UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

PURDUE PHARMA L.P.; THE P.F. LABORATORIES, INC.; PURDUE PHARMACEUTICALS, L.P.; and RHODES TECHNOLOGIES,	)	**Civil Action No. 15-13099-FDS**
Plaintiffs,	)	
v.	)	
COLLEGIUM PHARMACEUTICAL, INC.,	)	
Defendant.	)	

MEMORANDUM AND ORDER ON CLAIM CONSTRUCTION

SAYLOR, J.

This is a patent dispute concerning a pharmaceutical product: abuse-deterrent, extended-release oxycodone. Plaintiffs Purdue Pharma L.P.; The P.F. Laboratories, Inc.; Purdue Pharmaceuticals L.P.; and Rhodes Technologies (collectively, "Purdue") have brought suit against Collegium Pharmaceutical, Inc. The amended complaint asserts claims for infringement pursuant to 35 U.S.C. §§ 271(a), (b), (c), and (e)(2)(A) arising out of three related patents.

The case is at the claim-construction stage. The parties have submitted proposed constructions for seven terms, five of which are in dispute: (1) "irritant," (2) "effective amount of an irritant to impart an irritating sensation," (3) "an effective amount of an irritant to impart a burning sensation," (4) effective amount to discourage an abuser from tampering with the dosage form," and (5) "removing 8α, 14-dihydroxy-7,8-dihydrocodeinone."

I. Background

A. Factual Background

Purdue Pharma L.P. is the owner of the three patents at issue, all of which relate to abuse-deterrent and low-toxicity versions of the pain medication oxycodone. Purdue Pharma L.P. sells oxycodone in the United States under the OxyContin brand name. (First Am. Compl. ("FAC") ¶¶ 2, 12–14). The P.F. Laboratories, Inc. owns a patent that describes processes for producing oxycodone with low levels of toxicity, which plaintiffs refer to as the "low-toxicity patent." (*Id.* ¶ 3, 12). Purdue Pharmaceuticals L.P. also owns the low-toxicity patent and manufactures extended-release oxycodone pain-relief medication under the OxyContin brand name. (*Id.* ¶ 4, 12). Rhodes Technologies owns the low-toxicity patent and manufactures the active pharmaceutical ingredient used in OxyContin. (*Id.* ¶ 5, 12).

Collegium Pharmaceutical, Inc. recently filed a new drug application ("NDA") with the Food and Drug Administration to manufacture, use, sell, or import a product that plaintiffs allege infringes on their patents. (*Id.* ¶¶ 6, 15, 18–22).

The dispute concerns pharmaceutical products designed to deter abuse of addictive pain medications, such as oxycodone, as well as methods for reducing toxicity in oxycodone pharmaceuticals. (*Id.* ¶ 12–14). Oxycodone is an opioid, first developed in Germany in 1916, first used as a drug in 1917, and first introduced to the United States market in 1939. (*See* Def. CC at 1; Pl. Summ. Judg. Opp. at 4). Purdue developed an extended release ("ER") version of oxycodone, known as OxyContin, in 1995. (Pl. Summ. Judg. Opp. at 4).

Opioid drugs are often used to treat pain, but are also subject to abuse. (*Id.*). The FDA approved an abuse-deterring version of OxyContin in 2010. (*Id.* at 5). The drug incorporated two features to deter abuse: (1) a harder tablet, to resist crushing, and (2) a gelling agent, to

impede snorting and injecting of any powder resulting from successful crushing. (*Id.*). Those features are the subject of two of the patents at issue. In April 2013, the FDA granted abuse-deterrent OxyContin the first abuse-deterrent labeling. The FDA also declined to approve generic versions of original OxyContin because they lacked the new formulation's abuse-deterring features. (*Id.*).

Collegium recently developed a version of oxycodone, called XTAMPZA ER, which also contains abuse-deterring features. (Def. Summ. Judg. Br. at 4–5). XTAMPZA ER utilizes a "hydrophobic matrix of fatty acid and waxes" to "reduce[] the potential for dose dumping" and to "create[] barriers to abuse via oral ingestion, insufflation, or injection." (*Id.* at 5). The FDA approved XTAMPZA ER and made it the first and only ER opioid without a warning on its label related to crushing or chewing and the potential exposure to a fatal dose. (*Id.*). However, the XTAMPZA ER label includes a "Drug Abuse and Dependence" section warning that "abuse of Xtampza ER by injection and by the nasal route of administration, as well as by the oral route is still possible." (Pl. Summ. Judg. Opp. at 6).

Oxycodone contains a substance known as alpha, beta-unsaturated ketone ("ABUK"), that may damage human DNA. Pl. CC at 15 (citing Byrn Decl. Exs. 14–15). Purdue has also patented an oxycodone-based product that contains a low level of ABUK, as well as a method for removing a source of ABUK in the manufacturing process, by removing a toxin that the parties refer to as 8α. In 2016, three related Purdue-owned patents for low-ABUK oxycodone products were invalidated on obviousness grounds. *See Purdue Pharma L.P. v. Epic Pharma, LLC*, 811 F.3d 1345, 1348 (Fed. Cir. 2016).

B. Patents at Issue

Purdue Pharma L.P., is the named assignee on two patents related to abuse-deterring

oxycodone: U.S. Patent Nos. 8,652,497 ("the '497 patent") and 9,155,717 ("the '717 Patent"). FAC, Exs. B–C. Plaintiffs are the named assignees of the 8α-removing, low-ABUK patent: U.S. Patent No. 9,073,933 ("the '933 Patent").

1. The '497 Patent

The '497 patent is entitled "Pharmaceutical Formulation Containing Irritant." It was issued on February 18, 2014. ('497 Patent). It names Richard Sackler as the inventor and Purdue Pharma L.P. as the assignee. (*Id.*).

The '497 patent is generally directed to "provide an oral dosage form of an opioid analgesic which is subject to less parenteral . . . intranasal . . . [and] oral abuse than other dosage forms." (*Id.* col. 2 ll. 14–22). The patent is also directed to preventing abuse of drugs other than opioid analgesics that may be the subject of abuse. (*Id.* col. 5 ll. 35–40). At the time the patent was issued, a number of other techniques were known for deterring opioid abuse. (*Id.* col. 1 ll. 28–41, 55–67; *Id.* col. 1 ll. 1–4). In certain embodiments, the patent provides an opioid product that includes "an aversive agent such as an irritant to discourage from tampering with the dosage form and thereafter inhaling, injecting, or swallowing the tampered dosage form. Preferably, the irritant is released when the dosage form is tampered with and provides a burning or irritating effect to the abuser upon inhalation, injection, and/or swallowing of the tampered dosage form." (*Id.* col. 2 ll. 52–59).

2. The '717 Patent

The '717 patent is entitled "Pharmaceutical Formulation Containing Irritant." It was issued on October 13, 2015. ('717 Patent). It names Sackler as the inventor and Purdue Pharma L.P. as the assignee. (*Id.*). The '717 patent shares a specification with the '497 patent.

3. The ’933 Patent

The ’933 patent is entitled “Oxycodone Hydrocholoride Having less than 25 PPM 14-Hyrdroxycodeinone.” It was issued on July 7, 2015. (’933 Patent). It names Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors and Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., and Rhodes Technologies as the assignees. (*Id.*).

The ’933 patent is generally directed to a process for reducing the amount of 14-hyrdroxycodeinone in an oxycodone hydrochloride composition as compared to existing formulations. (*Id.* col. 2 ll. 20–23). Specifically, the patent is directed at producing oxycodone hydrochloride compositions with less than 25 ppm of 14-hyrdroxycodeinone in an oxycodone hydrochloride composition. (*Id.* col. 2 ll. 30–34). Methods for reducing the amount of 14-hyrdroxycodeinone in an oxycodone hydrochloride composition were known in the prior art. (*Id.* col.1, ll. 47–col. 2 ll. 2). At the time of the patent, existing procedures for reducing toxicity in oxycodone hydrochloride produced levels greater than 100 ppm. (*Id.* col. 2 ll. 12–19).

II. Legal Standard

The construction of claim terms is a question of law, which may in some cases rely on underlying factual determinations. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 835, 837–38 (2015); *Markman v. Westview Instruments*, 517 U.S. 370, 372 (1996) (“[T]he construction of a patent, including terms of art within its claim, is exclusively within the province of the court.”).

In *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*), the Federal Circuit clarified the proper approach to claim construction and set forth principles for determining the hierarchy and weight of the definitional sources that give a patent its meaning. The guiding

principle of construction is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of . . . the effective filing date of the patent application." *Id.* at 1313. Courts thus seek clarification of meaning in "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Id.* at 1314 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004)).

A. The Words of the Claim

The claim construction analysis normally begins with the claims themselves.[1] The claims of a patent "define the invention to which the patentee is entitled the right to exclude." *Phillips*, 415 F.3d at 1312 (citing *Innova*, 381 F.3d at 1115).

A court may construe a claim term to have its plain meaning when such a construction resolves a dispute between the parties. *See O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1361 (Fed. Cir. 2008); *see also U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997) ("Claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, . . . [but] is not an obligatory exercise in redundancy.").

[1] In *Phillips*, the Federal Circuit discredited the practice of starting the claim-construction analysis with broad definitions found in dictionaries and other extrinsic sources:

> [I]f the district court starts with the broad dictionary definition . . . and fails to fully appreciate how the specification implicitly limits that definition, the error will systematically cause the construction of the claim to be unduly expansive. The risk of systematic overbreadth is greatly reduced if the court instead focuses at the outset on how the patentee used the claim term in the claims, specification, and prosecution history, rather than starting with a broad definition and whittling it down.

415 F.3d at 1321. Of course, if no special meaning is apparent after reviewing the intrinsic evidence, claim construction might then "involve[] little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314.

In some instances, it is the arrangement of the disputed term in the claims that is dispositive. "This court's cases provide numerous . . . examples in which the use of a term within the claim provides a firm basis for construing the term." *Phillips*, 415 F.3d at 1314. For example, because claim terms are normally used consistently throughout the patent, the meaning of a term in one claim is likely the meaning of that same term in another. *Id.* In addition, "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1315.

B. The Specification

"The claims, of course, do not stand alone." *Id*. "Rather, they are part of a fully integrated written instrument, consisting principally of a specification that concludes with the claims." *Id.* (citations and quotations omitted). For that reason, the specification must always be consulted to determine a claim's intended meaning. The specification "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." *Id.* (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)).

"In general, the scope and outer boundary of claims is set by the patentee's description of his invention." *On Demand Mach. Corp. v. Ingram Indus., Inc.*, 442 F.3d 1331, 1338 (Fed. Cir. 2006); *see also Phillips*, 415 F.3d at 1315–17 ("[T]he interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim." (quoting *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998))). "[T]he specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess." *Phillips*, 415 F.3d at 1316. It may also reveal "an intentional disclaimer, or disavowal, of claim

scope by the inventor." *Id.* Therefore, the claims are to be construed in a way that makes them consistent with, and no broader than, the invention disclosed in the specification. *On Demand*, 442 F.3d at 1340 ("[C]laims cannot be of broader scope than the invention that is set forth in the specification."); *Phillips*, 415 F.3d at 1316 ("[C]laims must be construed so as to be consistent with the specification, of which they are a part." (quoting *Merck & Co. v. Teva Pharm. USA, Inc.*, 347 F.3d 1367, 1371 (Fed. Cir. 2003))).

Nevertheless, courts must be careful to "us[e] the specification [only] to interpret the meaning of a claim" and not to "import[] limitations from the specification into the claim." *Id.* at 1323. A patent's "claims, not specification embodiments, define the scope of patent protection." *Kara Tech. Inc. v. Stamps.com Inc.*, 582 F.3d 1341, 1348 (Fed. Cir. 2009); *see also Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1381 (Fed. Cir. 2009) ("[E]mbodiments appearing in the written description will not be used to limit claim language that has broader effect."). "In particular, [the Federal Circuit] ha[s] expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment." *Phillips*, 415 F.3d at 1323. This is "because persons of ordinary skill in the art rarely would confine their definitions of terms to the exact representations depicted in the embodiments." *Id.*

Although this distinction "can be a difficult one to apply in practice[,] . . . the line between construing terms and importing limitations can be discerned with reasonable certainty and predictability if the court's focus remains on understanding how a person of ordinary skill in the art would understand the claim terms." *Id.* "The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Id.* at 1316 (quoting *Renishaw*, 158 F.3d at 1250).

C. The Prosecution History

After the specification and the claims themselves, the prosecution history is the next best indicator of term meaning. The prosecution history "consists of the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent." *Id.* at 1317. "Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent." *Id.* "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

However, "because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Id.* As a result, courts generally require that "a patent applicant . . . clearly and unambiguously express surrender of subject matter" to disavow claim scope during prosecution. *Voda v. Cordis Corp.*, 536 F.3d 1311, 1321 (Fed. Cir. 2008) (quoting *Sorensen v. Int'l Trade Comm'n*, 427 F.3d 1375, 1378–79 (Fed. Cir. 2005)).

D. Extrinsic Sources

Extrinsic evidence consists of "all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317 (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995)). It "can help educate the court regarding the field of the invention and can help the court determine what a person of ordinary skill in the art would understand claim terms to mean." *Id.* at 1319. However, extrinsic evidence suffers from a number of defects, including its independence from

the patent, potential bias, and varying relevance. *Id.* at 1318–19. Such evidence is therefore "unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence," and courts may consider, or reject, such evidence at their discretion. *Id.* at 1319.

III. Analysis

There are five terms at issue in the patents:

Term	Plaintiffs' construction	Defendant's construction	Patent Number
"irritant"	"a compound that imparts an irritating or burning sensation to an abuser administering a tampered dosage form of the present invention"	"a compound used to impart an irritating or burning sensation to an abuser administering a tampered dosage form of the present invention"	'497, '717
"effective amount of an irritant to impart an irritating sensation"	"an amount of an irritant sufficient to impart an irritating sensation"	indefinite	'497
"an effective amount of an irritant to impart a burning sensation"	"an amount of an irritant sufficient to impart an burning sensation"	indefinite	'717
"effective amount to discourage an abuser from tampering with the dosage form"	"an amount sufficient to reduce the potential that an abuser will tamper with the dosage form"	indefinite	'717
"removing 8α, 14-dihydroxy-7,8-dihydrocodeinone"	"the amount of 8α, 14-dihydroxy-7,8-dihydrocodeinone present in the oxycodone base composition is reduced"	"selectively removing only 8α, 14-dihydroxy-7,8-dihydrocodeinone"	'933

A. The '497 Patent

There are two terms at issue in the '497 patent: (1) "irritant" and (2) "effective amount of an irritant to impart an irritating sensation." "Irritant" appears in claims 1 and 17, while "effective amount of an irritant to impart an irritating sensation" appears in

claim 1. Their use in claim 1 is illustrative. Claim 1 recites:

> An oral dosage form consisting of:
>
> A therapeutically effective amount of a drug susceptible to abuse; and
>
> a modified or a sustained release carrier,
>
> an **effective amount of an <u>irritant</u> to impart an irritating sensation** to an abuser upon administration of said dosage form after tampering, and
>
> one or more pharmaceutical excipients,
>
> wherein the modified or the sustained release carrier is selected from the group consisting of gums, cellulose ethers, acrylic resins, protein derived materials, waxes, shellac, oils and mixtures of any of the foregoing materials, and the irritant is coated with the modified or the sustained release carrier or is dispersed in a matrix of the modified or the sustained release carrier.

('497 patent col. 39 ll. 63–67, col. 40 ll. 1-11 (emphasis added)).

1. <u>Irritant</u>

Term	Plaintiffs' construction	Defendant's construction
"Irritant"	"a compound that imparts an irritating or burning sensation to an abuser administering a tampered dosage form of the present invention"	"a compound used to impart an irritating or burning sensation to an abuser administering a tampered dosage form of the present invention"

This aspect of the dispute may be framed as follows. The claim is for a pharmaceutical product that consists of four components: A (the drug) and B (a release carrier), C (an irritant), and D (an excipient).[2] Those four components have four different functions: A has therapeutic

[2] A release carrier is a substance that controls the release of the product into the body. Here, the sustained release carrier operates such that opioid levels in the users blood "are maintained within the therapeutic range but below toxic levels over an extended period of time[.]" ('497 patent col. 4 ll. 55–56).

A pharmaceutical excipient is "the inactive ingredient of a pharmaceutical product." *In re OxyContin Antitrust Litig.*, 994 F. Supp. 2d 367, 391 n.4 (S.D.N.Y. 2014). "Examples of excipients include fillers, extenders, diluents, wetting agents, solvents, emulsifiers, preservatives, flavors, absorption enhancers, sustained-release matrices, and coloring agents." Food and Drug Administration, *Guidance for Industry Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients*, (May 2005), 2005 WL 3628195, at *1. An excipient is also defined as "[a] more or less inert substance added in a prescription as a diluent or vehicle or to give form or

function W; B has carrier function X; C has irritant function Y; and D has incipient function Z. The claimed invention involves the inclusion of ingredient C ("an irritant") to perform function Y ("impart an irritating sensation to an abuser . . . after tampering").

The focus of the dispute between the parties is whether the claim requires intentional conduct on the part of the manufacturer of the product. Collegium contends that the term "irritant" should be construed to mean a "compound *used to impart* an irritating or burning sensation." It takes that language directly from the words of the specification. ('497 patent col. 5 ll. 9–12). According to Collegium, if no irritant is deliberately added, but if one or more ingredients happen—unintentionally—to impart an irritating sensation when abused, the patent is not infringed. Thus, according to Collegium, if it manufactures a product with ingredients A, B, and D, and it turns out that B or D (in addition to intended functions X or Z) also have irritating function Y, no infringement has occurred. Purdue, for its part, contends that intent is irrelevant, and that the term "irritant" should be construed simply to mean a "compound *that imparts* an irritating or burning sensation."

Purdue is correct that Collegium's proposed construction improperly imports the element of intent into the claim. Such an interpretation "injects subjective notions into the infringement analysis." *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1353 (Fed. Cir. 2001). Patent infringement is determined by whether an accused product or method reads on the claims of the patent, not by the intent of the accused infringer. *See Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995). Courts generally avoid assigning "a meaning to a patent claim that depends on the state of mind of the accused infringer."

consistency when the remedy is given in pill form." "Excipient" *Stedman's Medical Dictionary* (Nov. 2014 online database update entry 308800). The claim recites "one or more pharmaceutical excipients": for the sake of simplicity, the analysis will assume a single excipient.

Amazon.com, 239 F.3d at 1353. Thus, it does not matter whether the irritating effect (function Y) occurs by accident, or whether the alleged infringer had any idea that ingredients B or D happened to create an irritating sensation if an abuser tried to tamper with the product.

Collegium contends that Purdue should be held to the language of the patent because it acted as its own lexicographer in setting forth a definition of irritant within the patent specification, and therefore should be bound by that definition. But "[t]o act as its own lexicographer, a patentee must 'clearly set forth a definition of the disputed claim term' other than its plain and ordinary meaning." *Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (quoting *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)); *Luminara Worldwide v. Liown Elecs. Co.*, 814 F.3d 1343, 1353 (Fed. Cir. 2016) (describing the 'exacting' standards for finding lexicography). There is no such clear definition contrary to the plain and ordinary meaning of irritant here. Furthermore, the specification's "definition" of "irritant" begins with the word "includes." ('497 patent col. 5 ll. 9–12). Thus, even if intent were applied in certain formulations, the definition of the term in the specification is broader than Collegium's proposed construction. *See SanDisk Corp. v. Memorex Prod., Inc.*, 415 F.3d 1278, 1284 (Fed. Cir. 2005) ("As a patent law term of art, 'includes' means 'comprising.' Neither includes, nor comprising, forecloses additional elements that need not satisfy the stated claim limitations." (citations omitted)).

Purdue's proposed construction, however, creates at least one possible issue. Purdue did not invent an accidental or unpredictable side effect, and granting it protection for such an unintended effect would provide it with an unfair windfall. That potential issue, however, is likely resolved by the structure of the claim. The claim at issue indicates that the product "consist[s] of" four components, and it uses (or implies) the word "and" between each of those

four components. Thus, by its plain terms, the claim is for a product with four components (or types of components)—drug, a release carrier, an irritant, and an excipient (A, B, C, and D). A product with only three components (a drug, a release carrier, and an excipient, or A, B, and D) would not appear to infringe, even if one or more of those components happens (as an unintentional consequence) to impart an irritating sensation upon tampering. In other words, if a drug contains a pharmaceutical excipient (component D) with an excipient function (function Z) that also happens to irritate when the product is abused, that excipient would not qualify as an "irritant" under the claim, because excipients and irritants are different components, according to its plain language.

Purdue argues that an ingredient can fall within multiple categories of the Claim 1 list. Pl. CC at 10. However, Purdue disclaimed such a broad reading when prosecuting the prosecution patent. (*See* Sept. 22, 2005 Amendment and Remarks at 9, Thorkelson Decl., Ex. 4 (discussing absence of sequestered irritants to reduce abuse in the prior art)). Courts generally require that "a patent applicant . . . clearly and unambiguously express surrender of subject matter" to disavow claim scope during prosecution. *Voda v. Cordis Corp.*, 536 F.3d 1311, 1321 (Fed. Cir. 2008) (quoting *Sorensen v. Int'l Trade Comm'n*, 427 F.3d 1375, 1378–79 (Fed. Cir. 2005)). The prosecution history supports a finding that Purdue clearly and unambiguously expressed surrender of items that overlap—for example, as both a pharmaceutical excipient and an irritant. That prosecution history disclaimer also avoids potential issues of invalidity under 35 U.S.C. § 101. *See Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 911 (Fed. Cir. 2004) (noting axiom that claims should be construed to sustain validity if possible).

Accordingly, the term "irritant" will be construed to mean "a compound that imparts an irritating or burning sensation to an abuser administering a tampered dosage form of the present invention."

2. Effective Amount of an Irritant to Impart an Irritating Sensation

Term	Plaintiffs' construction	Defendant's construction
"effective amount of an irritant to impart an irritating sensation"	"an amount of an irritant sufficient to impart an irritating sensation"	indefinite

In multiple contexts, the parties dispute whether the term "effective amount" is sufficiently definite to give notice to other artisans of what the patent protects. But the term "effective amount" has a customary usage to a person or ordinary skill in the art. *See Abbott Labs v. Baxter Pharm. Prods., Inc.*, 334 F.3d 1274, 1277 (Fed. Cir. 2003) (noting that "the term 'effective amount' has a customary usage"); *Imagenetix, Inc. v. Robinson Pharma, Inc.*, No. 15-599, 2016 WL 6395941, at *4–*6 (C.D. Cal. Apr. 14, 2016) (finding "therapeutically effective amount" sufficiently definite under the "reasonable certainty" standard announced in *Nautilis, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120 (2014)); (Byrn Decl. ¶¶ 35, 37). In addition, Purdue has offered expert testimony describing how a person of ordinary skill in the art would understand the term "irritating sensation." (Byrn Decl. ¶ 41; Byrn Dep. 93:14–18, 94:15–25, 95:8–96:1). Defendant has not provided any expert testimony to contradict that conclusion. *See AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1053 (Fed. Cir. 2010) ("[A] district court cannot be faulted for relying on the only expert explanation of the technology that was presented." (alteration in original) (quoting *Network, LLC v. Centraal Corp.*, 242 F.3d 1347, 1356 (Fed. Cir. 2001))).

Furthermore, the specification discloses an example of an effective amount of an irritant

to impart an irritating sensation involving capsaicin. ('497 patent col. 6 ll. 32–38). That specification, coupled with the plain meaning of the term to a person of ordinary skill in the art, "provides an objective baseline through which to interpret the claim[]." *Sonix Tech. Co., Ltd. v. Publications Int'l, Ltd.*, 544 F.3d 1370, 1378 (Fed. Cir. 2017). Here, as in *Sonix*, "although the term may be a term of degree, it is not 'purely subjective.'" *Id.*; *cf. Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014) ("The claims, when read in light of the specification and the prosecution history, must provide objective boundaries for those of skill in the art."). Thus, there is not a "total absence of structure from the specification." *Default Proof Credit Card Sys. v. Home Depot U.S.A., Inc.*, 412 F.3d 1291, 1302 (Fed. Cir. 2005).

Accordingly, the term "effective amount of an irritant to impart an irritating sensation" will be construed to mean "an amount of an irritant sufficient to impart an irritating sensation."

B. <u>'717 Patent Terms</u>

There are two terms at issue unique to the '717 patent: (1) "an effective amount of an irritant to impart a burning sensation," and (2) "effective amount to discourage an abuser from tampering with the dosage form." The first term appears in claims 1, 13, and 18. The second term appears in claim 23. Their use in claims 1, and 23, respectively, is illustrative. Claim 1 of the '717 Patent recites:

> An oral dosage form consisting of:
>
> > a therapeutically effective amount of a drug susceptible to abuse;
> >
> > a plurality of particles collectively consisting of said therapeutically effective amount of said drug susceptible to abuse;
> >
> > **an effective amount of an irritant to impart a burning sensation** to an abuser upon inhalation or injection of said dosage form after crushing, shearing, grinding, chewing, dissolution in a solvent, heating, or any combination thereof, and
> >
> > one or more additional pharmaceutical excipients; and

> a capsule containing said plurality of particles;
>
> wherein the particles are from about 0.1 mm to 2.5 mm in diameter, and one of the additional pharmaceutical excipients is a sustained release carrier selected from the group consisting of gums, cellulose ethers, acrylic resigns, protein derived material, waxes, shellac, oils and mixtures of any of the foregoing materials.

('717 patent col. 40 ll. 34–52 (emphasis added)). Claim 23 of the '717 Patent recites:

> An oral dosage form consisting of:
>
> a therapeutically effective amount of oxycodone or a salt thereof;
>
> a plurality of particles collectively consisting of said therapeutically effective amount of said oxycodone or salt thereof;
>
> a sustained release carrier selected from the group consisting of gums, cellulose ethers, acrylic resins, protein derived materials, waxes, shellac, oils and mixtures of any of the foregoing materials,
>
> at least one aversive agent in an **effective amount to discourage an abuser from tampering with the dosage form** and thereafter inhaling, injecting, or swallowing the tampered dosage form, and
>
> additional pharmaceutical excipients; and
>
> a capsule containing said plurality of particles;
>
> wherein the particles are from about 0.1 mm to about 2.5 mm in diameter.

(Id. col. 41 ll. 45-56, col. 42 ll. 1-6 (emphasis added)).

1. <u>An Effective Amount of an Irritant to Impart a Burning Sensation</u>

Term	**Plaintiffs' construction**	**Defendant's construction**
"an effective amount of an irritant to impart a burning sensation"	"an amount of an irritant sufficient to impart a burning sensation"	Indefinite

For the same reasons the Court adopted Purdue's construction of the "irritating sensation" term, it will adopt Purdue's proposed construction here. Accordingly, the term "an effective amount of an irritant to impart a burning sensation" will be construed to mean "an amount of an irritant sufficient to impart a burning sensation."

2. Effective Amount to Discourage an Abuser from Tampering with the Dosage Form

Term	Plaintiffs' construction	Defendant's construction
"effective amount to discourage an abuser from tampering with the dosage form"	"an amount sufficient to reduce the potential that an abuser will tamper with the dosage form"	Indefinite

For the same reasons the Court adopted Purdue's construction of the two terms construed above, it will adopt Purdue's proposed construction here. Accordingly, the term "effective amount to discourage an abuser from tampering with the dosage form" will be construed to mean "an amount sufficient to reduce the potential that an abuser will tamper with the dosage form."

C. The '933 Patent

There is one term at issue in the '933 patent: (1) "removing 8α, 14-dihydroxy-7,8-dihydrocodeinone." The term appears in claim 10, which states as follows:

> A process for preparing an oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone, comprising **removing 8α, 14-dihydroxy-7,8-dihydrocodeinone** from an oxycodone base composition and converting the oxycodone base composition to an oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone.

('933 patent col. 34 ll. 52-58).

1. Removing 8α, 14-dihydroxy-7,8-dihydrocodeinone

Term	Plaintiffs' construction	Defendant's construction
"removing 8α, 14-dihydroxy-7,8-dihydrocodeinone"	"the amount of 8α, 14-dihydroxy-7,8-dihydrocodeinone present in the oxycodone base composition is reduced"	"selectively removing only 8α, 14-dihydroxy-7,8-dihydrocodeinone"

The parties dispute whether the word "removing" means both (1) removing *only* 8α and (2) *completely* removing 8α by the claimed process. Purdue contends that "removing" means reducing the amount of 8α, but not necessarily exclusively or completely eliminating 8α from the resulting compound. Collegium contends that the term should be construed as a process to

remove 8α exclusively (that is, to remove it and nothing else) and completely (that is, to remove all of it). Thus, according to Collegium, a process that removes 8β at the same time it removes 8α would not infringe the ’933 patent, nor would a process that results in a compound that still contains some amount of 8α. Collegium rests much of its argument on the contention that in the context of molecules, “reduce” is a term of art distinct from “remove.” (Def. CC at 16). However, Collegium has provided no expert testimony that a person of ordinary skill in the art would so understand the terms “reduce” or “remove.” *See AstraZeneca LP*, 633 F.3d at 1053.

In any event, Collegium’s proposed construction is foreclosed by the patent’s specification, which is inconsistent with a construction of the term that requires complete removal of 8α by the claimed process. *See Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 987 (Fed. Cir. 1988) (“Where a specification does not *require* a limitation, that limitation should not be read from the specification into the claims.” (emphasis in original)); *Arlington Indus. v. Bridgeport Fittings, Inc.*, 632 F.3d 1246, 1256 (Fed. Cir. 2011). Two claims in the ’933 patent are directed to low-ABUK oxycodone hydrochloride compositions that *contain* 8α. (’933 patent claims 1, 16).

Nor should the term be construed to require removal of 8α exclusively, and no other substance. Again, if the specification does not require a limitation, that limitation should not be read from the specification into the claim. *Specialty Composites*, 845 F.2d at 987. Here, the specification states: “[t]he process of the present invention also may result in the reduction of other alpha, beta, unsaturated ketones in oxycodone compositions, in addition to 14-hydroxycodeinone such as, e.g., codeinone.” (’933 patent col. 6, ll. 51–54). Essentially, Collegium seeks to add the modifier “only” to the contested term. That argument is inconsistent with canons of claim construction. *See InterDigital Commc’ns, LLC v. Int’l Trade Comm’n*, 690

F.3d 1318, 1325 n.1 (Fed. Cir. 2012) ("general descriptive terms are ordinarily given their full meaning; "modifiers will not be added to broad terms standing alone.") (quoting *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir.1999)).

Collegium also contends that the claim must be construed to require selective removal of 8α in order to avoid overlapping with prior art, which taught removal of 8β. (Def. CC at 20). However, the fact that the prior art taught removal of 8β does not equate with teaching removal of 8α and 8β simultaneously. Therefore, Collegium's construction is not necessary to avoid claim invalidity. *See Liebel-Flarsheim Co.*, 358 F.3d at 911.

Accordingly, the term "removing 8α, 14-dihydroxy-7,8-dihydrocodeinone" will be construed to mean "the amount of 8α, 14-dihydroxy-7,8-dihydrocodeinone present in the oxycodone base composition is reduced."

IV. Conclusion

For the foregoing reasons, the disputed claim terms are construed as follows:

1. "Irritant" in the '497 and '717 patents is construed to mean "a compound that imparts an irritating or burning sensation to an abuser administering a tampered dosage form of the present invention."
2. "Effective amount of an irritant to impart an irritating sensation" in the '497 patent is construed to mean "an amount of an irritant sufficient to impart an irritating sensation."
3. "An effective amount of an irritant to impart a burning sensation" in the '717 patent is construed to mean "an amount of an irritant sufficient to impart a burning sensation."

4. "Effective amount to discourage an abuser from tampering with the dosage form" in the '717 patent is construed to mean "an amount sufficient to reduce the potential that an abuser will tamper with the dosage form."

5. "Removing 8α, 14-dihydroxy-7,8-dihydrocodeinone" in the '933 patent is construed to mean "the amount of 8α, 14-dihydroxy-7,8-dihydrocodeinone present in the oxycodone base composition is reduced."

So Ordered.

/s/ F. Dennis Saylor IV
F. Dennis Saylor IV
United States District Judge

Dated: November 21, 2017