IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS INTERNATIONAL GMBH, TAKEDA PHARMACEUTICALS USA, INC., TAKEDA PHARMACEUTICALS AMERICA, INC., and OREXIGEN THERAPEUTICS, INC., Plaintiffs, v. ACTAVIS LABORATORIES FL, INC., Defendant.	Civil Action No. 15-451-RGA

MEMORANDUM OPINION

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ANDREWS, U.S. DISTRICT JUDGE:

Presently before the Court is the issue of claim construction of multiple terms in U.S. Patent Nos. 7,462,626 ("the '626 patent") and 8,916,195 ("the '195 patent"). The Court has considered the Parties' Joint Claim Construction Brief. (D.I. 49). The Court heard oral argument on May 24, 2016. (D.I. 55).

I. BACKGROUND

The present claim construction dispute arises from Hatch-Waxman litigation involving Contrave extended-release tablets, which is Plaintiffs' medication for weight management in overweight or obese adults. (D.I. 49 at p. 1). Although Plaintiffs are asserting four patents against Defendant in the underlying action, the present claim construction dispute only concerns the '626 and '195 patents. (*Id.* at p. 6). Broadly speaking, both the '626 and '195 patents claim methods of treating obesity by administering some combination of two active ingredients, naltrexone and bupropion, in order to cause weight loss. (*See, e.g.*, '626 patent, claim 1; '195 patent, claim 1).

II. LEGAL STANDARD

"It is a bedrock principle of patent law that the 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) (internal quotation marks omitted). "'[T]here is no magic formula or catechism for conducting claim construction.' Instead, the court is free to attach the appropriate weight to appropriate sources 'in light of the statutes and policies that inform patent law.'" *SoftView LLC v. Apple Inc.*, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting *Phillips*, 415 F.3d at 1324) (alteration in original). When construing patent claims, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v.*

Westview Instruments, Inc., 52 F.3d 967, 977–80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Of these sources, "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." *Phillips*, 415 F.3d at 1315 (internal quotation marks omitted).

"[T]he words of a claim are generally given their ordinary and customary meaning. . . . [Which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1312–13 (citations and internal quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314.

When a court relies solely upon the intrinsic evidence—the patent claims, the specification, and the prosecution history—the court's construction is a determination of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). The court may also make factual findings based upon consideration of extrinsic evidence, which "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 1317–19 (internal quotation marks omitted). Extrinsic evidence may assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Id.* Extrinsic evidence, however, is less reliable and less useful in claim construction than the patent and its prosecution history. *Id.*

"A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GMBH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (citation and internal quotation marks omitted).

III. CONSTRUCTION OF DISPUTED TERMS

A. The '626 and '195 patents

1. "administering"[1]

   a. *Plaintiffs' proposed construction*: "Delivering, or directing the delivery, into the body"

   b. *Defendant's proposed construction*: "Delivering into the body"

   c. *Court's construction*: "Delivering into the body"

The crux of the Parties' dispute here is straightforward: Defendant seeks to limit the term "administering" to the actual act of delivering the drug into the patient's body, while Plaintiffs want the term construed to include the act of a physician prescribing or otherwise directing a patient to take the drug. (D.I. 49 at p. 8). Plaintiffs argue that their construction reflects the ordinary meaning of "administering" in the context of prescription drugs and is supported by the intrinsic record. (*Id.*). Specifically, Plaintiffs contend that the specifications and claims of the two patents are written with the perspective of the healthcare provider in mind, because they are method of treatment claims and some of the claims contemplate a "diagnosing" step. (*Id.* at pp. 9–10). Plaintiffs also assert that the specifications primarily contemplate oral administration,

[1] The Parties' Joint Claim Construction Brief treats the term "administering" the same as used in both the '626 and '195 patents, even though they come from different patent families. (D.I. 49 at pp. 8–35). Likewise, at oral argument, the Parties told the Court that the term was used consistently in the '626 and '195 patents and did not need to be construed separately as to each patent. (D.I. 55 at 5, Tr. pp. 19–20). I agree with the Parties and will construe the term accordingly.

which typically does not require a physical act from the physician. (*Id.* at p. 10). Lastly, Plaintiffs maintain that extrinsic evidence, including dictionary definitions and case law, demonstrates that their construction is consistent with the plain and ordinary meaning of the term in the prescription drug context. (*Id.* at pp. 10–13).

Defendant argues that the specifications only refer to administering as being the specific act of delivering the drug into the body and distinguish between such delivery and a physician's prescribing activity. (*Id.* at pp. 14–17). For instance, Defendant points out that the specification of the '626 patent describes "multiple techniques of administering a compound," all of which are physical acts of delivering the compound into the body. (*Id.* at p. 16). Thus, Defendant asserts, "Plaintiffs have identified no examples from the intrinsic records where 'administering' is used to refer to activities such as prescribing, providing, managing, or supervising," all of which Plaintiffs contend should be encompassed by the term. (*Id.* at p. 31). Defendant also points to the '195 patent specification's discussion of various resulting effects caused by a compound that are described in terms of specific time intervals after "administration," which would not make sense in relation to when a physician merely told a patient to ingest the compound. (*Id.* at p. 17). Moreover, Defendant contends that Plaintiffs' record citations for the proposition that the patents discuss the perspective of a physician say nothing about the perspective of the healthcare provider with respect to the specific act of administering. (*Id.* at p. 18, 31). Finally, Defendant argues that extrinsic evidence is unnecessary in light of the clear intrinsic record, but that, to the extent the Court deems it necessary, Plaintiffs' proposed dictionary definition only provides equivocal support for Plaintiffs' position. (*Id.* at pp. 20–25).

The Court will adopt Defendant's proposed construction. I acknowledge that courts have come to differing conclusions when considering whether the term "administer" extends to the

verbal directives or management activities of physicians in the medical treatment context.[2] However, these decisions construe the term in the context of different claims and specifications. The use of administering in the specific claims and specifications of the '626 and '195 patents adequately guides the inquiry presently before me. *See Phillips*, 415 F.3d at 1315 ("Usually, [the specification] is dispositive; it is the single best guide to the meaning of a disputed term." (internal quotation marks omitted)).

The specifications of both the '626 and '195 patents consistently refer to the term "administering" solely to describe the physical act of delivering the drug into or onto the body. (*See, e.g.*, '626 patent, col. 23, ll. 47–49 ("Multiple techniques of administering a compound exist in the art including, but not limited to, oral, injection, aerosol, parenteral, and topical administration."); '195 patent, col. 11, ll. 30–31 ("The oral dosage form may be distributed, provided to a patient for self-administration or administered to a patient.")). Plaintiffs have not pointed to a single portion of either specification where some form of the word administer refers to the verbal directives or treatment management activities of physicians. Indeed, those types of activities, "distribut[ing], [and] provid[ing] to a patient for self-administration," are referred to separately and apart from the term administer. ('195 patent, col. 11, ll. 30–31). Moreover, many of the references to administration in both specifications would simply not make sense if administering were construed to also include directing the delivery into the body, as Plaintiffs

[2] *Compare Janssen Prods. L.P. v. Lupin Ltd.*, 2013 U.S. Dist. LEXIS 189016, at *36–38 (D.N.J. Oct. 9, 2013) (construing "administering" such as to "recognize and encompass 'the activities of doctors and other medical professionals who are involved in prescribing the claimed compounds or otherwise supervising [] care . . . .'"), *and Iovate Health Scis., Inc. v. Bio-Engineered Supplements & Nutrition, Inc.*, 2008 WL 2359961, at *2–3 (E.D. Tex. June 5, 2008) (construing "administering/administered" to mean "delivering into a body, or the management or supervision of the process whereby something is delivered into a body"), *with AstraZeneca AB v. Hanmi USA, Inc.*, 2012 WL 6203602, at *4–6 (D.N.J. Dec. 12, 2012) (rejecting argument that "administration" should include "'the prescription by a physician or other licensed healthcare professional, dispensing and ingestion'"), *and Med. Research Inst. v. Bio-Engineered Supplements & Nutrition, Inc.*, 2007 WL 128937, at *7 (E.D. Tex. Jan. 12, 2007) (construing "administer/administration" to mean "delivering the formulation-in-question into a person's body").

propose. (*See, e.g.*, '626 patent, col. 24, ll. 55–57 ("[O]ne may administer the compound in a local rather than systemic manner, for example, via injection of the compound directly in the renal or cardiac area . . . ."); '195 patent, col. 6, ll. 23–27 (observing that "immediate release" includes "release of a drug from a dosage form in a relatively brief period of time after administration"); *id.* col. 11, l. 31 ("self-administration"); *id.* col. 12, ll. 34–36 ("The sustained-release dosage forms described herein may be administered one, two or more times per day, without or without a loading dose.")).

Defendant's proposed construction is also consistent with the language of the claims themselves. (*See, e.g.*, '195 patent, claim 11 ("orally administering daily about 32 mg of naltrexone and about 360 mg of bupropion . . . .")). Being proceeded by the modifier "orally" highlights the fact that administering, as used in claim 11 of the '195 patent, refers to the physical means of delivering the medication into the patient's body. *Accord AstraZeneca AB v. Hanmi USA, Inc.*, 2012 WL 6203602, at *5 (D.N.J. Dec. 12, 2012). Plaintiffs' broad assertion that the claims at issue inherently include the perspective of physicians because they sometimes involve a diagnosing step is unconvincing, as it does not change the fact that administering is only used with regard to the physical act of taking or receiving treatment. In fact, the '626 patent's disclosure that a prescribing physician can choose the "route of administration and dosage" and "the manner of administration," reinforces the fact that administration in the context of the patent refers to delivering the drug into the body, not the prescribing and distributing activities of a physician which are separately referred to. ('626 patent col. 27, ll. 29–32; *id.* col. 28, ll. 21–25). Because the intrinsic evidence here—the claims themselves and the specifications—provides consistent, clear guidance for how administration is used in the context of the patents, I need not consider extrinsic evidence. *See, e.g.*, *Storage Tech. Corp. v. Cisco*

Systems, Inc., 329 F.3d 823, 832 (Fed. Cir. 2003) ("Resort to extrinsic evidence is appropriate only when an ambiguity remains after consulting the intrinsic evidence of record.").[3]

Ultimately, I conclude that Defendant's proposed construction comports with the literal language of the claims and the use of the term throughout the specification, while Plaintiffs stretch the term beyond the scope contemplated by the '626 and '195 patents. Accordingly, I will construe "administering" to mean "delivering into the body."[4]

2. "a weight loss effective amount of a first and second compound" ('626 patent only)

   a. *Plaintiffs' proposed construction*: "A weight loss effective amount of a first and second compound, in combination."

   b. *Defendant's proposed construction*: "A weight loss effective amount of a first compound and a weight loss effective amount of a second compound."

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[3] In any event, the extrinsic evidence Plaintiffs submit is unpersuasive and would not change my conclusion. Plaintiffs attempt to establish the plain and ordinary meaning of administer by pinpointing one of the definitions of administer from a 1994 edition of MERRIAM WEBSTER'S COLLEGIATE DICTIONARY. It is not an art-specific dictionary, and defines "administer" in numerous ways. (D.I. 49-1 at 76–79). The Federal Circuit has stated:

> By design, general dictionaries collect the definitions of a term as used not only in a particular art field, but in many different settings. In such circumstances, it is inevitable that the multiple dictionary definitions for a term will extend beyond the construction of the patent [that] is confirmed by the avowed understanding of the patentee, expressed by him, or on his behalf, when his application for the original patent was pending.

Phillips, 415 F.3d at 1321–22 (alteration in original) (internal quotation marks omitted). Plaintiffs merely cherry pick the most advantageous definition, out of numerous possibilities, for their current position: "to manage or supervise the execution, use, or conduct of <~ a trust fund>." (D.I. 49-1 at 79). However, another definition on the same page refers specifically to medicine and fits more closely with the use of administering throughout the specifications here: "to give remedially <~ a dose of medicine>." (*Id.*). Accordingly, Plaintiffs' extrinsic evidence does not persuasively establish the ordinary and customary meaning of the term in the relevant art.

[4] My understanding from the *Markman* hearing is that Defendant may pursue non-infringement arguments based upon a theory of divided infringement, because a physician often may not ultimately administer the compound under this construction. (D.I. 55 at 5–6, Tr. pp. 20–23). Although the issue is not presently before the Court, I am dubious as to whether Defendant's pursuit of such an argument will be successful in light of the Federal Circuit's *en banc* decision in *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1022 (Fed. Cir. 2015) (en banc) ("We will hold an entity responsible for others' performance of method steps . . . where that entity directs or controls others' performance . . . ."); *see also Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 126 F. Supp. 3d 1037, 1042–43 (S.D. Ind. 2015) ("The physician, based upon the patented method, directs the manner and timing of the patient's ingestion . . . . [Plaintiff] has shown, by a preponderance of the evidence that, in accordance with Defendants' proposed labeling, the physician directs or controls the patient's administration of folic acid such that performance of all the claimed steps, including the administration of folic acid, can be attributed to a single person, i.e. the physician."), *appeal docketed*, No. 15-2067 (Fed. Cir. Sept. 25, 2015). However, that is properly a question for another day and should not affect how this claim construction dispute is decided. Plaintiffs reach too far in an attempt to obviate the need for such a later inquiry.

c. *Court's construction*: "A weight loss effective amount of a first and second compound, in combination."

This term only appears in claim 25 of the '626 patent, which reads as follows:

> A method of treating overweight or obesity, comprising administering a *weight loss effective amount of a first and second compound* to an individual who has been diagnosed as suffering from overweight or obesity in order to treat said overweight or obesity, wherein said first compound is bupropion, or a pharmaceutically acceptable salt thereof, and said second compound is naltrexone, or a pharmaceutically acceptable salt thereof, and wherein the weight loss activity of said first and second compounds is enhanced compared to the administration of the same amount of either compound alone.

('626 patent, claim 25 (emphasis added)). Plaintiffs argue, "The disputed term refers to the combination of the first (bupropion) and second (naltrexone) compound being administered in a weight loss effective amount, and not each of the compounds being present individually in a weight loss effective amount." (D.I. 49 at p. 36). Plaintiffs further contend that the specification's "repeated and consistent reference to the combination of naltrexone and bupropion as affecting weight loss rather than the individual compounds affecting weight loss supports [their] construction." (*Id.* at p. 37).

Defendant asserts that the use of the plural "compounds" in the latter portion of claim 25 "shows that when the applicants wanted to refer to the weight loss activity of the first compound and second compound, in combination, they used the plural form 'compounds.'" (*Id.* at pp. 37–38). Moreover, Defendant contends that because "this limitation indicates that the weight loss activity of the 'compounds'—*i.e.*, in combination—is enhanced compared to the weight loss of activity of each compound alone, [it] indicates that each compound alone also has weight loss activity." (*Id.* at p. 38). Defendant further argues that the specification of the '626 patent describes bupropion and naltrexone as each individually having weight loss effects. (*Id.* at pp. 38–39). Defendant also points to "the results from the study reported in example 8 disclosed in

the specification [as] demonstrat[ing] that bupropion and naltrexone reduced food intake in rats when administered alone." (*Id.*). Lastly, Defendant maintains, "Plaintiff's assertion that the specification refers to the alleged invention as the combination of two compounds does not preclude the individual compounds in the combination from being present in a weight loss effective amount." (*Id.* at p. 41).

Plaintiffs respond by arguing that "the term 'amount' is singular, and refers to a single weight loss amount of what follows, not multiple weight loss effective amounts." (*Id.* at p. 42). Indeed, Plaintiffs contend, "[i]f the patentees intended for each compound to be present in a weight loss effective amount, then the claim would have been drafted in the plural to read 'weight loss effective amounts of a first and second compound.'" (*Id.* at pp. 42–43). Plaintiffs also argue that because the wherein clause of claim 25 only discusses enhanced "weight loss activity," as opposed to a "weight loss effective amount," there is no requirement in claim 25 that each individual compound have a non-zero weight loss activity. (*Id.* at p. 43). Moreover, Plaintiffs point to portions of the prosecution history where the patentee "(1) expressly state[d] that naltrexone is not an effective weight loss drug in humans and (2) disclosed[d] a clinical study of humans which shows that naltrexone is not an effective weight loss drug alone." (*Id.* at pp. 44–45 (citing D.I. 49-1 at 112)). Plaintiffs also note that they did their own clinical studies on humans, which demonstrated that naltrexone alone was less effective than a placebo, as demonstrated by the number of individuals losing 5% or more of their body weight. (*Id.* at p. 45 (citing D.I. 49-1 at 118–19)).

The Court will adopt Plaintiffs' construction. First, I think that as a matter of straightforward grammatical construction claim 25 refers to a singular "amount," *i.e.*, the combination. The combination is composed of two compounds, "a first and second compound."

The adjective "weight loss effective" modifies the singular noun "amount," and does not separately modify each component compound that makes up the amount. Second, this straightforward reading of claim 25 finds ample support in the specification of the '626 patent. The specification consistently focuses on the fact that a specific composition causes weight loss, the composition being a combination of two or more compounds. (*See, e.g.*, '626 patent, col. 3, ll. 33–34 ("The present invention provides a multi-faceted combination therapy approach to the problem of weight loss."); *id.* col. 8, ll. 33–35 ("[A]n individual is given a pharmaceutical composition comprising a combination of two or more compounds to affect weight loss.")). In fact, a full reading of the '626 patent makes clear that the invention itself is a method of treating obesity with the combination of naltrexone and bupropion, because they have a synergistic effect when used in combination. (*See, e.g.*, '626 patent col. 3, ll. 44–47 ("The present inventors have discovered that a combination of two or more of the compounds disclosed herein results in a synergistic effect that affects weight loss more quickly and on a more permanent basis.")).

Third, even assuming *arguendo* that the specification clearly disclosed that naltrexone alone can serve as an effective weight loss agent,[5] it would not change the result. Defendant's

[5] Defendant's case for this point is, at best, only an implication that can be drawn from the specification, and, at worst, inconsistent with other more explicit aspects of the intrinsic record. Defendant relies on the following passage to suggest that the specification clearly contemplates each compound being individually present in a weight loss effective amount: "[A] combination of two or more of the compounds disclosed herein results in a synergistic effect that affects weight loss more quickly and on a more permanent basis." (D.I. 49 at p. 38 (citing '626 patent, col. 3, ll. 44–47)). Defendant suggests that this "passage clearly compares the weight loss effect of the combination of the two compounds with the effect of each compound alone." (*Id.*). While that implication can be drawn, the passage does not actually address the purported weight loss effects of either compound alone. Defendant's reliance on the study from example 8 in the specification, which shows that naltrexone alone reduced food intake in mice, is likewise thin evidence that naltrexone alone is an effective weight loss compound for humans. On the other hand, these intrinsic references are directly contradicted by disclosures of clinical studies made by the patentee during prosecution, which directly state that naltrexone alone is not an effective weight loss agent in humans. (*See, e.g.*, D.I. 49-1 at 112 ("Despite some early evidence in animal models that naltrexone could cause weight loss, clinical studies indicate that it is a poor weight-loss drug in humans."); *id.* at 118–19 (reporting clinical trial results where only 15% of users of naltrexone alone lost at least 5% of their body weight, while 20% of the placebo group lost more than 5% of their body weight")).

At best, the intrinsic evidence Defendant cites implies that naltrexone or bupropion alone can theoretically cause weight loss. These portions of the intrinsic record, contradicted by more explicit intrinsic evidence stating that naltrexone alone is not an effective weight loss agent in humans, provide a rather thin basis to conclude that naltrexone

argument that the specification "does not preclude the individual compounds in the combination from being present in a weight loss effective amount" misses the mark. (D.I. 49 at p. 41). The point is that nothing in the specification requires each compound to be present individually in a weight loss effective amount. Defendant's entire argument rests on the faulty premise that if a compound alone can cause weight loss, any amount of the compound will automatically be "a weight loss effective amount." Yet even if naltrexone and bupropion alone can cause some "weight loss activity," it does not automatically follow that the patent requires each compound to be present individually in "weight loss effective amounts." All that claim 25 requires, read in light of the specification, is that the combination of naltrexone and bupropion be present in a weight loss effective amount.

Accordingly, I construe the term "a weight loss effective amount of a first and second compound" to mean "a weight loss effective amount of a first and second compound, in combination."

3. "having reduced adverse effects" ('915 patent only).

   a. *Plaintiffs' proposed construction*: The proposed phrase from the preamble is not limiting.

   b. *Defendant's proposed construction*: The proposed phrase from the preamble is limiting.

   c. *Court's construction*: The proposed phrase from the preamble is not limiting.

The sole dispute with regard to this term arises from claim 11 of the '195 patent. Specifically, the parties dispute whether "having reduced adverse effects," which appears in the preamble of claim 11, should be construed as a limitation.[6] Claim 11 reads as follows:

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alone can be used in weight loss effective amounts. In any event, these portions of the specification do not come close to affirmatively requiring that each compound individually be present in a weight loss effective amount.

[6] The preamble of claim 1 also contains the language, "having reduced adverse effects." ('195 patent, claim 1). In claim 1, however, the preamble is augmented by an express limitation in the body of the claim, which does not

A method of treating overweight or obesity *having reduced adverse effects* comprising orally administering daily about 32 mg of naltrexone and about 360 mg of bupropion, or pharmaceutically acceptable salts thereof, to a person in need thereof, wherein the bupropion or pharmaceutically acceptable salt thereof is administered as a sustained-release formulation, wherein the naltrexone or pharmaceutically acceptable salt thereof is administered as a sustained-release formulation, and wherein said sustained-release formulation of naltrexone has an in vitro naltrexone dissolution profile in a dissolution test of USP Apparatus 2 Paddle Method at 100 rpm in a dissolution medium of water at 37° C of:

a) between 39% and 70% of naltrexone released in one hour;
b) between 62% and 90% of naltrexone released in two hours; and
c) at least 99% in 8 hours;

wherein about 16 mg of said sustained-release formulation of naltrexone or a pharmaceutically acceptable salt thereof is administered twice daily, and about 180 mg of said sustained-release formulation of bupropion or a pharmaceutically acceptable salt thereof is administered twice daily.

('195 patent, claim 11).

"Whether to treat a preamble term as a claim limitation is determined on the facts of each case in light of the claim as a whole and the invention described in the patent." *Am. Med. Sys., Inc. v. Biolitec, Inc.*, 618 F.3d 1354, 1358 (Fed. Cir. 2010) (internal quotation marks omitted). "Generally, the preamble does not limit the claims." *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1346 (Fed. Cir. 2002). "[A] preamble limits the invention if it recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (internal quotation marks omitted). "Conversely, a preamble is not limiting where a patentee

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appear in claim 11: "whereby at least one adverse effect . . . is reduced." (*Id.*). Plaintiffs appear to concede that the preamble is limiting in claim 1, "because the preamble reflects express limitations found later in the body of the claim . . . ." (D.I. 49 at p. 49). While of little practical significance to this case, I think that the preambles in both claim 1 and claim 11 are not limiting, because, as discussed more fully below, they merely state the intended purpose or result of the claimed method. The reduction of at least one adverse effect is still a material limitation in claim 1, but only because it is expressly included as a limitation in the body of the claim. *See, e.g., Storage Tech. Corp. v. Cisco Sys., Inc.*, 329 F.3d 823, 830–31 (Fed. Cir. 2003) (holding that district court erred by limiting the scope of a claim based on language in the preamble where any claim in the patent that actually required what was set forth in the preamble also included "an explicit . . . limitation in the body of the claim" saying so).

defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention." *Id.* (internal quotation marks omitted).

"No litmus test defines when a preamble limits claim scope. Some guideposts, however, have emerged from various cases discussing the preamble's effect on claim scope." *Id.* (citation omitted). For instance, "when reciting additional structure or steps underscored as important by the specification, the preamble may operate as a claim limitation." *Id.* "Moreover, clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention." *Id.* "Without such reliance, however, a preamble generally is not limiting when the claim body describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention." *Id.* at 809. "Thus, preamble language merely extolling benefits or features of the claimed invention does not limit the claim scope without clear reliance on those benefits or features as patentably significant." *Id.* In method claims, statements of intended result or purpose in a preamble are generally not considered to be claim limitations where the "method [is] performed in the same way regardless whether or not the [intended result actually ensues] . . . ." *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1375 (Fed. Cir. 2001).

Plaintiffs argue that the preamble in claim 11 is "merely a statement of the asserted benefits of the invention" and that "the steps of the method are performed the same regardless whether the patient experiences reduced adverse effects." (D.I. 49 at p. 48). Plaintiffs also contrast claim 11 with claim 1, which has the same preamble but also expressly includes a limitation in the body of the claim requiring that at least one adverse effect be reduced. (*Id.* at p.

49). Thus, according to Plaintiffs, claim 11 reflects a deliberate choice not to require reduced adverse effects as a claim limitation. (*Id.*). Defendant argues that the preamble must be construed as a limitation "because it is clear from the specification and the prosecution history that [having reduced adverse affects] is an integral part of the alleged invention and material to the patentability of the claim." (*Id.*). Specifically, Defendant contends that the specification of the '195 patent "repeatedly discloses embodiments of the invention having one or more reduced adverse effects." (*Id.* at p. 50). Defendant also asserts that during prosecution the patentee repeatedly tried to distinguish the prior art in order to overcome the examiner's obviousness rejections by arguing that its specific dosage method for co-administering naltrexone and bupropion led to the unexpected result of having reduced adverse effects, which was not previously disclosed by the prior art. (*Id.* at pp. 50–53 (citing D.I. 49-1 at 134–36)).

Plaintiffs respond by pointing out that the prosecution history statements Defendant relies on occurred before claim 11 (formerly claim 79 of the '773 application) was introduced by a later amendment. (D.I. 49 at p. 58). Instead, Plaintiffs argue that, as to claim 11 in particular, the patentee relied on the specified dissolution profile in order to overcome the examiner's obviousness objection. (*Id.*). According to Plaintiffs, the patentee only generally referenced that it "previously provided arguments regarding unexpected results" and "argued generally that the Patent Office's discounting of those results was improper." (*Id.*).

The Court concludes that the proposed phrase from the preamble is not limiting. Claim 11 of the '195 patent sets forth a detailed method, which provides specific dosages of both naltrexone and bupropion, designates that each compound should be in a sustained-release formulation, and provides a specific dissolution profile for the naltrexone. ('195 patent, claim 11). Claim 11 describes all the steps required to completely and adequately carry out the

invented method and the language "having reduced adverse effects" in the preamble is merely a statement of the intended result of the method of treatment. *See Catalina Mktg.*, 289 F.3d at 808. Although the intended result of the method is "underscored as important by the specification," the preamble is not limiting because it does not "recit[e] additional structure or steps," but instead "merely extoll[s] benefits or features of the claimed invention."[7] *Id.*

In *Bristol-Myers*, the Federal Circuit considered similar arguments that the preambles of various method of treatment claims should be construed as limiting. *See Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1374–76 (Fed. Cir. 2001). The Federal Circuit emphasized that the asserted preamble phrases merely expressed a purpose or intended result of the specific method steps outlined in the body of the claims. *See id.* For instance, with regard to the preamble phrase "an antineoplastically effective amount," the court concluded:

> That expression of intended result essentially duplicates the dosage amounts recited in the claims that are also described in the specification as "antineoplastically effective." '803 patent, col. 5, ll. 40–44 ("It has also been surprisingly discovered that lower taxol dosages . . . [can] still be antineoplastically effective."). *The express dosage amounts are material claim limitations; the statement of the intended result of administering those amounts does not change those amounts or otherwise limit the claim.*

Id. at 1375 (emphasis added); *see also id.* at 1376 (concluding that preamble phrase "for treating a cancer patient to effect regression of a taxol-sensitive tumor, *said method being associated with reduced hematologic toxicity*" was "only a statement of purpose and intended result" and did "not result in a manipulative difference in the steps of the claim." (emphasis added)). The preamble phrase at issue here, "having reduced adverse effects," likewise only describes the

[7] This point is further underscored by juxtaposing claim 11 with claim 1. Claim 1, despite having a preamble identical to that of claim 11, includes an express limitation in the body of the claim requiring the reduction of at least one adverse effect. ('195 patent, claim 1 ("whereby at least one adverse effect . . . is reduced.")). Claim 1 demonstrates that the patentee knew how to make "reduced adverse effects" an express claim limitation, but deliberately chose not to in drafting claim 11. That choice should be given meaning. *See Phillips*, 415 F.3d at 1314.

intended result of administering the specific dosage amounts laid out in the body of claim 11 and does not result in a manipulative difference in the steps of the claim. Thus, as in *Bristol-Myers*, entirely deleting this language from the preamble of claim 11 would not change the way the method of claim 11 is performed in any way. In other words, the "method [is] performed in the same way regardless whether or not the [intended result actually ensues] . . . ." *Bristol-Myers*, 246 F.3d at 1375.

Lastly, Defendant's argument based on statements the patentee made during prosecution is unconvincing. The patentee's statements during prosecution regarding unexpected results ("having reduced adverse effects") that Defendant cites began well before claim 11 ever existed: the prosecution statements were first made on February 2, 2011, while the amendment that added claim 11 (then claim 79 of the '773 application) was introduced on December 2, 2013. (D.I. 49-1 at 134–37; D.I. 49-2 at 5–6, 15). On May 21, 2014, in response to an obviousness rejection of then claim 79, the patentee argued that the prior art failed to disclose any specific formulations of naltrexone falling within the claimed dissolution profile specified in claims 59 and 79. (D.I. 49-2 at 40–41). In addition, referencing twenty-one different claims that had been rejected on obviousness grounds, the patentee also broadly reiterated its continuing objection to the examiner's rejection of these claims for what it perceived as the examiner's failure to take into account the unexpected results of reduced adverse effects. (*Id.* at 41–44). Indeed, the prosecution history reveals that the patentee broadly objected to the examiner's purported failure to take into account unexpected results at all stages of the prosecution, both before and after the introduction of then claim 79, but the patentee never argued that reduced adverse effects were a differentiating factor unique to then claim 79. (D.I. 49-1 at 134–36; D.I. 49-2 at 12–14, 41–44). The patentee's broad, consistent references to the entire '195 patent's unexpected results during

prosecution do not provide adequate grounds to conclude that it relied upon the preamble of claim 11 to overcome the examiner's specific rejection of claim 11.[8]

Accordingly, I conclude that the phrase "having reduced adverse effects" in the preamble of claim 11 is not limiting.

IV. CONCLUSION

Within five days the parties shall submit a proposed order consistent with this Memorandum Opinion.

[8] In any event, I think there is a fundamental difference between arguing that a preamble of a specific claim renders that claim not anticipated by a prior art reference and touting the unexpected results of all claimed methods as a secondary consideration of nonobviousness during prosecution. Where a patentee relies on a preamble during prosecution essentially as an extra element allowing that specific claim to avoid anticipation, it makes sense that the preamble should be treated as a claim limitation, "because such reliance indicates use of the preamble to define, in part, the claimed invention." *Catalina Mktg.*, 289 F.3d at 808. While unexpected results are a secondary consideration of nonobviousness, they do not define the claimed invention in any real respect—they merely state one of the intended results or purposes of the claimed invention. *Cf. Genetics Inst., LLC v. Novartis Vaccines and Diagnostics, Inc.*, 655 F.3d 1291, 1307–08 (Fed. Cir. 2011) (treating unexpected results as a secondary consideration of nonobviousness and observing that "evidence of unexpected results may be used to rebut a case of *prima facie* obviousness even if that evidence was obtained after the patent's filing or issue date."). Accordingly, even if the patentee specifically relied on unexpected results with regard to claim 11—which I do not think it did here—I would be hesitant to conclude that such reliance should render claim 11's preamble limiting.