: the final salt must be oxycodone hydrochloride, but the intermediate salt need not be*

Claim 1 of the '800 Patent reads as follows, with emphasis on the disputed claim language:

> A process for preparing *an oxycodone salt substantially free of 14-hydroxycodeinone*, which process comprises steps of:
>
> (a) preparing a mixture of oxycodone free base, solvent and an acid, the oxycodone free base having an 8α,14-dihydroxy-7,8-dihydrocodeinone component;
>
> (b) incubating the mixture under conditions suitable to convert the oxycodone free base to *an oxycodone salt*, wherein said

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[8] As regards the Low-ABUK Patents, a person of ordinary skill in the art is an organic chemist with experience in synthetic and analytical chemistry. The parties do not dispute the qualifications of the skilled artisan as relevant to the Abuse-Proof Patents. (Hearing Tr. 50.)

> conditions promote an acid catalyzed dehydration consisting of conversion of the 8α,14-dihydroxy-7,8-dihydrocodeinone component to 14-hydroxycodeinone; and
>
> (c) preferentially removing the 14-hydroxycodeinone from *the oxycodone salt*.

'800 Patent at 34:22–35. Claim 57 features the same disputed language, but recites step (c) as "reducing an amount of [14-hydroxy] in the oxycodone salt formed in step (b) to produce an oxycodone salt composition having less than 25 ppm [14-hydroxy]." '800 Patent at 37:40–43.

The parties dispute whether the term "an oxycodone salt substantially free of 14-hydroxy" as used in the preamble must be the same salt as the "an oxycodone salt" referred to in step (b) of the body of the claim. The parties further dispute whether claim 1 and claim 57 of the '800 Patent describe *any* oxycodone salt in the preamble and at step (b) or only oxycodone *hydrochloride* salt. The Court does not read the claims to require the oxycodone salt of the preamble to be the same oxycodone salt as in step (b). The Court also will not limit the salts in claims 1 and 57 to hydrochloride salts alone.

a. The preamble refers to an oxycodone salt API

The parties dispute whether the preambles of claim 1 and claim 57 limit the process steps of those claims. They do. "[A] claim preamble has the import that the claim as a whole suggests for it." *Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332, 1339 (Fed. Cir. 2003) (quotation marks omitted).

The claim terms and specification indicate that the preamble constitutes a claim limitation. The phrasing of the preamble "an oxycodone salt substantially free of [14-hydroxy]" comports with the title of the patents, "Oxycodone Hydrochloride Having Less Than 25 ppm 14-Hydroxycodeinone" and discloses various pharmaceutical embodiments. Moreover, the examples in the patent specification show how to analyze the 14-hydroxy levels of the product after the hydrogenation reaction is run and the material is dried. *E.g.*, '800 Patent at 25:17–22, 25:55–60, 26:35–40. The context therefore suggests that their preambles identify and limit the end product of the described process. If the end product is an oxycodone salt API substantially free of 14-hydroxy, as the intrinsic evidence suggests, then the preamble's use of the phrase "an oxycodone

salt substantially free of [14-hydroxy]" must be limiting. Otherwise, the process steps would not achieve that result. The preambles of claims 1 and 57 "recite[] essential structure or steps" of the claims and are otherwise "necessary to give life, meaning, and vitality to the claim." *Am. Med. Sys., Inc. v. Biolitec, Inc.*, 618 F.3d 1354, 1358 (Fed. Cir. 2010) (quotation marks omitted).

This reading also comports with the patent prosecution history. During the prosecution of the '800 Patent, Purdue distinguished its claims to a low-ABUK "oxycodone hydrochloride composition" from the Chiu reference. (PTX 11 at P1034312–14.) Purdue emphasized that Chiu disclosed low-ABUK oxycodone free base and not a low-ABUK salt made from the purified free base. (*Id.*) Because an earlier step in Chiu's process involved an intermediate oxycodone salt mixture, (DTX 741 at Example 6), Purdue's process differed meaningfully from Chiu only in that Purdue's process resulted in an oxycodone salt API and not a crude oxycodone base. That is the very distinction captured by the preamble of claims 1 and 57 and what a skilled artisan would understand by this language. (Wuest Tr. 559.)

b. The phrase "an oxycodone salt substantially free of [14-hydroxy]" has a different meaning than the phrase "an oxycodone salt"

Defendants contend that the Court should construe the preamble's phrase "an oxycodone salt substantially free of [14-hydroxy]" to mean the same thing as "an oxycodone salt" as used in the process steps. The Court does not accept this reading.

"[T]he same terms appearing in different portions of the claims should be given the same meaning unless it is clear from the specification and prosecution history that the terms have different meanings at different portions of the claims." *PODS, Inc. v. Porta Stor, Inc.*, 484 F.3d 1359, 1366 (Fed. Cir. 2007). Here, the intrinsic evidence reveals such a distinction between the two instances of "an oxycodone salt."

- First, the modifying phrase "substantially free of 14-[hydroxy]" limits the term "an oxycodone salt" in the preamble, as compared to the unmodified phrase "an oxycodone salt" used at step (b). The Court presumes that these different phrases carry different

meanings. *See Epcon Gas Sys., Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1030–31 (Fed. Cir. 2002).

- Second, the indefinite article "an" appears before "oxycodone salt" in the preamble and before "oxycodone salt" in the body of the claim. Each use of that article implies that "one or more" oxycodone salts may fit within the claims. *See 01 Communique Lab., Inc. v. LogMeIn, Inc.*, 687 F.3d 1292, 1297 (Fed. Cir. 2012). Defendants' proposed construction thus artificially limits this term.
- Third, the specification discloses an embodiment where the final salt is an API but the process salt is an intermediate. '800 Patent at 8:66–9:7.

Accordingly, the salt of the preamble—the oxycodone API—need not be the salt of step (b). Because the specification identifies differences in meaning between "an oxycodone salt substantially free of 14-[hydroxy]" and "an oxycodone salt," the Court construes them differently. *See Microprocessor Enhancement Corp. v. Texas Instruments Inc.*, 520 F.3d 1367, 1375–76 (Fed. Cir. 2008).

c. The process steps refer to "any oxycodone salt," not necessarily oxycodone hydrochloride

A person of ordinary skill in the art would understand that neither the phrase "an oxycodone salt substantially free of 14-hydroxy" nor the phrase "an oxycodone salt" limit the claims to oxycodone hydrochloride salt. (Wuest Tr. 566; Crimmins Tr. 916; Heathcock Tr. 1135.) The appropriateness of that reading is confirmed by the context of the patent. Claim 31 and claim 77, for example, call for oxycodone *hydrochloride* salt. Because dependent claims 31 and 77 recite a specific type of salt but the independent claims 1 and 57 do not, the doctrine of "claim differentiation" presumes that the independent claims do not contain the limitations of the dependent claims. *See Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 805–06 (Fed. Cir. 2007). The specification supports this meaning because it includes an embodiment where the claimed process involves "reacting an oxycodone base composition with an acid having a higher pH than hydrochloric acid to form a corresponding acid addition salt of

oxycodone" and identifies suitable acids other than hydrochloric acid. '800 Patent at 8:66–9:7.

The specification and prosecution history do not provide a contrary "clear intention" to limit the phrases "an oxycodone salt substantially free of [14-hydroxy]" and "an oxycodone salt" to "oxycodone hydrochloride salt." *Contra Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1290 (Fed. Cir. 2009) (en banc). First, though the specification primarily describes oxycodone hydrochloride compositions, "the written description does not suggest that the invention must be used" in that form. *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1301 (Fed. Cir. 2003). Second, Purdue's statements to the Examiner did not disclaim the use of other oxycodone salts. When Purdue distinguished its claim from the Chiu reference it did not do so on the ground that it claimed an oxycodone *hydrochloride* salt rather than an oxycodone *acetate* salt of Chiu. (PTX 11 at P1034312–14.) Rather, Purdue drew a distinction between a low-ABUK free base and a low-ABUK salt formed from a purified free base. (*Id.*) That Purdue referred to "oxycodone hydrochloride salt" while discussing its proposed claim does not amount to "clear and unmistakable prosecution arguments limiting the meaning of a claim term in order to overcome a rejection." *SanDisk Corp. v. Memorex Prods., Inc.*, 415 F.3d 1278, 1286 (Fed. Cir. 2005). The specific independent claim at issue recited an oxycodone hydrochloride composition. (PTX 11 at P1034313.)

* * *

Accordingly, the Court construes claim 1 of the 800 Patent to require:

(1) A process for preparing an oxycodone salt API substantially free of 14-hydroxy, which process comprises (2) preparing a mixture of oxycodone free base, solvent and an acid, the oxycodone free base having an 8α component; (3) incubating the mixture under conditions suitable to convert the oxycodone free base to any salt of oxycodone, wherein said conditions promote an acid-catalyzed dehydration consisting of conversion of the 8α component to [14-hydroxy]; and (4) preferentially removing the [14-hydroxy] from the oxycodone salt.

The Court construes claim 57 of the '800 Patent the same way, except that element (4) requires "reducing an amount of [14-hydroxy] in the

oxycodone salt formed in step [3] to produce an oxycodone salt composition having less than 25 ppm [14-hydroxy]."

3. ***The '799 Patent requires some 8α to convert to 14-hydroxy at the salt formation step, the '072 Patent does not***

The relevant portions of claim 1 of the '072 Patent read as follows, with emphasis on the disputed claim language:

> An oxycodone hydrochloride active pharmaceutical ingredient having less than 25 ppm 14-hydroxycodeinone *wherein at least a portion of the 14-hydroxycodeinone is derived from 8α, 14-dihydroxy-7,8-dihydrocodeinone.*

'072 Patent at 34:57–60.

The relevant portions of claim 3 of the '799 Patent read as follows, with emphasis on the disputed claim language:

> An oral dosage form comprising: (i) from about 5 mg to about 320 mg of oxycodone hydrochloride active pharmaceutical ingredient having less than 25 ppm 14-hydroxycodeinone, *wherein at least a portion of the 14-hydroxycodeinone is derived from 8α,14-dihydroxy-7,8-dihydrocodeinone during conversion of oxycodone free base to oxycodone hydrochloride;* and (ii) a pharmaceutically acceptable excipient.

'799 Patent at 35:8–15.

The parties dispute whether the '799 Patent (claim 3) and the '072 Patent (claim 1) require the presence of 8α in the oxycodone base and require some 8α to convert to 14-hydroxy at the salt formation step.[9] Defendants' proposed construction advances two additional limitations: (1) the presence of 8α in the oxycodone base and (2) the conversion of some 8α to 14-hydroxy at the salt formation step. The Court concludes that the '799 Patent requires some 8α to convert to 14-hydroxy at the salt formation step and therefore construes the '799 Patent to require 8α in oxycodone base. The Court concludes that the '072 Patent does not have any requirement that 8α convert to 14-hydroxy at any particular process

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[9] The parties agree that the process of the '800 patent requires the presence 8α in the oxycodone base.

step and therefore does not require proof of 8α's conversion at any particular point.

a. The '799 Patent (claim 3) requires the presence of 8α in the oxycodone base.

The '799 Patent (claim 3) states that "at least a portion of the 14-[hydroxy] is derived from 8α[] during conversion of oxycodone free base to oxycodone hydrochloride." The Court construes this phrase according to its plain meaning to a skilled artisan. Accordingly, at least "a portion" of the 14-hydroxy in the API must be "derived from" 8α. Further, at least a portion of the 8α-derived 14-hydroxy must be so derived during the conversion of oxycodone free base to oxycodone hydrochloride. (Crimmins Tr. 796; Wuest Tr. 562.) The specification supports this construction, noting in the "Background of the Invention" section that "[d]uring conversion of the oxycodone free base to oxycodone hydrochloride, the impurity undergoes acid-catalyzed dehydration and is converted into [14-hydroxy]." '799 Patent at 2:2–5. If no 8α-derived 14-hydroxy present in the oxycodone hydrochloride were derived "during conversion of oxycodone free base to oxycodone hydrochloride," a central feature of the claim would be absent from the product.

Nonetheless, Purdue contends that any conversion of 8α to 14-hydroxy before the formation of the final oxycodone hydrochloride API is within the scope of the claims. Purdue's construction simply replaces the words "during conversion of oxycodone free base to oxycodone hydrochloride" with the words "at any time before the formation of the final oxycodone hydrochloride API." The Court must interpret the patent "as written, not as the patentees wish they had written it." *Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004). Neither the claim itself nor the specification supports the swap Purdue proposes.

That the specification discloses that "it may be necessary to perform . . . one or more relevant steps in the process of the present invention[] more than once" does not discredit a plain-language interpretation of the phrase "during conversion of." '799 Patent at 8:38–44. First, the Court notes that the only process step in the '799 Patent is the phrase "is derived from [8α] during conversion of oxycodone free base to oxycodone hydrochloride." Purdue does not explain why a repetition of that process step would fall

outside the limiting language "during conversion of." Second, the Court rejects Purdue's attempt to reverse-engineer claim 3 to read on "[a]nother alternative process . . . for preparing an oxycodone hydrochloride composition comprising reacting an oxycodone base composition with an acid having a higher pH than hydrochloric acid to form a corresponding acid addition salt of oxycodone, and converting the acid addition salt of oxycodone to oxycodone hydrochloride." '800 Patent at 8:66–9:4. This embodiment does not specify when 8α converts to 14-hydroxy. In any event, "[i]t is not necessary that each claim read on every embodiment." *Baran v. Med. Device Techs., Inc.*, 616 F.3d 1309, 1316 (Fed. Cir. 2010). Here, the preferred embodiments, the description of the invention, and the expert testimony all tilt in favor of reading the language of the claim to mean what it says.

In addition, Purdue unmistakably distinguished prior art during the prosecution of the patents by reference to the point in a synthesis scheme at which the 14-hydroxy would form:

> Furthermore, one skilled in the art would have expected that the **oxycodone hydrochloride salt** prepared from the **oxycodone free base** of the Chiu patent . . . would also have no [14-hydroxy], as there is nothing in the Chiu patent to suggest that [14-hydroxy] would reappear during hydrochloride salt formation.

(PTX 10 at P1052961–62 (emphasis original).)

Purdue's statements to the Examiner support the reading that the words "during conversion of oxycodone free base to oxycodone hydrochloride" do not mean "at any time before the formation of the final oxycodone hydrochloride salt." Rather, Purdue distinguished Chiu on the grounds that Chiu did not appreciate 14-hydroxy's reappearance "during hydrochloride salt formation." (*Id.*; *cf.* Crimmins Tr. 800:4–6 ("conversion during the HCL [hydrochloride] formation would not be expected to create any 14-[hydroxyl] based on the Chiu patent").) Thus, the patent prosecution history confirms the plain meaning of the limitation expressed in the '799 Patent (claim 3).

b. The '072 Patent (claim 1) does not require the presence of 8α at any particular process step.

The '072 Patent (claim 1) states that the API contains less than 25 ppm of 14-hydroxy "wherein at least a portion of the 14-[hydroxy] is derived from 8α." '072 Patent at 34:59–60. The language of the claim indicates that any 14-hydroxy derived from 8α would satisfy the "derived from" element. The claim does not limit when or how that derivation occurs. As the differences in their language suggest, the '072 Patent (claim 1) does not contain the "during conversion" limit found in the '799 Patent (claim 3). Thus, this claim reads on the alternative embodiment emphasized by Purdue with respect to the '799 claim and does so naturally. '072 Patent at 8:66–9:7.

Defendants urge the Court to conclude that Purdue limited claim '072 (claim 1) during prosecution by making arguments substantially identical to those made in support of the claims of the '799 Patent. The Court agrees with defendants that the statements to the Examiner emphasized the importance of 14-hydroxy's formation from 8α during the hydrochloride salt-formation step. (*E.g.*, PTX 11 at P1034313.) Nonetheless, the Court cannot conclude that the Purdue's statements amounted to a "clear and unmistakable" disavowal of claim scope. *See Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1374–75 (Fed. Cir. 2008). Unlike the circumstance of the '799 Patent, where Purdue's statements to the Examiner supported the ordinary meaning of its claim language, those same statements do not convince the Court that Purdue intended to relinquish the more broadly written claims of the '072 Patent.

* * *

Accordingly, claim 3 of the '799 Patent requires (1) an oral dosage form (2) containing "from about 5 mg to about 320 mg of oxycodone hydrochloride" API, (3) the presence in the oxycodone hydrochloride of more than zero and less than 25 ppm 14-hydroxy, (4) some of which must have been derived from 8α "during conversion of oxycodone free base to oxycodone hydrochloride," and (5) a pharmaceutically acceptable excipient. Claim 19 depends from claim 3, and therefore incorporates its elements, but further calls for the "acceptable excipient" to be a "sustained release carrier."

Claim 1 of '072 Patent requires (1) oxycodone hydrochloride API, (2) containing more than zero and less than 25 ppm 14-hydroxy, and (3) some of the 14-hydroxy present in the API must have been derived from 8α. Dependent claims 4 and 5 incorporate the limitations of claim 1, but specify lower levels of 14-hydroxy (less than 15 ppm and less than 10 ppm, respectively).

4. *The '799 and '072 Patents are products with process limitations*

The parties agree that claim 1 of the 072 Patent and claim 3 of the 799 Patent are limited by their respective wherein clauses. (Pls.' Opening Br. at 39; Defs.' Opening Br. at 5–6.) The parties disagree on the type of limitation those clauses create. Purdue contends that these claims describe a product purely by its structure. Defendants argue that these claims describe a product by the process used to obtain it.[10] The Court agrees with defendants.

Ordinarily, the product claimed by a patent "is not limited to the process by which it was made." *Vanguard Prods. Corp. v. Parker Hannifin Corp.*, 234 F3d 1370, 1372 (Fed. Cir. 2000). Thus, "method of manufacture, even when cited as advantageous, does not of itself convert product claims into claims limited to a particular process." *Id.* A limitation is not a process limitation if, when "read in context, [it] describes the product more by its *structure* than by the *process* used to obtain it." *Hazani v. U.S. Int'l Trade Comm'n*, 126 F.3d 1473, 1479 (Fed. Cir. 1997) (emphasis added); *see also Gemtron Corp. v. Saint-Gobain Corp.*, 572 F.3d 1371, 1379 (Fed. Cir. 2009) ("Defining a structural component by its functional as well as its physical characteristics is different from defining a structure solely by the process by which it is made."); *In re Garnero*, 412 F.2d 276, 279 (C.C.P.A. 1969) (phrase not a process limitation when it is capable of being a structural limitation).

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[10] Construing a claim as a product-by-process claim has two consequences. First, "the defining limitations of a claim . . . are also the terms that show infringement." *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1293 (Fed. Cir. 2009) (en banc). Second, the validity of a claim must be assessed without reference to the claim's process limitations. *Greenliant Sys., Inc. v. Xicor LLC*, 692 F.3d 1261, 1268 (Fed. Cir. 2012).

By contrast, a product-by-process claim is "'one in which the product is defined at least in part in terms of the method or process by which it is made.'" *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 158 n.* (1989) (quoting D. Chisum, Patents § 8.05 at 8-67 (1988)). A patentee can state a claim in product-by-process form by reciting a product and a series of steps by which that product is obtainable. *E.g.*, *Abbott Labs.*, 566 F.3d at 1295. For instance, when "the claimed physical properties of [a product] are attributable to the process that is used to make [it]," the claim is to a product made by a process. *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1372 (Fed. Cir. 2007).

The phrase "derived from 8α" in the '799 and '072 Patents does not describe the structure of 14-hydroxy. To a skilled artisan—indeed, to anyone—14-hydroxy is 14-hydroxy, whether its source is 8α or 8β. (Heathcock Tr. 1124–26; Wuest Tr. 1342–43 (hydrogenating 14-hydroxy produces the same result regardless of the source of the 14-hydroxy).) As a structural description, the phrase "derived from 8α" is meaningless. For example, the specification sets out a method for detecting 14-hydroxy without regard to its source. *E.g.*, '799 Patent at Examples 4 & 6. And the specification includes no embodiment where the described hydrogenation process changes depending on the source of the 14-hydroxy being hydrogenated. *E.g.*, '799 Patent at 6:59–7:55. Indeed, the written description defines 8,14-dihyroxy as 8α or 8β or a mixture of the two. '799 Patent at 5:54–57. The common specification gives no indication that 8α imparts some quality to 14-hydroxy.

Although the phrase "derived from 8α" cannot describe a structural feature of 14-hydroxy, it does describe the process used to obtain a particular molecule of 14-hydroxy. To a skilled artisan, the "derived from" language indicates a "chemical reaction is occurring where one chemical entity is being converted into another chemical entity." (Crimmins Tr. 808.) By focusing on 8α, rather than 8β, the plain language of the claims indicates the relevant starting material for the chemical reaction is 8α and not 8β. (Crimmins Tr. 808.) The "derived from" limitation therefore modifies the claims by excluding processes for obtaining 14-hydroxy that would not cause the acid-catalyzed dehydration of some 8α molecules. Reading these claims as product-by-process claims accords with the common specification's disclosure of process conditions under which

acidifying oxycodone free base will cause 8α to convert into 14-hydroxy. *E.g.*, '072 Patent at Figure 2 & Example 3. The prosecution history does not suggest otherwise.

In addition to the "derived from" limitation, the '799 Patent (claim 3) includes a further limitation: some conversion from 8α to 14-hydroxy must occur "during conversion of oxycodone free base to oxycodone hydrochloride." A skilled artisan would understand this limitation to be a process limitation specifying when at least a portion of the 14-hydroxy must be obtained from 8α. (Crimmins Tr. 808.) Purdue does not contend, nor does the Court find, that any structural or physical characteristic of 14-hydroxy that could be described by reference to the process step at which a molecule has been formed.

In sum, describing 14-hydroxy by reference to its chemical precursors, 8α and 8β, does not say anything about a structural component of 14-hydroxy, its physical characteristics, or its functional capacity. Instead, the claim language limits 14-hydroxy to that obtained by a process using 8α. These conditions do not describe a structural limitation. A skilled artisan would know nothing more about the structure of a 14-hydroxy molecule if he or she knew that 8α had been the molecule's source.

Nonetheless, Purdue contends that the Court should construe the "is derived from" language according to the rule that "[l]imitations . . . expressed in the past tense, have been found to be structural, not product-by-process." (Pls.' Opening Br. at 39.) But the "is derived from" language of the '072 and '799 claims is in the passive voice of the present tense—it is not a past tense verb. Moreover, the ultimate inquiry is whether the "is derived from" limitation "describes the product more by its structure [or] by the process used to obtain it." *Hazani*, 126 F.3d at 1479. Whatever tense or mood expressed in the patent, the phrase "is derived from" in the '799 Patent (claim 3) and '800 Patent (claim 1) has meaning only because it excludes from the claim processes that do not obtain any 14-hydroxy from 8α and, for the '799 Patent, that do not obtain any 14-hydroxy from 8α during the oxycodone hydrochloride formation step.

Last, the Court notes that the Federal Circuit has sometimes identified particular process-type phrases as "source limitations." *See, e.g., Amgen Inc. v. F. Hoffman-La Roche Ltd*, 580 F.3d 1340, 1366–67 (Fed. Cir. 2009); *Amgen*

Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1328–30 & n.5 (Fed. Cir. 2003). Applying that label to the phrase "derived from 8α" would have no practical effect on the action. The evidence conclusively demonstrates that a molecule of 14-hydroxy has no feature that can be attributed to its source. This distinguishes 8α and 8β from the human and non-human EPO at issue in the *Amgen* cases. There, the Federal Circuit concluded that a claim limited to EPO derived from "non-human" sources did not create a process limitation. *See Hoechst*, 314 F.3d at 1329. But as the Court later explained, human and non-human EPO exhibit "differences in carbohydrate composition." *Hoffman-La Roche*, 580 F.3d at 1367. Here the "derived from 8α" limitation adds no patentable significance to the product and is therefore irrelevant to show nonobviousness and novelty. "[A] claimed product shown to be present in the prior art cannot be rendered patentable solely by the addition of source or process limitations." *Hoechst*, 314 F.3d at 1354 n.20; *see also Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 373–74 (1938); *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1317–19 (Fed. Cir. 2006).

* * *

The Court has construed the '072 and '799 Patents to contain process limitations. The disputed phrase "derived from 8α" cannot be understood as a product limitation. By contrast, it can be understood to limit the processes by which the product may be obtained.

5. ***All patents: "detectable" amounts of 14-hydroxy and 8α are not required***

Defendants urge the Court to impose a limitation on all claims that the relevant levels of 14-hydroxy and 8α be at "detectable levels." The Court does not accept that requirement. Such a limitation would serve only to exclude methods of proving infringement other than by experimental detection. Neither the claim language nor the specification supports such a construction. The words "detectable levels" never appear in the patent claims or specification, and defendants do not point to any aspect of the prosecution history that would support such a reading. Defendants' best argument is that the specification discloses a method for detecting 14-hydroxy. But the disclosure of that method does not indicate that the inventors surrendered other methods of demonstrating the presence of 14-

hydroxy or 8α and thereby narrowed the scope of their claims. *See Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1333 (Fed. Cir. 2010).

IV. CONCLUSION

These patents will now proceed to trial. On the basis of the claim construction set forth above, the Court will determine whether defendants' ANDAs infringe the Abuse-Proof and Low-ABUK Patents and whether these patents are valid.

Dated: New York, New York
August 23, 2013

SO ORDERED:

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

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re: OXYCONTIN ANTITRUST LITIGATION	04 Md. 1603 (SHS)
PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., RHODES TECHNOLOGIES, and GRÜNENTHAL GMBH, Plaintiffs, -against- AMNEAL PHARMACEUTICALS, LLC, Defendant.	This document relates to: 11 Civ. 8153 (SHS)
PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., and RHODES TECHNOLOGIES, Plaintiffs, -against- EPIC PHARMA, LLC, Defendant.	13 Civ. 683 (SHS)
PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., RHODES TECHNOLOGIES, BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM, and GRÜNENTHAL GMBH, Plaintiffs, -against- IMPAX LABORATORIES, INC., Defendant.	11 Civ. 2400 (SHS)

PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., RHODES TECHNOLOGIES, BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM, and GRÜNENTHAL GMBH, Plaintiffs, -against- PAR PHARMACEUTICAL, INC., Defendant.	11 Civ. 2038 (SHS)
PURDUE PHARMA L.P and GRÜNENTHAL GMBH, Plaintiffs, -against- PAR PHARMACEUTICAL, INC., Defendant.	12 Civ. 5615 (SHS)
PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., RHODES TECHNOLOGIES, BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM, and GRÜNENTHAL GMBH, Plaintiffs, -against- SANDOZ INC., Defendant.	11 Civ. 4694 (SHS) 12 Civ. 897 (SHS)

PURDUE PHARMA L.P. and GRÜNENTHAL GMBH, Plaintiffs, -against- SANDOZ INC., Defendant.	12 Civ. 5082 (SHS) 12 Civ. 7582 (SHS)
PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., RHODES TECHNOLOGIES, and GRÜNENTHAL GMBH, Plaintiffs, -against- TEVA PHARMACEUTICALS, USA, INC., Defendant.	11 Civ. 2037 (SHS)
PURDUE PHARMA L.P. and GRÜNENTHAL GMBH, Plaintiffs, -against- TEVA PHARMACEUTICALS, USA, INC., Defendant.	12 Civ. 5083 (SHS)

CLAIM CONSTRUCTION OPINION & ORDER

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

This Hatch-Waxman Act litigation concerns the brand-name drug OxyContin, which is manufactured and sold by plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., and Rhodes Technologies (collectively, "Purdue"). Defendants—Amneal Pharmaceuticals, LLC; Epic Pharma, LLC; Impax Laboratories, Inc.; Par Pharmaceutical, Inc.; Sandoz Inc.; and Teva Pharmaceuticals, USA, Inc.—have filed Abbreviated New Drug Applications ("ANDAs") seeking to sell generic versions of OxyContin. Plaintiffs contend that defendants' ANDAs infringe six patents that claim the OxyContin formulation currently sold in the United States. Purdue, as well as plaintiffs the Board of Regents of the University of Texas System and Grünenthal GmbH (collectively with Purdue, "plaintiffs"), developed these patents to address two undesirable features of the original formulation of OxyContin. First, original OxyContin contained significant levels of 14-hydroxycodeinone, which belongs to a class of compounds known as ABUKs—alpha, beta unsaturated ketones—that may be genotoxic or carcinogenic. Second, original OxyContin tablets were often abused by snorting or injecting crushed or dissolved tablets.

The six patents that address these issues fall into two groups. Three are the "Abuse-Proof Patents":

- U.S. Patent No. 6,488,963 ("'963 Patent") (Rabenstein Decl., Ex. A)
- U.S. Patent No. 7,763,314 ("'314 Patent") (Rabenstein Decl., Ex. B)
- U.S. Patent No. 8,114,383 ("'383 Patent") (Rabenstein Decl., Ex. C)

And the other three are the "Low-ABUK Patents":

- U.S. Patent No. 7,674,799 ("'799 Patent") (PTX 2)[1]
- U.S. Patent No. 7,674,800 ("'800 Patent") (PTX 3)

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[1] The parties have incorporated the record of the trial held in *Purdue Pharma, L.P., et al. v. Ranbaxy, Inc., et al.*, No. 10 Civ. 3734, into this claim-construction proceeding. (Pls.' Opening Br. at 31 n.7; Defs.' Opening Br. at 3 n.3.)

- U.S. Patent No. 7,683,072 ("'072 Patent") (PTX 4)

On July 15, 2013, the Court held a consolidated *Markman* hearing to construe the disputed portions of the claims at issue in each of the patents listed above. This opinion and order is the result.

I. General Legal Standard

"[T]he claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quotation marks omitted). "The words of a claim are generally given their ordinary and customary meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Medtronic Inc. v. Boston Scientific Corp.*, 695 F.3d 1266, 1275 (Fed. Cir. 2012) (quotation marks and alterations omitted). "Claims, however, must be construed in light of the appropriate context in which the claim term is used." *Aventis Pharm. Inc. v. Amino Chems. Ltd.*, 715 F.3d 1363, 1373 (Fed. Cir. 2013). That context includes the specification, which "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (quotation marks omitted). "The prosecution history too, as part of the intrinsic record, has an important role in claim construction by supplying context to the claim language." *Aventis*, 715 F.3d at 1373.

The Court will set aside the rule that claim terms receive their ordinary and customary meaning in just two circumstances: "1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution." *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, No. 2012-1567, 2013 WL 3836240, at *7 (Fed. Cir. July 26, 2013) (quotation marks omitted). "A disclaimer must be clear and unmistakable, and unclear prosecution history cannot be used to limit claims." *Cordis Corp. v. Boston Scientific Corp.*, 561 F.3d 1319, 1329 (Fed. Cir. 2009) (quotation marks omitted).

With these legal principles in mind, the Court addresses the disputed claims, first in the Abuse-Proof Patents, then in the Low-ABUK Patents.

II. THE ABUSE-PROOF PATENTS

A. Background

The FDA first approved the sale of OxyContin tablets in 1995. *See* Determination that the OXYCONTIN (Oxycodone Hydrochloride) Drug Products Covered by New Drug Application 20-553 Were Withdrawn from Sale for Reasons of Safety or Effectiveness, 78 Fed. Reg. 23,273, 23,273 (Apr. 18, 2013) [hereinafter "FDA Determination"]. In approximately 2000, Purdue began receiving reports that its original OxyContin tablets were being abused. (Rabenstein Decl., Ex. 1 at 46.) The vast majority of abuse consisted of users swallowing too many pills. (*Id.* at 46.) Some abusers, however, were crushing the tablets and then either snorting them or, after dissolving the crushed tablets in a small amount of liquid, injecting them intravenously. (*Id.* at 44–46.)

As a result of these reports, Purdue began to take steps to make its tablets resistant to abuse. (*Id.* at 47, 49.) Purdue's early efforts centered on combining OxyContin's active pharmaceutical ingredient ("API") with other agents to block the effects of snorting or injecting the drug. (*Id.* at 49–52.) These avenues turned out to be dead ends. (*Id.* at 73; Rabenstein Decl., Ex. 4 at 0265164.)

Purdue thus began to look for third-party solutions to reduce abuse. In mid-2004, Purdue representatives visited the offices of Grünenthal in Germany for a demonstration of a prototype abuse-deterrent tablet. (Rabenstein Decl., Ex. 5 at PRF2704014–15.) The prototype tablet was very hard and difficult to crush. (*Id.* at PRF2704015.) The tablet also contained hydrogel, which made the tablet difficult to dissolve in water. (*Id.*) And if snorted, the hydrogel would "cause significant nasal discomfort, similar to nasal congestion from a cold or flu." (*Id.*) By November 2004, Purdue believed that Grünenthal's tablet "appear[ed] to be superior" to "all of the non-agonist abuse resistant technologies" that Purdue knew about. (Rabenstein Decl., Ex. 6 at PRF2699737.) Purdue and Grünenthal began negotiations about a possible licensing agreement in late 2004 and early 2005. (Rabenstein Decl., Ex. 7 at 178, 182.)

Also in 2004–2005, Purdue had an in-house team working on crush-resistant tablets. (Rabenstein Decl., Ex. 8 at 43–44.) In November 2005, scientists at Purdue experimented with tablet formulations that included a

high-molecular-weight form of polyethylene oxide ("PEO") as one of the components. (Rabenstein Decl., Ex. 8 at 78–79, 154; Rabenstein Decl., Ex. 20.) Purdue scientists found that if tablets containing PEO were put through a "curing step" of melting the tablet then cooling it, the resulting tablet became exceptionally hard. (Rabenstein Decl., Ex. 8 at 208.) Purdue scientists also found that if the tablets containing PEO were crushed and then mixed with water, the mixture formed a gel-like substance. (Rabenstein Decl., Ex. 8 at 403.)

Purdue's development of the PEO-based tablet led them to file New Drug Application ("NDA") 22-272, an updated version of the original OxyContin. Original OxyContin was the subject of NDA 20-553. The FDA approved NDA 22-272 in April 2010. *See* FDA Determination, 78 Fed. Reg. at 23,273. The drug that references NDA 22-272, so-called "Reformulated OxyContin," is now the only form of OxyContin that Purdue sells in the United States. (Rabenstein Decl., Ex. 14 at 40–41.)

Once Purdue was committed to moving forward with the PEO-based tablets, Purdue entered into licensing agreements with Grünenthal (Rabenstein Decl., Ex. 7 at 192) and the University of Texas System. *E.g.*, *Purdue Pharma L.P. v. Sandoz Inc.*, No. 12 Civ. 897, Dkt. No. 1 ¶ 15. Those two entities had applied for and received the three Abuse-Proof Patents in suit.

B. Construction of the Disputed Claims in the '963 Patent

The '963 Patent is a product of the research of Dr. James McGinty, a professor at the University of Texas at Austin, and one of his then-graduate students, Fen Zhang. McGinty and Zhang were researching whether high-molecular-weight PEO tablets could be made using a heat-based system. The particular method they explored was known as "hot-melt extrusion." Several steps went into McGinty and Zhang's hot-melt extrusion process. First, a powdered form of a therapeutic compound was mixed with high-molecular-weight PEO. '963 Patent at 8:8–11. This mixture was then placed into a machine called an extruder. *Id.* at 8:17–19. The mixture then passed through the heated area of the extruder at a temperature sufficient to melt or soften the PEO. *Id.* at 8:19–22. The softened mixture exited the extruder through a die, after which the mixture could be sliced into tablets. *Id.* at 8:22–28, 13:10–11.

Only two of the '963 Patent's six claims are at issue in this litigation. Plaintiffs assert that defendants' ANDAs infringe claim 6, which depends from claim 1. These two claims recite:

> 1. A non-film controlled release pharmaceutical formulation comprising an effective amount of a therapeutic compound and a high molecular weight poly(ethylene oxide), wherein the poly(ethylene oxide) has a molecular weight of about 1,000,000 to about 10,000,000 Daltons, and wherein the poly(ethylene oxide) and the therapeutic compound comprise a ratio of poly(ethylene oxide) to therapeutic compound of from about 99.99:.01 weight percent to about 50:50 weight percent.
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> 6. The non-film controlled release pharmaceutical formulation of claim 1 wherein said formulation is prepared by a process of hot-melt extrusion.

'963 Patent at 14:26–34, 51–53. The parties dispute the meaning of just two terms, both of them in claim 1. First, the parties contest the meaning of the term "non-film controlled release pharmaceutical formulation." Second, the parties dispute the meaning of the weight-ratio term of claim 1.

1. *The final formulation cannot be a film or comprised of layered films*

The parties first dispute the meaning of the preamble of claim 1: "non-film controlled release pharmaceutical formulation . . . ." All agree that this preamble limits the claims. (Pls.' Opening Br. at 10 n.4.) The dispute centers on the scope of the term "non-film." Defendants argue that this term means that the claimed formulation cannot, in its final form, be a film. Plaintiffs contend that the term "non-film" is broader (and thus that the claims are narrower). According to them, "non-film" means that the final formulation is not a film or made of films.

The term "non-film" is not defined in the claims, and the specification discusses it only briefly. In the "Field of the Invention" section of the '963 Patent, the inventors recite that the invention relates to PEO-based formulations "that are not film-like preparations." '963 Patent at 1:13. The use of the term "film-like" suggests that the invention excludes a broader class of final formulations than simple films. In addition, none of the

examples discloses a preparation in which the final formulation is made of films.

Neither the inventors nor the Examiner discussed the non-film term in any detail during prosecution. However, prior art cited to the Examiner demonstrates that, to those skilled in the art, the term "film" has both a broad and a narrow definition. *See ArcelorMittal France v. AK Steel Corp.*, 700 F.3d 1314, 1321–22 (Fed. Cir. 2012) ("[W]hen an inventor's understanding of a claim term is expressed in the prior art, it can be evidence of how those skilled in the art would have understood that term at the time of the invention." (quotation marks and citations omitted)). In particular, the inventors cited U.S. Patent No. Re. 33,093, known as "Schiraldi," which teaches a "controlled-releasing medicament-containing preparation for intra-oral use." (Rabenstein Decl., Ex. G at 7101, 1:12–14.) The principal form of the invention was "a very thin extruded thermoplastic film (which can be in single layer or laminated multi-layer form)." (*Id.* at 1:15–17.) The Schiraldi patent goes on to claim such a "single or multi-layered thin film." (*Id.* at 7105, 9:41–42.) "Mooney," another piece of prior art cited during prosecution (*id.* at 7195), also discloses formulations made of multiple layers extruded one onto the other. (*Id.* at 7206.) Mooney labels these preparations "multilayered films." (*Id.*) Mooney and Schiraldi thus make clear that the term "film" can be used to mean (and is used in the art to mean) alternatively: (1) single-layer films, or (2) the broader category of films, which encompasses single and multi-layered films.

The parties have also presented the Court with extrinsic sources—not cited in the '963 Patent or during prosecution—that shed some light on the meaning of "film." One article, known as "Apicella," teaches PEO-based "tablets" made by layering films. *See* A. Apicella et al., *Poly(ethylene oxide) (PEO) and different molecular weight PEO blends monolithic devices for drug release*, 24 Biomaterials 83, 83, 86 (1993) (Rabenstein Resp. Decl., Ex. 7). Specifically, Apicella teaches preparing polymer films containing an API, layering these films, then compression molding the layers at 75° C "to form sheets from which were cut circular tablets." *Id.* at 86. In other words, Apicella made a formulation comprised of layered films and called that formulation a "tablet." At the same time, however, Apicella never

explicitly states that its tablet does not also fall within the broader meaning of the term "film."

Plaintiffs point to an article known as "Kim" that characterized Apicella as teaching that "drug release from un-cross-linked low molecular weight PEO of MW = 0.6×10^6 (laminated films) ensures a constant release rate by achieving synchronized gel thickness." Cherng-ju Kim, *Drug Release from Compressed Hydrophilic POLYOX-WSR Tablets*, 84 J. Pharm. Sci. 303, 303 (1995) (Rabenstein Resp. Decl., Ex. 8). The parenthetical makes clear that Kim understood Apicella to teach "laminated films."

In light of all the available evidence, the Court concludes that one skilled in the art would read "non-film" to mean "not a film or comprised of layered films."[2] The prior art cited during prosecution make clear that film has both a broad and a narrow meaning. Layered films—even layered films that are heated—fall within the broader meaning of "film." And the use of the term "film-like" in the specification of the '963 Patent conclusively demonstrates that when the inventors claimed the term "non-film," they meant the broader meaning of that term. Since "film," as that word is used in claim 1, encompasses layered films, then the term "non-film" cannot encompass them. The ambiguous extrinsic evidence cannot overcome what is clear from the specification and cited prior art. As such, the Court will read the term "A non-film controlled release pharmaceutical formulation . . ." as "A controlled release pharmaceutical formulation, which, in its final form, is not a film or comprised of layered films . . . ."

2. *The final formulation must contain at least 50% PEO by weight*

The parties next dispute the weight-ratio term of claim 1, which provides that the PEO and API in the formulation shall "comprise a ratio of [PEO] to [API] of from about 99.99:.01 weight percent to about 50:50

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[2] The inclusion of the "Rippie" reference in the '963 Patent demonstrates that the inventors did not mean to exclude formulations in which a film was merely used at some intermediate step. *See* '963 Patent at 14:2; E.G. Rippie & J.R. Johnson, *Regulation of Dissolution Rate by Pellet Geometry*, 58 J. Pharm. Sci. 428, 429 (1969) (Prutzman Decl., Ex. 18).

weight percent." The parties agree that this term requires that the PEO and API be present in the final formulation in a ratio, by weight, of about 99.99:.01 to about 50:50. They disagree whether this term requires that the final formulation contain some minimum amount of PEO, measured by weight. Plaintiffs argue that the weight-ratio term specifies that the formulation comprises at least 50% PEO by weight. (Pls.' & Defs.' Proposed Constructions for Claim Terms at 1; Hearing Tr. 19.) Defendants assert that the plain meaning of the term contains no such limitation.

The Court agrees that a skilled artisan would not ordinarily understand the weight-ratio term to limit the amount of PEO in the final formulation. However, during prosecution, the inventors clearly and explicitly limited their invention to a final formulation in which PEO comprises at least 50% by weight.

a. The Inventors Limited Their Invention During Prosecution

As originally filed in March 1999, the application for the '963 Patent contained two claims (3 and 10) that specified a ratio of PEO to therapeutic compound. (Rabenstein Decl., Ex. G at 6907–08.) Claim 3 specified that the PEO and therapeutic compound would "comprise a ratio of from about 99.99:01 [sic] % wt. to about 80:20 % wt." (*Id.* at 6907.) Claim 10 specified that the PEO and therapeutic compound would be included in the formulation "in a ratio of about 99.99:0.01 to about 80:20% wt." (*Id.* at 6908.)

In May 2000, the Examiner rejected all of the proposed claims. Among other reasons, the Examiner rejected claims 1–18 as anticipated by U.S. Patent No. 4,629,621, referred to as "Snipes '621," which teaches formulations containing high-molecular-weight PEO in amounts up to 2%. (*Id.* at 7097.) The Examiner did not simply reject the claims, he gave the inventors a roadmap for overcoming this objection: "Applicants may overcome Snipes '621," he noted, "by specifying % PEO *with respect to the total composition*." (*Id.* (emphasis added).)

The inventors responded in October 2000. In their updated application, the inventors cancelled claims 3 and 10—the claims with the PEO ratios—and transposed the ratio term into amended claims 1 and 9. (*Id.* at 7111–13.) Although the inventors changed the placement of the ratio terms, they did not change their language—amended claims 1 and 9 contained

identical language to original claims 3 and 10, respectively. The inventors explained these amendments as follows: "The Examiner has recommended the specification of the percent [PEO] to distinguish the compositions over Snipes '621. Applicants have incorporated language in the amended claims that provide further definition of the formulation." (*Id.* at 7115.)

In January 2001, however, the Examiner once again rejected all of the proposed claims, including amended claims 1 and 9. (*Id.* at 7139–40.) This time, the Examiner stated that claims 1 and 9 were rejected as anticipated by U.S. Patent No. 4,764,378, known as "Keith." (*Id.* at 7141.) Keith, similar to Snipes '621, taught a composition comprising less than 50% high-molecular-weight PEO. (*Id.*)

In April 2001, the inventors submitted their final amendment. Claim 9 was left unchanged, but the inventors did alter claim 1 in two ways. First, the inventors replaced the term "% wt." with "weight percent," and second they also replaced the term "80:20" with "50:50." (*Id.* at 7150.) The inventors explained why the newly amended claim 1 was not anticipated by either Keith or Snipes '621. (*Id.* at 7147–48.) In Keith, PEO in amounts from 1% to 40% was given as one possible polymer to "'adjust the matrix'" of the formulation. (*Id.* at 7147.) By contrast, "[i]n the amended Claims to the present invention, *the percentage of PEO is never less than 50%.*" (*Id.* (emphasis added).) The inventors further argued that, "[s]imilarly, *Snipes* '621 teaches the use of PEO up to 2%, while *the present invention never contains less than 50%, as amended in this Response.*" (*Id.* at 7148 (emphasis added).)

The April 2001 amendment was successful. In August of that year, the Examiner allowed claim 1, with the amended term "weight percent" and its amended ratio of "50:50." (*Id.* at 7151–52.) But the Examiner again rejected claim 9—the claim whose language had not changed since the original application. (*Id.*)

The prosecution history clearly demonstrates that the inventors disclaimed embodiments of the '963 Patent that contain less than 50% PEO in the final formulation. The Examiner suggested that the inventors make this precise change to overcome Snipes '621 and the inventors complied in two ways. First, they amended the language of claim 1 to replace "% wt." with "weight percent" and the term "80:20" with "50:50." Second, they

explained this amendment as confirming that "the present invention never contains less than 50% [PEO], as amended in this Response." These direct responses to the Examiner's direct request constitute a "clear and unmistakable disavowal of scope" on the part of the inventors. *Purdue Pharma L.P. v. Endo Pharm. Inc.*, 438 F.3d 1123, 1136 (Fed. Cir. 2006); *see Regents of Univ. of Cal. v. Dakocytomation Cal., Inc.*, 517 F.3d 1364, 1373 (Fed. Cir. 2008); *Norian Corp. v. Stryker Corp.*, 432 F.3d 1356, 1362 (Fed. Cir. 2005). Defendants argue that the inventors' statements were not clear enough to constitute prosecution disclaimer. But it would be difficult for the inventors to speak more clearly than "the present invention never contains less than 50% [PEO], as amended in this Response." This statement is as clear, if not clearer, than other statements made during prosecution that the Federal Circuit has held to constitute a disclaimer. *See, e.g., ERBE Elektromedizin GmbH v. Canady Tech. LLC*, 629 F.3d 1278, 1285–86 (Fed. Cir. 2010); *Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1376–77 (Fed. Cir. 2008).

Defendants also assert that the inventors' statement does not refer to the amount of PEO in the final formulation. In order to accept this reading, however, the Court must blind itself to the uncontested fact that the Examiner himself requested that the inventors specify the "% PEO *with respect to the total composition*." (Rabenstein Decl., Ex. G at 7097 (emphasis added).) Moreover, the inventors clearly stated that the "*invention* never contains less than 50%" PEO. As all parties agree, the invention is a "non-film controlled release pharmaceutical formulation"—in other words, a final formulation. Defendants' arguments fail to dislodge the inventors' clear prosecution disclaimer.

b. The Intrinsic Evidence Does Not Overcome the Prosecution Disclaimer

The text of the '963 Patent does not change the impact of the inventors' clear prosecution disclaimer. In fact, plaintiffs find a good deal of support there. The claimed invention in the '963 Patent is a "controlled release pharmaceutical formulation." '963 Patent at 14:26–27. The specification makes clear that the amount of PEO in the final formulation greatly affects the tablet's controlled release properties. As the inventors stated, "[t]he amount of PEO used in the formulation will depend upon . . . [the] desired

release profile [among] other such reasons." '963 Patent at 3:57–65. Figure 1 teaches that altering the molecular weight of the PEO "affects the release profile of the formulation." '963 Patent at 4:13. The "Field of the Invention" section emphasizes that "[t]he present invention relates to the field of [PEO] based hot-melt extrudable pharmaceutical formulations . . . ." '963 Patent at 1:10–12. These portions from the specification strongly suggest that the final formulation must contain a minimum amount of PEO in order for the formulation to have the claimed controlled release properties. Further, none of the embodiments of the invention set forth in the specification contains less than 50% PEO in the formulation as a whole. Indeed, the smallest amount of PEO in any of the examples is 54% and the median amount of PEO is 81%. '963 Patent at 13:30–45.

Defendants, however, urge that the Court's construction impermissibly limits too many other portions of the '963 Patent. For example, claim 2 claims the formulation of claim 1 with the addition of a plasticizer. '963 Patent at 14:35–36. With three ingredients, the final formulation cannot at the same time have at least 50% PEO and have the ratio of PEO to API be 50:50. Defendants are correct that claim 2 does not claim the full scope of claim 1's weight-ratio range, because an exact 50:50 ratio is unavailable. They are incorrect, however, that this limitation presents a conflict. "It does not follow that because" claim 1 encompasses at least 50% PEO and a PEO to API ratio of at least 50:50, "its dependent claims must also be broad enough to encompass" both of these embodiments. *Am. Piledriving Equip., Inc. v. Geoquip, Inc.*, 637 F.3d 1324, 1335 (Fed. Cir. 2011). Dependent claim 2 need not cover the entirety of claim 1's ratio term.

Defendants also point to two portions of the '963 Patent that indicate that formulations with less than 50% PEO would still be covered by the asserted claims. The weight-ratio term from claim 1 claims ratios from "about 99.99:.01 to *about* 50:50," and one portion of the specification states: "When present, the relative amount of plasticizer used may be expressed by the ratio high molecular weight PEO % wt.:plasticizer % wt., and will generally fall in the range of about 100:0 to about 60:40. The amount of plasticizer will generally not exceed the amount of PEO." '963 Patent at 5:24–28. These passages suggest that some embodiments would contain less than 50% PEO yet still be contemplated by claim 1 and the

specification. But these isolated passages must be read in the context of the clear and unmistakable prosecution disclaimer. *See Solvay S.A. v. Honeywell Int'l, Inc.*, 622 F.3d 1367, 1385 (Fed. Cir. 2010). That explicit disclaimer mandates the Court's conclusion.

In the end, the specification and other claims do not alter the fact that the inventors disclaimed final formulations with less than 50% PEO. The Court will therefore construe the term "wherein the poly(ethylene oxide) and the therapeutic compound comprise a ratio of poly(ethylene oxide) to therapeutic compound of from about 99.99:.01 weight percent to about 50:50 weight percent" to read "wherein the poly(ethylene oxide) and the therapeutic compound comprise a ratio, by weight, of poly(ethylene oxide) to therapeutic compound of from about 99.99:.01 to about 50:50, with the poly(ethylene oxide) comprising at least 50% of the formulation."

* * *

The Court therefore construes claim 1 to read as follows:

> 1. A controlled release pharmaceutical formulation, which is not a film or comprised of layered films, comprising an effective amount of a therapeutic compound and a high molecular weight poly(ethylene oxide), wherein the poly(ethylene oxide) has a molecular weight of about 1,000,000 to about 10,000,000 Daltons, and wherein the poly(ethylene oxide) and the therapeutic compound comprise a ratio, by weight, of poly(ethylene oxide) to therapeutic compound of from about 99.99:.01 to about 50:50, with the poly(ethylene oxide) comprising at least 50% of the formulation.

C. Construction of the Disputed Claims in the '314 Patent

In the early 2000s, once reports of abuse of opioid drugs became common, researchers at Grünenthal began investigating ways to deter abusers from injecting intravenously the API from oral tablets. (Davies Decl. ¶ 39.) Johannes Bartholomäus and Henrich Kugelmann developed a product in which a "solid dosage form" would include a "viscosity-increasing agent." '314 Patent at 1:8–11. If the solid dosage form were crushed and mixed with liquid, the combination would form a gel that would "remain[] visually distinguishable even after being introduced into a further quantity of aqueous liquid" and passing through a syringe. *Id.* at

1:14–16. This result was intended to have two effects. First, the resulting gel, with its "turbid appearance, [would] provide[] the potential abuser with an additional optical warning and discourage[] him/her from administering the gel parenterally." *Id.* at 6:6–9. Second, if the abuser is not put off by the turbid appearance, "[i]ntravenous administration of such an extract would most probably result in obstruction of blood vessels, associated with serious embolism or even death of the abuser." *Id.* at 2:31–33.

The '314 Patent contains 12 claims, but the only claims in issue are independent claim 1 and dependent claims 2, 6, and 9. Of these, the parties only dispute terms from claim 1, which reads as follows:

> 1. A parenteral abuse-proofed solid dosage form for oral administration, comprising, in addition to one or more active ingredients with potential for abuse selected from the group consisting of opiates, opioids, tranquillizers, stimulants and narcotics, at least one viscosity-increasing agent in a quantity equal to or greater than 5 mg per dosage form and such that an aqueous extract obtained from the dosage form with 10 ml of water at 25° C. forms a gel which can still pass through a needle having a diameter of 0.9 mm and remains visually distinguishable when introduced by a needle into a further quantity of an aqueous liquid.

'314 Patent at 11:66–12:31. Two terms are at issue in this opinion. First, the parties dispute the meaning of "parenteral abuse-proofed." (Parenteral refers to any way of getting a substance into one's body other than orally.) Second, the parties contest the proper meaning of the term "visually distinguishable" or "remains visually distinguishable."[3]

1. *"Parenteral abuse-proofed" means "reduced potential for parenteral abuse"*

The preamble of claim 1 recites: "[a] parenteral abuse-proofed solid dosage form for oral administration." Once again, the parties agree that

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[3] Defendants also argue that the claims at issue in the '314 Patent are indefinite, and thus invalid. *See* 35 U.S.C. § 112(b). The Court declines to rule on this issue prior to trial.

this preamble limits the claim. (Pls.' Opening Br. at 10 n.4.) The parties disagree on the meaning of the term "parenteral abuse-proofed." Plaintiffs assert that this term means "reduced potential for parenteral abuse," while defendants claim that it means "preventing parenteral abuse under any circumstances." (Pls.' Opening Br. at 19; Defs.' Opening Br. at 33.) The Court agrees with plaintiffs' interpretation.

The Court begins with the plain meaning of the term. Defendants urge that the plain meaning unambiguously favors their interpretation. They point to Webster's dictionary, which defines the suffix "-proof" as "sometimes distinguished from *resistant*" (D'Amore Decl., Ex. 20), and "bulletproof" as "impenetrable to bullets." (D'Amore Decl., Ex. 21.) A bulletproof jacket, defendants argue, may not stop all bullets however large they might be, but it guarantees protection against *some* bullets. (Hearing Tr. 52.) Similarly, they assert that "parenteral abuse-proofed" does not connote that the claimed formulation will prevent any and all abuse—but it does claim that the invention will stop parenteral abuse.

"[J]udges may 'rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents.'" *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 429 F.3d 1364, 1375 (Fed. Cir. 2005) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1322–23 (Fed. Cir. 2005)) (quotation marks omitted). In this case, defendants' dictionaries do not unambiguously support their position. The Webster's reference explicitly states that the suffix -proof is only *sometimes* distinguished from resistant. But even if the dictionary definition were clear and unambiguous, the intrinsic evidence of the '314 Patent shows that one skilled in the art would not understand "abuse-proofed" in the manner defendants suggest. The inventors made clear in the specification that the object of the invention "has been achieved by the provision of the solid dosage form according to the invention with *at least reduced potential* for parenteral abuse . . . ." '314 Patent at 1:66–2:1 (emphasis added). "At least reduced potential for parenteral abuse" is a far cry from preventing all parenteral abuse.

The inventors' discussion of the prior art during prosecution also reveals that one skilled in the art would not read "abuse-proofed" as strictly as defendants suggest. In response to one of the Examiner's many rejections of the '314 Patent, the inventors commented that the "abuse-

proofing" of two pieces of prior art "proceed[] on a fundamentally different principle." (PRF0007668.) But neither of these pieces of prior art—international patent application WO 99/32120, known as "Palermo," and U.S. Patent No. 4,070,494 ("'494 Patent")—teaches abuse-proofing in the manner defendants suggest. Palermo claims a "method of *reducing* the abuse potential of an oral dosage form of an opioid analgesic," WO 99/32120 at 1, 42 (emphasis added), and the '494 Patent teaches improvements to "*inhibit or prevent* the abuse of the agent through parenteral injection." '494 Patent at 1:18–20 (emphasis added). Moreover, when the inventors distinguished Palermo to the Examiner, they did so by comparing their invention with the particular method Palermo employed to achieve its abuse-reducing potential. (PRF0007629–30; PRF0007665–68; PRF0007710.) The inventors never distinguished Palermo on the basis that it did not teach "abuse-proofing" as defendants interpret that term.

The Court therefore concludes that one skilled in the art would understand "abuse-proofed" to mean a "reduced potential for abuse."

2. ***The patentees defined "visually distinguishable"***

Claim 1 of the '314 Patent provides that the gel formed by mixing the claimed dosage form with water "remains visually distinguishable when introduced by a needle into a further quantity of an aqueous liquid." The parties dispute what the "remains visually distinguishable" term means.

"In construing the terms of a patent, the court must [] examine the specification to determine whether the patentee used the claim term consistent with its ordinary meaning or acted as his own lexicographer in defining the term." *Glaxo Grp. Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1346 (Fed. Cir. 2004). If the patentee does act as his own lexicographer, the definition provided "offers practically incontrovertible directions about claim meaning." *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1288 (Fed. Cir. 2009) (en banc). Put another way, "[i]f the special meaning of claim language [provided by the patentee] is reasonably clear and precise, the court's role in claim construction is to pronounce that meaning as the acquired meaning of the word used in the claim." Herbert F. Schwartz & Robert J. Goldman, Patent Law & Practice 153 (7th ed. 2011).

As plaintiffs admit, "the inventors explicitly defined 'visually distinguishable' in the specification." (Pls.' Opening Br. at 20.) Defendants

agree. (Defs.' Opening Br. at 20.) The portion of the specification that defines "visually distinguishable" reads:

> For the purposes of the present invention, visually distinguishable means that the active ingredient-containing gel formed by extraction from the dosage form with the assistance of a necessary minimum quantity of aqueous liquid, when introduced with a hypodermic needle with a diameter of 0.9 mm into a further quantity of aqueous liquid at 37° C., remains substantially insoluble and cohesive and cannot straightforwardly be dispersed in such a manner that it can safely be administered parenterally, in particular intravenously. The material preferably remains visually distinguishable for at least one minute, preferably for at least 10 min.
>
> The increase in viscosity of the gel with the assistance of the selected viscosity-increasing agent means that, although this has been rendered more difficult, the gel may still be passed through a needle or injected. It also means that when the resultant extract or gel is introduced at 37° C. into a further quantity of aqueous liquid, for example also by injection into blood, a largely cohesive thread is initially obtained which, while it may be broken up into smaller fragments by mechanical action, it cannot be dispersed or even dissolved in such a manner that it may safely be administered parenterally, in particular intravenously.

'314 Patent at 2:9–30. The Court must employ the definition supplied by the inventors.

Plaintiffs, however, take the position that even though the patentees acted as their own lexicographers, the Court should read into this definition additional glosses from the patent's examples. Specifically, plaintiffs suggest deleting the term "largely cohesive thread" (that forms when the gel extract is injected into the further quantity of liquid) and replacing it with "thread or thread-like fragments." (Pls.' Resp. Br. at 20.) Plaintiffs also suggest importing a requirement that the "broken up" threads be visible to the naked eye, and that the "mechanical action" be narrowed to mean "stirred." (*Id.* at 20.) Ultimately, plaintiffs "don't want to be litigating the question of the adverbs" contained in the patentees' own definition of "visually distinguishable." (Hearing Tr. 46.)

Plaintiffs simply ask the Court to do an end run around the patentees' own definition. Once the inventor acts as his own lexicographer, that definition overrules the traditional tools of claim construction. *See 3M Innovative Props. Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1374 (Fed. Cir. 2003). The scattered references to "thread-like fragments" in the '314 Patent's examples do not overcome the "practically incontrovertible directions" of the patentees' own definition. *Abbott Labs.*, 566 F.3d at 1288. Because the patentees set out their own definition, their "lexicography governs." *Phillips*, 415 F.3d at 1316.[4]

* * *

For these reasons, the Court construes claim 1 of the '314 Patent to read as follows:

> 1. A solid dosage form for oral administration with reduced potential for parenteral abuse, comprising, in addition to one or more active ingredients with potential for abuse selected from the group consisting of opiates, opioids, tranquillizers, stimulants and narcotics, at least one viscosity-increasing agent in a quantity equal to or greater than 5 mg per dosage form and such that an aqueous extract obtained from the dosage form with 10 ml of water at 25° C. forms a gel which can still pass through a needle having a diameter of 0.9 mm and, when introduced by such a needle into a further quantity of an aqueous liquid at 37° C., a largely cohesive thread is initially obtained which, while it may be broken up into smaller fragments by mechanical action, remains substantially insoluble and cohesive and cannot straightforwardly be dispersed in such a manner that it can safely be administered parenterally, in particular intravenously.

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[4] At oral argument, plaintiffs cautioned the Court against adopting a construction of "visually distinguishable" that defendants argued was indefinite. (Hearing Tr. 62.) But defendants argue that this term is indefinite based on allegedly missing steps in the visually distinguishable test. (Defs.' Opening Br. at 28.) Plaintiffs' proffered construction simply glosses some of the words in the patentees' own definition—it does not address the issue of the allegedly missing steps. (Pls.' Opening Br. at 20–23.) Thus, even if the Court adopted plaintiffs' proposed construction, that decision would not resolve defendants' indefiniteness argument.

D. Construction of the Disputed Claims in the '383 Patent

In the early 2000s, scientists at Grünenthal investigated whether they could make a tablet that would be difficult to crush—a first step before the drug can be snorted by an abuser—but at the same time be able to release the tablet's API when swallowed whole. '383 Patent at 1:16–39, 1:64–2:6; Davies Decl. ¶¶ 53–54. Three Grünenthal scientists—Johannes Bartholomäus, Heinrich Kugelmann, and Elisabeth Arkenau-Marić—succeeded in developing a tablet with a breaking strength of 500 Newtons, more than double a person's average chewing force. (Davies Decl. ¶¶ 53–55.) The claimed invention achieved this goal by including a polymer in the tablet formulation and exposing that formulation to heat and pressure. '383 Patent at 21:2–14.

Plaintiffs allege that defendants' ANDAs infringe five of the '383 Patent's nine claims: independent claim 1 and dependent claims 2, 5, 7, and 8. The parties, though, only dispute the meaning of two terms in claim 1. That claim recites:

> 1. A thermoformed dosage form comprising:
>
> i) one or more active ingredients with abuse potential (A) selected from the group consisting of opiates and opioids,
>
> ii) optionally physiologically acceptable auxiliary substances (B),
>
> iii) at least 30% by weight of polyalkylene oxide (C) having a molecular weight of 1-15 million according to rheological measurements, and
>
> iv) optionally at least one wax (D),
>
> wherein said dosage form has a breaking strength of at least 500 N and wherein the active ingredient with abuse potential (A) is present in a controlled release matrix of component (C).

Id. at 21:2–22:14. The two terms in dispute are "thermoformed dosage form" and "breaking strength of at least 500 N."

1. *"Thermoformed dosage form" means pressure with preceding or simultaneous application of heat*

The preamble of independent claim 1 claims a "thermoformed dosage form."[5] The parties agree that "thermoforming" encompasses formulations made by applying pressure with preceding or simultaneous application of heat. They disagree whether thermoforming can also encompass the application of pressure with *subsequent* heat—plaintiffs claim that it does, defendants disagree. The Court holds that the term "thermoform" does not include subsequent heat.

The Court begins with the claims of the '383 Patent, but the claims do not settle the parties' dispute. Plaintiffs do not assert that thermoforming bears a plain, ordinary meaning among those skilled in the art. Defendants, though, argue that thermoforming does have such a meaning—one that excludes subsequent heat. In support, defendants cite numerous general purpose and technical dictionaries and treatises. (Amiji Decl., Exs. D–H.) These extrinsic sources "'can shed useful light on the relevant art,' [but] this court considers such evidence 'less significant than the intrinsic record in determining the legally operative meaning of claim language.'" *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1362 (Fed. Cir. 2008) (quoting *Phillips*, 415 F.3d at 1317). At a minimum, defendants' dictionaries do establish that plaintiffs' proposed definition would be an outlier among these other lay and specialized meanings.

While claim 1 does not define "thermoformed," dependent claim 5 appears to provide some context. Claim 5 claims a process for producing the dosage form of claim 1, involving "mixing" the components specified in claim 1, "and, optionally after granulation, press-forming the mixture with preceding, simultaneous, or subsequent exposure to heat." '383 Patent at 22:6–8. Plaintiffs point out that dependent claim 5 must fit within the scope of claim 1. Plaintiffs are correct, *see Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n.9 (Fed. Cir. 1989), but this does not end the analysis. Even if "thermoform" does not encompass subsequent heat, claim 1 does not exclude dosage forms that include a subsequent heating step—provided that the dosage form was already "thermoformed." The

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[5] The parties again agree that the preamble limits claim 1. (Defs.' Opening Br. at 41 n.17.)

preamble of claim 1 is linked to the substantive claim language by the open-ended term "comprising." *See, e.g., In re Skvorecz*, 580 F.3d 1262, 1267 (Fed. Cir. 2009). Therefore, a dosage form that is thermoformed according to defendants' construction can still undergo a subsequent heating step and fit within the confines of claim 1. Claim 5 merely spells out this possibility.[6]

The Court next turns to the specification of the '383 Patent. The inventors did not take the opportunity in the specification to act as their own lexicographer, but the specification is replete with examples of thermoforming. None of the numbered examples discloses a method that involves a subsequent application of heat—every one of them utilizes pressure with either simultaneous or preceding heat. In fact, the specification discusses subsequent applications of heat only once, in column 11:

> 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. The mixture may, for example, be formed into tablets by direct tabletting. In direct tabletting with simultaneous exposure to heat, the tabletting tool, i.e. bottom punch, top punch and die are briefly heated at least to the softening temperature of the polymer (C) and pressed together. *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.*

'383 Patent at 11:16–28 (emphasis added). Plaintiffs naturally cite this passage and urge that any definition of thermoforming that excludes subsequent heat would exclude this preferred embodiment of the invention. Plaintiffs once again correctly state the law, *see SynQor, Inc. v. Artesyn Techs., Inc.*, 709 F.3d 1365, 1378–79 (Fed. Cir. 2013), but misconstrue the patent.

The disclosed method of direct tableting with subsequent heat makes clear that after the formed tablets are heated, they are "cooled *again*." The

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[6] Defendants claim that the entire press-forming step of claim 5 is optional. They are incorrect. The term "optionally" in claim 5 modifies "after granulation."

emphasized word means what it says—the tablets formed by this method had already been cooled, meaning they had already been heated. In other words, the tablets had already been thermoformed before they were subjected to subsequent heat.

Plaintiffs belittle this point, but do nothing to reduce its impact. They argue that defendants' reliance on the word "again" is nothing more than an attempt to summon up a "hidden previous heating step." (Pls.' Resp. Br. at 27 n.21.) Plaintiffs, though, have no better explanation for the word. They contend that "cooled again" means that the tablet is cooled to its original temperature. (*See id.*) But this reading simply deletes the word "again," or else has it modify something other than the verb "are . . . cooled."

Finally, the Court turns to the prosecution history. During prosecution, the inventors did not discuss the precise term "thermoform." The inventors did, however, repeatedly stress to the Examiner the importance to their invention of simultaneous pressure and heat. For example, in response to the Examiner's first rejection of all proposed claims, the inventors emphasized that "[t]he 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." (PRF0008744 (emphasis added).) The inventors repeated this point word-for-word in response to the Examiner's second rejection. (PRF0008828.)

Plaintiffs counter that even when the inventors stressed the simultaneous application of heat and pressure, they still cited portions of the application that discussed subsequent heating. This ambiguity may militate against a finding of prosecution disclaimer, but it does not detract from the thrust of the inventors' representations to the Examiner. Pressure and heat, applied together, were the crucial elements of the invention.

The claims and specification make clear that if the formulation is subjected to heat after it has already been pressed, that formulation must have already been "thermoformed." Pressure and prior or simultaneous heat are simply the essence of the claimed invention, as the inventors repeatedly stressed to the Examiner. Read in the complete context of the claims, the specification, and the prosecution history, it is plain that a

person of ordinary skill in the art would understand "[a] thermoformed dosage form" to mean "a dosage form that is formed by the application of pressure to the components with the simultaneous or preceding application of heat."[7]

2. *"Breaking strength" means "breaking strength"*

The parties also appear to contest the meaning of the term "a breaking strength of at least 500 N" from claim 1. But on closer inspection, there is no conflict at all. The parties agree that plastic deformation—i.e., squashing—does not constitute "breaking." (Defs.' Resp. Br. at 29.) Plaintiffs also urge that chipping of the color coating would not constitute "breaking." The Court agrees—the product that has "a breaking strength of at least 500 N" is the thermoformed dosage form. No construction of the term "breaking strength" is required.

* * *

For these reasons, the Court will construe claim 1 to read as follows:

> 1. A dosage form that is formed by the application of pressure to the components with the simultaneous or preceding application of heat comprising:
>
> i) one or more active ingredients with abuse potential (A) selected from the group consisting of opiates and opioids,
>
> ii) optionally physiologically acceptable auxiliary substances (B),
>
> iii) at least 30% by weight of polyalkylene oxide (C) having a molecular weight of 1-15 million according to rheological measurements, and
>
> iv) optionally at least one wax (D),
>
> wherein said dosage form has a breaking strength of at least 500 N and wherein the active ingredient with abuse potential (A) is present in a controlled release matrix of component (C).

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[7] This reasoning also compels the Court to conclude that claim 1 is not a product-by-process claim. The thermoforming of the claimed invention imparts structural characteristics to the final dosage form. *See Hazani v. U.S. Int'l Trade Comm'n*, 126 F.3d 1473, 1479 (Fed. Cir. 1997); *In re Garnero*, 412 F.2d 276, 279 (C.C.P.A. 1969).

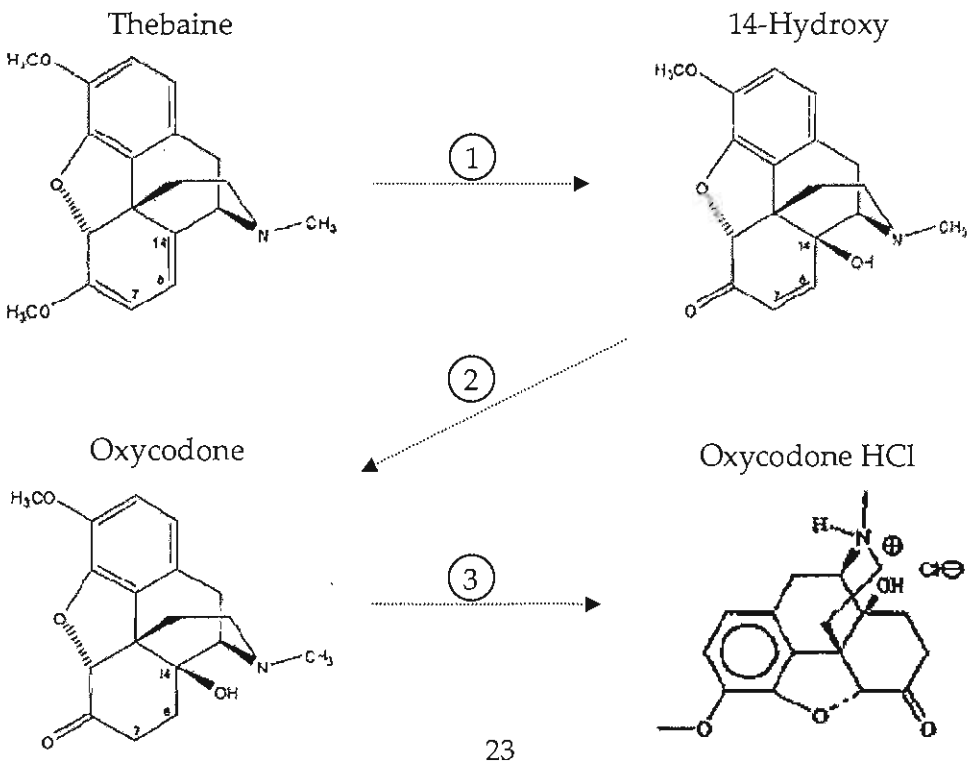
III. THE LOW-ABUK PATENTS

A. Background

1. *Purdue's development of low-ABUK oxycodone*

In 2004, the FDA mandated that manufacturers of oxycodone API—including Purdue and its subsidiary Rhodes—provide information about the impurity 14-hydroxycodeinone ("14-hydroxy"). Among other things, the FDA directed Rhodes to either (1) provide evidence that the level of 14-hydroxy in Rhodes's oxycodone API was safe or (2) lower the level of 14-hydroxy in Rhodes's oxycodone API to less than 10 ppm. (PTX 266.)

By the fall of 2004, Rhodes had developed a method to reduce the amount of 14-hydroxy and submitted an amendment to its drug master file to the FDA. (Kelly Tr. 517–18.) Rhodes's ability to rapidly achieve the FDA's 14-hydroxy purity standard reflected laboratory work undertaken years before the FDA mandate. Rhodes had previously developed a three-step process to synthesize oxycodone from thebaine: (1) Rhodes oxidized thebaine to form 14-hydroxy; (2) Rhodes hydrogenated 14-hydroxy to form oxycodone; and (3) Rhodes added hydrochloric acid to form oxycodone hydrochloride. (Shamblen Tr. 80; Kupper Tr. 124–25.)



In 2001 and 2002, scientists at Rhodes attempted to control levels of 14-hydroxy in the oxycodone API by ensuring that "the hydrogenation reaction from [14-hydroxy] [to] oxycodone free base was run to completion." (Kupper Tr. 129.) After this extended hydrogenation—step two of the method for synthesizing oxycodone—scientists were unable to detect 14-hydroxy in the free base. But after step three—transforming the oxycodone free base into oxycodone hydrochloride—Rhodes's scientists discovered that the 14-hydroxy had returned. (Kupper Tr. 135, 137–38.)

The scientists at Rhodes did not know at first why the 14-hydroxy had reappeared. In a report written in late 2002, though, Rhodes research scientist Lonn Rider hypothesized that the 14-hydroxy present in the API formed due to the dehydration of two impurities, 8α, 14-dihydroxy-7,8-dihydrocodeinone ("8α") and 8β, 14-dihydroxy-7,8-dihydrocodeinone ("8β"). (Kupper Tr. 139–41.) 8α and 8β are diastereomers of 8,14-dihydroxy-7,8-dihydrocodeinone ("8,14-dihydroxy"). As diastereomers, 8α and 8β are two forms of 8,14-dihydroxy: "[t]hey have the same atoms connected to other atoms but they differ in the[] three-dimensional arrangement of the atoms." (Heathcock Tr. 1144; *see also Chapman v. Casner*, 315 F. App'x 294, 295–96 (Fed. Cir. 2009) (discussing 8,14-dihydroxy's stereoisomers).)

Rider's focus on 8,14-dihydroxy reflected two reactions that occur within the Rhodes synthesis process. One, during the first step in the synthesis process, thebaine molecules convert into 14-hydroxy molecules by oxidation. While this reaction principally yields 14-hydroxy, it also produces "several overoxidation products [] in small amounts," including 8,14-dihydroxy. (Kupper Tr. 140.) Two, Rhodes and Rider knew that 8,14-dihydroxy could undergo acid-catalyzed dehydration to form 14-hydroxy. (Heathcock Tr. 1141–42.) Rhodes suspected that the addition of acid at the third manufacturing step was converting the 8,14-dihydroxy to 14-hydroxy. (Kupper Tr. 138.)

After additional experimentation, Rhodes scientists concluded that 8α was the source of the reappearing 14-hydroxy. They then began to consider "methods for controlling the levels of 14-[hydroxy] in oxycodone hydrochloride based on this knowledge." (Rider Tr. 219.) After considering several alternatives, Rhodes "decided that the best course of action . . . would be another hydrogenation step to remove the 14-

[hydroxy] . . . ." (Kupper Tr. 151; Rider Tr. 221.) This second hydrogenation step did not, however, exactly replicate the first. The first, original, hydrogenation step used water and formic acid to produce a formate salt, which was "converted to the free base by an addition of a base of sodium hydroxide." (Rider Tr. 298; Kupper Tr. 151–52.) The newly added second hydrogenation was performed after the free base had been converted to oxycodone hydrochloride. (Rider Tr. 299.) The second hydrogenation converted 14-hydroxy into oxycodone but did not react with previously formed oxycodone hydrochloride. (Rider Tr. 300–01.)

With this method in hand, Rhodes sought approval from the FDA and patent protection for their new method.

2. *Purdue obtains the '799, '800, and '072 Patents*

Purdue and Rhodes attempted to patent their work on low-ABUK oxycodone. This effort concluded in March 2010 when Purdue secured the three Low-ABUK Patents:

- U.S. Patent No. 7,674,799
- U.S. Patent No. 7,674,800
- U.S. Patent No. 7,683,072

Broadly speaking, the '800 Patent claims "a process for preparing an oxycodone salt substantially free of 14-[hydroxy]." '800 Patent at 34:22–23. The '072 Patent claims low-ABUK oxycodone hydrochloride API. '072 Patent at 34:57–60. The '799 Patent claims an "oral dosage form" of low-ABUK oxycodone hydrochloride. '799 Patent at 34:54.

The '799, '800, and '072 Patents continue from an earlier application, No. 11/391,897 ("Chapman application"). The Chapman application continues from the March 30, 2005 application No. 11/093,626, which issued as U.S. Patent No. 7,129,248. The '799 Patent continued as Serial No. 11/653,531 and was issued on March 9, 2010. The '800 Patent continued as Serial No. 11/729,741 and issued on March 9, 2010. The '072 Patent continued as Serial No. 11/653,529 and issued on March 23, 2010.

The Patent Office initially rejected as obvious a number of asserted claims of the patents as they were then drafted. The Examiner paid particular attention to one prior art reference, Chiu, which disclosed a

process for preparing a low-ABUK oxycodone crude base. (PTX 10 at P1052803–04; PTX 11 at P1034148–49; PTX 12 at P1045523–24; DTX 741.) The Examiner also questioned the nonobviousness of the patents on the grounds that 8,14-dihydroxy had been disclosed in the art. Accordingly, the Examiner directed the inventors to explain why prior art regarding 8β did not render obvious claims relating to 8α: "unless applicants provide some unexpected results of 8,14-dihydroxy[] with trans hydroxyl groups as compared to 8,14-dihydroxy[] with cis hydroxyl groups, it would have been obvious to one skilled in the art to prepare Oxycodone salt with reduced amount of 14-hydroxy[] with reasonable expectation of success." (PTX 11 at P1035381–82; Heathcock Tr. 1143.)

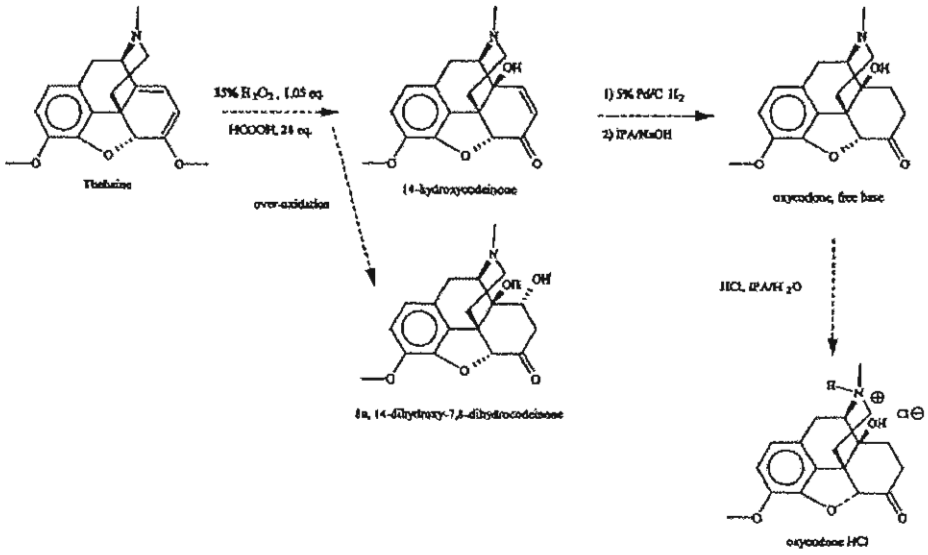
Purdue's response distinguished the prior art based on stereochemistry and the process steps involved in the Chiu reference. As to the stereochemistry, Purdue submitted the declaration of Steven Baldwin, Ph.D., to demonstrate the "unexpected results" of 8α to the Patent Office. Baldwin stated that 8α and 8β are "different compounds and have surprisingly different properties (e.g., reactivities)." (PTX 11 at P1035678; Heathcock Tr. 1143.) As to the Chiu reference, Purdue explained that the prior art reference concerned 14-hydroxy in oxycodone base, not 14-hydroxy that "would reappear during hydrochloride salt formation." (PTX 10 at P1052961–62; Crimmins Tr. 799–800.)

Purdue prevailed. The Examiner approved the patents, in part "due to [Purdue's] persuasive arguments and declaration by Dr. Baldwin." (PTX 10 at P1059552.)

a. The common specification

The '799, '800, and '072 Patents have substantially identical specifications but differ in the nature of the claims. Figure 1 depicts a scheme to synthesize oxycodone hydrochloride from thebaine.

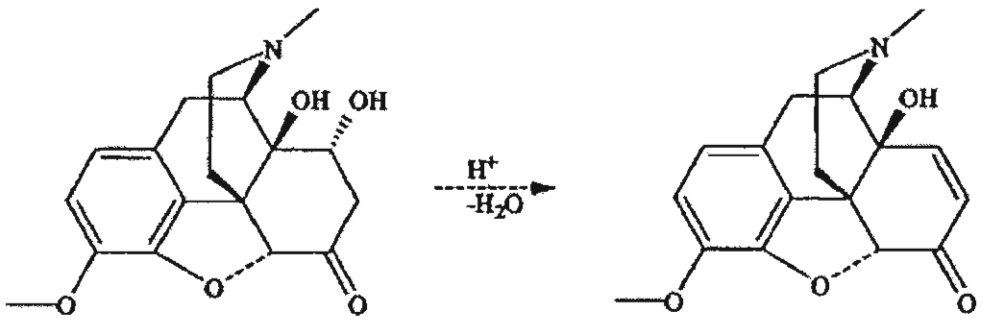
Figure 1



First, thebaine is oxidized to form 14-hydroxy. Second, 14-hydroxy is hydrogenated to form oxycodone free base. Third, the oxycodone free base is acidified to form oxycodone hydrochloride. In addition, Figure 1 depicts the formation of 8α as a result of the overoxidation of thebaine. (Wuest Tr. 554–55, 1253–54.)

Figure 2 depicts the conversion of 8α into 14-hydroxy as a result of dehydration in the presence of acid. *E.g.*, '800 Patent at 6:18–19; Wuest Tr. 1254.

Figure 2



8a,14-dihydroxy-7,8-dihydrocodeinone

14-hydroxycodeinone

The specification states that "[t]he term 8,14-dihydroxy-7,8-dihydrocodeinone includes either 8α,14-dihydroxy-7,8-dihydrocodeinone; or 8β,14-dihydroxy-7,8-dihydrocodeinone or can include a mixture of both compounds." *E.g.*, '800 Patent at 5:54–57.

The description recites the chemical structure of 8α and the nature of the reaction that produces it. For example, the specification states that 8,14-dihydroxy converts to 14-hydroxy "during salt formation reactions known in the art." '800 Patent at 8:4–11. The patents' written description does not explicitly identify conditions that transform 8α, but not 8β, into 14-hydroxy. (*E.g.*, Rider Tr. 278.) The specification also does not disclose a pH range at which 8α will not form. (Rider Tr. 278–79; Wuest Tr. 1330–31.) But Example 3 of the specification demonstrates conditions that suffice to convert 8α into 14-hydroxy. (Wuest Tr. 1258.) Wuest further explained that a skilled artisan "would understand that the 8β compound is essentially inert under [the] conditions [of Example 3] and would not undergo this acid-induced transformation." (Wuest Tr. 1258.) The specification includes no method for detecting 8α. (Kupper Tr. 191; Wuest Tr. 1324–25.)

B. Construction of the Disputed Claims in the Low-ABUK Patents

Purdue has asserted that defendants' ANDAs infringe claims 3 and 19 of the '799 Patent; claims 30–34 and 76–79 of the '800 Patent; and claims 1, 4, and 5 of the '072 Patent. The parties contest the meaning of various claim terms of each patent. Those disputes fit roughly into the following groups:

1) Whether terms of each claim require the presence of 14-hydroxy in the final oxycodone salt
2) Whether the process claims of the '800 Patent encompass processes that involve intermediate salt-formation steps that use salts other than oxycodone hydrochloride
3) Whether the '799 and '072 Patents require 8α to be present in the synthesis process and, if so, whether some portion of it must convert to 14-hydroxy at the final salt formation step
4) Whether the '799 and '072 Patents contain process limitations

5) Whether the presence of 14-hydroxy and 8α must be at "detectable levels"

The Court considers each issue below.

1. *All patents: 14-hydroxy must be present in the final salt*

Defendants urge the Court to construe the '800 Patent (claims 1 & 57), the '072 Patent (claim 1), and the '799 Patent (claim 3) as requiring 14-hydroxy in the final oxycodone salt. The Court adopts this construction.

Purdue does not seriously contest that an infringing product must have some 14-hydroxy present in the final oxycodone salt. After all, if a product had no 14-hydroxy whatsoever, it would have no 14-hydroxy derived from 8α as required by the claims. (Crimmins Tr. 803.) The specification supports this reading because it contains no embodiment where the level of 14-hydroxy is described as zero. To the contrary, Example 6 recites an analytical method "to determine the amount of codeinone and 14-[hydroxy] present." '799 Patent at 31:16–18. Therefore, the Court does not accept that a skilled artisan would understand the phrase "a portion of the [14-hydroxy]" to encompass the absence of 14-hydroxy.[8]

2. *'800 Patent: the final salt must be oxycodone hydrochloride, but the intermediate salt need not be*

Claim 1 of the '800 Patent reads as follows, with emphasis on the disputed claim language:

> A process for preparing *an oxycodone salt substantially free of 14-hydroxycodeinone*, which process comprises steps of:
>
> (a) preparing a mixture of oxycodone free base, solvent and an acid, the oxycodone free base having an 8α,14-dihydroxy-7,8-dihydrocodeinone component;
>
> (b) incubating the mixture under conditions suitable to convert the oxycodone free base to *an oxycodone salt*, wherein said

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[8] As regards the Low-ABUK Patents, a person of ordinary skill in the art is an organic chemist with experience in synthetic and analytical chemistry. The parties do not dispute the qualifications of the skilled artisan as relevant to the Abuse-Proof Patents. (Hearing Tr. 50.)

> conditions promote an acid catalyzed dehydration consisting of conversion of the 8α,14-dihydroxy-7,8-dihydrocodeinone component to 14-hydroxycodeinone; and
>
> (c) preferentially removing the 14-hydroxycodeinone from *the oxycodone salt*.

'800 Patent at 34:22–35. Claim 57 features the same disputed language, but recites step (c) as "reducing an amount of [14-hydroxy] in the oxycodone salt formed in step (b) to produce an oxycodone salt composition having less than 25 ppm [14-hydroxy]." '800 Patent at 37:40–43.

The parties dispute whether the term "an oxycodone salt substantially free of 14-hydroxy" as used in the preamble must be the same salt as the "an oxycodone salt" referred to in step (b) of the body of the claim. The parties further dispute whether claim 1 and claim 57 of the '800 Patent describe *any* oxycodone salt in the preamble and at step (b) or only oxycodone *hydrochloride* salt. The Court does not read the claims to require the oxycodone salt of the preamble to be the same oxycodone salt as in step (b). The Court also will not limit the salts in claims 1 and 57 to hydrochloride salts alone.

a. The preamble refers to an oxycodone salt API

The parties dispute whether the preambles of claim 1 and claim 57 limit the process steps of those claims. They do. "[A] claim preamble has the import that the claim as a whole suggests for it." *Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332, 1339 (Fed. Cir. 2003) (quotation marks omitted).

The claim terms and specification indicate that the preamble constitutes a claim limitation. The phrasing of the preamble "an oxycodone salt substantially free of [14-hydroxy]" comports with the title of the patents, "Oxycodone Hydrochloride Having Less Than 25 ppm 14-Hydroxycodeinone" and discloses various pharmaceutical embodiments. Moreover, the examples in the patent specification show how to analyze the 14-hydroxy levels of the product after the hydrogenation reaction is run and the material is dried. *E.g.*, '800 Patent at 25:17–22, 25:55–60, 26:35–40. The context therefore suggests that their preambles identify and limit the end product of the described process. If the end product is an oxycodone salt API substantially free of 14-hydroxy, as the intrinsic evidence suggests, then the preamble's use of the phrase "an oxycodone

salt substantially free of [14-hydroxy]" must be limiting. Otherwise, the process steps would not achieve that result. The preambles of claims 1 and 57 "recite[] essential structure or steps" of the claims and are otherwise "necessary to give life, meaning, and vitality to the claim." *Am. Med. Sys., Inc. v. Biolitec, Inc.*, 618 F.3d 1354, 1358 (Fed. Cir. 2010) (quotation marks omitted).

This reading also comports with the patent prosecution history. During the prosecution of the '800 Patent, Purdue distinguished its claims to a low-ABUK "oxycodone hydrochloride composition" from the Chiu reference. (PTX 11 at P1034312–14.) Purdue emphasized that Chiu disclosed low-ABUK oxycodone free base and not a low-ABUK salt made from the purified free base. (*Id.*) Because an earlier step in Chiu's process involved an intermediate oxycodone salt mixture, (DTX 741 at Example 6), Purdue's process differed meaningfully from Chiu only in that Purdue's process resulted in an oxycodone salt API and not a crude oxycodone base. That is the very distinction captured by the preamble of claims 1 and 57 and what a skilled artisan would understand by this language. (Wuest Tr. 559.)

b. The phrase "an oxycodone salt substantially free of [14-hydroxy]" has a different meaning than the phrase "an oxycodone salt"

Defendants contend that the Court should construe the preamble's phrase "an oxycodone salt substantially free of [14-hydroxy]" to mean the same thing as "an oxycodone salt" as used in the process steps. The Court does not accept this reading.

"[T]he same terms appearing in different portions of the claims should be given the same meaning unless it is clear from the specification and prosecution history that the terms have different meanings at different portions of the claims." *PODS, Inc. v. Porta Stor, Inc.*, 484 F.3d 1359, 1366 (Fed. Cir. 2007). Here, the intrinsic evidence reveals such a distinction between the two instances of "an oxycodone salt."

- First, the modifying phrase "substantially free of 14-[hydroxy]" limits the term "an oxycodone salt" in the preamble, as compared to the unmodified phrase "an oxycodone salt" used at step (b). The Court presumes that these different phrases carry different

meanings. *See Epcon Gas Sys., Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1030–31 (Fed. Cir. 2002).

- Second, the indefinite article "an" appears before "oxycodone salt" in the preamble and before "oxycodone salt" in the body of the claim. Each use of that article implies that "one or more" oxycodone salts may fit within the claims. *See 01 Communique Lab., Inc. v. LogMeIn, Inc.*, 687 F.3d 1292, 1297 (Fed. Cir. 2012). Defendants' proposed construction thus artificially limits this term.
- Third, the specification discloses an embodiment where the final salt is an API but the process salt is an intermediate. '800 Patent at 8:66–9:7.

Accordingly, the salt of the preamble—the oxycodone API—need not be the salt of step (b). Because the specification identifies differences in meaning between "an oxycodone salt substantially free of 14-[hydroxy]" and "an oxycodone salt," the Court construes them differently. *See Microprocessor Enhancement Corp. v. Texas Instruments Inc.*, 520 F.3d 1367, 1375–76 (Fed. Cir. 2008).

c. The process steps refer to "any oxycodone salt," not necessarily oxycodone hydrochloride

A person of ordinary skill in the art would understand that neither the phrase "an oxycodone salt substantially free of 14-hydroxy" nor the phrase "an oxycodone salt" limit the claims to oxycodone hydrochloride salt. (Wuest Tr. 566; Crimmins Tr. 916; Heathcock Tr. 1135.) The appropriateness of that reading is confirmed by the context of the patent. Claim 31 and claim 77, for example, call for oxycodone *hydrochloride* salt. Because dependent claims 31 and 77 recite a specific type of salt but the independent claims 1 and 57 do not, the doctrine of "claim differentiation" presumes that the independent claims do not contain the limitations of the dependent claims. *See Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 805–06 (Fed. Cir. 2007). The specification supports this meaning because it includes an embodiment where the claimed process involves "reacting an oxycodone base composition with an acid having a higher pH than hydrochloric acid to form a corresponding acid addition salt of

oxycodone" and identifies suitable acids other than hydrochloric acid. '800 Patent at 8:66–9:7.

The specification and prosecution history do not provide a contrary "clear intention" to limit the phrases "an oxycodone salt substantially free of [14-hydroxy]" and "an oxycodone salt" to "oxycodone hydrochloride salt." *Contra Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1290 (Fed. Cir. 2009) (en banc). First, though the specification primarily describes oxycodone hydrochloride compositions, "the written description does not suggest that the invention must be used" in that form. *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1301 (Fed. Cir. 2003). Second, Purdue's statements to the Examiner did not disclaim the use of other oxycodone salts. When Purdue distinguished its claim from the Chiu reference it did not do so on the ground that it claimed an oxycodone *hydrochloride* salt rather than an oxycodone *acetate* salt of Chiu. (PTX 11 at P1034312–14.) Rather, Purdue drew a distinction between a low-ABUK free base and a low-ABUK salt formed from a purified free base. (*Id.*) That Purdue referred to "oxycodone hydrochloride salt" while discussing its proposed claim does not amount to "clear and unmistakable prosecution arguments limiting the meaning of a claim term in order to overcome a rejection." *SanDisk Corp. v. Memorex Prods., Inc.*, 415 F.3d 1278, 1286 (Fed. Cir. 2005). The specific independent claim at issue recited an oxycodone hydrochloride composition. (PTX 11 at P1034313.)

* * *

Accordingly, the Court construes claim 1 of the 800 Patent to require:

(1) A process for preparing an oxycodone salt API substantially free of 14-hydroxy, which process comprises (2) preparing a mixture of oxycodone free base, solvent and an acid, the oxycodone free base having an 8α component; (3) incubating the mixture under conditions suitable to convert the oxycodone free base to any salt of oxycodone, wherein said conditions promote an acid-catalyzed dehydration consisting of conversion of the 8α component to [14-hydroxy]; and (4) preferentially removing the [14-hydroxy] from the oxycodone salt.

The Court construes claim 57 of the '800 Patent the same way, except that element (4) requires "reducing an amount of [14-hydroxy] in the

oxycodone salt formed in step [3] to produce an oxycodone salt composition having less than 25 ppm [14-hydroxy]."

3. ***The '799 Patent requires some 8α to convert to 14-hydroxy at the salt formation step, the '072 Patent does not***

The relevant portions of claim 1 of the '072 Patent read as follows, with emphasis on the disputed claim language:

> An oxycodone hydrochloride active pharmaceutical ingredient having less than 25 ppm 14-hydroxycodeinone *wherein at least a portion of the 14-hydroxycodeinone is derived from 8α, 14-dihydroxy-7,8-dihydrocodeinone.*

'072 Patent at 34:57–60.

The relevant portions of claim 3 of the '799 Patent read as follows, with emphasis on the disputed claim language:

> An oral dosage form comprising: (i) from about 5 mg to about 320 mg of oxycodone hydrochloride active pharmaceutical ingredient having less than 25 ppm 14-hydroxycodeinone, *wherein at least a portion of the 14-hydroxycodeinone is derived from 8α,14-dihydroxy-7,8-dihydrocodeinone during conversion of oxycodone free base to oxycodone hydrochloride;* and (ii) a pharmaceutically acceptable excipient.

'799 Patent at 35:8–15.

The parties dispute whether the '799 Patent (claim 3) and the '072 Patent (claim 1) require the presence of 8α in the oxycodone base and require some 8α to convert to 14-hydroxy at the salt formation step.[9] Defendants' proposed construction advances two additional limitations: (1) the presence of 8α in the oxycodone base and (2) the conversion of some 8α to 14-hydroxy at the salt formation step. The Court concludes that the '799 Patent requires some 8α to convert to 14-hydroxy at the salt formation step and therefore construes the '799 Patent to require 8α in oxycodone base. The Court concludes that the '072 Patent does not have any requirement that 8α convert to 14-hydroxy at any particular process

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[9] The parties agree that the process of the '800 patent requires the presence 8α in the oxycodone base.

step and therefore does not require proof of 8α's conversion at any particular point.

a. The '799 Patent (claim 3) requires the presence of 8α in the oxycodone base.

The '799 Patent (claim 3) states that "at least a portion of the 14-[hydroxy] is derived from 8α[] during conversion of oxycodone free base to oxycodone hydrochloride." The Court construes this phrase according to its plain meaning to a skilled artisan. Accordingly, at least "a portion" of the 14-hydroxy in the API must be "derived from" 8α. Further, at least a portion of the 8α-derived 14-hydroxy must be so derived during the conversion of oxycodone free base to oxycodone hydrochloride. (Crimmins Tr. 796; Wuest Tr. 562.) The specification supports this construction, noting in the "Background of the Invention" section that "[d]uring conversion of the oxycodone free base to oxycodone hydrochloride, the impurity undergoes acid-catalyzed dehydration and is converted into [14-hydroxy]." '799 Patent at 2:2–5. If no 8α-derived 14-hydroxy present in the oxycodone hydrochloride were derived "during conversion of oxycodone free base to oxycodone hydrochloride," a central feature of the claim would be absent from the product.

Nonetheless, Purdue contends that any conversion of 8α to 14-hydroxy before the formation of the final oxycodone hydrochloride API is within the scope of the claims. Purdue's construction simply replaces the words "during conversion of oxycodone free base to oxycodone hydrochloride" with the words "at any time before the formation of the final oxycodone hydrochloride API." The Court must interpret the patent "as written, not as the patentees wish they had written it." *Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004). Neither the claim itself nor the specification supports the swap Purdue proposes.

That the specification discloses that "it may be necessary to perform . . . one or more relevant steps in the process of the present invention[] more than once" does not discredit a plain-language interpretation of the phrase "during conversion of." '799 Patent at 8:38–44. First, the Court notes that the only process step in the '799 Patent is the phrase "is derived from [8α] during conversion of oxycodone free base to oxycodone hydrochloride." Purdue does not explain why a repetition of that process step would fall

outside the limiting language "during conversion of." Second, the Court rejects Purdue's attempt to reverse-engineer claim 3 to read on "[a]nother alternative process . . . for preparing an oxycodone hydrochloride composition comprising reacting an oxycodone base composition with an acid having a higher pH than hydrochloric acid to form a corresponding acid addition salt of oxycodone, and converting the acid addition salt of oxycodone to oxycodone hydrochloride." '800 Patent at 8:66–9:4. This embodiment does not specify when 8α converts to 14-hydroxy. In any event, "[i]t is not necessary that each claim read on every embodiment." *Baran v. Med. Device Techs., Inc.*, 616 F.3d 1309, 1316 (Fed. Cir. 2010). Here, the preferred embodiments, the description of the invention, and the expert testimony all tilt in favor of reading the language of the claim to mean what it says.

In addition, Purdue unmistakably distinguished prior art during the prosecution of the patents by reference to the point in a synthesis scheme at which the 14-hydroxy would form:

> Furthermore, one skilled in the art would have expected that the **oxycodone hydrochloride salt** prepared from the **oxycodone free base** of the Chiu patent . . . would also have no [14-hydroxy], as there is nothing in the Chiu patent to suggest that [14-hydroxy] would reappear during hydrochloride salt formation.

(PTX 10 at P1052961–62 (emphasis original).)

Purdue's statements to the Examiner support the reading that the words "during conversion of oxycodone free base to oxycodone hydrochloride" do not mean "at any time before the formation of the final oxycodone hydrochloride salt." Rather, Purdue distinguished Chiu on the grounds that Chiu did not appreciate 14-hydroxy's reappearance "during hydrochloride salt formation." (*Id.*; *cf.* Crimmins Tr. 800:4–6 ("conversion during the HCL [hydrochloride] formation would not be expected to create any 14-[hydroxyl] based on the Chiu patent").) Thus, the patent prosecution history confirms the plain meaning of the limitation expressed in the '799 Patent (claim 3).

b. The '072 Patent (claim 1) does not require the presence of 8α at any particular process step.

The '072 Patent (claim 1) states that the API contains less than 25 ppm of 14-hydroxy "wherein at least a portion of the 14-[hydroxy] is derived from 8α." '072 Patent at 34:59–60. The language of the claim indicates that any 14-hydroxy derived from 8α would satisfy the "derived from" element. The claim does not limit when or how that derivation occurs. As the differences in their language suggest, the '072 Patent (claim 1) does not contain the "during conversion" limit found in the '799 Patent (claim 3). Thus, this claim reads on the alternative embodiment emphasized by Purdue with respect to the '799 claim and does so naturally. '072 Patent at 8:66–9:7.

Defendants urge the Court to conclude that Purdue limited claim '072 (claim 1) during prosecution by making arguments substantially identical to those made in support of the claims of the '799 Patent. The Court agrees with defendants that the statements to the Examiner emphasized the importance of 14-hydroxy's formation from 8α during the hydrochloride salt-formation step. (*E.g.*, PTX 11 at P1034313.) Nonetheless, the Court cannot conclude that the Purdue's statements amounted to a "clear and unmistakable" disavowal of claim scope. *See Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1374–75 (Fed. Cir. 2008). Unlike the circumstance of the '799 Patent, where Purdue's statements to the Examiner supported the ordinary meaning of its claim language, those same statements do not convince the Court that Purdue intended to relinquish the more broadly written claims of the '072 Patent.

* * *

Accordingly, claim 3 of the '799 Patent requires (1) an oral dosage form (2) containing "from about 5 mg to about 320 mg of oxycodone hydrochloride" API, (3) the presence in the oxycodone hydrochloride of more than zero and less than 25 ppm 14-hydroxy, (4) some of which must have been derived from 8α "during conversion of oxycodone free base to oxycodone hydrochloride," and (5) a pharmaceutically acceptable excipient. Claim 19 depends from claim 3, and therefore incorporates its elements, but further calls for the "acceptable excipient" to be a "sustained release carrier."

Claim 1 of '072 Patent requires (1) oxycodone hydrochloride API, (2) containing more than zero and less than 25 ppm 14-hydroxy, and (3) some of the 14-hydroxy present in the API must have been derived from 8α. Dependent claims 4 and 5 incorporate the limitations of claim 1, but specify lower levels of 14-hydroxy (less than 15 ppm and less than 10 ppm, respectively).

4. *The '799 and '072 Patents are products with process limitations*

The parties agree that claim 1 of the 072 Patent and claim 3 of the 799 Patent are limited by their respective wherein clauses. (Pls.' Opening Br. at 39; Defs.' Opening Br. at 5–6.) The parties disagree on the type of limitation those clauses create. Purdue contends that these claims describe a product purely by its structure. Defendants argue that these claims describe a product by the process used to obtain it.[10] The Court agrees with defendants.

Ordinarily, the product claimed by a patent "is not limited to the process by which it was made." *Vanguard Prods. Corp. v. Parker Hannifin Corp.*, 234 F3d 1370, 1372 (Fed. Cir. 2000). Thus, "method of manufacture, even when cited as advantageous, does not of itself convert product claims into claims limited to a particular process." *Id.* A limitation is not a process limitation if, when "read in context, [it] describes the product more by its *structure* than by the *process* used to obtain it." *Hazani v. U.S. Int'l Trade Comm'n*, 126 F.3d 1473, 1479 (Fed. Cir. 1997) (emphasis added); *see also Gemtron Corp. v. Saint-Gobain Corp.*, 572 F.3d 1371, 1379 (Fed. Cir. 2009) ("Defining a structural component by its functional as well as its physical characteristics is different from defining a structure solely by the process by which it is made."); *In re Garnero*, 412 F.2d 276, 279 (C.C.P.A. 1969) (phrase not a process limitation when it is capable of being a structural limitation).

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[10] Construing a claim as a product-by-process claim has two consequences. First, "the defining limitations of a claim . . . are also the terms that show infringement." *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1293 (Fed. Cir. 2009) (en banc). Second, the validity of a claim must be assessed without reference to the claim's process limitations. *Greenliant Sys., Inc. v. Xicor LLC*, 692 F.3d 1261, 1268 (Fed. Cir. 2012).

By contrast, a product-by-process claim is "'one in which the product is defined at least in part in terms of the method or process by which it is made.'" *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 158 n.* (1989) (quoting D. Chisum, Patents § 8.05 at 8-67 (1988)). A patentee can state a claim in product-by-process form by reciting a product and a series of steps by which that product is obtainable. *E.g.*, *Abbott Labs.*, 566 F.3d at 1295. For instance, when "the claimed physical properties of [a product] are attributable to the process that is used to make [it]," the claim is to a product made by a process. *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1372 (Fed. Cir. 2007).

The phrase "derived from 8α" in the '799 and '072 Patents does not describe the structure of 14-hydroxy. To a skilled artisan—indeed, to anyone—14-hydroxy is 14-hydroxy, whether its source is 8α or 8β. (Heathcock Tr. 1124–26; Wuest Tr. 1342–43 (hydrogenating 14-hydroxy produces the same result regardless of the source of the 14-hydroxy).) As a structural description, the phrase "derived from 8α" is meaningless. For example, the specification sets out a method for detecting 14-hydroxy without regard to its source. *E.g.*, '799 Patent at Examples 4 & 6. And the specification includes no embodiment where the described hydrogenation process changes depending on the source of the 14-hydroxy being hydrogenated. *E.g.*, '799 Patent at 6:59–7:55. Indeed, the written description defines 8,14-dihyroxy as 8α or 8β or a mixture of the two. '799 Patent at 5:54–57. The common specification gives no indication that 8α imparts some quality to 14-hydroxy.

Although the phrase "derived from 8α" cannot describe a structural feature of 14-hydroxy, it does describe the process used to obtain a particular molecule of 14-hydroxy. To a skilled artisan, the "derived from" language indicates a "chemical reaction is occurring where one chemical entity is being converted into another chemical entity." (Crimmins Tr. 808.) By focusing on 8α, rather than 8β, the plain language of the claims indicates the relevant starting material for the chemical reaction is 8α and not 8β. (Crimmins Tr. 808.) The "derived from" limitation therefore modifies the claims by excluding processes for obtaining 14-hydroxy that would not cause the acid-catalyzed dehydration of some 8α molecules. Reading these claims as product-by-process claims accords with the common specification's disclosure of process conditions under which

acidifying oxycodone free base will cause 8α to convert into 14-hydroxy. *E.g.*, '072 Patent at Figure 2 & Example 3. The prosecution history does not suggest otherwise.

In addition to the "derived from" limitation, the '799 Patent (claim 3) includes a further limitation: some conversion from 8α to 14-hydroxy must occur "during conversion of oxycodone free base to oxycodone hydrochloride." A skilled artisan would understand this limitation to be a process limitation specifying when at least a portion of the 14-hydroxy must be obtained from 8α. (Crimmins Tr. 808.) Purdue does not contend, nor does the Court find, that any structural or physical characteristic of 14-hydroxy that could be described by reference to the process step at which a molecule has been formed.

In sum, describing 14-hydroxy by reference to its chemical precursors, 8α and 8β, does not say anything about a structural component of 14-hydroxy, its physical characteristics, or its functional capacity. Instead, the claim language limits 14-hydroxy to that obtained by a process using 8α. These conditions do not describe a structural limitation. A skilled artisan would know nothing more about the structure of a 14-hydroxy molecule if he or she knew that 8α had been the molecule's source.

Nonetheless, Purdue contends that the Court should construe the "is derived from" language according to the rule that "[l]imitations . . . expressed in the past tense, have been found to be structural, not product-by-process." (Pls.' Opening Br. at 39.) But the "is derived from" language of the '072 and '799 claims is in the passive voice of the present tense—it is not a past tense verb. Moreover, the ultimate inquiry is whether the "is derived from" limitation "describes the product more by its structure [or] by the process used to obtain it." *Hazani*, 126 F.3d at 1479. Whatever tense or mood expressed in the patent, the phrase "is derived from" in the '799 Patent (claim 3) and '800 Patent (claim 1) has meaning only because it excludes from the claim processes that do not obtain any 14-hydroxy from 8α and, for the '799 Patent, that do not obtain any 14-hydroxy from 8α during the oxycodone hydrochloride formation step.

Last, the Court notes that the Federal Circuit has sometimes identified particular process-type phrases as "source limitations." *See, e.g., Amgen Inc. v. F. Hoffman-La Roche Ltd*, 580 F.3d 1340, 1366–67 (Fed. Cir. 2009); *Amgen*

Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1328–30 & n.5 (Fed. Cir. 2003). Applying that label to the phrase "derived from 8α" would have no practical effect on the action. The evidence conclusively demonstrates that a molecule of 14-hydroxy has no feature that can be attributed to its source. This distinguishes 8α and 8β from the human and non-human EPO at issue in the *Amgen* cases. There, the Federal Circuit concluded that a claim limited to EPO derived from "non-human" sources did not create a process limitation. *See Hoechst*, 314 F.3d at 1329. But as the Court later explained, human and non-human EPO exhibit "differences in carbohydrate composition." *Hoffman-La Roche*, 580 F.3d at 1367. Here the "derived from 8α" limitation adds no patentable significance to the product and is therefore irrelevant to show nonobviousness and novelty. "[A] claimed product shown to be present in the prior art cannot be rendered patentable solely by the addition of source or process limitations." *Hoechst*, 314 F.3d at 1354 n.20; *see also Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 373–74 (1938); *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1317–19 (Fed. Cir. 2006).

* * *

The Court has construed the '072 and '799 Patents to contain process limitations. The disputed phrase "derived from 8α" cannot be understood as a product limitation. By contrast, it can be understood to limit the processes by which the product may be obtained.

5. ***All patents: "detectable" amounts of 14-hydroxy and 8α are not required***

Defendants urge the Court to impose a limitation on all claims that the relevant levels of 14-hydroxy and 8α be at "detectable levels." The Court does not accept that requirement. Such a limitation would serve only to exclude methods of proving infringement other than by experimental detection. Neither the claim language nor the specification supports such a construction. The words "detectable levels" never appear in the patent claims or specification, and defendants do not point to any aspect of the prosecution history that would support such a reading. Defendants' best argument is that the specification discloses a method for detecting 14-hydroxy. But the disclosure of that method does not indicate that the inventors surrendered other methods of demonstrating the presence of 14-

hydroxy or 8α and thereby narrowed the scope of their claims. *See Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1333 (Fed. Cir. 2010).

IV. CONCLUSION

These patents will now proceed to trial. On the basis of the claim construction set forth above, the Court will determine whether defendants' ANDAs infringe the Abuse-Proof and Low-ABUK Patents and whether these patents are valid.

Dated: New York, New York
August 23, 2013

SO ORDERED:

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

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re: OXYCONTIN ANTITRUST LITIGATION	04 Md. 1603 (SHS)
PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., RHODES TECHNOLOGIES, and GRÜNENTHAL GMBH, Plaintiffs, -against- AMNEAL PHARMACEUTICALS, LLC, Defendant.	This document relates to: 11 Civ. 8153 (SHS)
PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., and RHODES TECHNOLOGIES, Plaintiffs, -against- EPIC PHARMA, LLC, Defendant.	13 Civ. 683 (SHS)
PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., RHODES TECHNOLOGIES, BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM, and GRÜNENTHAL GMBH, Plaintiffs, -against- IMPAX LABORATORIES, INC., Defendant.	11 Civ. 2400 (SHS)

PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., RHODES TECHNOLOGIES, BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM, and GRÜNENTHAL GMBH, Plaintiffs, -against- PAR PHARMACEUTICAL, INC., Defendant.	11 Civ. 2038 (SHS)
PURDUE PHARMA L.P and GRÜNENTHAL GMBH, Plaintiffs, -against- PAR PHARMACEUTICAL, INC., Defendant.	12 Civ. 5615 (SHS)
PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., RHODES TECHNOLOGIES, BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM, and GRÜNENTHAL GMBH, Plaintiffs, -against- SANDOZ INC., Defendant.	11 Civ. 4694 (SHS) 12 Civ. 897 (SHS)

PURDUE PHARMA L.P. and GRÜNENTHAL GMBH, Plaintiffs, -against- SANDOZ INC., Defendant.	12 Civ. 5082 (SHS) 12 Civ. 7582 (SHS)
PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., RHODES TECHNOLOGIES, and GRÜNENTHAL GMBH, Plaintiffs, -against- TEVA PHARMACEUTICALS, USA, INC., Defendant.	11 Civ. 2037 (SHS)
PURDUE PHARMA L.P. and GRÜNENTHAL GMBH, Plaintiffs, -against- TEVA PHARMACEUTICALS, USA, INC., Defendant.	12 Civ. 5083 (SHS)

CLAIM CONSTRUCTION OPINION & ORDER

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

This Hatch-Waxman Act litigation concerns the brand-name drug OxyContin, which is manufactured and sold by plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., and Rhodes Technologies (collectively, "Purdue"). Defendants—Amneal Pharmaceuticals, LLC; Epic Pharma, LLC; Impax Laboratories, Inc.; Par Pharmaceutical, Inc.; Sandoz Inc.; and Teva Pharmaceuticals, USA, Inc.—have filed Abbreviated New Drug Applications ("ANDAs") seeking to sell generic versions of OxyContin. Plaintiffs contend that defendants' ANDAs infringe six patents that claim the OxyContin formulation currently sold in the United States. Purdue, as well as plaintiffs the Board of Regents of the University of Texas System and Grünenthal GmbH (collectively with Purdue, "plaintiffs"), developed these patents to address two undesirable features of the original formulation of OxyContin. First, original OxyContin contained significant levels of 14-hydroxycodeinone, which belongs to a class of compounds known as ABUKs—alpha, beta unsaturated ketones—that may be genotoxic or carcinogenic. Second, original OxyContin tablets were often abused by snorting or injecting crushed or dissolved tablets.

The six patents that address these issues fall into two groups. Three are the "Abuse-Proof Patents":

- U.S. Patent No. 6,488,963 ("'963 Patent") (Rabenstein Decl., Ex. A)
- U.S. Patent No. 7,763,314 ("'314 Patent") (Rabenstein Decl., Ex. B)
- U.S. Patent No. 8,114,383 ("'383 Patent") (Rabenstein Decl., Ex. C)

And the other three are the "Low-ABUK Patents":

- U.S. Patent No. 7,674,799 ("'799 Patent") (PTX 2)[1]
- U.S. Patent No. 7,674,800 ("'800 Patent") (PTX 3)

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[1] The parties have incorporated the record of the trial held in *Purdue Pharma, L.P., et al. v. Ranbaxy, Inc., et al.*, No. 10 Civ. 3734, into this claim-construction proceeding. (Pls.' Opening Br. at 31 n.7; Defs.' Opening Br. at 3 n.3.)

- U.S. Patent No. 7,683,072 ("'072 Patent") (PTX 4)

On July 15, 2013, the Court held a consolidated *Markman* hearing to construe the disputed portions of the claims at issue in each of the patents listed above. This opinion and order is the result.

I. General Legal Standard

"[T]he claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quotation marks omitted). "The words of a claim are generally given their ordinary and customary meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Medtronic Inc. v. Boston Scientific Corp.*, 695 F.3d 1266, 1275 (Fed. Cir. 2012) (quotation marks and alterations omitted). "Claims, however, must be construed in light of the appropriate context in which the claim term is used." *Aventis Pharm. Inc. v. Amino Chems. Ltd.*, 715 F.3d 1363, 1373 (Fed. Cir. 2013). That context includes the specification, which "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (quotation marks omitted). "The prosecution history too, as part of the intrinsic record, has an important role in claim construction by supplying context to the claim language." *Aventis*, 715 F.3d at 1373.

The Court will set aside the rule that claim terms receive their ordinary and customary meaning in just two circumstances: "1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution." *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, No. 2012-1567, 2013 WL 3836240, at *7 (Fed. Cir. July 26, 2013) (quotation marks omitted). "A disclaimer must be clear and unmistakable, and unclear prosecution history cannot be used to limit claims." *Cordis Corp. v. Boston Scientific Corp.*, 561 F.3d 1319, 1329 (Fed. Cir. 2009) (quotation marks omitted).

With these legal principles in mind, the Court addresses the disputed claims, first in the Abuse-Proof Patents, then in the Low-ABUK Patents.

II. THE ABUSE-PROOF PATENTS

A. Background

The FDA first approved the sale of OxyContin tablets in 1995. *See* Determination that the OXYCONTIN (Oxycodone Hydrochloride) Drug Products Covered by New Drug Application 20-553 Were Withdrawn from Sale for Reasons of Safety or Effectiveness, 78 Fed. Reg. 23,273, 23,273 (Apr. 18, 2013) [hereinafter "FDA Determination"]. In approximately 2000, Purdue began receiving reports that its original OxyContin tablets were being abused. (Rabenstein Decl., Ex. 1 at 46.) The vast majority of abuse consisted of users swallowing too many pills. (*Id.* at 46.) Some abusers, however, were crushing the tablets and then either snorting them or, after dissolving the crushed tablets in a small amount of liquid, injecting them intravenously. (*Id.* at 44–46.)

As a result of these reports, Purdue began to take steps to make its tablets resistant to abuse. (*Id.* at 47, 49.) Purdue's early efforts centered on combining OxyContin's active pharmaceutical ingredient ("API") with other agents to block the effects of snorting or injecting the drug. (*Id.* at 49–52.) These avenues turned out to be dead ends. (*Id.* at 73; Rabenstein Decl., Ex. 4 at 0265164.)

Purdue thus began to look for third-party solutions to reduce abuse. In mid-2004, Purdue representatives visited the offices of Grünenthal in Germany for a demonstration of a prototype abuse-deterrent tablet. (Rabenstein Decl., Ex. 5 at PRF2704014–15.) The prototype tablet was very hard and difficult to crush. (*Id.* at PRF2704015.) The tablet also contained hydrogel, which made the tablet difficult to dissolve in water. (*Id.*) And if snorted, the hydrogel would "cause significant nasal discomfort, similar to nasal congestion from a cold or flu." (*Id.*) By November 2004, Purdue believed that Grünenthal's tablet "appear[ed] to be superior" to "all of the non-agonist abuse resistant technologies" that Purdue knew about. (Rabenstein Decl., Ex. 6 at PRF2699737.) Purdue and Grünenthal began negotiations about a possible licensing agreement in late 2004 and early 2005. (Rabenstein Decl., Ex. 7 at 178, 182.)

Also in 2004–2005, Purdue had an in-house team working on crush-resistant tablets. (Rabenstein Decl., Ex. 8 at 43–44.) In November 2005, scientists at Purdue experimented with tablet formulations that included a

high-molecular-weight form of polyethylene oxide ("PEO") as one of the components. (Rabenstein Decl., Ex. 8 at 78–79, 154; Rabenstein Decl., Ex. 20.) Purdue scientists found that if tablets containing PEO were put through a "curing step" of melting the tablet then cooling it, the resulting tablet became exceptionally hard. (Rabenstein Decl., Ex. 8 at 208.) Purdue scientists also found that if the tablets containing PEO were crushed and then mixed with water, the mixture formed a gel-like substance. (Rabenstein Decl., Ex. 8 at 403.)

Purdue's development of the PEO-based tablet led them to file New Drug Application ("NDA") 22-272, an updated version of the original OxyContin. Original OxyContin was the subject of NDA 20-553. The FDA approved NDA 22-272 in April 2010. *See* FDA Determination, 78 Fed. Reg. at 23,273. The drug that references NDA 22-272, so-called "Reformulated OxyContin," is now the only form of OxyContin that Purdue sells in the United States. (Rabenstein Decl., Ex. 14 at 40–41.)

Once Purdue was committed to moving forward with the PEO-based tablets, Purdue entered into licensing agreements with Grünenthal (Rabenstein Decl., Ex. 7 at 192) and the University of Texas System. *E.g.*, *Purdue Pharma L.P. v. Sandoz Inc.*, No. 12 Civ. 897, Dkt. No. 1 ¶ 15. Those two entities had applied for and received the three Abuse-Proof Patents in suit.

B. Construction of the Disputed Claims in the '963 Patent

The '963 Patent is a product of the research of Dr. James McGinty, a professor at the University of Texas at Austin, and one of his then-graduate students, Fen Zhang. McGinty and Zhang were researching whether high-molecular-weight PEO tablets could be made using a heat-based system. The particular method they explored was known as "hot-melt extrusion." Several steps went into McGinty and Zhang's hot-melt extrusion process. First, a powdered form of a therapeutic compound was mixed with high-molecular-weight PEO. '963 Patent at 8:8–11. This mixture was then placed into a machine called an extruder. *Id.* at 8:17–19. The mixture then passed through the heated area of the extruder at a temperature sufficient to melt or soften the PEO. *Id.* at 8:19–22. The softened mixture exited the extruder through a die, after which the mixture could be sliced into tablets. *Id.* at 8:22–28, 13:10–11.

Only two of the '963 Patent's six claims are at issue in this litigation. Plaintiffs assert that defendants' ANDAs infringe claim 6, which depends from claim 1. These two claims recite:

> 1. A non-film controlled release pharmaceutical formulation comprising an effective amount of a therapeutic compound and a high molecular weight poly(ethylene oxide), wherein the poly(ethylene oxide) has a molecular weight of about 1,000,000 to about 10,000,000 Daltons, and wherein the poly(ethylene oxide) and the therapeutic compound comprise a ratio of poly(ethylene oxide) to therapeutic compound of from about 99.99:.01 weight percent to about 50:50 weight percent.
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> 6. The non-film controlled release pharmaceutical formulation of claim 1 wherein said formulation is prepared by a process of hot-melt extrusion.

'963 Patent at 14:26–34, 51–53. The parties dispute the meaning of just two terms, both of them in claim 1. First, the parties contest the meaning of the term "non-film controlled release pharmaceutical formulation." Second, the parties dispute the meaning of the weight-ratio term of claim 1.

1. *The final formulation cannot be a film or comprised of layered films*

The parties first dispute the meaning of the preamble of claim 1: "non-film controlled release pharmaceutical formulation . . . ." All agree that this preamble limits the claims. (Pls.' Opening Br. at 10 n.4.) The dispute centers on the scope of the term "non-film." Defendants argue that this term means that the claimed formulation cannot, in its final form, be a film. Plaintiffs contend that the term "non-film" is broader (and thus that the claims are narrower). According to them, "non-film" means that the final formulation is not a film or made of films.

The term "non-film" is not defined in the claims, and the specification discusses it only briefly. In the "Field of the Invention" section of the '963 Patent, the inventors recite that the invention relates to PEO-based formulations "that are not film-like preparations." '963 Patent at 1:13. The use of the term "film-like" suggests that the invention excludes a broader class of final formulations than simple films. In addition, none of the

examples discloses a preparation in which the final formulation is made of films.

Neither the inventors nor the Examiner discussed the non-film term in any detail during prosecution. However, prior art cited to the Examiner demonstrates that, to those skilled in the art, the term "film" has both a broad and a narrow definition. *See ArcelorMittal France v. AK Steel Corp.*, 700 F.3d 1314, 1321–22 (Fed. Cir. 2012) ("[W]hen an inventor's understanding of a claim term is expressed in the prior art, it can be evidence of how those skilled in the art would have understood that term at the time of the invention." (quotation marks and citations omitted)). In particular, the inventors cited U.S. Patent No. Re. 33,093, known as "Schiraldi," which teaches a "controlled-releasing medicament-containing preparation for intra-oral use." (Rabenstein Decl., Ex. G at 7101, 1:12–14.) The principal form of the invention was "a very thin extruded thermoplastic film (which can be in single layer or laminated multi-layer form)." (*Id.* at 1:15–17.) The Schiraldi patent goes on to claim such a "single or multi-layered thin film." (*Id.* at 7105, 9:41–42.) "Mooney," another piece of prior art cited during prosecution (*id.* at 7195), also discloses formulations made of multiple layers extruded one onto the other. (*Id.* at 7206.) Mooney labels these preparations "multilayered films." (*Id.*) Mooney and Schiraldi thus make clear that the term "film" can be used to mean (and is used in the art to mean) alternatively: (1) single-layer films, or (2) the broader category of films, which encompasses single and multi-layered films.

The parties have also presented the Court with extrinsic sources—not cited in the '963 Patent or during prosecution—that shed some light on the meaning of "film." One article, known as "Apicella," teaches PEO-based "tablets" made by layering films. *See* A. Apicella et al., *Poly(ethylene oxide) (PEO) and different molecular weight PEO blends monolithic devices for drug release*, 24 Biomaterials 83, 83, 86 (1993) (Rabenstein Resp. Decl., Ex. 7). Specifically, Apicella teaches preparing polymer films containing an API, layering these films, then compression molding the layers at 75° C "to form sheets from which were cut circular tablets." *Id.* at 86. In other words, Apicella made a formulation comprised of layered films and called that formulation a "tablet." At the same time, however, Apicella never

explicitly states that its tablet does not also fall within the broader meaning of the term "film."

Plaintiffs point to an article known as "Kim" that characterized Apicella as teaching that "drug release from un-cross-linked low molecular weight PEO of MW = 0.6×10^6 (laminated films) ensures a constant release rate by achieving synchronized gel thickness." Cherng-ju Kim, *Drug Release from Compressed Hydrophilic POLYOX-WSR Tablets*, 84 J. Pharm. Sci. 303, 303 (1995) (Rabenstein Resp. Decl., Ex. 8). The parenthetical makes clear that Kim understood Apicella to teach "laminated films."

In light of all the available evidence, the Court concludes that one skilled in the art would read "non-film" to mean "not a film or comprised of layered films."[2] The prior art cited during prosecution make clear that film has both a broad and a narrow meaning. Layered films—even layered films that are heated—fall within the broader meaning of "film." And the use of the term "film-like" in the specification of the '963 Patent conclusively demonstrates that when the inventors claimed the term "non-film," they meant the broader meaning of that term. Since "film," as that word is used in claim 1, encompasses layered films, then the term "non-film" cannot encompass them. The ambiguous extrinsic evidence cannot overcome what is clear from the specification and cited prior art. As such, the Court will read the term "A non-film controlled release pharmaceutical formulation . . ." as "A controlled release pharmaceutical formulation, which, in its final form, is not a film or comprised of layered films . . . ."

2. *The final formulation must contain at least 50% PEO by weight*

The parties next dispute the weight-ratio term of claim 1, which provides that the PEO and API in the formulation shall "comprise a ratio of [PEO] to [API] of from about 99.99:.01 weight percent to about 50:50

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[2] The inclusion of the "Rippie" reference in the '963 Patent demonstrates that the inventors did not mean to exclude formulations in which a film was merely used at some intermediate step. *See* '963 Patent at 14:2; E.G. Rippie & J.R. Johnson, *Regulation of Dissolution Rate by Pellet Geometry*, 58 J. Pharm. Sci. 428, 429 (1969) (Prutzman Decl., Ex. 18).

weight percent." The parties agree that this term requires that the PEO and API be present in the final formulation in a ratio, by weight, of about 99.99:.01 to about 50:50. They disagree whether this term requires that the final formulation contain some minimum amount of PEO, measured by weight. Plaintiffs argue that the weight-ratio term specifies that the formulation comprises at least 50% PEO by weight. (Pls.' & Defs.' Proposed Constructions for Claim Terms at 1; Hearing Tr. 19.) Defendants assert that the plain meaning of the term contains no such limitation.

The Court agrees that a skilled artisan would not ordinarily understand the weight-ratio term to limit the amount of PEO in the final formulation. However, during prosecution, the inventors clearly and explicitly limited their invention to a final formulation in which PEO comprises at least 50% by weight.

a. The Inventors Limited Their Invention During Prosecution

As originally filed in March 1999, the application for the '963 Patent contained two claims (3 and 10) that specified a ratio of PEO to therapeutic compound. (Rabenstein Decl., Ex. G at 6907–08.) Claim 3 specified that the PEO and therapeutic compound would "comprise a ratio of from about 99.99:01 [sic] % wt. to about 80:20 % wt." (*Id.* at 6907.) Claim 10 specified that the PEO and therapeutic compound would be included in the formulation "in a ratio of about 99.99:0.01 to about 80:20% wt." (*Id.* at 6908.)

In May 2000, the Examiner rejected all of the proposed claims. Among other reasons, the Examiner rejected claims 1–18 as anticipated by U.S. Patent No. 4,629,621, referred to as "Snipes '621," which teaches formulations containing high-molecular-weight PEO in amounts up to 2%. (*Id.* at 7097.) The Examiner did not simply reject the claims, he gave the inventors a roadmap for overcoming this objection: "Applicants may overcome Snipes '621," he noted, "by specifying % PEO *with respect to the total composition*." (*Id.* (emphasis added).)

The inventors responded in October 2000. In their updated application, the inventors cancelled claims 3 and 10—the claims with the PEO ratios—and transposed the ratio term into amended claims 1 and 9. (*Id.* at 7111–13.) Although the inventors changed the placement of the ratio terms, they did not change their language—amended claims 1 and 9 contained

identical language to original claims 3 and 10, respectively. The inventors explained these amendments as follows: "The Examiner has recommended the specification of the percent [PEO] to distinguish the compositions over Snipes '621. Applicants have incorporated language in the amended claims that provide further definition of the formulation." (*Id.* at 7115.)

In January 2001, however, the Examiner once again rejected all of the proposed claims, including amended claims 1 and 9. (*Id.* at 7139–40.) This time, the Examiner stated that claims 1 and 9 were rejected as anticipated by U.S. Patent No. 4,764,378, known as "Keith." (*Id.* at 7141.) Keith, similar to Snipes '621, taught a composition comprising less than 50% high-molecular-weight PEO. (*Id.*)

In April 2001, the inventors submitted their final amendment. Claim 9 was left unchanged, but the inventors did alter claim 1 in two ways. First, the inventors replaced the term "% wt." with "weight percent," and second they also replaced the term "80:20" with "50:50." (*Id.* at 7150.) The inventors explained why the newly amended claim 1 was not anticipated by either Keith or Snipes '621. (*Id.* at 7147–48.) In Keith, PEO in amounts from 1% to 40% was given as one possible polymer to "'adjust the matrix'" of the formulation. (*Id.* at 7147.) By contrast, "[i]n the amended Claims to the present invention, *the percentage of PEO is never less than 50%.*" (*Id.* (emphasis added).) The inventors further argued that, "[s]imilarly, *Snipes* '621 teaches the use of PEO up to 2%, while *the present invention never contains less than 50%, as amended in this Response.*" (*Id.* at 7148 (emphasis added).)

The April 2001 amendment was successful. In August of that year, the Examiner allowed claim 1, with the amended term "weight percent" and its amended ratio of "50:50." (*Id.* at 7151–52.) But the Examiner again rejected claim 9—the claim whose language had not changed since the original application. (*Id.*)

The prosecution history clearly demonstrates that the inventors disclaimed embodiments of the '963 Patent that contain less than 50% PEO in the final formulation. The Examiner suggested that the inventors make this precise change to overcome Snipes '621 and the inventors complied in two ways. First, they amended the language of claim 1 to replace "% wt." with "weight percent" and the term "80:20" with "50:50." Second, they

explained this amendment as confirming that "the present invention never contains less than 50% [PEO], as amended in this Response." These direct responses to the Examiner's direct request constitute a "clear and unmistakable disavowal of scope" on the part of the inventors. *Purdue Pharma L.P. v. Endo Pharm. Inc.*, 438 F.3d 1123, 1136 (Fed. Cir. 2006); *see Regents of Univ. of Cal. v. Dakocytomation Cal., Inc.*, 517 F.3d 1364, 1373 (Fed. Cir. 2008); *Norian Corp. v. Stryker Corp.*, 432 F.3d 1356, 1362 (Fed. Cir. 2005). Defendants argue that the inventors' statements were not clear enough to constitute prosecution disclaimer. But it would be difficult for the inventors to speak more clearly than "the present invention never contains less than 50% [PEO], as amended in this Response." This statement is as clear, if not clearer, than other statements made during prosecution that the Federal Circuit has held to constitute a disclaimer. *See, e.g., ERBE Elektromedizin GmbH v. Canady Tech. LLC*, 629 F.3d 1278, 1285–86 (Fed. Cir. 2010); *Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1376–77 (Fed. Cir. 2008).

Defendants also assert that the inventors' statement does not refer to the amount of PEO in the final formulation. In order to accept this reading, however, the Court must blind itself to the uncontested fact that the Examiner himself requested that the inventors specify the "% PEO *with respect to the total composition*." (Rabenstein Decl., Ex. G at 7097 (emphasis added).) Moreover, the inventors clearly stated that the "*invention* never contains less than 50%" PEO. As all parties agree, the invention is a "non-film controlled release pharmaceutical formulation"—in other words, a final formulation. Defendants' arguments fail to dislodge the inventors' clear prosecution disclaimer.

b. The Intrinsic Evidence Does Not Overcome the Prosecution Disclaimer

The text of the '963 Patent does not change the impact of the inventors' clear prosecution disclaimer. In fact, plaintiffs find a good deal of support there. The claimed invention in the '963 Patent is a "controlled release pharmaceutical formulation." '963 Patent at 14:26–27. The specification makes clear that the amount of PEO in the final formulation greatly affects the tablet's controlled release properties. As the inventors stated, "[t]he amount of PEO used in the formulation will depend upon . . . [the] desired

release profile [among] other such reasons." '963 Patent at 3:57–65. Figure 1 teaches that altering the molecular weight of the PEO "affects the release profile of the formulation." '963 Patent at 4:13. The "Field of the Invention" section emphasizes that "[t]he present invention relates to the field of [PEO] based hot-melt extrudable pharmaceutical formulations . . . ." '963 Patent at 1:10–12. These portions from the specification strongly suggest that the final formulation must contain a minimum amount of PEO in order for the formulation to have the claimed controlled release properties. Further, none of the embodiments of the invention set forth in the specification contains less than 50% PEO in the formulation as a whole. Indeed, the smallest amount of PEO in any of the examples is 54% and the median amount of PEO is 81%. '963 Patent at 13:30–45.

Defendants, however, urge that the Court's construction impermissibly limits too many other portions of the '963 Patent. For example, claim 2 claims the formulation of claim 1 with the addition of a plasticizer. '963 Patent at 14:35–36. With three ingredients, the final formulation cannot at the same time have at least 50% PEO and have the ratio of PEO to API be 50:50. Defendants are correct that claim 2 does not claim the full scope of claim 1's weight-ratio range, because an exact 50:50 ratio is unavailable. They are incorrect, however, that this limitation presents a conflict. "It does not follow that because" claim 1 encompasses at least 50% PEO and a PEO to API ratio of at least 50:50, "its dependent claims must also be broad enough to encompass" both of these embodiments. *Am. Piledriving Equip., Inc. v. Geoquip, Inc.*, 637 F.3d 1324, 1335 (Fed. Cir. 2011). Dependent claim 2 need not cover the entirety of claim 1's ratio term.

Defendants also point to two portions of the '963 Patent that indicate that formulations with less than 50% PEO would still be covered by the asserted claims. The weight-ratio term from claim 1 claims ratios from "about 99.99:.01 to *about* 50:50," and one portion of the specification states: "When present, the relative amount of plasticizer used may be expressed by the ratio high molecular weight PEO % wt.:plasticizer % wt., and will generally fall in the range of about 100:0 to about 60:40. The amount of plasticizer will generally not exceed the amount of PEO." '963 Patent at 5:24–28. These passages suggest that some embodiments would contain less than 50% PEO yet still be contemplated by claim 1 and the

specification. But these isolated passages must be read in the context of the clear and unmistakable prosecution disclaimer. *See Solvay S.A. v. Honeywell Int'l, Inc.*, 622 F.3d 1367, 1385 (Fed. Cir. 2010). That explicit disclaimer mandates the Court's conclusion.

In the end, the specification and other claims do not alter the fact that the inventors disclaimed final formulations with less than 50% PEO. The Court will therefore construe the term "wherein the poly(ethylene oxide) and the therapeutic compound comprise a ratio of poly(ethylene oxide) to therapeutic compound of from about 99.99:.01 weight percent to about 50:50 weight percent" to read "wherein the poly(ethylene oxide) and the therapeutic compound comprise a ratio, by weight, of poly(ethylene oxide) to therapeutic compound of from about 99.99:.01 to about 50:50, with the poly(ethylene oxide) comprising at least 50% of the formulation."

* * *

The Court therefore construes claim 1 to read as follows:

> 1. A controlled release pharmaceutical formulation, which is not a film or comprised of layered films, comprising an effective amount of a therapeutic compound and a high molecular weight poly(ethylene oxide), wherein the poly(ethylene oxide) has a molecular weight of about 1,000,000 to about 10,000,000 Daltons, and wherein the poly(ethylene oxide) and the therapeutic compound comprise a ratio, by weight, of poly(ethylene oxide) to therapeutic compound of from about 99.99:.01 to about 50:50, with the poly(ethylene oxide) comprising at least 50% of the formulation.

C. Construction of the Disputed Claims in the '314 Patent

In the early 2000s, once reports of abuse of opioid drugs became common, researchers at Grünenthal began investigating ways to deter abusers from injecting intravenously the API from oral tablets. (Davies Decl. ¶ 39.) Johannes Bartholomäus and Henrich Kugelmann developed a product in which a "solid dosage form" would include a "viscosity-increasing agent." '314 Patent at 1:8–11. If the solid dosage form were crushed and mixed with liquid, the combination would form a gel that would "remain[] visually distinguishable even after being introduced into a further quantity of aqueous liquid" and passing through a syringe. *Id.* at

1:14–16. This result was intended to have two effects. First, the resulting gel, with its "turbid appearance, [would] provide[] the potential abuser with an additional optical warning and discourage[] him/her from administering the gel parenterally." *Id.* at 6:6–9. Second, if the abuser is not put off by the turbid appearance, "[i]ntravenous administration of such an extract would most probably result in obstruction of blood vessels, associated with serious embolism or even death of the abuser." *Id.* at 2:31–33.

The '314 Patent contains 12 claims, but the only claims in issue are independent claim 1 and dependent claims 2, 6, and 9. Of these, the parties only dispute terms from claim 1, which reads as follows:

> 1. A parenteral abuse-proofed solid dosage form for oral administration, comprising, in addition to one or more active ingredients with potential for abuse selected from the group consisting of opiates, opioids, tranquillizers, stimulants and narcotics, at least one viscosity-increasing agent in a quantity equal to or greater than 5 mg per dosage form and such that an aqueous extract obtained from the dosage form with 10 ml of water at 25° C. forms a gel which can still pass through a needle having a diameter of 0.9 mm and remains visually distinguishable when introduced by a needle into a further quantity of an aqueous liquid.

'314 Patent at 11:66–12:31. Two terms are at issue in this opinion. First, the parties dispute the meaning of "parenteral abuse-proofed." (Parenteral refers to any way of getting a substance into one's body other than orally.) Second, the parties contest the proper meaning of the term "visually distinguishable" or "remains visually distinguishable."[3]

1. *"Parenteral abuse-proofed" means "reduced potential for parenteral abuse"*

The preamble of claim 1 recites: "[a] parenteral abuse-proofed solid dosage form for oral administration." Once again, the parties agree that

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[3] Defendants also argue that the claims at issue in the '314 Patent are indefinite, and thus invalid. *See* 35 U.S.C. § 112(b). The Court declines to rule on this issue prior to trial.

this preamble limits the claim. (Pls.' Opening Br. at 10 n.4.) The parties disagree on the meaning of the term "parenteral abuse-proofed." Plaintiffs assert that this term means "reduced potential for parenteral abuse," while defendants claim that it means "preventing parenteral abuse under any circumstances." (Pls.' Opening Br. at 19; Defs.' Opening Br. at 33.) The Court agrees with plaintiffs' interpretation.

The Court begins with the plain meaning of the term. Defendants urge that the plain meaning unambiguously favors their interpretation. They point to Webster's dictionary, which defines the suffix "-proof" as "sometimes distinguished from *resistant*" (D'Amore Decl., Ex. 20), and "bulletproof" as "impenetrable to bullets." (D'Amore Decl., Ex. 21.) A bulletproof jacket, defendants argue, may not stop all bullets however large they might be, but it guarantees protection against *some* bullets. (Hearing Tr. 52.) Similarly, they assert that "parenteral abuse-proofed" does not connote that the claimed formulation will prevent any and all abuse—but it does claim that the invention will stop parenteral abuse.

"[J]udges may 'rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents.'" *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 429 F.3d 1364, 1375 (Fed. Cir. 2005) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1322–23 (Fed. Cir. 2005)) (quotation marks omitted). In this case, defendants' dictionaries do not unambiguously support their position. The Webster's reference explicitly states that the suffix -proof is only *sometimes* distinguished from resistant. But even if the dictionary definition were clear and unambiguous, the intrinsic evidence of the '314 Patent shows that one skilled in the art would not understand "abuse-proofed" in the manner defendants suggest. The inventors made clear in the specification that the object of the invention "has been achieved by the provision of the solid dosage form according to the invention with *at least reduced potential* for parenteral abuse . . . ." '314 Patent at 1:66–2:1 (emphasis added). "At least reduced potential for parenteral abuse" is a far cry from preventing all parenteral abuse.

The inventors' discussion of the prior art during prosecution also reveals that one skilled in the art would not read "abuse-proofed" as strictly as defendants suggest. In response to one of the Examiner's many rejections of the '314 Patent, the inventors commented that the "abuse-

proofing" of two pieces of prior art "proceed[] on a fundamentally different principle." (PRF0007668.) But neither of these pieces of prior art—international patent application WO 99/32120, known as "Palermo," and U.S. Patent No. 4,070,494 ("'494 Patent")—teaches abuse-proofing in the manner defendants suggest. Palermo claims a "method of *reducing* the abuse potential of an oral dosage form of an opioid analgesic," WO 99/32120 at 1, 42 (emphasis added), and the '494 Patent teaches improvements to "*inhibit or prevent* the abuse of the agent through parenteral injection." '494 Patent at 1:18–20 (emphasis added). Moreover, when the inventors distinguished Palermo to the Examiner, they did so by comparing their invention with the particular method Palermo employed to achieve its abuse-reducing potential. (PRF0007629–30; PRF0007665–68; PRF0007710.) The inventors never distinguished Palermo on the basis that it did not teach "abuse-proofing" as defendants interpret that term.

The Court therefore concludes that one skilled in the art would understand "abuse-proofed" to mean a "reduced potential for abuse."

2. ***The patentees defined "visually distinguishable"***

Claim 1 of the '314 Patent provides that the gel formed by mixing the claimed dosage form with water "remains visually distinguishable when introduced by a needle into a further quantity of an aqueous liquid." The parties dispute what the "remains visually distinguishable" term means.

"In construing the terms of a patent, the court must [] examine the specification to determine whether the patentee used the claim term consistent with its ordinary meaning or acted as his own lexicographer in defining the term." *Glaxo Grp. Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1346 (Fed. Cir. 2004). If the patentee does act as his own lexicographer, the definition provided "offers practically incontrovertible directions about claim meaning." *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1288 (Fed. Cir. 2009) (en banc). Put another way, "[i]f the special meaning of claim language [provided by the patentee] is reasonably clear and precise, the court's role in claim construction is to pronounce that meaning as the acquired meaning of the word used in the claim." Herbert F. Schwartz & Robert J. Goldman, Patent Law & Practice 153 (7th ed. 2011).

As plaintiffs admit, "the inventors explicitly defined 'visually distinguishable' in the specification." (Pls.' Opening Br. at 20.) Defendants

agree. (Defs.' Opening Br. at 20.) The portion of the specification that defines "visually distinguishable" reads:

> For the purposes of the present invention, visually distinguishable means that the active ingredient-containing gel formed by extraction from the dosage form with the assistance of a necessary minimum quantity of aqueous liquid, when introduced with a hypodermic needle with a diameter of 0.9 mm into a further quantity of aqueous liquid at 37° C., remains substantially insoluble and cohesive and cannot straightforwardly be dispersed in such a manner that it can safely be administered parenterally, in particular intravenously. The material preferably remains visually distinguishable for at least one minute, preferably for at least 10 min.
>
> The increase in viscosity of the gel with the assistance of the selected viscosity-increasing agent means that, although this has been rendered more difficult, the gel may still be passed through a needle or injected. It also means that when the resultant extract or gel is introduced at 37° C. into a further quantity of aqueous liquid, for example also by injection into blood, a largely cohesive thread is initially obtained which, while it may be broken up into smaller fragments by mechanical action, it cannot be dispersed or even dissolved in such a manner that it may safely be administered parenterally, in particular intravenously.

'314 Patent at 2:9–30. The Court must employ the definition supplied by the inventors.

Plaintiffs, however, take the position that even though the patentees acted as their own lexicographers, the Court should read into this definition additional glosses from the patent's examples. Specifically, plaintiffs suggest deleting the term "largely cohesive thread" (that forms when the gel extract is injected into the further quantity of liquid) and replacing it with "thread or thread-like fragments." (Pls.' Resp. Br. at 20.) Plaintiffs also suggest importing a requirement that the "broken up" threads be visible to the naked eye, and that the "mechanical action" be narrowed to mean "stirred." (*Id.* at 20.) Ultimately, plaintiffs "don't want to be litigating the question of the adverbs" contained in the patentees' own definition of "visually distinguishable." (Hearing Tr. 46.)

Plaintiffs simply ask the Court to do an end run around the patentees' own definition. Once the inventor acts as his own lexicographer, that definition overrules the traditional tools of claim construction. *See 3M Innovative Props. Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1374 (Fed. Cir. 2003). The scattered references to "thread-like fragments" in the '314 Patent's examples do not overcome the "practically incontrovertible directions" of the patentees' own definition. *Abbott Labs.*, 566 F.3d at 1288. Because the patentees set out their own definition, their "lexicography governs." *Phillips*, 415 F.3d at 1316.[4]

* * *

For these reasons, the Court construes claim 1 of the '314 Patent to read as follows:

> 1. A solid dosage form for oral administration with reduced potential for parenteral abuse, comprising, in addition to one or more active ingredients with potential for abuse selected from the group consisting of opiates, opioids, tranquillizers, stimulants and narcotics, at least one viscosity-increasing agent in a quantity equal to or greater than 5 mg per dosage form and such that an aqueous extract obtained from the dosage form with 10 ml of water at 25° C. forms a gel which can still pass through a needle having a diameter of 0.9 mm and, when introduced by such a needle into a further quantity of an aqueous liquid at 37° C., a largely cohesive thread is initially obtained which, while it may be broken up into smaller fragments by mechanical action, remains substantially insoluble and cohesive and cannot straightforwardly be dispersed in such a manner that it can safely be administered parenterally, in particular intravenously.

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[4] At oral argument, plaintiffs cautioned the Court against adopting a construction of "visually distinguishable" that defendants argued was indefinite. (Hearing Tr. 62.) But defendants argue that this term is indefinite based on allegedly missing steps in the visually distinguishable test. (Defs.' Opening Br. at 28.) Plaintiffs' proffered construction simply glosses some of the words in the patentees' own definition—it does not address the issue of the allegedly missing steps. (Pls.' Opening Br. at 20–23.) Thus, even if the Court adopted plaintiffs' proposed construction, that decision would not resolve defendants' indefiniteness argument.

D. Construction of the Disputed Claims in the '383 Patent

In the early 2000s, scientists at Grünenthal investigated whether they could make a tablet that would be difficult to crush—a first step before the drug can be snorted by an abuser—but at the same time be able to release the tablet's API when swallowed whole. '383 Patent at 1:16–39, 1:64–2:6; Davies Decl. ¶¶ 53–54. Three Grünenthal scientists—Johannes Bartholomäus, Heinrich Kugelmann, and Elisabeth Arkenau-Marić—succeeded in developing a tablet with a breaking strength of 500 Newtons, more than double a person's average chewing force. (Davies Decl. ¶¶ 53–55.) The claimed invention achieved this goal by including a polymer in the tablet formulation and exposing that formulation to heat and pressure. '383 Patent at 21:2–14.

Plaintiffs allege that defendants' ANDAs infringe five of the '383 Patent's nine claims: independent claim 1 and dependent claims 2, 5, 7, and 8. The parties, though, only dispute the meaning of two terms in claim 1. That claim recites:

> 1. A thermoformed dosage form comprising:
>
> i) one or more active ingredients with abuse potential (A) selected from the group consisting of opiates and opioids,
>
> ii) optionally physiologically acceptable auxiliary substances (B),
>
> iii) at least 30% by weight of polyalkylene oxide (C) having a molecular weight of 1-15 million according to rheological measurements, and
>
> iv) optionally at least one wax (D),
>
> wherein said dosage form has a breaking strength of at least 500 N and wherein the active ingredient with abuse potential (A) is present in a controlled release matrix of component (C).

Id. at 21:2–22:14. The two terms in dispute are "thermoformed dosage form" and "breaking strength of at least 500 N."

1. *"Thermoformed dosage form" means pressure with preceding or simultaneous application of heat*

The preamble of independent claim 1 claims a "thermoformed dosage form."[5] The parties agree that "thermoforming" encompasses formulations made by applying pressure with preceding or simultaneous application of heat. They disagree whether thermoforming can also encompass the application of pressure with *subsequent* heat—plaintiffs claim that it does, defendants disagree. The Court holds that the term "thermoform" does not include subsequent heat.

The Court begins with the claims of the '383 Patent, but the claims do not settle the parties' dispute. Plaintiffs do not assert that thermoforming bears a plain, ordinary meaning among those skilled in the art. Defendants, though, argue that thermoforming does have such a meaning—one that excludes subsequent heat. In support, defendants cite numerous general purpose and technical dictionaries and treatises. (Amiji Decl., Exs. D–H.) These extrinsic sources "'can shed useful light on the relevant art,' [but] this court considers such evidence 'less significant than the intrinsic record in determining the legally operative meaning of claim language.'" *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1362 (Fed. Cir. 2008) (quoting *Phillips*, 415 F.3d at 1317). At a minimum, defendants' dictionaries do establish that plaintiffs' proposed definition would be an outlier among these other lay and specialized meanings.

While claim 1 does not define "thermoformed," dependent claim 5 appears to provide some context. Claim 5 claims a process for producing the dosage form of claim 1, involving "mixing" the components specified in claim 1, "and, optionally after granulation, press-forming the mixture with preceding, simultaneous, or subsequent exposure to heat." '383 Patent at 22:6–8. Plaintiffs point out that dependent claim 5 must fit within the scope of claim 1. Plaintiffs are correct, *see Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n.9 (Fed. Cir. 1989), but this does not end the analysis. Even if "thermoform" does not encompass subsequent heat, claim 1 does not exclude dosage forms that include a subsequent heating step—provided that the dosage form was already "thermoformed." The

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[5] The parties again agree that the preamble limits claim 1. (Defs.' Opening Br. at 41 n.17.)

preamble of claim 1 is linked to the substantive claim language by the open-ended term "comprising." *See, e.g., In re Skvorecz*, 580 F.3d 1262, 1267 (Fed. Cir. 2009). Therefore, a dosage form that is thermoformed according to defendants' construction can still undergo a subsequent heating step and fit within the confines of claim 1. Claim 5 merely spells out this possibility.[6]

The Court next turns to the specification of the '383 Patent. The inventors did not take the opportunity in the specification to act as their own lexicographer, but the specification is replete with examples of thermoforming. None of the numbered examples discloses a method that involves a subsequent application of heat—every one of them utilizes pressure with either simultaneous or preceding heat. In fact, the specification discusses subsequent applications of heat only once, in column 11:

> 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. The mixture may, for example, be formed into tablets by direct tabletting. In direct tabletting with simultaneous exposure to heat, the tabletting tool, i.e. bottom punch, top punch and die are briefly heated at least to the softening temperature of the polymer (C) and pressed together. *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.*

'383 Patent at 11:16–28 (emphasis added). Plaintiffs naturally cite this passage and urge that any definition of thermoforming that excludes subsequent heat would exclude this preferred embodiment of the invention. Plaintiffs once again correctly state the law, *see SynQor, Inc. v. Artesyn Techs., Inc.*, 709 F.3d 1365, 1378–79 (Fed. Cir. 2013), but misconstrue the patent.

The disclosed method of direct tableting with subsequent heat makes clear that after the formed tablets are heated, they are "cooled *again*." The

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[6] Defendants claim that the entire press-forming step of claim 5 is optional. They are incorrect. The term "optionally" in claim 5 modifies "after granulation."

emphasized word means what it says—the tablets formed by this method had already been cooled, meaning they had already been heated. In other words, the tablets had already been thermoformed before they were subjected to subsequent heat.

Plaintiffs belittle this point, but do nothing to reduce its impact. They argue that defendants' reliance on the word "again" is nothing more than an attempt to summon up a "hidden previous heating step." (Pls.' Resp. Br. at 27 n.21.) Plaintiffs, though, have no better explanation for the word. They contend that "cooled again" means that the tablet is cooled to its original temperature. (*See id.*) But this reading simply deletes the word "again," or else has it modify something other than the verb "are . . . cooled."

Finally, the Court turns to the prosecution history. During prosecution, the inventors did not discuss the precise term "thermoform." The inventors did, however, repeatedly stress to the Examiner the importance to their invention of simultaneous pressure and heat. For example, in response to the Examiner's first rejection of all proposed claims, the inventors emphasized that "[t]he 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." (PRF0008744 (emphasis added).) The inventors repeated this point word-for-word in response to the Examiner's second rejection. (PRF0008828.)

Plaintiffs counter that even when the inventors stressed the simultaneous application of heat and pressure, they still cited portions of the application that discussed subsequent heating. This ambiguity may militate against a finding of prosecution disclaimer, but it does not detract from the thrust of the inventors' representations to the Examiner. Pressure and heat, applied together, were the crucial elements of the invention.

The claims and specification make clear that if the formulation is subjected to heat after it has already been pressed, that formulation must have already been "thermoformed." Pressure and prior or simultaneous heat are simply the essence of the claimed invention, as the inventors repeatedly stressed to the Examiner. Read in the complete context of the claims, the specification, and the prosecution history, it is plain that a

person of ordinary skill in the art would understand "[a] thermoformed dosage form" to mean "a dosage form that is formed by the application of pressure to the components with the simultaneous or preceding application of heat."[7]

2. *"Breaking strength" means "breaking strength"*

The parties also appear to contest the meaning of the term "a breaking strength of at least 500 N" from claim 1. But on closer inspection, there is no conflict at all. The parties agree that plastic deformation—i.e., squashing—does not constitute "breaking." (Defs.' Resp. Br. at 29.) Plaintiffs also urge that chipping of the color coating would not constitute "breaking." The Court agrees—the product that has "a breaking strength of at least 500 N" is the thermoformed dosage form. No construction of the term "breaking strength" is required.

* * *

For these reasons, the Court will construe claim 1 to read as follows:

> 1. A dosage form that is formed by the application of pressure to the components with the simultaneous or preceding application of heat comprising:
>
> i) one or more active ingredients with abuse potential (A) selected from the group consisting of opiates and opioids,
>
> ii) optionally physiologically acceptable auxiliary substances (B),
>
> iii) at least 30% by weight of polyalkylene oxide (C) having a molecular weight of 1-15 million according to rheological measurements, and
>
> iv) optionally at least one wax (D),
>
> wherein said dosage form has a breaking strength of at least 500 N and wherein the active ingredient with abuse potential (A) is present in a controlled release matrix of component (C).

---

[7] This reasoning also compels the Court to conclude that claim 1 is not a product-by-process claim. The thermoforming of the claimed invention imparts structural characteristics to the final dosage form. *See Hazani v. U.S. Int'l Trade Comm'n*, 126 F.3d 1473, 1479 (Fed. Cir. 1997); *In re Garnero*, 412 F.2d 276, 279 (C.C.P.A. 1969).

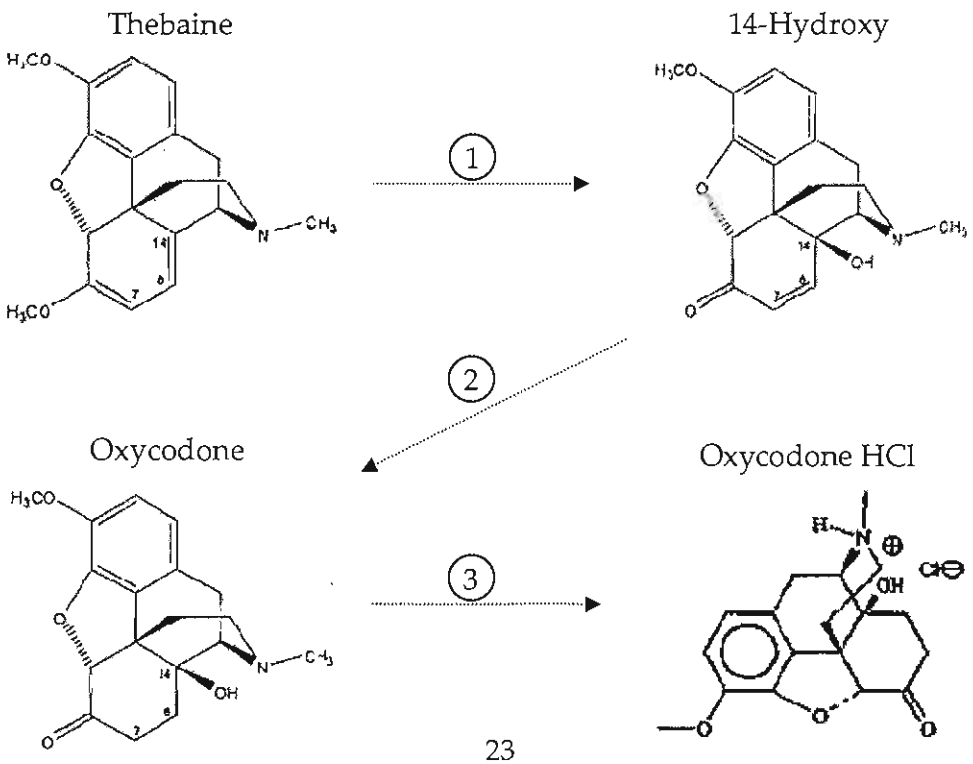
III. THE LOW-ABUK PATENTS

A. Background

1. *Purdue's development of low-ABUK oxycodone*

In 2004, the FDA mandated that manufacturers of oxycodone API—including Purdue and its subsidiary Rhodes—provide information about the impurity 14-hydroxycodeinone ("14-hydroxy"). Among other things, the FDA directed Rhodes to either (1) provide evidence that the level of 14-hydroxy in Rhodes's oxycodone API was safe or (2) lower the level of 14-hydroxy in Rhodes's oxycodone API to less than 10 ppm. (PTX 266.)

By the fall of 2004, Rhodes had developed a method to reduce the amount of 14-hydroxy and submitted an amendment to its drug master file to the FDA. (Kelly Tr. 517–18.) Rhodes's ability to rapidly achieve the FDA's 14-hydroxy purity standard reflected laboratory work undertaken years before the FDA mandate. Rhodes had previously developed a three-step process to synthesize oxycodone from thebaine: (1) Rhodes oxidized thebaine to form 14-hydroxy; (2) Rhodes hydrogenated 14-hydroxy to form oxycodone; and (3) Rhodes added hydrochloric acid to form oxycodone hydrochloride. (Shamblen Tr. 80; Kupper Tr. 124–25.)



In 2001 and 2002, scientists at Rhodes attempted to control levels of 14-hydroxy in the oxycodone API by ensuring that "the hydrogenation reaction from [14-hydroxy] [to] oxycodone free base was run to completion." (Kupper Tr. 129.) After this extended hydrogenation—step two of the method for synthesizing oxycodone—scientists were unable to detect 14-hydroxy in the free base. But after step three—transforming the oxycodone free base into oxycodone hydrochloride—Rhodes's scientists discovered that the 14-hydroxy had returned. (Kupper Tr. 135, 137–38.)

The scientists at Rhodes did not know at first why the 14-hydroxy had reappeared. In a report written in late 2002, though, Rhodes research scientist Lonn Rider hypothesized that the 14-hydroxy present in the API formed due to the dehydration of two impurities, 8α, 14-dihydroxy-7,8-dihydrocodeinone ("8α") and 8β, 14-dihydroxy-7,8-dihydrocodeinone ("8β"). (Kupper Tr. 139–41.) 8α and 8β are diastereomers of 8,14-dihydroxy-7,8-dihydrocodeinone ("8,14-dihydroxy"). As diastereomers, 8α and 8β are two forms of 8,14-dihydroxy: "[t]hey have the same atoms connected to other atoms but they differ in the[] three-dimensional arrangement of the atoms." (Heathcock Tr. 1144; *see also Chapman v. Casner*, 315 F. App'x 294, 295–96 (Fed. Cir. 2009) (discussing 8,14-dihydroxy's stereoisomers).)

Rider's focus on 8,14-dihydroxy reflected two reactions that occur within the Rhodes synthesis process. One, during the first step in the synthesis process, thebaine molecules convert into 14-hydroxy molecules by oxidation. While this reaction principally yields 14-hydroxy, it also produces "several overoxidation products [] in small amounts," including 8,14-dihydroxy. (Kupper Tr. 140.) Two, Rhodes and Rider knew that 8,14-dihydroxy could undergo acid-catalyzed dehydration to form 14-hydroxy. (Heathcock Tr. 1141–42.) Rhodes suspected that the addition of acid at the third manufacturing step was converting the 8,14-dihydroxy to 14-hydroxy. (Kupper Tr. 138.)

After additional experimentation, Rhodes scientists concluded that 8α was the source of the reappearing 14-hydroxy. They then began to consider "methods for controlling the levels of 14-[hydroxy] in oxycodone hydrochloride based on this knowledge." (Rider Tr. 219.) After considering several alternatives, Rhodes "decided that the best course of action . . . would be another hydrogenation step to remove the 14-

[hydroxy] . . . ." (Kupper Tr. 151; Rider Tr. 221.) This second hydrogenation step did not, however, exactly replicate the first. The first, original, hydrogenation step used water and formic acid to produce a formate salt, which was "converted to the free base by an addition of a base of sodium hydroxide." (Rider Tr. 298; Kupper Tr. 151–52.) The newly added second hydrogenation was performed after the free base had been converted to oxycodone hydrochloride. (Rider Tr. 299.) The second hydrogenation converted 14-hydroxy into oxycodone but did not react with previously formed oxycodone hydrochloride. (Rider Tr. 300–01.)

With this method in hand, Rhodes sought approval from the FDA and patent protection for their new method.

2. *Purdue obtains the '799, '800, and '072 Patents*

Purdue and Rhodes attempted to patent their work on low-ABUK oxycodone. This effort concluded in March 2010 when Purdue secured the three Low-ABUK Patents:

- U.S. Patent No. 7,674,799
- U.S. Patent No. 7,674,800
- U.S. Patent No. 7,683,072

Broadly speaking, the '800 Patent claims "a process for preparing an oxycodone salt substantially free of 14-[hydroxy]." '800 Patent at 34:22–23. The '072 Patent claims low-ABUK oxycodone hydrochloride API. '072 Patent at 34:57–60. The '799 Patent claims an "oral dosage form" of low-ABUK oxycodone hydrochloride. '799 Patent at 34:54.

The '799, '800, and '072 Patents continue from an earlier application, No. 11/391,897 ("Chapman application"). The Chapman application continues from the March 30, 2005 application No. 11/093,626, which issued as U.S. Patent No. 7,129,248. The '799 Patent continued as Serial No. 11/653,531 and was issued on March 9, 2010. The '800 Patent continued as Serial No. 11/729,741 and issued on March 9, 2010. The '072 Patent continued as Serial No. 11/653,529 and issued on March 23, 2010.

The Patent Office initially rejected as obvious a number of asserted claims of the patents as they were then drafted. The Examiner paid particular attention to one prior art reference, Chiu, which disclosed a

process for preparing a low-ABUK oxycodone crude base. (PTX 10 at P1052803–04; PTX 11 at P1034148–49; PTX 12 at P1045523–24; DTX 741.) The Examiner also questioned the nonobviousness of the patents on the grounds that 8,14-dihydroxy had been disclosed in the art. Accordingly, the Examiner directed the inventors to explain why prior art regarding 8β did not render obvious claims relating to 8α: "unless applicants provide some unexpected results of 8,14-dihydroxy[] with trans hydroxyl groups as compared to 8,14-dihydroxy[] with cis hydroxyl groups, it would have been obvious to one skilled in the art to prepare Oxycodone salt with reduced amount of 14-hydroxy[] with reasonable expectation of success." (PTX 11 at P1035381–82; Heathcock Tr. 1143.)

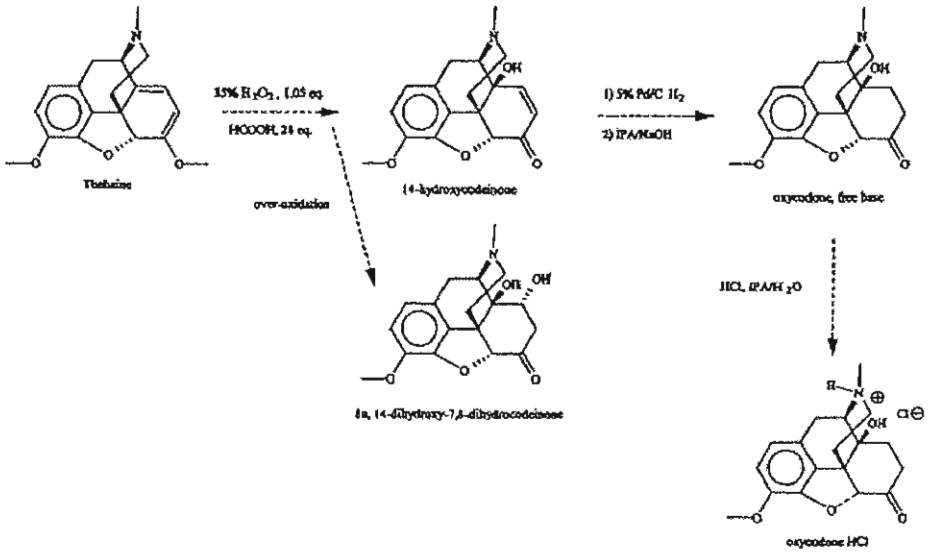
Purdue's response distinguished the prior art based on stereochemistry and the process steps involved in the Chiu reference. As to the stereochemistry, Purdue submitted the declaration of Steven Baldwin, Ph.D., to demonstrate the "unexpected results" of 8α to the Patent Office. Baldwin stated that 8α and 8β are "different compounds and have surprisingly different properties (e.g., reactivities)." (PTX 11 at P1035678; Heathcock Tr. 1143.) As to the Chiu reference, Purdue explained that the prior art reference concerned 14-hydroxy in oxycodone base, not 14-hydroxy that "would reappear during hydrochloride salt formation." (PTX 10 at P1052961–62; Crimmins Tr. 799–800.)

Purdue prevailed. The Examiner approved the patents, in part "due to [Purdue's] persuasive arguments and declaration by Dr. Baldwin." (PTX 10 at P1059552.)

a. The common specification

The '799, '800, and '072 Patents have substantially identical specifications but differ in the nature of the claims. Figure 1 depicts a scheme to synthesize oxycodone hydrochloride from thebaine.

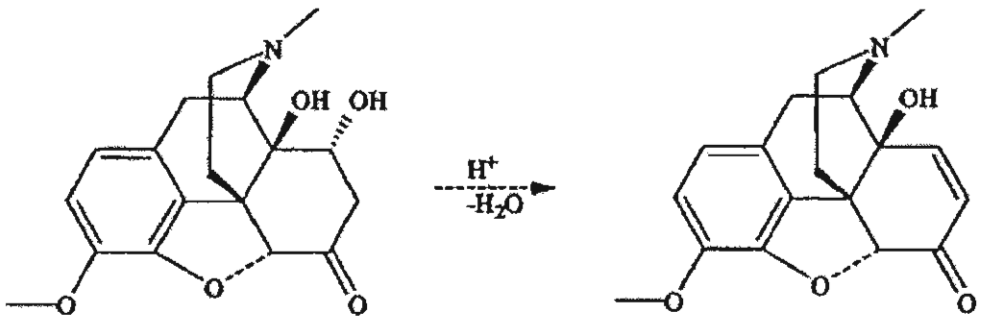
Figure 1



First, thebaine is oxidized to form 14-hydroxy. Second, 14-hydroxy is hydrogenated to form oxycodone free base. Third, the oxycodone free base is acidified to form oxycodone hydrochloride. In addition, Figure 1 depicts the formation of 8α as a result of the overoxidation of thebaine. (Wuest Tr. 554–55, 1253–54.)

Figure 2 depicts the conversion of 8α into 14-hydroxy as a result of dehydration in the presence of acid. *E.g.*, '800 Patent at 6:18–19; Wuest Tr. 1254.

Figure 2



8a,14-dihydroxy-7,8-dihydrocodeinone

14-hydroxycodeinone

The specification states that "[t]he term 8,14-dihydroxy-7,8-dihydrocodeinone includes either 8α,14-dihydroxy-7,8-dihydrocodeinone; or 8β,14-dihydroxy-7,8-dihydrocodeinone or can include a mixture of both compounds." *E.g.*, '800 Patent at 5:54–57.

The description recites the chemical structure of 8α and the nature of the reaction that produces it. For example, the specification states that 8,14-dihydroxy converts to 14-hydroxy "during salt formation reactions known in the art." '800 Patent at 8:4–11. The patents' written description does not explicitly identify conditions that transform 8α, but not 8β, into 14-hydroxy. (*E.g.*, Rider Tr. 278.) The specification also does not disclose a pH range at which 8α will not form. (Rider Tr. 278–79; Wuest Tr. 1330–31.) But Example 3 of the specification demonstrates conditions that suffice to convert 8α into 14-hydroxy. (Wuest Tr. 1258.) Wuest further explained that a skilled artisan "would understand that the 8β compound is essentially inert under [the] conditions [of Example 3] and would not undergo this acid-induced transformation." (Wuest Tr. 1258.) The specification includes no method for detecting 8α. (Kupper Tr. 191; Wuest Tr. 1324–25.)

B. Construction of the Disputed Claims in the Low-ABUK Patents

Purdue has asserted that defendants' ANDAs infringe claims 3 and 19 of the '799 Patent; claims 30–34 and 76–79 of the '800 Patent; and claims 1, 4, and 5 of the '072 Patent. The parties contest the meaning of various claim terms of each patent. Those disputes fit roughly into the following groups:

1) Whether terms of each claim require the presence of 14-hydroxy in the final oxycodone salt
2) Whether the process claims of the '800 Patent encompass processes that involve intermediate salt-formation steps that use salts other than oxycodone hydrochloride
3) Whether the '799 and '072 Patents require 8α to be present in the synthesis process and, if so, whether some portion of it must convert to 14-hydroxy at the final salt formation step
4) Whether the '799 and '072 Patents contain process limitations

5) Whether the presence of 14-hydroxy and 8α must be at "detectable levels"

The Court considers each issue below.

1. *All patents: 14-hydroxy must be present in the final salt*

Defendants urge the Court to construe the '800 Patent (claims 1 & 57), the '072 Patent (claim 1), and the '799 Patent (claim 3) as requiring 14-hydroxy in the final oxycodone salt. The Court adopts this construction.

Purdue does not seriously contest that an infringing product must have some 14-hydroxy present in the final oxycodone salt. After all, if a product had no 14-hydroxy whatsoever, it would have no 14-hydroxy derived from 8α as required by the claims. (Crimmins Tr. 803.) The specification supports this reading because it contains no embodiment where the level of 14-hydroxy is described as zero. To the contrary, Example 6 recites an analytical method "to determine the amount of codeinone and 14-[hydroxy] present." '799 Patent at 31:16–18. Therefore, the Court does not accept that a skilled artisan would understand the phrase "a portion of the [14-hydroxy]" to encompass the absence of 14-hydroxy.[8]

2. *'800 Patent: the final salt must be oxycodone hydrochloride, but the intermediate salt need not be*

Claim 1 of the '800 Patent reads as follows, with emphasis on the disputed claim language:

> A process for preparing *an oxycodone salt substantially free of 14-hydroxycodeinone*, which process comprises steps of:
>
> (a) preparing a mixture of oxycodone free base, solvent and an acid, the oxycodone free base having an 8α,14-dihydroxy-7,8-dihydrocodeinone component;
>
> (b) incubating the mixture under conditions suitable to convert the oxycodone free base to *an oxycodone salt*, wherein said

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[8] As regards the Low-ABUK Patents, a person of ordinary skill in the art is an organic chemist with experience in synthetic and analytical chemistry. The parties do not dispute the qualifications of the skilled artisan as relevant to the Abuse-Proof Patents. (Hearing Tr. 50.)

> conditions promote an acid catalyzed dehydration consisting of conversion of the 8α,14-dihydroxy-7,8-dihydrocodeinone component to 14-hydroxycodeinone; and
>
> (c) preferentially removing the 14-hydroxycodeinone from *the oxycodone salt*.

'800 Patent at 34:22–35. Claim 57 features the same disputed language, but recites step (c) as "reducing an amount of [14-hydroxy] in the oxycodone salt formed in step (b) to produce an oxycodone salt composition having less than 25 ppm [14-hydroxy]." '800 Patent at 37:40–43.

The parties dispute whether the term "an oxycodone salt substantially free of 14-hydroxy" as used in the preamble must be the same salt as the "an oxycodone salt" referred to in step (b) of the body of the claim. The parties further dispute whether claim 1 and claim 57 of the '800 Patent describe *any* oxycodone salt in the preamble and at step (b) or only oxycodone *hydrochloride* salt. The Court does not read the claims to require the oxycodone salt of the preamble to be the same oxycodone salt as in step (b). The Court also will not limit the salts in claims 1 and 57 to hydrochloride salts alone.

a. The preamble refers to an oxycodone salt API

The parties dispute whether the preambles of claim 1 and claim 57 limit the process steps of those claims. They do. "[A] claim preamble has the import that the claim as a whole suggests for it." *Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332, 1339 (Fed. Cir. 2003) (quotation marks omitted).

The claim terms and specification indicate that the preamble constitutes a claim limitation. The phrasing of the preamble "an oxycodone salt substantially free of [14-hydroxy]" comports with the title of the patents, "Oxycodone Hydrochloride Having Less Than 25 ppm 14-Hydroxycodeinone" and discloses various pharmaceutical embodiments. Moreover, the examples in the patent specification show how to analyze the 14-hydroxy levels of the product after the hydrogenation reaction is run and the material is dried. *E.g.*, '800 Patent at 25:17–22, 25:55–60, 26:35–40. The context therefore suggests that their preambles identify and limit the end product of the described process. If the end product is an oxycodone salt API substantially free of 14-hydroxy, as the intrinsic evidence suggests, then the preamble's use of the phrase "an oxycodone

salt substantially free of [14-hydroxy]" must be limiting. Otherwise, the process steps would not achieve that result. The preambles of claims 1 and 57 "recite[] essential structure or steps" of the claims and are otherwise "necessary to give life, meaning, and vitality to the claim." *Am. Med. Sys., Inc. v. Biolitec, Inc.*, 618 F.3d 1354, 1358 (Fed. Cir. 2010) (quotation marks omitted).

This reading also comports with the patent prosecution history. During the prosecution of the '800 Patent, Purdue distinguished its claims to a low-ABUK "oxycodone hydrochloride composition" from the Chiu reference. (PTX 11 at P1034312–14.) Purdue emphasized that Chiu disclosed low-ABUK oxycodone free base and not a low-ABUK salt made from the purified free base. (*Id.*) Because an earlier step in Chiu's process involved an intermediate oxycodone salt mixture, (DTX 741 at Example 6), Purdue's process differed meaningfully from Chiu only in that Purdue's process resulted in an oxycodone salt API and not a crude oxycodone base. That is the very distinction captured by the preamble of claims 1 and 57 and what a skilled artisan would understand by this language. (Wuest Tr. 559.)

b. The phrase "an oxycodone salt substantially free of [14-hydroxy]" has a different meaning than the phrase "an oxycodone salt"

Defendants contend that the Court should construe the preamble's phrase "an oxycodone salt substantially free of [14-hydroxy]" to mean the same thing as "an oxycodone salt" as used in the process steps. The Court does not accept this reading.

"[T]he same terms appearing in different portions of the claims should be given the same meaning unless it is clear from the specification and prosecution history that the terms have different meanings at different portions of the claims." *PODS, Inc. v. Porta Stor, Inc.*, 484 F.3d 1359, 1366 (Fed. Cir. 2007). Here, the intrinsic evidence reveals such a distinction between the two instances of "an oxycodone salt."

- First, the modifying phrase "substantially free of 14-[hydroxy]" limits the term "an oxycodone salt" in the preamble, as compared to the unmodified phrase "an oxycodone salt" used at step (b). The Court presumes that these different phrases carry different

meanings. *See Epcon Gas Sys., Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1030–31 (Fed. Cir. 2002).

- Second, the indefinite article "an" appears before "oxycodone salt" in the preamble and before "oxycodone salt" in the body of the claim. Each use of that article implies that "one or more" oxycodone salts may fit within the claims. *See 01 Communique Lab., Inc. v. LogMeIn, Inc.*, 687 F.3d 1292, 1297 (Fed. Cir. 2012). Defendants' proposed construction thus artificially limits this term.
- Third, the specification discloses an embodiment where the final salt is an API but the process salt is an intermediate. '800 Patent at 8:66–9:7.

Accordingly, the salt of the preamble—the oxycodone API—need not be the salt of step (b). Because the specification identifies differences in meaning between "an oxycodone salt substantially free of 14-[hydroxy]" and "an oxycodone salt," the Court construes them differently. *See Microprocessor Enhancement Corp. v. Texas Instruments Inc.*, 520 F.3d 1367, 1375–76 (Fed. Cir. 2008).

c. The process steps refer to "any oxycodone salt," not necessarily oxycodone hydrochloride

A person of ordinary skill in the art would understand that neither the phrase "an oxycodone salt substantially free of 14-hydroxy" nor the phrase "an oxycodone salt" limit the claims to oxycodone hydrochloride salt. (Wuest Tr. 566; Crimmins Tr. 916; Heathcock Tr. 1135.) The appropriateness of that reading is confirmed by the context of the patent. Claim 31 and claim 77, for example, call for oxycodone *hydrochloride* salt. Because dependent claims 31 and 77 recite a specific type of salt but the independent claims 1 and 57 do not, the doctrine of "claim differentiation" presumes that the independent claims do not contain the limitations of the dependent claims. *See Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 805–06 (Fed. Cir. 2007). The specification supports this meaning because it includes an embodiment where the claimed process involves "reacting an oxycodone base composition with an acid having a higher pH than hydrochloric acid to form a corresponding acid addition salt of

oxycodone" and identifies suitable acids other than hydrochloric acid. '800 Patent at 8:66–9:7.

The specification and prosecution history do not provide a contrary "clear intention" to limit the phrases "an oxycodone salt substantially free of [14-hydroxy]" and "an oxycodone salt" to "oxycodone hydrochloride salt." *Contra Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1290 (Fed. Cir. 2009) (en banc). First, though the specification primarily describes oxycodone hydrochloride compositions, "the written description does not suggest that the invention must be used" in that form. *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1301 (Fed. Cir. 2003). Second, Purdue's statements to the Examiner did not disclaim the use of other oxycodone salts. When Purdue distinguished its claim from the Chiu reference it did not do so on the ground that it claimed an oxycodone *hydrochloride* salt rather than an oxycodone *acetate* salt of Chiu. (PTX 11 at P1034312–14.) Rather, Purdue drew a distinction between a low-ABUK free base and a low-ABUK salt formed from a purified free base. (*Id.*) That Purdue referred to "oxycodone hydrochloride salt" while discussing its proposed claim does not amount to "clear and unmistakable prosecution arguments limiting the meaning of a claim term in order to overcome a rejection." *SanDisk Corp. v. Memorex Prods., Inc.*, 415 F.3d 1278, 1286 (Fed. Cir. 2005). The specific independent claim at issue recited an oxycodone hydrochloride composition. (PTX 11 at P1034313.)

* * *

Accordingly, the Court construes claim 1 of the 800 Patent to require:

(1) A process for preparing an oxycodone salt API substantially free of 14-hydroxy, which process comprises (2) preparing a mixture of oxycodone free base, solvent and an acid, the oxycodone free base having an 8α component; (3) incubating the mixture under conditions suitable to convert the oxycodone free base to any salt of oxycodone, wherein said conditions promote an acid-catalyzed dehydration consisting of conversion of the 8α component to [14-hydroxy]; and (4) preferentially removing the [14-hydroxy] from the oxycodone salt.

The Court construes claim 57 of the '800 Patent the same way, except that element (4) requires "reducing an amount of [14-hydroxy] in the

oxycodone salt formed in step [3] to produce an oxycodone salt composition having less than 25 ppm [14-hydroxy]."

3. ***The '799 Patent requires some 8α to convert to 14-hydroxy at the salt formation step, the '072 Patent does not***

The relevant portions of claim 1 of the '072 Patent read as follows, with emphasis on the disputed claim language:

> An oxycodone hydrochloride active pharmaceutical ingredient having less than 25 ppm 14-hydroxycodeinone *wherein at least a portion of the 14-hydroxycodeinone is derived from 8α, 14-dihydroxy-7,8-dihydrocodeinone.*

'072 Patent at 34:57–60.

The relevant portions of claim 3 of the '799 Patent read as follows, with emphasis on the disputed claim language:

> An oral dosage form comprising: (i) from about 5 mg to about 320 mg of oxycodone hydrochloride active pharmaceutical ingredient having less than 25 ppm 14-hydroxycodeinone, *wherein at least a portion of the 14-hydroxycodeinone is derived from 8α,14-dihydroxy-7,8-dihydrocodeinone during conversion of oxycodone free base to oxycodone hydrochloride;* and (ii) a pharmaceutically acceptable excipient.

'799 Patent at 35:8–15.

The parties dispute whether the '799 Patent (claim 3) and the '072 Patent (claim 1) require the presence of 8α in the oxycodone base and require some 8α to convert to 14-hydroxy at the salt formation step.[9] Defendants' proposed construction advances two additional limitations: (1) the presence of 8α in the oxycodone base and (2) the conversion of some 8α to 14-hydroxy at the salt formation step. The Court concludes that the '799 Patent requires some 8α to convert to 14-hydroxy at the salt formation step and therefore construes the '799 Patent to require 8α in oxycodone base. The Court concludes that the '072 Patent does not have any requirement that 8α convert to 14-hydroxy at any particular process

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[9] The parties agree that the process of the '800 patent requires the presence 8α in the oxycodone base.

step and therefore does not require proof of 8α's conversion at any particular point.

a. The '799 Patent (claim 3) requires the presence of 8α in the oxycodone base.

The '799 Patent (claim 3) states that "at least a portion of the 14-[hydroxy] is derived from 8α[] during conversion of oxycodone free base to oxycodone hydrochloride." The Court construes this phrase according to its plain meaning to a skilled artisan. Accordingly, at least "a portion" of the 14-hydroxy in the API must be "derived from" 8α. Further, at least a portion of the 8α-derived 14-hydroxy must be so derived during the conversion of oxycodone free base to oxycodone hydrochloride. (Crimmins Tr. 796; Wuest Tr. 562.) The specification supports this construction, noting in the "Background of the Invention" section that "[d]uring conversion of the oxycodone free base to oxycodone hydrochloride, the impurity undergoes acid-catalyzed dehydration and is converted into [14-hydroxy]." '799 Patent at 2:2–5. If no 8α-derived 14-hydroxy present in the oxycodone hydrochloride were derived "during conversion of oxycodone free base to oxycodone hydrochloride," a central feature of the claim would be absent from the product.

Nonetheless, Purdue contends that any conversion of 8α to 14-hydroxy before the formation of the final oxycodone hydrochloride API is within the scope of the claims. Purdue's construction simply replaces the words "during conversion of oxycodone free base to oxycodone hydrochloride" with the words "at any time before the formation of the final oxycodone hydrochloride API." The Court must interpret the patent "as written, not as the patentees wish they had written it." *Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004). Neither the claim itself nor the specification supports the swap Purdue proposes.

That the specification discloses that "it may be necessary to perform . . . one or more relevant steps in the process of the present invention[] more than once" does not discredit a plain-language interpretation of the phrase "during conversion of." '799 Patent at 8:38–44. First, the Court notes that the only process step in the '799 Patent is the phrase "is derived from [8α] during conversion of oxycodone free base to oxycodone hydrochloride." Purdue does not explain why a repetition of that process step would fall

outside the limiting language "during conversion of." Second, the Court rejects Purdue's attempt to reverse-engineer claim 3 to read on "[a]nother alternative process . . . for preparing an oxycodone hydrochloride composition comprising reacting an oxycodone base composition with an acid having a higher pH than hydrochloric acid to form a corresponding acid addition salt of oxycodone, and converting the acid addition salt of oxycodone to oxycodone hydrochloride." '800 Patent at 8:66–9:4. This embodiment does not specify when 8α converts to 14-hydroxy. In any event, "[i]t is not necessary that each claim read on every embodiment." *Baran v. Med. Device Techs., Inc.*, 616 F.3d 1309, 1316 (Fed. Cir. 2010). Here, the preferred embodiments, the description of the invention, and the expert testimony all tilt in favor of reading the language of the claim to mean what it says.

In addition, Purdue unmistakably distinguished prior art during the prosecution of the patents by reference to the point in a synthesis scheme at which the 14-hydroxy would form:

> Furthermore, one skilled in the art would have expected that the **oxycodone hydrochloride salt** prepared from the **oxycodone free base** of the Chiu patent . . . would also have no [14-hydroxy], as there is nothing in the Chiu patent to suggest that [14-hydroxy] would reappear during hydrochloride salt formation.

(PTX 10 at P1052961–62 (emphasis original).)

Purdue's statements to the Examiner support the reading that the words "during conversion of oxycodone free base to oxycodone hydrochloride" do not mean "at any time before the formation of the final oxycodone hydrochloride salt." Rather, Purdue distinguished Chiu on the grounds that Chiu did not appreciate 14-hydroxy's reappearance "during hydrochloride salt formation." (*Id.*; *cf.* Crimmins Tr. 800:4–6 ("conversion during the HCL [hydrochloride] formation would not be expected to create any 14-[hydroxyl] based on the Chiu patent").) Thus, the patent prosecution history confirms the plain meaning of the limitation expressed in the '799 Patent (claim 3).

b. The '072 Patent (claim 1) does not require the presence of 8α at any particular process step.

The '072 Patent (claim 1) states that the API contains less than 25 ppm of 14-hydroxy "wherein at least a portion of the 14-[hydroxy] is derived from 8α." '072 Patent at 34:59–60. The language of the claim indicates that any 14-hydroxy derived from 8α would satisfy the "derived from" element. The claim does not limit when or how that derivation occurs. As the differences in their language suggest, the '072 Patent (claim 1) does not contain the "during conversion" limit found in the '799 Patent (claim 3). Thus, this claim reads on the alternative embodiment emphasized by Purdue with respect to the '799 claim and does so naturally. '072 Patent at 8:66–9:7.

Defendants urge the Court to conclude that Purdue limited claim '072 (claim 1) during prosecution by making arguments substantially identical to those made in support of the claims of the '799 Patent. The Court agrees with defendants that the statements to the Examiner emphasized the importance of 14-hydroxy's formation from 8α during the hydrochloride salt-formation step. (*E.g.*, PTX 11 at P1034313.) Nonetheless, the Court cannot conclude that the Purdue's statements amounted to a "clear and unmistakable" disavowal of claim scope. *See Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1374–75 (Fed. Cir. 2008). Unlike the circumstance of the '799 Patent, where Purdue's statements to the Examiner supported the ordinary meaning of its claim language, those same statements do not convince the Court that Purdue intended to relinquish the more broadly written claims of the '072 Patent.

* * *

Accordingly, claim 3 of the '799 Patent requires (1) an oral dosage form (2) containing "from about 5 mg to about 320 mg of oxycodone hydrochloride" API, (3) the presence in the oxycodone hydrochloride of more than zero and less than 25 ppm 14-hydroxy, (4) some of which must have been derived from 8α "during conversion of oxycodone free base to oxycodone hydrochloride," and (5) a pharmaceutically acceptable excipient. Claim 19 depends from claim 3, and therefore incorporates its elements, but further calls for the "acceptable excipient" to be a "sustained release carrier."

Claim 1 of '072 Patent requires (1) oxycodone hydrochloride API, (2) containing more than zero and less than 25 ppm 14-hydroxy, and (3) some of the 14-hydroxy present in the API must have been derived from 8α. Dependent claims 4 and 5 incorporate the limitations of claim 1, but specify lower levels of 14-hydroxy (less than 15 ppm and less than 10 ppm, respectively).

4. *The '799 and '072 Patents are products with process limitations*

The parties agree that claim 1 of the 072 Patent and claim 3 of the 799 Patent are limited by their respective wherein clauses. (Pls.' Opening Br. at 39; Defs.' Opening Br. at 5–6.) The parties disagree on the type of limitation those clauses create. Purdue contends that these claims describe a product purely by its structure. Defendants argue that these claims describe a product by the process used to obtain it.[10] The Court agrees with defendants.

Ordinarily, the product claimed by a patent "is not limited to the process by which it was made." *Vanguard Prods. Corp. v. Parker Hannifin Corp.*, 234 F3d 1370, 1372 (Fed. Cir. 2000). Thus, "method of manufacture, even when cited as advantageous, does not of itself convert product claims into claims limited to a particular process." *Id.* A limitation is not a process limitation if, when "read in context, [it] describes the product more by its *structure* than by the *process* used to obtain it." *Hazani v. U.S. Int'l Trade Comm'n*, 126 F.3d 1473, 1479 (Fed. Cir. 1997) (emphasis added); *see also Gemtron Corp. v. Saint-Gobain Corp.*, 572 F.3d 1371, 1379 (Fed. Cir. 2009) ("Defining a structural component by its functional as well as its physical characteristics is different from defining a structure solely by the process by which it is made."); *In re Garnero*, 412 F.2d 276, 279 (C.C.P.A. 1969) (phrase not a process limitation when it is capable of being a structural limitation).

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[10] Construing a claim as a product-by-process claim has two consequences. First, "the defining limitations of a claim . . . are also the terms that show infringement." *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1293 (Fed. Cir. 2009) (en banc). Second, the validity of a claim must be assessed without reference to the claim's process limitations. *Greenliant Sys., Inc. v. Xicor LLC*, 692 F.3d 1261, 1268 (Fed. Cir. 2012).

By contrast, a product-by-process claim is "'one in which the product is defined at least in part in terms of the method or process by which it is made.'" *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 158 n.* (1989) (quoting D. Chisum, Patents § 8.05 at 8-67 (1988)). A patentee can state a claim in product-by-process form by reciting a product and a series of steps by which that product is obtainable. *E.g.*, *Abbott Labs.*, 566 F.3d at 1295. For instance, when "the claimed physical properties of [a product] are attributable to the process that is used to make [it]," the claim is to a product made by a process. *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1372 (Fed. Cir. 2007).

The phrase "derived from 8α" in the '799 and '072 Patents does not describe the structure of 14-hydroxy. To a skilled artisan—indeed, to anyone—14-hydroxy is 14-hydroxy, whether its source is 8α or 8β. (Heathcock Tr. 1124–26; Wuest Tr. 1342–43 (hydrogenating 14-hydroxy produces the same result regardless of the source of the 14-hydroxy).) As a structural description, the phrase "derived from 8α" is meaningless. For example, the specification sets out a method for detecting 14-hydroxy without regard to its source. *E.g.*, '799 Patent at Examples 4 & 6. And the specification includes no embodiment where the described hydrogenation process changes depending on the source of the 14-hydroxy being hydrogenated. *E.g.*, '799 Patent at 6:59–7:55. Indeed, the written description defines 8,14-dihyroxy as 8α or 8β or a mixture of the two. '799 Patent at 5:54–57. The common specification gives no indication that 8α imparts some quality to 14-hydroxy.

Although the phrase "derived from 8α" cannot describe a structural feature of 14-hydroxy, it does describe the process used to obtain a particular molecule of 14-hydroxy. To a skilled artisan, the "derived from" language indicates a "chemical reaction is occurring where one chemical entity is being converted into another chemical entity." (Crimmins Tr. 808.) By focusing on 8α, rather than 8β, the plain language of the claims indicates the relevant starting material for the chemical reaction is 8α and not 8β. (Crimmins Tr. 808.) The "derived from" limitation therefore modifies the claims by excluding processes for obtaining 14-hydroxy that would not cause the acid-catalyzed dehydration of some 8α molecules. Reading these claims as product-by-process claims accords with the common specification's disclosure of process conditions under which

acidifying oxycodone free base will cause 8α to convert into 14-hydroxy. *E.g.*, '072 Patent at Figure 2 & Example 3. The prosecution history does not suggest otherwise.

In addition to the "derived from" limitation, the '799 Patent (claim 3) includes a further limitation: some conversion from 8α to 14-hydroxy must occur "during conversion of oxycodone free base to oxycodone hydrochloride." A skilled artisan would understand this limitation to be a process limitation specifying when at least a portion of the 14-hydroxy must be obtained from 8α. (Crimmins Tr. 808.) Purdue does not contend, nor does the Court find, that any structural or physical characteristic of 14-hydroxy that could be described by reference to the process step at which a molecule has been formed.

In sum, describing 14-hydroxy by reference to its chemical precursors, 8α and 8β, does not say anything about a structural component of 14-hydroxy, its physical characteristics, or its functional capacity. Instead, the claim language limits 14-hydroxy to that obtained by a process using 8α. These conditions do not describe a structural limitation. A skilled artisan would know nothing more about the structure of a 14-hydroxy molecule if he or she knew that 8α had been the molecule's source.

Nonetheless, Purdue contends that the Court should construe the "is derived from" language according to the rule that "[l]imitations . . . expressed in the past tense, have been found to be structural, not product-by-process." (Pls.' Opening Br. at 39.) But the "is derived from" language of the '072 and '799 claims is in the passive voice of the present tense—it is not a past tense verb. Moreover, the ultimate inquiry is whether the "is derived from" limitation "describes the product more by its structure [or] by the process used to obtain it." *Hazani*, 126 F.3d at 1479. Whatever tense or mood expressed in the patent, the phrase "is derived from" in the '799 Patent (claim 3) and '800 Patent (claim 1) has meaning only because it excludes from the claim processes that do not obtain any 14-hydroxy from 8α and, for the '799 Patent, that do not obtain any 14-hydroxy from 8α during the oxycodone hydrochloride formation step.

Last, the Court notes that the Federal Circuit has sometimes identified particular process-type phrases as "source limitations." *See, e.g., Amgen Inc. v. F. Hoffman-La Roche Ltd*, 580 F.3d 1340, 1366–67 (Fed. Cir. 2009); *Amgen*

Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1328–30 & n.5 (Fed. Cir. 2003). Applying that label to the phrase "derived from 8α" would have no practical effect on the action. The evidence conclusively demonstrates that a molecule of 14-hydroxy has no feature that can be attributed to its source. This distinguishes 8α and 8β from the human and non-human EPO at issue in the *Amgen* cases. There, the Federal Circuit concluded that a claim limited to EPO derived from "non-human" sources did not create a process limitation. *See Hoechst*, 314 F.3d at 1329. But as the Court later explained, human and non-human EPO exhibit "differences in carbohydrate composition." *Hoffman-La Roche*, 580 F.3d at 1367. Here the "derived from 8α" limitation adds no patentable significance to the product and is therefore irrelevant to show nonobviousness and novelty. "[A] claimed product shown to be present in the prior art cannot be rendered patentable solely by the addition of source or process limitations." *Hoechst*, 314 F.3d at 1354 n.20; *see also Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 373–74 (1938); *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1317–19 (Fed. Cir. 2006).

* * *

The Court has construed the '072 and '799 Patents to contain process limitations. The disputed phrase "derived from 8α" cannot be understood as a product limitation. By contrast, it can be understood to limit the processes by which the product may be obtained.

5. ***All patents: "detectable" amounts of 14-hydroxy and 8α are not required***

Defendants urge the Court to impose a limitation on all claims that the relevant levels of 14-hydroxy and 8α be at "detectable levels." The Court does not accept that requirement. Such a limitation would serve only to exclude methods of proving infringement other than by experimental detection. Neither the claim language nor the specification supports such a construction. The words "detectable levels" never appear in the patent claims or specification, and defendants do not point to any aspect of the prosecution history that would support such a reading. Defendants' best argument is that the specification discloses a method for detecting 14-hydroxy. But the disclosure of that method does not indicate that the inventors surrendered other methods of demonstrating the presence of 14-

hydroxy or 8α and thereby narrowed the scope of their claims. *See Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1333 (Fed. Cir. 2010).

IV. CONCLUSION

These patents will now proceed to trial. On the basis of the claim construction set forth above, the Court will determine whether defendants' ANDAs infringe the Abuse-Proof and Low-ABUK Patents and whether these patents are valid.

Dated: New York, New York
August 23, 2013

SO ORDERED:

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

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re: OXYCONTIN ANTITRUST LITIGATION	04 Md. 1603 (SHS)
PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., RHODES TECHNOLOGIES, and GRÜNENTHAL GMBH, Plaintiffs, -against- AMNEAL PHARMACEUTICALS, LLC, Defendant.	This document relates to: 11 Civ. 8153 (SHS)
PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., and RHODES TECHNOLOGIES, Plaintiffs, -against- EPIC PHARMA, LLC, Defendant.	13 Civ. 683 (SHS)
PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., RHODES TECHNOLOGIES, BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM, and GRÜNENTHAL GMBH, Plaintiffs, -against- IMPAX LABORATORIES, INC., Defendant.	11 Civ. 2400 (SHS)

PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., RHODES TECHNOLOGIES, BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM, and GRÜNENTHAL GMBH, Plaintiffs, -against- PAR PHARMACEUTICAL, INC., Defendant.	11 Civ. 2038 (SHS)
PURDUE PHARMA L.P and GRÜNENTHAL GMBH, Plaintiffs, -against- PAR PHARMACEUTICAL, INC., Defendant.	12 Civ. 5615 (SHS)
PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., RHODES TECHNOLOGIES, BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM, and GRÜNENTHAL GMBH, Plaintiffs, -against- SANDOZ INC., Defendant.	11 Civ. 4694 (SHS) 12 Civ. 897 (SHS)

PURDUE PHARMA L.P. and GRÜNENTHAL GMBH, Plaintiffs, -against- SANDOZ INC., Defendant.	12 Civ. 5082 (SHS) 12 Civ. 7582 (SHS)
PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., RHODES TECHNOLOGIES, and GRÜNENTHAL GMBH, Plaintiffs, -against- TEVA PHARMACEUTICALS, USA, INC., Defendant.	11 Civ. 2037 (SHS)
PURDUE PHARMA L.P. and GRÜNENTHAL GMBH, Plaintiffs, -against- TEVA PHARMACEUTICALS, USA, INC., Defendant.	12 Civ. 5083 (SHS)

CLAIM CONSTRUCTION OPINION & ORDER

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

This Hatch-Waxman Act litigation concerns the brand-name drug OxyContin, which is manufactured and sold by plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., and Rhodes Technologies (collectively, "Purdue"). Defendants—Amneal Pharmaceuticals, LLC; Epic Pharma, LLC; Impax Laboratories, Inc.; Par Pharmaceutical, Inc.; Sandoz Inc.; and Teva Pharmaceuticals, USA, Inc.—have filed Abbreviated New Drug Applications ("ANDAs") seeking to sell generic versions of OxyContin. Plaintiffs contend that defendants' ANDAs infringe six patents that claim the OxyContin formulation currently sold in the United States. Purdue, as well as plaintiffs the Board of Regents of the University of Texas System and Grünenthal GmbH (collectively with Purdue, "plaintiffs"), developed these patents to address two undesirable features of the original formulation of OxyContin. First, original OxyContin contained significant levels of 14-hydroxycodeinone, which belongs to a class of compounds known as ABUKs—alpha, beta unsaturated ketones—that may be genotoxic or carcinogenic. Second, original OxyContin tablets were often abused by snorting or injecting crushed or dissolved tablets.

The six patents that address these issues fall into two groups. Three are the "Abuse-Proof Patents":

- U.S. Patent No. 6,488,963 ("'963 Patent") (Rabenstein Decl., Ex. A)
- U.S. Patent No. 7,763,314 ("'314 Patent") (Rabenstein Decl., Ex. B)
- U.S. Patent No. 8,114,383 ("'383 Patent") (Rabenstein Decl., Ex. C)

And the other three are the "Low-ABUK Patents":

- U.S. Patent No. 7,674,799 ("'799 Patent") (PTX 2)[1]
- U.S. Patent No. 7,674,800 ("'800 Patent") (PTX 3)

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[1] The parties have incorporated the record of the trial held in *Purdue Pharma, L.P., et al. v. Ranbaxy, Inc., et al.*, No. 10 Civ. 3734, into this claim-construction proceeding. (Pls.' Opening Br. at 31 n.7; Defs.' Opening Br. at 3 n.3.)

- U.S. Patent No. 7,683,072 ("'072 Patent") (PTX 4)

On July 15, 2013, the Court held a consolidated *Markman* hearing to construe the disputed portions of the claims at issue in each of the patents listed above. This opinion and order is the result.

I. General Legal Standard

"[T]he claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quotation marks omitted). "The words of a claim are generally given their ordinary and customary meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Medtronic Inc. v. Boston Scientific Corp.*, 695 F.3d 1266, 1275 (Fed. Cir. 2012) (quotation marks and alterations omitted). "Claims, however, must be construed in light of the appropriate context in which the claim term is used." *Aventis Pharm. Inc. v. Amino Chems. Ltd.*, 715 F.3d 1363, 1373 (Fed. Cir. 2013). That context includes the specification, which "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (quotation marks omitted). "The prosecution history too, as part of the intrinsic record, has an important role in claim construction by supplying context to the claim language." *Aventis*, 715 F.3d at 1373.

The Court will set aside the rule that claim terms receive their ordinary and customary meaning in just two circumstances: "1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution." *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, No. 2012-1567, 2013 WL 3836240, at *7 (Fed. Cir. July 26, 2013) (quotation marks omitted). "A disclaimer must be clear and unmistakable, and unclear prosecution history cannot be used to limit claims." *Cordis Corp. v. Boston Scientific Corp.*, 561 F.3d 1319, 1329 (Fed. Cir. 2009) (quotation marks omitted).

With these legal principles in mind, the Court addresses the disputed claims, first in the Abuse-Proof Patents, then in the Low-ABUK Patents.

II. THE ABUSE-PROOF PATENTS

A. Background

The FDA first approved the sale of OxyContin tablets in 1995. *See* Determination that the OXYCONTIN (Oxycodone Hydrochloride) Drug Products Covered by New Drug Application 20-553 Were Withdrawn from Sale for Reasons of Safety or Effectiveness, 78 Fed. Reg. 23,273, 23,273 (Apr. 18, 2013) [hereinafter "FDA Determination"]. In approximately 2000, Purdue began receiving reports that its original OxyContin tablets were being abused. (Rabenstein Decl., Ex. 1 at 46.) The vast majority of abuse consisted of users swallowing too many pills. (*Id.* at 46.) Some abusers, however, were crushing the tablets and then either snorting them or, after dissolving the crushed tablets in a small amount of liquid, injecting them intravenously. (*Id.* at 44–46.)

As a result of these reports, Purdue began to take steps to make its tablets resistant to abuse. (*Id.* at 47, 49.) Purdue's early efforts centered on combining OxyContin's active pharmaceutical ingredient ("API") with other agents to block the effects of snorting or injecting the drug. (*Id.* at 49–52.) These avenues turned out to be dead ends. (*Id.* at 73; Rabenstein Decl., Ex. 4 at 0265164.)

Purdue thus began to look for third-party solutions to reduce abuse. In mid-2004, Purdue representatives visited the offices of Grünenthal in Germany for a demonstration of a prototype abuse-deterrent tablet. (Rabenstein Decl., Ex. 5 at PRF2704014–15.) The prototype tablet was very hard and difficult to crush. (*Id.* at PRF2704015.) The tablet also contained hydrogel, which made the tablet difficult to dissolve in water. (*Id.*) And if snorted, the hydrogel would "cause significant nasal discomfort, similar to nasal congestion from a cold or flu." (*Id.*) By November 2004, Purdue believed that Grünenthal's tablet "appear[ed] to be superior" to "all of the non-agonist abuse resistant technologies" that Purdue knew about. (Rabenstein Decl., Ex. 6 at PRF2699737.) Purdue and Grünenthal began negotiations about a possible licensing agreement in late 2004 and early 2005. (Rabenstein Decl., Ex. 7 at 178, 182.)

Also in 2004–2005, Purdue had an in-house team working on crush-resistant tablets. (Rabenstein Decl., Ex. 8 at 43–44.) In November 2005, scientists at Purdue experimented with tablet formulations that included a

high-molecular-weight form of polyethylene oxide ("PEO") as one of the components. (Rabenstein Decl., Ex. 8 at 78–79, 154; Rabenstein Decl., Ex. 20.) Purdue scientists found that if tablets containing PEO were put through a "curing step" of melting the tablet then cooling it, the resulting tablet became exceptionally hard. (Rabenstein Decl., Ex. 8 at 208.) Purdue scientists also found that if the tablets containing PEO were crushed and then mixed with water, the mixture formed a gel-like substance. (Rabenstein Decl., Ex. 8 at 403.)

Purdue's development of the PEO-based tablet led them to file New Drug Application ("NDA") 22-272, an updated version of the original OxyContin. Original OxyContin was the subject of NDA 20-553. The FDA approved NDA 22-272 in April 2010. *See* FDA Determination, 78 Fed. Reg. at 23,273. The drug that references NDA 22-272, so-called "Reformulated OxyContin," is now the only form of OxyContin that Purdue sells in the United States. (Rabenstein Decl., Ex. 14 at 40–41.)

Once Purdue was committed to moving forward with the PEO-based tablets, Purdue entered into licensing agreements with Grünenthal (Rabenstein Decl., Ex. 7 at 192) and the University of Texas System. *E.g.*, *Purdue Pharma L.P. v. Sandoz Inc.*, No. 12 Civ. 897, Dkt. No. 1 ¶ 15. Those two entities had applied for and received the three Abuse-Proof Patents in suit.

B. Construction of the Disputed Claims in the '963 Patent

The '963 Patent is a product of the research of Dr. James McGinty, a professor at the University of Texas at Austin, and one of his then-graduate students, Fen Zhang. McGinty and Zhang were researching whether high-molecular-weight PEO tablets could be made using a heat-based system. The particular method they explored was known as "hot-melt extrusion." Several steps went into McGinty and Zhang's hot-melt extrusion process. First, a powdered form of a therapeutic compound was mixed with high-molecular-weight PEO. '963 Patent at 8:8–11. This mixture was then placed into a machine called an extruder. *Id.* at 8:17–19. The mixture then passed through the heated area of the extruder at a temperature sufficient to melt or soften the PEO. *Id.* at 8:19–22. The softened mixture exited the extruder through a die, after which the mixture could be sliced into tablets. *Id.* at 8:22–28, 13:10–11.

Only two of the '963 Patent's six claims are at issue in this litigation. Plaintiffs assert that defendants' ANDAs infringe claim 6, which depends from claim 1. These two claims recite:

> 1. A non-film controlled release pharmaceutical formulation comprising an effective amount of a therapeutic compound and a high molecular weight poly(ethylene oxide), wherein the poly(ethylene oxide) has a molecular weight of about 1,000,000 to about 10,000,000 Daltons, and wherein the poly(ethylene oxide) and the therapeutic compound comprise a ratio of poly(ethylene oxide) to therapeutic compound of from about 99.99:.01 weight percent to about 50:50 weight percent.
>
> 6. The non-film controlled release pharmaceutical formulation of claim 1 wherein said formulation is prepared by a process of hot-melt extrusion.

'963 Patent at 14:26–34, 51–53. The parties dispute the meaning of just two terms, both of them in claim 1. First, the parties contest the meaning of the term "non-film controlled release pharmaceutical formulation." Second, the parties dispute the meaning of the weight-ratio term of claim 1.

1. *The final formulation cannot be a film or comprised of layered films*

The parties first dispute the meaning of the preamble of claim 1: "non-film controlled release pharmaceutical formulation . . . ." All agree that this preamble limits the claims. (Pls.' Opening Br. at 10 n.4.) The dispute centers on the scope of the term "non-film." Defendants argue that this term means that the claimed formulation cannot, in its final form, be a film. Plaintiffs contend that the term "non-film" is broader (and thus that the claims are narrower). According to them, "non-film" means that the final formulation is not a film or made of films.

The term "non-film" is not defined in the claims, and the specification discusses it only briefly. In the "Field of the Invention" section of the '963 Patent, the inventors recite that the invention relates to PEO-based formulations "that are not film-like preparations." '963 Patent at 1:13. The use of the term "film-like" suggests that the invention excludes a broader class of final formulations than simple films. In addition, none of the

examples discloses a preparation in which the final formulation is made of films.

Neither the inventors nor the Examiner discussed the non-film term in any detail during prosecution. However, prior art cited to the Examiner demonstrates that, to those skilled in the art, the term "film" has both a broad and a narrow definition. *See ArcelorMittal France v. AK Steel Corp.*, 700 F.3d 1314, 1321–22 (Fed. Cir. 2012) ("[W]hen an inventor's understanding of a claim term is expressed in the prior art, it can be evidence of how those skilled in the art would have understood that term at the time of the invention." (quotation marks and citations omitted)). In particular, the inventors cited U.S. Patent No. Re. 33,093, known as "Schiraldi," which teaches a "controlled-releasing medicament-containing preparation for intra-oral use." (Rabenstein Decl., Ex. G at 7101, 1:12–14.) The principal form of the invention was "a very thin extruded thermoplastic film (which can be in single layer or laminated multi-layer form)." (*Id.* at 1:15–17.) The Schiraldi patent goes on to claim such a "single or multi-layered thin film." (*Id.* at 7105, 9:41–42.) "Mooney," another piece of prior art cited during prosecution (*id.* at 7195), also discloses formulations made of multiple layers extruded one onto the other. (*Id.* at 7206.) Mooney labels these preparations "multilayered films." (*Id.*) Mooney and Schiraldi thus make clear that the term "film" can be used to mean (and is used in the art to mean) alternatively: (1) single-layer films, or (2) the broader category of films, which encompasses single and multi-layered films.

The parties have also presented the Court with extrinsic sources—not cited in the '963 Patent or during prosecution—that shed some light on the meaning of "film." One article, known as "Apicella," teaches PEO-based "tablets" made by layering films. *See* A. Apicella et al., *Poly(ethylene oxide) (PEO) and different molecular weight PEO blends monolithic devices for drug release*, 24 Biomaterials 83, 83, 86 (1993) (Rabenstein Resp. Decl., Ex. 7). Specifically, Apicella teaches preparing polymer films containing an API, layering these films, then compression molding the layers at 75° C "to form sheets from which were cut circular tablets." *Id.* at 86. In other words, Apicella made a formulation comprised of layered films and called that formulation a "tablet." At the same time, however, Apicella never

explicitly states that its tablet does not also fall within the broader meaning of the term "film."

Plaintiffs point to an article known as "Kim" that characterized Apicella as teaching that "drug release from un-cross-linked low molecular weight PEO of MW = 0.6×10^6 (laminated films) ensures a constant release rate by achieving synchronized gel thickness." Cherng-ju Kim, *Drug Release from Compressed Hydrophilic POLYOX-WSR Tablets*, 84 J. Pharm. Sci. 303, 303 (1995) (Rabenstein Resp. Decl., Ex. 8). The parenthetical makes clear that Kim understood Apicella to teach "laminated films."

In light of all the available evidence, the Court concludes that one skilled in the art would read "non-film" to mean "not a film or comprised of layered films."[2] The prior art cited during prosecution make clear that film has both a broad and a narrow meaning. Layered films—even layered films that are heated—fall within the broader meaning of "film." And the use of the term "film-like" in the specification of the '963 Patent conclusively demonstrates that when the inventors claimed the term "non-film," they meant the broader meaning of that term. Since "film," as that word is used in claim 1, encompasses layered films, then the term "non-film" cannot encompass them. The ambiguous extrinsic evidence cannot overcome what is clear from the specification and cited prior art. As such, the Court will read the term "A non-film controlled release pharmaceutical formulation . . ." as "A controlled release pharmaceutical formulation, which, in its final form, is not a film or comprised of layered films . . . ."

2. *The final formulation must contain at least 50% PEO by weight*

The parties next dispute the weight-ratio term of claim 1, which provides that the PEO and API in the formulation shall "comprise a ratio of [PEO] to [API] of from about 99.99:.01 weight percent to about 50:50

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[2] The inclusion of the "Rippie" reference in the '963 Patent demonstrates that the inventors did not mean to exclude formulations in which a film was merely used at some intermediate step. *See* '963 Patent at 14:2; E.G. Rippie & J.R. Johnson, *Regulation of Dissolution Rate by Pellet Geometry*, 58 J. Pharm. Sci. 428, 429 (1969) (Prutzman Decl., Ex. 18).

weight percent." The parties agree that this term requires that the PEO and API be present in the final formulation in a ratio, by weight, of about 99.99:.01 to about 50:50. They disagree whether this term requires that the final formulation contain some minimum amount of PEO, measured by weight. Plaintiffs argue that the weight-ratio term specifies that the formulation comprises at least 50% PEO by weight. (Pls.' & Defs.' Proposed Constructions for Claim Terms at 1; Hearing Tr. 19.) Defendants assert that the plain meaning of the term contains no such limitation.

The Court agrees that a skilled artisan would not ordinarily understand the weight-ratio term to limit the amount of PEO in the final formulation. However, during prosecution, the inventors clearly and explicitly limited their invention to a final formulation in which PEO comprises at least 50% by weight.

a. The Inventors Limited Their Invention During Prosecution

As originally filed in March 1999, the application for the '963 Patent contained two claims (3 and 10) that specified a ratio of PEO to therapeutic compound. (Rabenstein Decl., Ex. G at 6907–08.) Claim 3 specified that the PEO and therapeutic compound would "comprise a ratio of from about 99.99:01 [sic] % wt. to about 80:20 % wt." (*Id.* at 6907.) Claim 10 specified that the PEO and therapeutic compound would be included in the formulation "in a ratio of about 99.99:0.01 to about 80:20% wt." (*Id.* at 6908.)

In May 2000, the Examiner rejected all of the proposed claims. Among other reasons, the Examiner rejected claims 1–18 as anticipated by U.S. Patent No. 4,629,621, referred to as "Snipes '621," which teaches formulations containing high-molecular-weight PEO in amounts up to 2%. (*Id.* at 7097.) The Examiner did not simply reject the claims, he gave the inventors a roadmap for overcoming this objection: "Applicants may overcome Snipes '621," he noted, "by specifying % PEO *with respect to the total composition*." (*Id.* (emphasis added).)

The inventors responded in October 2000. In their updated application, the inventors cancelled claims 3 and 10—the claims with the PEO ratios—and transposed the ratio term into amended claims 1 and 9. (*Id.* at 7111–13.) Although the inventors changed the placement of the ratio terms, they did not change their language—amended claims 1 and 9 contained

identical language to original claims 3 and 10, respectively. The inventors explained these amendments as follows: "The Examiner has recommended the specification of the percent [PEO] to distinguish the compositions over Snipes '621. Applicants have incorporated language in the amended claims that provide further definition of the formulation." (*Id.* at 7115.)

In January 2001, however, the Examiner once again rejected all of the proposed claims, including amended claims 1 and 9. (*Id.* at 7139–40.) This time, the Examiner stated that claims 1 and 9 were rejected as anticipated by U.S. Patent No. 4,764,378, known as "Keith." (*Id.* at 7141.) Keith, similar to Snipes '621, taught a composition comprising less than 50% high-molecular-weight PEO. (*Id.*)

In April 2001, the inventors submitted their final amendment. Claim 9 was left unchanged, but the inventors did alter claim 1 in two ways. First, the inventors replaced the term "% wt." with "weight percent," and second they also replaced the term "80:20" with "50:50." (*Id.* at 7150.) The inventors explained why the newly amended claim 1 was not anticipated by either Keith or Snipes '621. (*Id.* at 7147–48.) In Keith, PEO in amounts from 1% to 40% was given as one possible polymer to "'adjust the matrix'" of the formulation. (*Id.* at 7147.) By contrast, "[i]n the amended Claims to the present invention, *the percentage of PEO is never less than 50%.*" (*Id.* (emphasis added).) The inventors further argued that, "[s]imilarly, *Snipes* '621 teaches the use of PEO up to 2%, while *the present invention never contains less than 50%, as amended in this Response.*" (*Id.* at 7148 (emphasis added).)

The April 2001 amendment was successful. In August of that year, the Examiner allowed claim 1, with the amended term "weight percent" and its amended ratio of "50:50." (*Id.* at 7151–52.) But the Examiner again rejected claim 9—the claim whose language had not changed since the original application. (*Id.*)

The prosecution history clearly demonstrates that the inventors disclaimed embodiments of the '963 Patent that contain less than 50% PEO in the final formulation. The Examiner suggested that the inventors make this precise change to overcome Snipes '621 and the inventors complied in two ways. First, they amended the language of claim 1 to replace "% wt." with "weight percent" and the term "80:20" with "50:50." Second, they

explained this amendment as confirming that "the present invention never contains less than 50% [PEO], as amended in this Response." These direct responses to the Examiner's direct request constitute a "clear and unmistakable disavowal of scope" on the part of the inventors. *Purdue Pharma L.P. v. Endo Pharm. Inc.*, 438 F.3d 1123, 1136 (Fed. Cir. 2006); *see Regents of Univ. of Cal. v. Dakocytomation Cal., Inc.*, 517 F.3d 1364, 1373 (Fed. Cir. 2008); *Norian Corp. v. Stryker Corp.*, 432 F.3d 1356, 1362 (Fed. Cir. 2005). Defendants argue that the inventors' statements were not clear enough to constitute prosecution disclaimer. But it would be difficult for the inventors to speak more clearly than "the present invention never contains less than 50% [PEO], as amended in this Response." This statement is as clear, if not clearer, than other statements made during prosecution that the Federal Circuit has held to constitute a disclaimer. *See, e.g., ERBE Elektromedizin GmbH v. Canady Tech. LLC*, 629 F.3d 1278, 1285–86 (Fed. Cir. 2010); *Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1376–77 (Fed. Cir. 2008).

Defendants also assert that the inventors' statement does not refer to the amount of PEO in the final formulation. In order to accept this reading, however, the Court must blind itself to the uncontested fact that the Examiner himself requested that the inventors specify the "% PEO *with respect to the total composition*." (Rabenstein Decl., Ex. G at 7097 (emphasis added).) Moreover, the inventors clearly stated that the "*invention* never contains less than 50%" PEO. As all parties agree, the invention is a "non-film controlled release pharmaceutical formulation"—in other words, a final formulation. Defendants' arguments fail to dislodge the inventors' clear prosecution disclaimer.

b. The Intrinsic Evidence Does Not Overcome the Prosecution Disclaimer

The text of the '963 Patent does not change the impact of the inventors' clear prosecution disclaimer. In fact, plaintiffs find a good deal of support there. The claimed invention in the '963 Patent is a "controlled release pharmaceutical formulation." '963 Patent at 14:26–27. The specification makes clear that the amount of PEO in the final formulation greatly affects the tablet's controlled release properties. As the inventors stated, "[t]he amount of PEO used in the formulation will depend upon . . . [the] desired

release profile [among] other such reasons." '963 Patent at 3:57–65. Figure 1 teaches that altering the molecular weight of the PEO "affects the release profile of the formulation." '963 Patent at 4:13. The "Field of the Invention" section emphasizes that "[t]he present invention relates to the field of [PEO] based hot-melt extrudable pharmaceutical formulations . . . ." '963 Patent at 1:10–12. These portions from the specification strongly suggest that the final formulation must contain a minimum amount of PEO in order for the formulation to have the claimed controlled release properties. Further, none of the embodiments of the invention set forth in the specification contains less than 50% PEO in the formulation as a whole. Indeed, the smallest amount of PEO in any of the examples is 54% and the median amount of PEO is 81%. '963 Patent at 13:30–45.

Defendants, however, urge that the Court's construction impermissibly limits too many other portions of the '963 Patent. For example, claim 2 claims the formulation of claim 1 with the addition of a plasticizer. '963 Patent at 14:35–36. With three ingredients, the final formulation cannot at the same time have at least 50% PEO and have the ratio of PEO to API be 50:50. Defendants are correct that claim 2 does not claim the full scope of claim 1's weight-ratio range, because an exact 50:50 ratio is unavailable. They are incorrect, however, that this limitation presents a conflict. "It does not follow that because" claim 1 encompasses at least 50% PEO and a PEO to API ratio of at least 50:50, "its dependent claims must also be broad enough to encompass" both of these embodiments. *Am. Piledriving Equip., Inc. v. Geoquip, Inc.*, 637 F.3d 1324, 1335 (Fed. Cir. 2011). Dependent claim 2 need not cover the entirety of claim 1's ratio term.

Defendants also point to two portions of the '963 Patent that indicate that formulations with less than 50% PEO would still be covered by the asserted claims. The weight-ratio term from claim 1 claims ratios from "about 99.99:.01 to *about* 50:50," and one portion of the specification states: "When present, the relative amount of plasticizer used may be expressed by the ratio high molecular weight PEO % wt.:plasticizer % wt., and will generally fall in the range of about 100:0 to about 60:40. The amount of plasticizer will generally not exceed the amount of PEO." '963 Patent at 5:24–28. These passages suggest that some embodiments would contain less than 50% PEO yet still be contemplated by claim 1 and the

specification. But these isolated passages must be read in the context of the clear and unmistakable prosecution disclaimer. *See Solvay S.A. v. Honeywell Int'l, Inc.*, 622 F.3d 1367, 1385 (Fed. Cir. 2010). That explicit disclaimer mandates the Court's conclusion.

In the end, the specification and other claims do not alter the fact that the inventors disclaimed final formulations with less than 50% PEO. The Court will therefore construe the term "wherein the poly(ethylene oxide) and the therapeutic compound comprise a ratio of poly(ethylene oxide) to therapeutic compound of from about 99.99:.01 weight percent to about 50:50 weight percent" to read "wherein the poly(ethylene oxide) and the therapeutic compound comprise a ratio, by weight, of poly(ethylene oxide) to therapeutic compound of from about 99.99:.01 to about 50:50, with the poly(ethylene oxide) comprising at least 50% of the formulation."

* * *

The Court therefore construes claim 1 to read as follows:

> 1. A controlled release pharmaceutical formulation, which is not a film or comprised of layered films, comprising an effective amount of a therapeutic compound and a high molecular weight poly(ethylene oxide), wherein the poly(ethylene oxide) has a molecular weight of about 1,000,000 to about 10,000,000 Daltons, and wherein the poly(ethylene oxide) and the therapeutic compound comprise a ratio, by weight, of poly(ethylene oxide) to therapeutic compound of from about 99.99:.01 to about 50:50, with the poly(ethylene oxide) comprising at least 50% of the formulation.

C. Construction of the Disputed Claims in the '314 Patent

In the early 2000s, once reports of abuse of opioid drugs became common, researchers at Grünenthal began investigating ways to deter abusers from injecting intravenously the API from oral tablets. (Davies Decl. ¶ 39.) Johannes Bartholomäus and Henrich Kugelmann developed a product in which a "solid dosage form" would include a "viscosity-increasing agent." '314 Patent at 1:8–11. If the solid dosage form were crushed and mixed with liquid, the combination would form a gel that would "remain[] visually distinguishable even after being introduced into a further quantity of aqueous liquid" and passing through a syringe. *Id.* at

1:14–16. This result was intended to have two effects. First, the resulting gel, with its "turbid appearance, [would] provide[] the potential abuser with an additional optical warning and discourage[] him/her from administering the gel parenterally." *Id.* at 6:6–9. Second, if the abuser is not put off by the turbid appearance, "[i]ntravenous administration of such an extract would most probably result in obstruction of blood vessels, associated with serious embolism or even death of the abuser." *Id.* at 2:31–33.

The '314 Patent contains 12 claims, but the only claims in issue are independent claim 1 and dependent claims 2, 6, and 9. Of these, the parties only dispute terms from claim 1, which reads as follows:

> 1. A parenteral abuse-proofed solid dosage form for oral administration, comprising, in addition to one or more active ingredients with potential for abuse selected from the group consisting of opiates, opioids, tranquillizers, stimulants and narcotics, at least one viscosity-increasing agent in a quantity equal to or greater than 5 mg per dosage form and such that an aqueous extract obtained from the dosage form with 10 ml of water at 25° C. forms a gel which can still pass through a needle having a diameter of 0.9 mm and remains visually distinguishable when introduced by a needle into a further quantity of an aqueous liquid.

'314 Patent at 11:66–12:31. Two terms are at issue in this opinion. First, the parties dispute the meaning of "parenteral abuse-proofed." (Parenteral refers to any way of getting a substance into one's body other than orally.) Second, the parties contest the proper meaning of the term "visually distinguishable" or "remains visually distinguishable."[3]

1. *"Parenteral abuse-proofed" means "reduced potential for parenteral abuse"*

The preamble of claim 1 recites: "[a] parenteral abuse-proofed solid dosage form for oral administration." Once again, the parties agree that

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[3] Defendants also argue that the claims at issue in the '314 Patent are indefinite, and thus invalid. *See* 35 U.S.C. § 112(b). The Court declines to rule on this issue prior to trial.

this preamble limits the claim. (Pls.' Opening Br. at 10 n.4.) The parties disagree on the meaning of the term "parenteral abuse-proofed." Plaintiffs assert that this term means "reduced potential for parenteral abuse," while defendants claim that it means "preventing parenteral abuse under any circumstances." (Pls.' Opening Br. at 19; Defs.' Opening Br. at 33.) The Court agrees with plaintiffs' interpretation.

The Court begins with the plain meaning of the term. Defendants urge that the plain meaning unambiguously favors their interpretation. They point to Webster's dictionary, which defines the suffix "-proof" as "sometimes distinguished from *resistant*" (D'Amore Decl., Ex. 20), and "bulletproof" as "impenetrable to bullets." (D'Amore Decl., Ex. 21.) A bulletproof jacket, defendants argue, may not stop all bullets however large they might be, but it guarantees protection against *some* bullets. (Hearing Tr. 52.) Similarly, they assert that "parenteral abuse-proofed" does not connote that the claimed formulation will prevent any and all abuse—but it does claim that the invention will stop parenteral abuse.

"[J]udges may 'rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents.'" *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 429 F.3d 1364, 1375 (Fed. Cir. 2005) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1322–23 (Fed. Cir. 2005)) (quotation marks omitted). In this case, defendants' dictionaries do not unambiguously support their position. The Webster's reference explicitly states that the suffix -proof is only *sometimes* distinguished from resistant. But even if the dictionary definition were clear and unambiguous, the intrinsic evidence of the '314 Patent shows that one skilled in the art would not understand "abuse-proofed" in the manner defendants suggest. The inventors made clear in the specification that the object of the invention "has been achieved by the provision of the solid dosage form according to the invention with *at least reduced potential* for parenteral abuse . . . ." '314 Patent at 1:66–2:1 (emphasis added). "At least reduced potential for parenteral abuse" is a far cry from preventing all parenteral abuse.

The inventors' discussion of the prior art during prosecution also reveals that one skilled in the art would not read "abuse-proofed" as strictly as defendants suggest. In response to one of the Examiner's many rejections of the '314 Patent, the inventors commented that the "abuse-

proofing" of two pieces of prior art "proceed[] on a fundamentally different principle." (PRF0007668.) But neither of these pieces of prior art—international patent application WO 99/32120, known as "Palermo," and U.S. Patent No. 4,070,494 ("'494 Patent")—teaches abuse-proofing in the manner defendants suggest. Palermo claims a "method of *reducing* the abuse potential of an oral dosage form of an opioid analgesic," WO 99/32120 at 1, 42 (emphasis added), and the '494 Patent teaches improvements to "*inhibit or prevent* the abuse of the agent through parenteral injection." '494 Patent at 1:18–20 (emphasis added). Moreover, when the inventors distinguished Palermo to the Examiner, they did so by comparing their invention with the particular method Palermo employed to achieve its abuse-reducing potential. (PRF0007629–30; PRF0007665–68; PRF0007710.) The inventors never distinguished Palermo on the basis that it did not teach "abuse-proofing" as defendants interpret that term.

The Court therefore concludes that one skilled in the art would understand "abuse-proofed" to mean a "reduced potential for abuse."

2. ***The patentees defined "visually distinguishable"***

Claim 1 of the '314 Patent provides that the gel formed by mixing the claimed dosage form with water "remains visually distinguishable when introduced by a needle into a further quantity of an aqueous liquid." The parties dispute what the "remains visually distinguishable" term means.

"In construing the terms of a patent, the court must [] examine the specification to determine whether the patentee used the claim term consistent with its ordinary meaning or acted as his own lexicographer in defining the term." *Glaxo Grp. Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1346 (Fed. Cir. 2004). If the patentee does act as his own lexicographer, the definition provided "offers practically incontrovertible directions about claim meaning." *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1288 (Fed. Cir. 2009) (en banc). Put another way, "[i]f the special meaning of claim language [provided by the patentee] is reasonably clear and precise, the court's role in claim construction is to pronounce that meaning as the acquired meaning of the word used in the claim." Herbert F. Schwartz & Robert J. Goldman, Patent Law & Practice 153 (7th ed. 2011).

As plaintiffs admit, "the inventors explicitly defined 'visually distinguishable' in the specification." (Pls.' Opening Br. at 20.) Defendants

agree. (Defs.' Opening Br. at 20.) The portion of the specification that defines "visually distinguishable" reads:

> For the purposes of the present invention, visually distinguishable means that the active ingredient-containing gel formed by extraction from the dosage form with the assistance of a necessary minimum quantity of aqueous liquid, when introduced with a hypodermic needle with a diameter of 0.9 mm into a further quantity of aqueous liquid at 37° C., remains substantially insoluble and cohesive and cannot straightforwardly be dispersed in such a manner that it can safely be administered parenterally, in particular intravenously. The material preferably remains visually distinguishable for at least one minute, preferably for at least 10 min.
>
> The increase in viscosity of the gel with the assistance of the selected viscosity-increasing agent means that, although this has been rendered more difficult, the gel may still be passed through a needle or injected. It also means that when the resultant extract or gel is introduced at 37° C. into a further quantity of aqueous liquid, for example also by injection into blood, a largely cohesive thread is initially obtained which, while it may be broken up into smaller fragments by mechanical action, it cannot be dispersed or even dissolved in such a manner that it may safely be administered parenterally, in particular intravenously.

'314 Patent at 2:9–30. The Court must employ the definition supplied by the inventors.

Plaintiffs, however, take the position that even though the patentees acted as their own lexicographers, the Court should read into this definition additional glosses from the patent's examples. Specifically, plaintiffs suggest deleting the term "largely cohesive thread" (that forms when the gel extract is injected into the further quantity of liquid) and replacing it with "thread or thread-like fragments." (Pls.' Resp. Br. at 20.) Plaintiffs also suggest importing a requirement that the "broken up" threads be visible to the naked eye, and that the "mechanical action" be narrowed to mean "stirred." (*Id.* at 20.) Ultimately, plaintiffs "don't want to be litigating the question of the adverbs" contained in the patentees' own definition of "visually distinguishable." (Hearing Tr. 46.)

Plaintiffs simply ask the Court to do an end run around the patentees' own definition. Once the inventor acts as his own lexicographer, that definition overrules the traditional tools of claim construction. *See 3M Innovative Props. Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1374 (Fed. Cir. 2003). The scattered references to "thread-like fragments" in the '314 Patent's examples do not overcome the "practically incontrovertible directions" of the patentees' own definition. *Abbott Labs.*, 566 F.3d at 1288. Because the patentees set out their own definition, their "lexicography governs." *Phillips*, 415 F.3d at 1316.[4]

* * *

For these reasons, the Court construes claim 1 of the '314 Patent to read as follows:

> 1. A solid dosage form for oral administration with reduced potential for parenteral abuse, comprising, in addition to one or more active ingredients with potential for abuse selected from the group consisting of opiates, opioids, tranquillizers, stimulants and narcotics, at least one viscosity-increasing agent in a quantity equal to or greater than 5 mg per dosage form and such that an aqueous extract obtained from the dosage form with 10 ml of water at 25° C. forms a gel which can still pass through a needle having a diameter of 0.9 mm and, when introduced by such a needle into a further quantity of an aqueous liquid at 37° C., a largely cohesive thread is initially obtained which, while it may be broken up into smaller fragments by mechanical action, remains substantially insoluble and cohesive and cannot straightforwardly be dispersed in such a manner that it can safely be administered parenterally, in particular intravenously.

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[4] At oral argument, plaintiffs cautioned the Court against adopting a construction of "visually distinguishable" that defendants argued was indefinite. (Hearing Tr. 62.) But defendants argue that this term is indefinite based on allegedly missing steps in the visually distinguishable test. (Defs.' Opening Br. at 28.) Plaintiffs' proffered construction simply glosses some of the words in the patentees' own definition—it does not address the issue of the allegedly missing steps. (Pls.' Opening Br. at 20–23.) Thus, even if the Court adopted plaintiffs' proposed construction, that decision would not resolve defendants' indefiniteness argument.

D. Construction of the Disputed Claims in the '383 Patent

In the early 2000s, scientists at Grünenthal investigated whether they could make a tablet that would be difficult to crush—a first step before the drug can be snorted by an abuser—but at the same time be able to release the tablet's API when swallowed whole. '383 Patent at 1:16–39, 1:64–2:6; Davies Decl. ¶¶ 53–54. Three Grünenthal scientists—Johannes Bartholomäus, Heinrich Kugelmann, and Elisabeth Arkenau-Marić—succeeded in developing a tablet with a breaking strength of 500 Newtons, more than double a person's average chewing force. (Davies Decl. ¶¶ 53–55.) The claimed invention achieved this goal by including a polymer in the tablet formulation and exposing that formulation to heat and pressure. '383 Patent at 21:2–14.

Plaintiffs allege that defendants' ANDAs infringe five of the '383 Patent's nine claims: independent claim 1 and dependent claims 2, 5, 7, and 8. The parties, though, only dispute the meaning of two terms in claim 1. That claim recites:

> 1. A thermoformed dosage form comprising:
>
> i) one or more active ingredients with abuse potential (A) selected from the group consisting of opiates and opioids,
>
> ii) optionally physiologically acceptable auxiliary substances (B),
>
> iii) at least 30% by weight of polyalkylene oxide (C) having a molecular weight of 1-15 million according to rheological measurements, and
>
> iv) optionally at least one wax (D),
>
> wherein said dosage form has a breaking strength of at least 500 N and wherein the active ingredient with abuse potential (A) is present in a controlled release matrix of component (C).

Id. at 21:2–22:14. The two terms in dispute are "thermoformed dosage form" and "breaking strength of at least 500 N."

1. *"Thermoformed dosage form" means pressure with preceding or simultaneous application of heat*

The preamble of independent claim 1 claims a "thermoformed dosage form."[5] The parties agree that "thermoforming" encompasses formulations made by applying pressure with preceding or simultaneous application of heat. They disagree whether thermoforming can also encompass the application of pressure with *subsequent* heat—plaintiffs claim that it does, defendants disagree. The Court holds that the term "thermoform" does not include subsequent heat.

The Court begins with the claims of the '383 Patent, but the claims do not settle the parties' dispute. Plaintiffs do not assert that thermoforming bears a plain, ordinary meaning among those skilled in the art. Defendants, though, argue that thermoforming does have such a meaning—one that excludes subsequent heat. In support, defendants cite numerous general purpose and technical dictionaries and treatises. (Amiji Decl., Exs. D–H.) These extrinsic sources "'can shed useful light on the relevant art,' [but] this court considers such evidence 'less significant than the intrinsic record in determining the legally operative meaning of claim language.'" *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1362 (Fed. Cir. 2008) (quoting *Phillips*, 415 F.3d at 1317). At a minimum, defendants' dictionaries do establish that plaintiffs' proposed definition would be an outlier among these other lay and specialized meanings.

While claim 1 does not define "thermoformed," dependent claim 5 appears to provide some context. Claim 5 claims a process for producing the dosage form of claim 1, involving "mixing" the components specified in claim 1, "and, optionally after granulation, press-forming the mixture with preceding, simultaneous, or subsequent exposure to heat." '383 Patent at 22:6–8. Plaintiffs point out that dependent claim 5 must fit within the scope of claim 1. Plaintiffs are correct, *see Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n.9 (Fed. Cir. 1989), but this does not end the analysis. Even if "thermoform" does not encompass subsequent heat, claim 1 does not exclude dosage forms that include a subsequent heating step—provided that the dosage form was already "thermoformed." The

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[5] The parties again agree that the preamble limits claim 1. (Defs.' Opening Br. at 41 n.17.)

preamble of claim 1 is linked to the substantive claim language by the open-ended term "comprising." *See, e.g., In re Skvorecz*, 580 F.3d 1262, 1267 (Fed. Cir. 2009). Therefore, a dosage form that is thermoformed according to defendants' construction can still undergo a subsequent heating step and fit within the confines of claim 1. Claim 5 merely spells out this possibility.[6]

The Court next turns to the specification of the '383 Patent. The inventors did not take the opportunity in the specification to act as their own lexicographer, but the specification is replete with examples of thermoforming. None of the numbered examples discloses a method that involves a subsequent application of heat—every one of them utilizes pressure with either simultaneous or preceding heat. In fact, the specification discusses subsequent applications of heat only once, in column 11:

> 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. The mixture may, for example, be formed into tablets by direct tabletting. In direct tabletting with simultaneous exposure to heat, the tabletting tool, i.e. bottom punch, top punch and die are briefly heated at least to the softening temperature of the polymer (C) and pressed together. *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.*

'383 Patent at 11:16–28 (emphasis added). Plaintiffs naturally cite this passage and urge that any definition of thermoforming that excludes subsequent heat would exclude this preferred embodiment of the invention. Plaintiffs once again correctly state the law, *see SynQor, Inc. v. Artesyn Techs., Inc.*, 709 F.3d 1365, 1378–79 (Fed. Cir. 2013), but misconstrue the patent.

The disclosed method of direct tableting with subsequent heat makes clear that after the formed tablets are heated, they are "cooled *again*." The

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[6] Defendants claim that the entire press-forming step of claim 5 is optional. They are incorrect. The term "optionally" in claim 5 modifies "after granulation."

emphasized word means what it says—the tablets formed by this method had already been cooled, meaning they had already been heated. In other words, the tablets had already been thermoformed before they were subjected to subsequent heat.

Plaintiffs belittle this point, but do nothing to reduce its impact. They argue that defendants' reliance on the word "again" is nothing more than an attempt to summon up a "hidden previous heating step." (Pls.' Resp. Br. at 27 n.21.) Plaintiffs, though, have no better explanation for the word. They contend that "cooled again" means that the tablet is cooled to its original temperature. (*See id.*) But this reading simply deletes the word "again," or else has it modify something other than the verb "are . . . cooled."

Finally, the Court turns to the prosecution history. During prosecution, the inventors did not discuss the precise term "thermoform." The inventors did, however, repeatedly stress to the Examiner the importance to their invention of simultaneous pressure and heat. For example, in response to the Examiner's first rejection of all proposed claims, the inventors emphasized that "[t]he 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." (PRF0008744 (emphasis added).) The inventors repeated this point word-for-word in response to the Examiner's second rejection. (PRF0008828.)

Plaintiffs counter that even when the inventors stressed the simultaneous application of heat and pressure, they still cited portions of the application that discussed subsequent heating. This ambiguity may militate against a finding of prosecution disclaimer, but it does not detract from the thrust of the inventors' representations to the Examiner. Pressure and heat, applied together, were the crucial elements of the invention.

The claims and specification make clear that if the formulation is subjected to heat after it has already been pressed, that formulation must have already been "thermoformed." Pressure and prior or simultaneous heat are simply the essence of the claimed invention, as the inventors repeatedly stressed to the Examiner. Read in the complete context of the claims, the specification, and the prosecution history, it is plain that a

person of ordinary skill in the art would understand "[a] thermoformed dosage form" to mean "a dosage form that is formed by the application of pressure to the components with the simultaneous or preceding application of heat."[7]

2. *"Breaking strength" means "breaking strength"*

The parties also appear to contest the meaning of the term "a breaking strength of at least 500 N" from claim 1. But on closer inspection, there is no conflict at all. The parties agree that plastic deformation—i.e., squashing—does not constitute "breaking." (Defs.' Resp. Br. at 29.) Plaintiffs also urge that chipping of the color coating would not constitute "breaking." The Court agrees—the product that has "a breaking strength of at least 500 N" is the thermoformed dosage form. No construction of the term "breaking strength" is required.

* * *

For these reasons, the Court will construe claim 1 to read as follows:

> 1. A dosage form that is formed by the application of pressure to the components with the simultaneous or preceding application of heat comprising:
>
> i) one or more active ingredients with abuse potential (A) selected from the group consisting of opiates and opioids,
>
> ii) optionally physiologically acceptable auxiliary substances (B),
>
> iii) at least 30% by weight of polyalkylene oxide (C) having a molecular weight of 1-15 million according to rheological measurements, and
>
> iv) optionally at least one wax (D),
>
> wherein said dosage form has a breaking strength of at least 500 N and wherein the active ingredient with abuse potential (A) is present in a controlled release matrix of component (C).

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[7] This reasoning also compels the Court to conclude that claim 1 is not a product-by-process claim. The thermoforming of the claimed invention imparts structural characteristics to the final dosage form. *See Hazani v. U.S. Int'l Trade Comm'n*, 126 F.3d 1473, 1479 (Fed. Cir. 1997); *In re Garnero*, 412 F.2d 276, 279 (C.C.P.A. 1969).

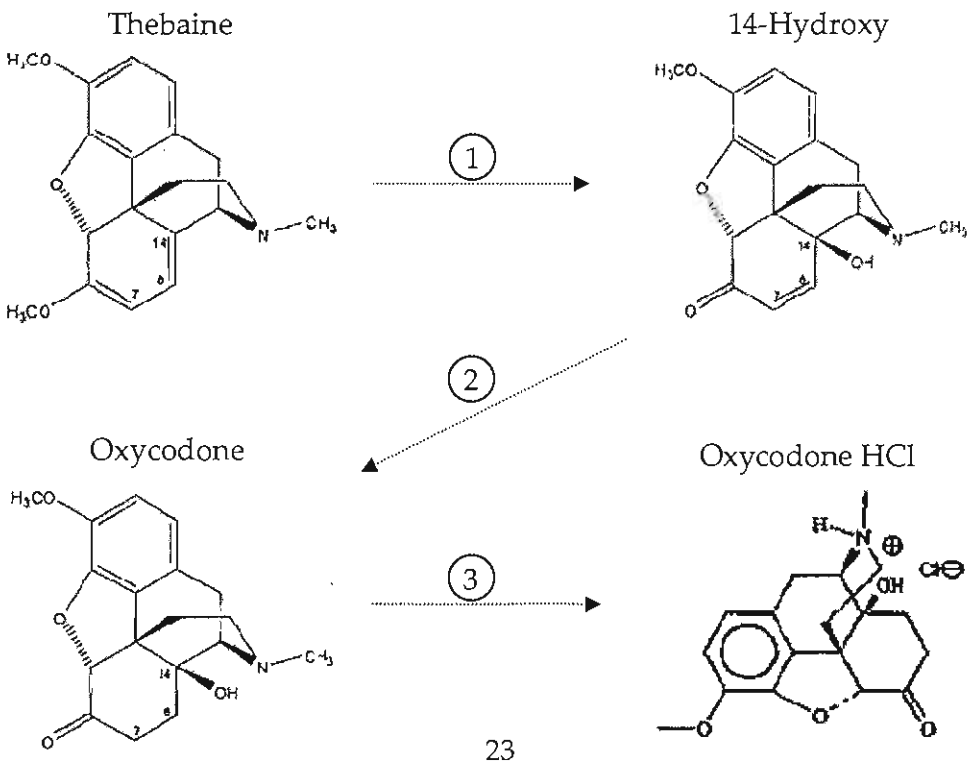
III. THE LOW-ABUK PATENTS

A. Background

1. *Purdue's development of low-ABUK oxycodone*

In 2004, the FDA mandated that manufacturers of oxycodone API—including Purdue and its subsidiary Rhodes—provide information about the impurity 14-hydroxycodeinone ("14-hydroxy"). Among other things, the FDA directed Rhodes to either (1) provide evidence that the level of 14-hydroxy in Rhodes's oxycodone API was safe or (2) lower the level of 14-hydroxy in Rhodes's oxycodone API to less than 10 ppm. (PTX 266.)

By the fall of 2004, Rhodes had developed a method to reduce the amount of 14-hydroxy and submitted an amendment to its drug master file to the FDA. (Kelly Tr. 517–18.) Rhodes's ability to rapidly achieve the FDA's 14-hydroxy purity standard reflected laboratory work undertaken years before the FDA mandate. Rhodes had previously developed a three-step process to synthesize oxycodone from thebaine: (1) Rhodes oxidized thebaine to form 14-hydroxy; (2) Rhodes hydrogenated 14-hydroxy to form oxycodone; and (3) Rhodes added hydrochloric acid to form oxycodone hydrochloride. (Shamblen Tr. 80; Kupper Tr. 124–25.)



In 2001 and 2002, scientists at Rhodes attempted to control levels of 14-hydroxy in the oxycodone API by ensuring that "the hydrogenation reaction from [14-hydroxy] [to] oxycodone free base was run to completion." (Kupper Tr. 129.) After this extended hydrogenation—step two of the method for synthesizing oxycodone—scientists were unable to detect 14-hydroxy in the free base. But after step three—transforming the oxycodone free base into oxycodone hydrochloride—Rhodes's scientists discovered that the 14-hydroxy had returned. (Kupper Tr. 135, 137–38.)

The scientists at Rhodes did not know at first why the 14-hydroxy had reappeared. In a report written in late 2002, though, Rhodes research scientist Lonn Rider hypothesized that the 14-hydroxy present in the API formed due to the dehydration of two impurities, 8α, 14-dihydroxy-7,8-dihydrocodeinone ("8α") and 8β, 14-dihydroxy-7,8-dihydrocodeinone ("8β"). (Kupper Tr. 139–41.) 8α and 8β are diastereomers of 8,14-dihydroxy-7,8-dihydrocodeinone ("8,14-dihydroxy"). As diastereomers, 8α and 8β are two forms of 8,14-dihydroxy: "[t]hey have the same atoms connected to other atoms but they differ in the[] three-dimensional arrangement of the atoms." (Heathcock Tr. 1144; *see also Chapman v. Casner*, 315 F. App'x 294, 295–96 (Fed. Cir. 2009) (discussing 8,14-dihydroxy's stereoisomers).)

Rider's focus on 8,14-dihydroxy reflected two reactions that occur within the Rhodes synthesis process. One, during the first step in the synthesis process, thebaine molecules convert into 14-hydroxy molecules by oxidation. While this reaction principally yields 14-hydroxy, it also produces "several overoxidation products [] in small amounts," including 8,14-dihydroxy. (Kupper Tr. 140.) Two, Rhodes and Rider knew that 8,14-dihydroxy could undergo acid-catalyzed dehydration to form 14-hydroxy. (Heathcock Tr. 1141–42.) Rhodes suspected that the addition of acid at the third manufacturing step was converting the 8,14-dihydroxy to 14-hydroxy. (Kupper Tr. 138.)

After additional experimentation, Rhodes scientists concluded that 8α was the source of the reappearing 14-hydroxy. They then began to consider "methods for controlling the levels of 14-[hydroxy] in oxycodone hydrochloride based on this knowledge." (Rider Tr. 219.) After considering several alternatives, Rhodes "decided that the best course of action . . . would be another hydrogenation step to remove the 14-

[hydroxy] . . . ." (Kupper Tr. 151; Rider Tr. 221.) This second hydrogenation step did not, however, exactly replicate the first. The first, original, hydrogenation step used water and formic acid to produce a formate salt, which was "converted to the free base by an addition of a base of sodium hydroxide." (Rider Tr. 298; Kupper Tr. 151–52.) The newly added second hydrogenation was performed after the free base had been converted to oxycodone hydrochloride. (Rider Tr. 299.) The second hydrogenation converted 14-hydroxy into oxycodone but did not react with previously formed oxycodone hydrochloride. (Rider Tr. 300–01.)

With this method in hand, Rhodes sought approval from the FDA and patent protection for their new method.

2. *Purdue obtains the '799, '800, and '072 Patents*

Purdue and Rhodes attempted to patent their work on low-ABUK oxycodone. This effort concluded in March 2010 when Purdue secured the three Low-ABUK Patents:

- U.S. Patent No. 7,674,799
- U.S. Patent No. 7,674,800
- U.S. Patent No. 7,683,072

Broadly speaking, the '800 Patent claims "a process for preparing an oxycodone salt substantially free of 14-[hydroxy]." '800 Patent at 34:22–23. The '072 Patent claims low-ABUK oxycodone hydrochloride API. '072 Patent at 34:57–60. The '799 Patent claims an "oral dosage form" of low-ABUK oxycodone hydrochloride. '799 Patent at 34:54.

The '799, '800, and '072 Patents continue from an earlier application, No. 11/391,897 ("Chapman application"). The Chapman application continues from the March 30, 2005 application No. 11/093,626, which issued as U.S. Patent No. 7,129,248. The '799 Patent continued as Serial No. 11/653,531 and was issued on March 9, 2010. The '800 Patent continued as Serial No. 11/729,741 and issued on March 9, 2010. The '072 Patent continued as Serial No. 11/653,529 and issued on March 23, 2010.

The Patent Office initially rejected as obvious a number of asserted claims of the patents as they were then drafted. The Examiner paid particular attention to one prior art reference, Chiu, which disclosed a

process for preparing a low-ABUK oxycodone crude base. (PTX 10 at P1052803–04; PTX 11 at P1034148–49; PTX 12 at P1045523–24; DTX 741.) The Examiner also questioned the nonobviousness of the patents on the grounds that 8,14-dihydroxy had been disclosed in the art. Accordingly, the Examiner directed the inventors to explain why prior art regarding 8β did not render obvious claims relating to 8α: "unless applicants provide some unexpected results of 8,14-dihydroxy[] with trans hydroxyl groups as compared to 8,14-dihydroxy[] with cis hydroxyl groups, it would have been obvious to one skilled in the art to prepare Oxycodone salt with reduced amount of 14-hydroxy[] with reasonable expectation of success." (PTX 11 at P1035381–82; Heathcock Tr. 1143.)

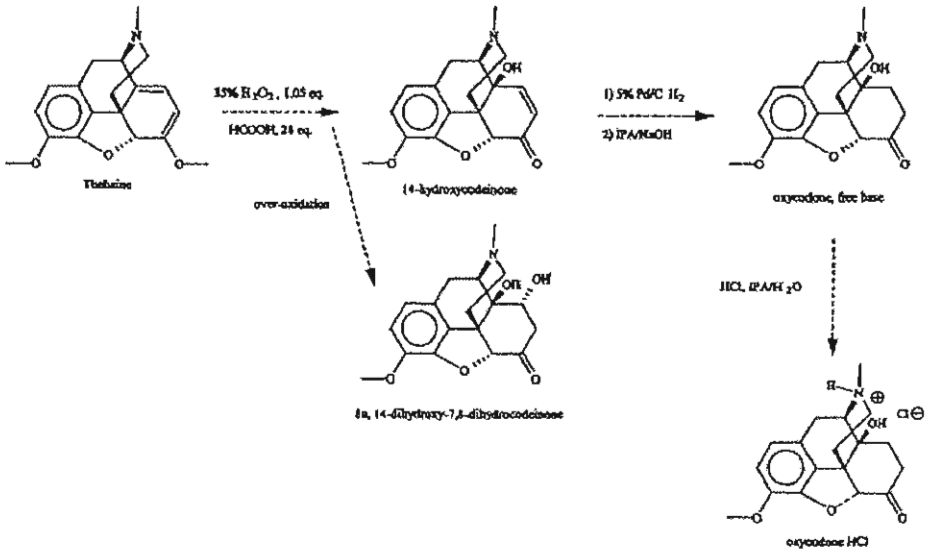
Purdue's response distinguished the prior art based on stereochemistry and the process steps involved in the Chiu reference. As to the stereochemistry, Purdue submitted the declaration of Steven Baldwin, Ph.D., to demonstrate the "unexpected results" of 8α to the Patent Office. Baldwin stated that 8α and 8β are "different compounds and have surprisingly different properties (e.g., reactivities)." (PTX 11 at P1035678; Heathcock Tr. 1143.) As to the Chiu reference, Purdue explained that the prior art reference concerned 14-hydroxy in oxycodone base, not 14-hydroxy that "would reappear during hydrochloride salt formation." (PTX 10 at P1052961–62; Crimmins Tr. 799–800.)

Purdue prevailed. The Examiner approved the patents, in part "due to [Purdue's] persuasive arguments and declaration by Dr. Baldwin." (PTX 10 at P1059552.)

a. The common specification

The '799, '800, and '072 Patents have substantially identical specifications but differ in the nature of the claims. Figure 1 depicts a scheme to synthesize oxycodone hydrochloride from thebaine.

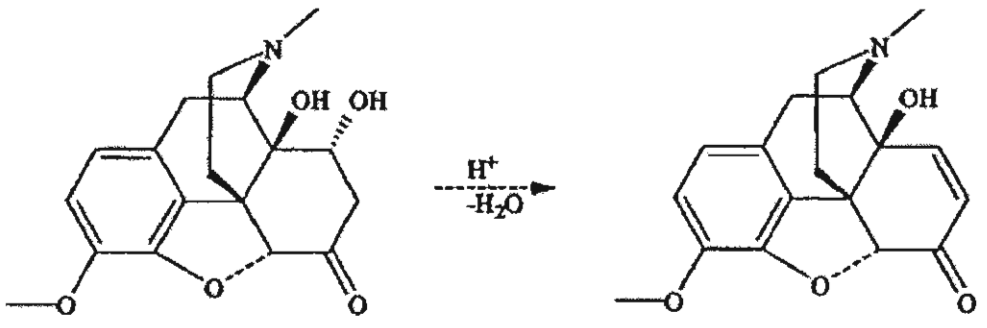
Figure 1



First, thebaine is oxidized to form 14-hydroxy. Second, 14-hydroxy is hydrogenated to form oxycodone free base. Third, the oxycodone free base is acidified to form oxycodone hydrochloride. In addition, Figure 1 depicts the formation of 8α as a result of the overoxidation of thebaine. (Wuest Tr. 554–55, 1253–54.)

Figure 2 depicts the conversion of 8α into 14-hydroxy as a result of dehydration in the presence of acid. *E.g.*, '800 Patent at 6:18–19; Wuest Tr. 1254.

Figure 2



8a,14-dihydroxy-7,8-dihydrocodeinone

14-hydroxycodeinone

The specification states that "[t]he term 8,14-dihydroxy-7,8-dihydrocodeinone includes either 8α,14-dihydroxy-7,8-dihydrocodeinone; or 8β,14-dihydroxy-7,8-dihydrocodeinone or can include a mixture of both compounds." *E.g.*, '800 Patent at 5:54–57.

The description recites the chemical structure of 8α and the nature of the reaction that produces it. For example, the specification states that 8,14-dihydroxy converts to 14-hydroxy "during salt formation reactions known in the art." '800 Patent at 8:4–11. The patents' written description does not explicitly identify conditions that transform 8α, but not 8β, into 14-hydroxy. (*E.g.*, Rider Tr. 278.) The specification also does not disclose a pH range at which 8α will not form. (Rider Tr. 278–79; Wuest Tr. 1330–31.) But Example 3 of the specification demonstrates conditions that suffice to convert 8α into 14-hydroxy. (Wuest Tr. 1258.) Wuest further explained that a skilled artisan "would understand that the 8β compound is essentially inert under [the] conditions [of Example 3] and would not undergo this acid-induced transformation." (Wuest Tr. 1258.) The specification includes no method for detecting 8α. (Kupper Tr. 191; Wuest Tr. 1324–25.)

B. Construction of the Disputed Claims in the Low-ABUK Patents

Purdue has asserted that defendants' ANDAs infringe claims 3 and 19 of the '799 Patent; claims 30–34 and 76–79 of the '800 Patent; and claims 1, 4, and 5 of the '072 Patent. The parties contest the meaning of various claim terms of each patent. Those disputes fit roughly into the following groups:

1) Whether terms of each claim require the presence of 14-hydroxy in the final oxycodone salt
2) Whether the process claims of the '800 Patent encompass processes that involve intermediate salt-formation steps that use salts other than oxycodone hydrochloride
3) Whether the '799 and '072 Patents require 8α to be present in the synthesis process and, if so, whether some portion of it must convert to 14-hydroxy at the final salt formation step
4) Whether the '799 and '072 Patents contain process limitations

5) Whether the presence of 14-hydroxy and 8α must be at "detectable levels"

The Court considers each issue below.

1. *All patents: 14-hydroxy must be present in the final salt*

Defendants urge the Court to construe the '800 Patent (claims 1 & 57), the '072 Patent (claim 1), and the '799 Patent (claim 3) as requiring 14-hydroxy in the final oxycodone salt. The Court adopts this construction.

Purdue does not seriously contest that an infringing product must have some 14-hydroxy present in the final oxycodone salt. After all, if a product had no 14-hydroxy whatsoever, it would have no 14-hydroxy derived from 8α as required by the claims. (Crimmins Tr. 803.) The specification supports this reading because it contains no embodiment where the level of 14-hydroxy is described as zero. To the contrary, Example 6 recites an analytical method "to determine the amount of codeinone and 14-[hydroxy] present." '799 Patent at 31:16–18. Therefore, the Court does not accept that a skilled artisan would understand the phrase "a portion of the [14-hydroxy]" to encompass the absence of 14-hydroxy.[8]

2. *'800 Patent: the final salt must be oxycodone hydrochloride, but the intermediate salt need not be*

Claim 1 of the '800 Patent reads as follows, with emphasis on the disputed claim language:

> A process for preparing *an oxycodone salt substantially free of 14-hydroxycodeinone*, which process comprises steps of:
>
> (a) preparing a mixture of oxycodone free base, solvent and an acid, the oxycodone free base having an 8α,14-dihydroxy-7,8-dihydrocodeinone component;
>
> (b) incubating the mixture under conditions suitable to convert the oxycodone free base to *an oxycodone salt*, wherein said

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[8] As regards the Low-ABUK Patents, a person of ordinary skill in the art is an organic chemist with experience in synthetic and analytical chemistry. The parties do not dispute the qualifications of the skilled artisan as relevant to the Abuse-Proof Patents. (Hearing Tr. 50.)

> conditions promote an acid catalyzed dehydration consisting of conversion of the 8α,14-dihydroxy-7,8-dihydrocodeinone component to 14-hydroxycodeinone; and
>
> (c) preferentially removing the 14-hydroxycodeinone from *the oxycodone salt*.

'800 Patent at 34:22–35. Claim 57 features the same disputed language, but recites step (c) as "reducing an amount of [14-hydroxy] in the oxycodone salt formed in step (b) to produce an oxycodone salt composition having less than 25 ppm [14-hydroxy]." '800 Patent at 37:40–43.

The parties dispute whether the term "an oxycodone salt substantially free of 14-hydroxy" as used in the preamble must be the same salt as the "an oxycodone salt" referred to in step (b) of the body of the claim. The parties further dispute whether claim 1 and claim 57 of the '800 Patent describe *any* oxycodone salt in the preamble and at step (b) or only oxycodone *hydrochloride* salt. The Court does not read the claims to require the oxycodone salt of the preamble to be the same oxycodone salt as in step (b). The Court also will not limit the salts in claims 1 and 57 to hydrochloride salts alone.

a. The preamble refers to an oxycodone salt API

The parties dispute whether the preambles of claim 1 and claim 57 limit the process steps of those claims. They do. "[A] claim preamble has the import that the claim as a whole suggests for it." *Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332, 1339 (Fed. Cir. 2003) (quotation marks omitted).

The claim terms and specification indicate that the preamble constitutes a claim limitation. The phrasing of the preamble "an oxycodone salt substantially free of [14-hydroxy]" comports with the title of the patents, "Oxycodone Hydrochloride Having Less Than 25 ppm 14-Hydroxycodeinone" and discloses various pharmaceutical embodiments. Moreover, the examples in the patent specification show how to analyze the 14-hydroxy levels of the product after the hydrogenation reaction is run and the material is dried. *E.g.*, '800 Patent at 25:17–22, 25:55–60, 26:35–40. The context therefore suggests that their preambles identify and limit the end product of the described process. If the end product is an oxycodone salt API substantially free of 14-hydroxy, as the intrinsic evidence suggests, then the preamble's use of the phrase "an oxycodone

salt substantially free of [14-hydroxy]" must be limiting. Otherwise, the process steps would not achieve that result. The preambles of claims 1 and 57 "recite[] essential structure or steps" of the claims and are otherwise "necessary to give life, meaning, and vitality to the claim." *Am. Med. Sys., Inc. v. Biolitec, Inc.*, 618 F.3d 1354, 1358 (Fed. Cir. 2010) (quotation marks omitted).

This reading also comports with the patent prosecution history. During the prosecution of the '800 Patent, Purdue distinguished its claims to a low-ABUK "oxycodone hydrochloride composition" from the Chiu reference. (PTX 11 at P1034312–14.) Purdue emphasized that Chiu disclosed low-ABUK oxycodone free base and not a low-ABUK salt made from the purified free base. (*Id.*) Because an earlier step in Chiu's process involved an intermediate oxycodone salt mixture, (DTX 741 at Example 6), Purdue's process differed meaningfully from Chiu only in that Purdue's process resulted in an oxycodone salt API and not a crude oxycodone base. That is the very distinction captured by the preamble of claims 1 and 57 and what a skilled artisan would understand by this language. (Wuest Tr. 559.)

b. The phrase "an oxycodone salt substantially free of [14-hydroxy]" has a different meaning than the phrase "an oxycodone salt"

Defendants contend that the Court should construe the preamble's phrase "an oxycodone salt substantially free of [14-hydroxy]" to mean the same thing as "an oxycodone salt" as used in the process steps. The Court does not accept this reading.

"[T]he same terms appearing in different portions of the claims should be given the same meaning unless it is clear from the specification and prosecution history that the terms have different meanings at different portions of the claims." *PODS, Inc. v. Porta Stor, Inc.*, 484 F.3d 1359, 1366 (Fed. Cir. 2007). Here, the intrinsic evidence reveals such a distinction between the two instances of "an oxycodone salt."

- First, the modifying phrase "substantially free of 14-[hydroxy]" limits the term "an oxycodone salt" in the preamble, as compared to the unmodified phrase "an oxycodone salt" used at step (b). The Court presumes that these different phrases carry different

meanings. *See Epcon Gas Sys., Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1030–31 (Fed. Cir. 2002).

- Second, the indefinite article "an" appears before "oxycodone salt" in the preamble and before "oxycodone salt" in the body of the claim. Each use of that article implies that "one or more" oxycodone salts may fit within the claims. *See 01 Communique Lab., Inc. v. LogMeIn, Inc.*, 687 F.3d 1292, 1297 (Fed. Cir. 2012). Defendants' proposed construction thus artificially limits this term.
- Third, the specification discloses an embodiment where the final salt is an API but the process salt is an intermediate. '800 Patent at 8:66–9:7.

Accordingly, the salt of the preamble—the oxycodone API—need not be the salt of step (b). Because the specification identifies differences in meaning between "an oxycodone salt substantially free of 14-[hydroxy]" and "an oxycodone salt," the Court construes them differently. *See Microprocessor Enhancement Corp. v. Texas Instruments Inc.*, 520 F.3d 1367, 1375–76 (Fed. Cir. 2008).

c. The process steps refer to "any oxycodone salt," not necessarily oxycodone hydrochloride

A person of ordinary skill in the art would understand that neither the phrase "an oxycodone salt substantially free of 14-hydroxy" nor the phrase "an oxycodone salt" limit the claims to oxycodone hydrochloride salt. (Wuest Tr. 566; Crimmins Tr. 916; Heathcock Tr. 1135.) The appropriateness of that reading is confirmed by the context of the patent. Claim 31 and claim 77, for example, call for oxycodone *hydrochloride* salt. Because dependent claims 31 and 77 recite a specific type of salt but the independent claims 1 and 57 do not, the doctrine of "claim differentiation" presumes that the independent claims do not contain the limitations of the dependent claims. *See Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 805–06 (Fed. Cir. 2007). The specification supports this meaning because it includes an embodiment where the claimed process involves "reacting an oxycodone base composition with an acid having a higher pH than hydrochloric acid to form a corresponding acid addition salt of

oxycodone" and identifies suitable acids other than hydrochloric acid. '800 Patent at 8:66–9:7.

The specification and prosecution history do not provide a contrary "clear intention" to limit the phrases "an oxycodone salt substantially free of [14-hydroxy]" and "an oxycodone salt" to "oxycodone hydrochloride salt." *Contra Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1290 (Fed. Cir. 2009) (en banc). First, though the specification primarily describes oxycodone hydrochloride compositions, "the written description does not suggest that the invention must be used" in that form. *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1301 (Fed. Cir. 2003). Second, Purdue's statements to the Examiner did not disclaim the use of other oxycodone salts. When Purdue distinguished its claim from the Chiu reference it did not do so on the ground that it claimed an oxycodone *hydrochloride* salt rather than an oxycodone *acetate* salt of Chiu. (PTX 11 at P1034312–14.) Rather, Purdue drew a distinction between a low-ABUK free base and a low-ABUK salt formed from a purified free base. (*Id.*) That Purdue referred to "oxycodone hydrochloride salt" while discussing its proposed claim does not amount to "clear and unmistakable prosecution arguments limiting the meaning of a claim term in order to overcome a rejection." *SanDisk Corp. v. Memorex Prods., Inc.*, 415 F.3d 1278, 1286 (Fed. Cir. 2005). The specific independent claim at issue recited an oxycodone hydrochloride composition. (PTX 11 at P1034313.)

* * *

Accordingly, the Court construes claim 1 of the 800 Patent to require:

(1) A process for preparing an oxycodone salt API substantially free of 14-hydroxy, which process comprises (2) preparing a mixture of oxycodone free base, solvent and an acid, the oxycodone free base having an 8α component; (3) incubating the mixture under conditions suitable to convert the oxycodone free base to any salt of oxycodone, wherein said conditions promote an acid-catalyzed dehydration consisting of conversion of the 8α component to [14-hydroxy]; and (4) preferentially removing the [14-hydroxy] from the oxycodone salt.

The Court construes claim 57 of the '800 Patent the same way, except that element (4) requires "reducing an amount of [14-hydroxy] in the

oxycodone salt formed in step [3] to produce an oxycodone salt composition having less than 25 ppm [14-hydroxy]."

3. *The '799 Patent requires some 8α to convert to 14-hydroxy at the salt formation step, the '072 Patent does not*

The relevant portions of claim 1 of the '072 Patent read as follows, with emphasis on the disputed claim language:

> An oxycodone hydrochloride active pharmaceutical ingredient having less than 25 ppm 14-hydroxycodeinone *wherein at least a portion of the 14-hydroxycodeinone is derived from 8α, 14-dihydroxy-7,8-dihydrocodeinone.*

'072 Patent at 34:57–60.

The relevant portions of claim 3 of the '799 Patent read as follows, with emphasis on the disputed claim language:

> An oral dosage form comprising: (i) from about 5 mg to about 320 mg of oxycodone hydrochloride active pharmaceutical ingredient having less than 25 ppm 14-hydroxycodeinone, *wherein at least a portion of the 14-hydroxycodeinone is derived from 8α,14-dihydroxy-7,8-dihydrocodeinone during conversion of oxycodone free base to oxycodone hydrochloride;* and (ii) a pharmaceutically acceptable excipient.

'799 Patent at 35:8–15.

The parties dispute whether the '799 Patent (claim 3) and the '072 Patent (claim 1) require the presence of 8α in the oxycodone base and require some 8α to convert to 14-hydroxy at the salt formation step.[9] Defendants' proposed construction advances two additional limitations: (1) the presence of 8α in the oxycodone base and (2) the conversion of some 8α to 14-hydroxy at the salt formation step. The Court concludes that the '799 Patent requires some 8α to convert to 14-hydroxy at the salt formation step and therefore construes the '799 Patent to require 8α in oxycodone base. The Court concludes that the '072 Patent does not have any requirement that 8α convert to 14-hydroxy at any particular process

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[9] The parties agree that the process of the '800 patent requires the presence 8α in the oxycodone base.

step and therefore does not require proof of 8α's conversion at any particular point.

a. The '799 Patent (claim 3) requires the presence of 8α in the oxycodone base.

The '799 Patent (claim 3) states that "at least a portion of the 14-[hydroxy] is derived from 8α[] during conversion of oxycodone free base to oxycodone hydrochloride." The Court construes this phrase according to its plain meaning to a skilled artisan. Accordingly, at least "a portion" of the 14-hydroxy in the API must be "derived from" 8α. Further, at least a portion of the 8α-derived 14-hydroxy must be so derived during the conversion of oxycodone free base to oxycodone hydrochloride. (Crimmins Tr. 796; Wuest Tr. 562.) The specification supports this construction, noting in the "Background of the Invention" section that "[d]uring conversion of the oxycodone free base to oxycodone hydrochloride, the impurity undergoes acid-catalyzed dehydration and is converted into [14-hydroxy]." '799 Patent at 2:2–5. If no 8α-derived 14-hydroxy present in the oxycodone hydrochloride were derived "during conversion of oxycodone free base to oxycodone hydrochloride," a central feature of the claim would be absent from the product.

Nonetheless, Purdue contends that any conversion of 8α to 14-hydroxy before the formation of the final oxycodone hydrochloride API is within the scope of the claims. Purdue's construction simply replaces the words "during conversion of oxycodone free base to oxycodone hydrochloride" with the words "at any time before the formation of the final oxycodone hydrochloride API." The Court must interpret the patent "as written, not as the patentees wish they had written it." *Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004). Neither the claim itself nor the specification supports the swap Purdue proposes.

That the specification discloses that "it may be necessary to perform . . . one or more relevant steps in the process of the present invention[] more than once" does not discredit a plain-language interpretation of the phrase "during conversion of." '799 Patent at 8:38–44. First, the Court notes that the only process step in the '799 Patent is the phrase "is derived from [8α] during conversion of oxycodone free base to oxycodone hydrochloride." Purdue does not explain why a repetition of that process step would fall

outside the limiting language "during conversion of." Second, the Court rejects Purdue's attempt to reverse-engineer claim 3 to read on "[a]nother alternative process . . . for preparing an oxycodone hydrochloride composition comprising reacting an oxycodone base composition with an acid having a higher pH than hydrochloric acid to form a corresponding acid addition salt of oxycodone, and converting the acid addition salt of oxycodone to oxycodone hydrochloride." '800 Patent at 8:66–9:4. This embodiment does not specify when 8α converts to 14-hydroxy. In any event, "[i]t is not necessary that each claim read on every embodiment." *Baran v. Med. Device Techs., Inc.*, 616 F.3d 1309, 1316 (Fed. Cir. 2010). Here, the preferred embodiments, the description of the invention, and the expert testimony all tilt in favor of reading the language of the claim to mean what it says.

In addition, Purdue unmistakably distinguished prior art during the prosecution of the patents by reference to the point in a synthesis scheme at which the 14-hydroxy would form:

> Furthermore, one skilled in the art would have expected that the **oxycodone hydrochloride salt** prepared from the **oxycodone free base** of the Chiu patent . . . would also have no [14-hydroxy], as there is nothing in the Chiu patent to suggest that [14-hydroxy] would reappear during hydrochloride salt formation.

(PTX 10 at P1052961–62 (emphasis original).)

Purdue's statements to the Examiner support the reading that the words "during conversion of oxycodone free base to oxycodone hydrochloride" do not mean "at any time before the formation of the final oxycodone hydrochloride salt." Rather, Purdue distinguished Chiu on the grounds that Chiu did not appreciate 14-hydroxy's reappearance "during hydrochloride salt formation." (*Id.*; *cf.* Crimmins Tr. 800:4–6 ("conversion during the HCL [hydrochloride] formation would not be expected to create any 14-[hydroxyl] based on the Chiu patent").) Thus, the patent prosecution history confirms the plain meaning of the limitation expressed in the '799 Patent (claim 3).

b. The '072 Patent (claim 1) does not require the presence of 8α at any particular process step.

The '072 Patent (claim 1) states that the API contains less than 25 ppm of 14-hydroxy "wherein at least a portion of the 14-[hydroxy] is derived from 8α." '072 Patent at 34:59–60. The language of the claim indicates that any 14-hydroxy derived from 8α would satisfy the "derived from" element. The claim does not limit when or how that derivation occurs. As the differences in their language suggest, the '072 Patent (claim 1) does not contain the "during conversion" limit found in the '799 Patent (claim 3). Thus, this claim reads on the alternative embodiment emphasized by Purdue with respect to the '799 claim and does so naturally. '072 Patent at 8:66–9:7.

Defendants urge the Court to conclude that Purdue limited claim '072 (claim 1) during prosecution by making arguments substantially identical to those made in support of the claims of the '799 Patent. The Court agrees with defendants that the statements to the Examiner emphasized the importance of 14-hydroxy's formation from 8α during the hydrochloride salt-formation step. (*E.g.*, PTX 11 at P1034313.) Nonetheless, the Court cannot conclude that the Purdue's statements amounted to a "clear and unmistakable" disavowal of claim scope. *See Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1374–75 (Fed. Cir. 2008). Unlike the circumstance of the '799 Patent, where Purdue's statements to the Examiner supported the ordinary meaning of its claim language, those same statements do not convince the Court that Purdue intended to relinquish the more broadly written claims of the '072 Patent.

* * *

Accordingly, claim 3 of the '799 Patent requires (1) an oral dosage form (2) containing "from about 5 mg to about 320 mg of oxycodone hydrochloride" API, (3) the presence in the oxycodone hydrochloride of more than zero and less than 25 ppm 14-hydroxy, (4) some of which must have been derived from 8α "during conversion of oxycodone free base to oxycodone hydrochloride," and (5) a pharmaceutically acceptable excipient. Claim 19 depends from claim 3, and therefore incorporates its elements, but further calls for the "acceptable excipient" to be a "sustained release carrier."

Claim 1 of '072 Patent requires (1) oxycodone hydrochloride API, (2) containing more than zero and less than 25 ppm 14-hydroxy, and (3) some of the 14-hydroxy present in the API must have been derived from 8α. Dependent claims 4 and 5 incorporate the limitations of claim 1, but specify lower levels of 14-hydroxy (less than 15 ppm and less than 10 ppm, respectively).

4. *The '799 and '072 Patents are products with process limitations*

The parties agree that claim 1 of the 072 Patent and claim 3 of the 799 Patent are limited by their respective wherein clauses. (Pls.' Opening Br. at 39; Defs.' Opening Br. at 5–6.) The parties disagree on the type of limitation those clauses create. Purdue contends that these claims describe a product purely by its structure. Defendants argue that these claims describe a product by the process used to obtain it.[10] The Court agrees with defendants.

Ordinarily, the product claimed by a patent "is not limited to the process by which it was made." *Vanguard Prods. Corp. v. Parker Hannifin Corp.*, 234 F3d 1370, 1372 (Fed. Cir. 2000). Thus, "method of manufacture, even when cited as advantageous, does not of itself convert product claims into claims limited to a particular process." *Id.* A limitation is not a process limitation if, when "read in context, [it] describes the product more by its *structure* than by the *process* used to obtain it." *Hazani v. U.S. Int'l Trade Comm'n*, 126 F.3d 1473, 1479 (Fed. Cir. 1997) (emphasis added); *see also Gemtron Corp. v. Saint-Gobain Corp.*, 572 F.3d 1371, 1379 (Fed. Cir. 2009) ("Defining a structural component by its functional as well as its physical characteristics is different from defining a structure solely by the process by which it is made."); *In re Garnero*, 412 F.2d 276, 279 (C.C.P.A. 1969) (phrase not a process limitation when it is capable of being a structural limitation).

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[10] Construing a claim as a product-by-process claim has two consequences. First, "the defining limitations of a claim . . . are also the terms that show infringement." *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1293 (Fed. Cir. 2009) (en banc). Second, the validity of a claim must be assessed without reference to the claim's process limitations. *Greenliant Sys., Inc. v. Xicor LLC*, 692 F.3d 1261, 1268 (Fed. Cir. 2012).

By contrast, a product-by-process claim is "'one in which the product is defined at least in part in terms of the method or process by which it is made.'" *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 158 n.* (1989) (quoting D. Chisum, Patents § 8.05 at 8-67 (1988)). A patentee can state a claim in product-by-process form by reciting a product and a series of steps by which that product is obtainable. *E.g.*, *Abbott Labs.*, 566 F.3d at 1295. For instance, when "the claimed physical properties of [a product] are attributable to the process that is used to make [it]," the claim is to a product made by a process. *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1372 (Fed. Cir. 2007).

The phrase "derived from 8α" in the '799 and '072 Patents does not describe the structure of 14-hydroxy. To a skilled artisan—indeed, to anyone—14-hydroxy is 14-hydroxy, whether its source is 8α or 8β. (Heathcock Tr. 1124–26; Wuest Tr. 1342–43 (hydrogenating 14-hydroxy produces the same result regardless of the source of the 14-hydroxy).) As a structural description, the phrase "derived from 8α" is meaningless. For example, the specification sets out a method for detecting 14-hydroxy without regard to its source. *E.g.*, '799 Patent at Examples 4 & 6. And the specification includes no embodiment where the described hydrogenation process changes depending on the source of the 14-hydroxy being hydrogenated. *E.g.*, '799 Patent at 6:59–7:55. Indeed, the written description defines 8,14-dihyroxy as 8α or 8β or a mixture of the two. '799 Patent at 5:54–57. The common specification gives no indication that 8α imparts some quality to 14-hydroxy.

Although the phrase "derived from 8α" cannot describe a structural feature of 14-hydroxy, it does describe the process used to obtain a particular molecule of 14-hydroxy. To a skilled artisan, the "derived from" language indicates a "chemical reaction is occurring where one chemical entity is being converted into another chemical entity." (Crimmins Tr. 808.) By focusing on 8α, rather than 8β, the plain language of the claims indicates the relevant starting material for the chemical reaction is 8α and not 8β. (Crimmins Tr. 808.) The "derived from" limitation therefore modifies the claims by excluding processes for obtaining 14-hydroxy that would not cause the acid-catalyzed dehydration of some 8α molecules. Reading these claims as product-by-process claims accords with the common specification's disclosure of process conditions under which

acidifying oxycodone free base will cause 8α to convert into 14-hydroxy. *E.g.*, '072 Patent at Figure 2 & Example 3. The prosecution history does not suggest otherwise.

In addition to the "derived from" limitation, the '799 Patent (claim 3) includes a further limitation: some conversion from 8α to 14-hydroxy must occur "during conversion of oxycodone free base to oxycodone hydrochloride." A skilled artisan would understand this limitation to be a process limitation specifying when at least a portion of the 14-hydroxy must be obtained from 8α. (Crimmins Tr. 808.) Purdue does not contend, nor does the Court find, that any structural or physical characteristic of 14-hydroxy that could be described by reference to the process step at which a molecule has been formed.

In sum, describing 14-hydroxy by reference to its chemical precursors, 8α and 8β, does not say anything about a structural component of 14-hydroxy, its physical characteristics, or its functional capacity. Instead, the claim language limits 14-hydroxy to that obtained by a process using 8α. These conditions do not describe a structural limitation. A skilled artisan would know nothing more about the structure of a 14-hydroxy molecule if he or she knew that 8α had been the molecule's source.

Nonetheless, Purdue contends that the Court should construe the "is derived from" language according to the rule that "[l]imitations . . . expressed in the past tense, have been found to be structural, not product-by-process." (Pls.' Opening Br. at 39.) But the "is derived from" language of the '072 and '799 claims is in the passive voice of the present tense—it is not a past tense verb. Moreover, the ultimate inquiry is whether the "is derived from" limitation "describes the product more by its structure [or] by the process used to obtain it." *Hazani*, 126 F.3d at 1479. Whatever tense or mood expressed in the patent, the phrase "is derived from" in the '799 Patent (claim 3) and '800 Patent (claim 1) has meaning only because it excludes from the claim processes that do not obtain any 14-hydroxy from 8α and, for the '799 Patent, that do not obtain any 14-hydroxy from 8α during the oxycodone hydrochloride formation step.

Last, the Court notes that the Federal Circuit has sometimes identified particular process-type phrases as "source limitations." *See, e.g., Amgen Inc. v. F. Hoffman-La Roche Ltd*, 580 F.3d 1340, 1366–67 (Fed. Cir. 2009); *Amgen*

Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1328–30 & n.5 (Fed. Cir. 2003). Applying that label to the phrase "derived from 8α" would have no practical effect on the action. The evidence conclusively demonstrates that a molecule of 14-hydroxy has no feature that can be attributed to its source. This distinguishes 8α and 8β from the human and non-human EPO at issue in the *Amgen* cases. There, the Federal Circuit concluded that a claim limited to EPO derived from "non-human" sources did not create a process limitation. *See Hoechst*, 314 F.3d at 1329. But as the Court later explained, human and non-human EPO exhibit "differences in carbohydrate composition." *Hoffman-La Roche*, 580 F.3d at 1367. Here the "derived from 8α" limitation adds no patentable significance to the product and is therefore irrelevant to show nonobviousness and novelty. "[A] claimed product shown to be present in the prior art cannot be rendered patentable solely by the addition of source or process limitations." *Hoechst*, 314 F.3d at 1354 n.20; *see also Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 373–74 (1938); *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1317–19 (Fed. Cir. 2006).

* * *

The Court has construed the '072 and '799 Patents to contain process limitations. The disputed phrase "derived from 8α" cannot be understood as a product limitation. By contrast, it can be understood to limit the processes by which the product may be obtained.

5. ***All patents: "detectable" amounts of 14-hydroxy and 8α are not required***

Defendants urge the Court to impose a limitation on all claims that the relevant levels of 14-hydroxy and 8α be at "detectable levels." The Court does not accept that requirement. Such a limitation would serve only to exclude methods of proving infringement other than by experimental detection. Neither the claim language nor the specification supports such a construction. The words "detectable levels" never appear in the patent claims or specification, and defendants do not point to any aspect of the prosecution history that would support such a reading. Defendants' best argument is that the specification discloses a method for detecting 14-hydroxy. But the disclosure of that method does not indicate that the inventors surrendered other methods of demonstrating the presence of 14-

hydroxy or 8α and thereby narrowed the scope of their claims. *See Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1333 (Fed. Cir. 2010).

IV. CONCLUSION

These patents will now proceed to trial. On the basis of the claim construction set forth above, the Court will determine whether defendants' ANDAs infringe the Abuse-Proof and Low-ABUK Patents and whether these patents are valid.

Dated: New York, New York
August 23, 2013

SO ORDERED:

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