UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

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AMARIN PHARMA, INC., et al., Plaintiffs, v. WEST-WARD PHARMACEUTICALS CORP., et al., Defendants.	Lead Case No. 2:16-cv-02525-MMD-NJK Member Case Nos.: 2:16-cv-02658-MMD-NJK, 2:16-cv-2562-MMD-NJK, 2:17-cv-02641-MMD-NJK **CLAIM CONSTRUCTION ORDER**

This Order addresses the disputed claim terms presented for the Court to construe in connection with the patent infringement claims filed by Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Limited (collectively "Amarin"). (ECF No. 1.[1]) The Court has reviewed the Joint Claim Construction and Prehearing Statement (ECF No. 83), Amarin's opening brief (ECF No. 89), Defendants' response and supplement (ECF No. 102, 122), and Amarin's reply (ECF No. 113). The Court also held a hearing on April 24, 2018 ("the Hearing"). (ECF No. 121.)

I. BACKGROUND

Amarin initiated this action against various Defendants who have prepared and filed Abbreviated New Drug Applications ("ANDA") with the Food and Drug

[1]All references to electronic filings are to those filed in the lead case, 2:16-cv-2525-MMD-NJK, unless otherwise indicated.

Administration ("FDA") under a paragraph IV certification[2] in order to market a generic version of Amarin's VASCEPA® product. (See, e.g., ECF No. 1 at ¶ 11.) The claims involved in this action are directed to methods of treating very high triglycerides without negatively affecting other lipid parameters. (ECF No. 130 at 7.) At issue is the construction of claims in 14 patents. All but one of the patents at issue stem from the same initial application. The family of patents[3] are for "Methods of treating hypertriglyceridemia" and include: (1) U.S. Patent No. 8,293,728 ("the '728 patent"); (2) U.S. Patent No. 8,318,715 ("the '715 patent"); (3) U.S. Patent No. 8,357,677 ("the '677 patent"); (4) U.S. Patent No. 8,367,652 ("the '652 patent"); (5) U.S. Patent No. 8,377,920 ("the '920 patent"); (6) U.S. Patent No. 8,399,446 ("the '446 patent"); (7) U.S. Patent No. 8,415,335 ("the '335 patent"); (8) U.S. Patent No. 8,426,399 ("the '399 patent"); (9) U.S. Patent No. 8,431,560 ("the '560 patent"); (10) U.S. Patent No. 8,440,650 ("the '650 patent"); (11) U.S. Patent No. 8,518,929 ("the '929 patent"); (12) U.S. Patent No. 8,524,698 ("the '698 patent"); and (13) U.S. Patent No. 8,546,372 ("the '372 patent"). (ECF No. 89 at 9 n.2.) The other patent, U.S. Patent No. 8,617,594 ("the '594 patent"), is entitled "Stable pharmaceutical composition and methods of using the same." (Id. at 9-10.)

The parties agree there is no meaningful difference in the specification or prosecution histories so the parties' arguments relate to claims across all patents at issue in this case. (See, e.g., ECF No. 130 at 21.)

II. LEGAL STANDARD

[2]Under the Hatch-Waxman Act, Paragraph IV certifications permit generic manufacturers to enter the marketplace before expiration of the brand name's patent on the basis that the patent is invalid. *Fed'l Trade Comm'n v. Actavis, Inc.*, 133 S. Ct. 2223, 2224 (2013). The mere act of filing an ANDA application with this form of certification may be considered an act of infringement itself for which the brand name may then initiate an infringement lawsuit. Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp., 482 F.3d 1330, 1334 (Fed. Cir. 2007).

[3]The original patent from which the listed patents are continuations is not asserted in this case but is discussed. It is U.S. Patent No. 8,293,727 ("the '727 patent").

Patent claim construction is a question of law for the Court. Markman v. Westview Instruments, Inc., 517 U.S. 370, 372 (1996). When interpreting claims, a court's primary focus should be on the intrinsic evidence of record, which consists of the claims, the specification, and the prosecution history. Phillips v. AWH Corp., 415 F.3d 1303, 1314-17 (Fed. Cir. 2005) (en banc). The court should begin by examining the claim language. Id. at 1312. Claim language should be viewed through the lens of a person of "ordinary skill in the relevant art at the time of the invention" or a "POSA." SanDisk Corp. v. Memorex Prods., Inc., 415 F.3d 1278, 1283 (Fed. Cir. 2005). If the claim language is clear on its face, then consideration of the other intrinsic evidence is limited "to determining if a deviation from the clear language of the claims is specified." Interactive Gift Exp., Inc. v. Compuserve Inc., 256 F.3d 1323, 1331 (Fed. Cir. 2001).

A court should give the claim's words their "ordinary and customary meaning." Phillips, 415 F.3d at 1312-13 (quotation omitted). In construing a claim term's ordinary meaning, the context in which a term is used must be considered. ACTV, Inc. v. Walt Disney Co., 346 F.3d 1082, 1088 (Fed. Cir. 2003). Both asserted and unasserted claims of the patent also can add meaning to a disputed claim term as claim terms normally are used consistently throughout the patent. Phillips, 415 F.3d at 1314.

"[C]laims must be read in view of the specification, of which they are a part." Phillips, 415 F.3d at 1315 (quotation omitted). The specification can offer "practically incontrovertible directions about a claim meaning." Abbott Labs. v. Sandoz, Inc., 566 F.3d 1282, 1288 (Fed. Cir. 2009). "When consulting the specification to clarify the meaning of claim terms, courts must take care not to import limitations into the claims from the specification." Id. "[A]lthough the specification may well indicate that certain embodiments are preferred, particular embodiments appearing in the specification will not be read into claims when the claim language is broader than such embodiments." Tate Access Floors, Inc. v. Maxcess Techns., Inc., 222 F.3d 958, 966 (Fed. Cir. 2000) (quotation omitted). "By the same token, the claims cannot enlarge what is patented beyond what the inventor has described in the invention." Abbott Labs., 566 F.3d at

1288 (internal quotation omitted). "Likewise, inventors and applicants may intentionally disclaim, or disavow, subject matter that would otherwise fall within the scope of the claim." Id. at 1288.

In addition to the specification, a court should consider the patent's prosecution history, which consists of "the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent." Phillips, 415 F.3d at 1317. However, because the prosecution represents an "ongoing negotiation" rather than the "final product" of the negotiation, "it often lacks the clarity of the specification and thus is less useful for claim construction purposes." Id. Consulting the prosecution history can, however, be helpful in determining whether the patentee disclaimed an interpretation during prosecution. Research Plastics, Inc. v. Federal Packaging Corp., 421 F.3d 1290, 1296 (Fed. Cir. 2005). "Under the doctrine of prosecution disclaimer, a patentee may limit the meaning of a claim term by making a clear and unmistakable disavowal of scope during prosecution." Purdue Pharma L.P. v. Endo Pharm. Inc., 438 F.3d 1123, 1136 (Fed. Cir. 2006).

If the claim language is not clear after reviewing all intrinsic evidence, then the Court may refer to extrinsic evidence such as expert testimony, inventor testimony, dictionaries, and learned treatises. Zodiac Pool Care, Inc. v. Hoffinger Indus., Inc., 206 F.3d 1408, 1414 (Fed. Cir. 2000). Here, the Court has not considered any extrinsic evidence. The Court finds that the claim language is clear after reviewing the intrinsic evidence. Moreover, the parties rely primarily on the intrinsic evidence to support their proposed constructions.

III. DISCUSSION

The parties have narrowed the contested claim terms to five: (1) "concurrent/concomitant lipid altering therapy"; (2) "orally administering/administered";[4] (3) the LDL-C terms; (4) the Effect Steps; and (5) "compared to." Summaries of their

[4]The parties agreed to revised versions of "[orally] administered/administering" (although the claim term is still in dispute).

proposed construction of each disputed term are presented in comparison charts below. The Court will address each of the disputed terms.

A. "Concurrent/concomitant lipid altering therapy"

The parties dispute the meaning of the term "concurrent/concomitant lipid altering therapy" as used in the following claims: claims 1, 8, and 19 of the '728 patent; claims 1, 12, 13, 16, 17 and 19 of the '715 patent; claim 1 of the '399 patent; and claims 22 through 29 of the '335 patent.

Plaintiffs' Proposed Construction	Defendants' Proposed Construction
A medication to alter lipid levels in a subject whereby the medication is administered concurrently/concomitantly with the administration of a pharmaceutical composition comprising ethyl eicosapentaenoate	Any treatment that can cause an alteration in lipid levels whereby such treatment takes place concurrently/concomitantly with the administration of a pharmaceutical composition comprising ethyl eicosapentaenoate

The dispute between the parties is whether Defendants' proposed construction of "any treatment that can cause an alteration in lipid levels" for "concurrent/concomitant lipid-altering therapy" refers to medication only or whether the term "treatment" is broader to include lifestyle modification, such as diet and exercise. At the Hearing, the parties clarified that they both agree that "treatment" includes medication, but they disagree as to whether "treatment" also includes diet and exercise. (ECF No. 130 at 32.)

Plaintiffs argue that a POSA would understand such terms as "concomitant lipid altering therapy," "concurrent lipid altering therapy," and "combination lipid altering therapy" to refer to "multiple medications that are given at the same time." (ECF No. 89 at 14-15.) Defendants do not directly address this argument in their Answering Brief and instead generally argue that Amarin is attempting to narrow its construction in these proceedings. (See ECF No. 102 at 16.) The Court disagrees and finds that Plaintiffs' construction is supported by the claim language, specification, and prosecution history.

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At the Hearing, Amarin pointed out that the modifier "concurrent" or "concomitant" carries a particular meaning to a POSA and refers specifically to "medical interventions at the same time" when used in the patent claims. (See ECF No. 130 at 34.) This view is supported by the specification. First, the '728 patent presents one embodiment wherein "lipid altering therapy" includes "for example statin, fibrate, niacin, and or ezetimibe therapy." (ECF No.89 at 15 (quoting ECF No. 89-6 at 20).) While a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment, see Superguide Corp. v. DirecTV Enters., Inc., 358 F.3d 870, 875 (Fed. Cir. 2004), the Court does not find that the claim language is broader than this particular embodiment. Moreover, the Court finds that the specification of the '728 patent uses the phrase "non-statin, lipid-altering medications" interchangeably with "non-statin, lipid-altering therapy" (ECF No. 113 at 8 (quoting ECF No. 89-6 at 21)), lending support that the claim term refers to medication only. See Wasica Finance GmbH v. Continental Auto. Sys., Inc., 853 F.3d 1272, 1282 (Fed. Cir. 2017) (finding that interchangeable use in the specification of the words "emit" and "transmit" was akin to a definition equating the two).

At the Hearing, counsel for Amarin argued that diet and exercise is generally understood as an adjunctive therapy, not a concomitant or concurrent one, and admitted that outside of the patent the term lipid-altering therapy could be construed more broadly to cover diet and exercise. (ECF No. 130 at 40, 59.) The one example provided for in the specification of the '728 patent clearly limits the scope of the term "lipid-altering therapy" in the claim language of the relevant patents. In that example of a clinical study, potential study subjects were required to cease lipid-altering therapy prior to the start of the study and undergo a "diet and lifestyle stabilization period" before beginning the study. (ECF No. 89 at 15 (citing to ECF No. 89-6 at 21-22).) The example then identifies two forms of medication-based therapies potential study subjects may take but then must cease before the study: (1) a statin therapy with or without ezetimibe and (2) a "non statin, lipid-altering medication such as niacin, fibrates, fish oils, other

products containing omega-3 fatty acids, or other herbal products or dietary supplements with potential lipid-altering effects" (ECF No. 89-6 at 21). In the specification, therapies are used only to refer to medication, which is buttressed by the use of "concurrent" and "concomitant" in the claim language. Moreover, the Examiner of the '728 patent indicated that "concomitant lipid-altering therapy" refers to "concomitant drugs" in the context of the prior art. (See ECF No. 89-24 at 42; see also ECF No. 89-27 at 43.)

The Court therefore adopts Plaintiffs' proposed construction of the term "concurrent/concomitant lipid-altering therapy."

B. "[Orally] Administering/Administered"

The parties dispute the meaning of the term "[orally] administering/administered," which affects all claims in all of the asserted patents. The parties agreed to revised constructions of the term at the Hearing as follows (ECF No. 130 at 84-85):

Plaintiffs' Proposed Construction	Defendants' Proposed Construction
The doctor prescribing the medication, and the medication is delivered into the patient's body at the doctor's direction	The doctor prescribing the medication, and the medication is delivered into the patient's body

The main dispute appears to be whether "administered/administering" encompasses a role for the prescribing physician beyond merely prescribing the medication. The Court adopts Amarin's proposed construction based on the claim language.

Before the Hearing, Defendants argued that "[orally] administered/administering" should be construed to mean only "delivering/delivered into the patient's body [or mouth]." (ECF No. 102 at 21.) At the Hearing, Defendant agreed that the process of administering includes the physician writing a prescription but clarified that "administering" must also include the "patient ingesting." (ECF No. 130 at 79.) The

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parties agree that these two elements are encompassed by "administering," but Defendants refused to agree to the additional modification that the delivery of the pharmaceutical be at the doctor's direction. At the Hearing, Amarin clarified that "at the doctor's direction" encompasses advice and instructions given to the patient as to how delivery occurs (i.e., taking it as prescribed). (See ECF No. 130 at 66, 76, 81.)

Plaintiffs' proposed construction is consistent with the plain language of the claims. For instance, claim 1 of the '728 patent states "administering orally to the subject about 4 g per day of a pharmaceutical composition." (ECF No. 89-6 at 22.) The following claim (claim 2 of the '728 patent) further limits how the 4g is administered—in either 1 to 4 doses during a day. (Id.) This method of administration would be dictated by the prescription of a physician; therefore, how the pharmaceutical composition is delivered into the patient's body—whether it occurs through one capsule containing 4g of the composition, four capsules containing 1g of the composition, eight capsules containing 0.5g of the composition, or some other combination thereof (see id. at 23 ("the method of claim 2 wherein, the pharmaceutical composition is present in one or more capsules"))—is dependent on the physician's directions.

The Court therefore adopts Amarin's construction of "[orally] administered/administering" as "the doctor prescribing the medication, and the medication is delivered into the patient's body at the doctor's direction."

C. LDL-C Terms

Only Amarin proposed constructions of these claim terms. Defendants do not propose any construction and instead argue that Amarin's constructions still render the claims indefinite. (ECF No. 102 at 38-46.) The claims affected by these terms are: claims 1, 8, and 9 of the '728 patent; claims 1, 6, and 7 of the '677 patent; claims 1, 6, 7, 10, 15, and 16 of the '652 patent; claims 1, 4 and 6 of the '446 patent; claims 1, 6, and 6 of the '399 patent; claims 2 and 6 of the '355 patent; and claim 4 of the '715 patent (ECF No. 89 at 31 n.21).

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Claim Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
Without substantially increasing LDL-C	Without a clinically meaningful increase in LDL-C	Terms are indefinite under 35 U.S.C. 112
Without effecting a statistically significant increase in LDL-C	Without bringing about a rise in LDL-C attributable to the treatment rather than to chance	
Substantially no increase or a reduction in fasting LDL-C	Without a clinical meaningful increase in LDL-C	
Substantially no increase in LDL-C	Without a clinically meaningful increase in LDL-C	

1. "Without substantially increasing LDL-C"; "substantially no increase or a reduction in fasting LDL-C"; "substantially no increase in LDL-C"

Defendants do not dispute the construction presented by Amarin for the three "substantial" claims or that the construction "clinically meaningful" is based on the intrinsic evidence. Instead, Defendants argue that even with this construction the claim terms do not inform a POSA with reasonably certainty what the scope of Amarin's invention is. (ECF No. 102 at 39.) To the extent Defendants argue that there is a lack of intrinsic evidence to support Amarin's constructions, Defendants conflate claim construction and an indefiniteness analysis in light of claim construction. For instance, Defendants acknowledge that the specification includes a wide range of increases that are considered "substantial" or "clinically meaningful." (See id. at 40.) But they argue that because "[t]here is no other section of the specification that provides an objective boundary to the LDL-C terms" (i.e., a specific percentage) and because "[e]ach clinician has different standards for treatment for each patient depending on a patient's family history, lifestyle, age and other factors," this leaves no meaningful guidance for a POSA to determine what is "substantial" or "clinically meaningful." (Id.) Thus, while the intrinsic evidence may support the construction of "clinically meaningful," Defendants argue that this construction is just as ambiguous as "substantial" and does not limit the claim's

scope. The Court therefore accepts Amarin's constructions of these disputed terms and finds that the indefiniteness analysis is more appropriately addressed at the summary judgment stage.

2. "without effecting a statistically significant increase in LDL-C"

As for the construction of "without effecting a statistically significant increase in LDL-C," Amarin argues that the intrinsic evidence supports that this means "without bringing about a rise in LDL-C attributable to the treatment rather than to chance." (ECF No. 89 at 38.) By contrast, Defendants do not contest that Amarin's construction of "statistical significance" is incorrect; instead, they argue that "it does not inform a skilled artisan with reasonable certainty when an increase in LDL-C" meets this threshold and is therefore indefinite. (*See* ECF No. 102 at 45.) The Court also finds that it need not consider the indefiniteness argument at this stage and accepts Amarin's construction of this disputed term.

D. Effect Terms: "To effect [a] . . ."; "effective to . . ."; "exhibits [a] . . . ."; "effects [a] . . ."

The parties dispute the meaning of the effect terms, including "to effect [a]," "effective to," exhibits," and "effects." The claims containing these terms are: claims 1, 5-8, 12-14 and 19 of the '728 patent; claims 1, 4-10, 13, 14 and 17 of the '715 patent; claims 1 and 6-9 of the '677 patent; claims 1, 6-10, and 15-18 of the '652 patent; claims 1 and 6-10 of the '920 patent; claims 1 and 4-7 of the '446 patent; claims 1, 2, 6-9, 13, 14, 18-22, and 26-29 of the '335 patent; claims 1 and 6-9 of the '399 patent; claims 1, 4-7, 11, and 14-17 of the '560 patent; claims 1, 4-8, and 11-14 of the '650 patent; claims 4-6 of the '929 patent; claims 1, 4, and 5 of the '689 patent; claims 4-6, 13-15 and 20-22 of the '372 patent; and claims 1, 4-6,10, 13-15, 17, and 20-22 of the '594 patent. (ECF No. 89 at 26 n.17.)

Plaintiffs' Proposed Construction	Defendants' Proposed Construction
Claim limitation encompassing the intentional purpose for which the method	Claim limitation and not merely a statement of intended result or effect

must be performed Plain and ordinary meaning applies	Plain and ordinary meaning applies

The parties agree that the Effect Steps are material to patentability. Plaintiffs argue that "these terms should be construed to require that the clinician performing the claimed method have the specific intent to confer the claimed lipid effects to the subject." (ECF No. 89 at 26.) By contrast, Defendants argue that the claim limitation is not merely an abstract intent but rather "the claimed lipid effects must actually be observed in the subject(s) receiving the drug." (ECF No. 102 at 30.) The Court agrees with Defendants and finds that the Effect Steps encompass a claim limitation and not merely a statement of intended result—in other words, the patent requires that the intended effect actually occur. This construction is supported by the prosecution history.

Amarin states that the "'effect' language was added to pending claims to overcome a rejection by the Examiner that the previously drafted limitations were not entitled to patentable weight. . . . because they 'simply express the intended result of a process step positively recited.'" (ECF No. 89 at 27 (quoting ECF No. 89-25 at 1-2).) Thus, in its resubmission, it clarified that "the requirement for a reduction or no increase in the various lipid parameters" should be "accorded patentable weight." (ECF No. 89-27 at 65 (emphasis added).) Amarin therefore disclaimed that the Effect Steps apply only to the clinician's intent during prosecution. See Research Plastics, Inc., 421 F.3d at 1296; see also Purdue Pharma L.P., 438 F.3d at 1136.

The Court accordingly finds that the terms encompassed in the Effect Steps are claim limitations and not merely statements of intended results.

E. "Compared To"

While the parties state that they rely on the "plain and ordinary meaning" of "compared to," both parties have different views of what this plain and ordinary meaning is. The claims containing these terms are: claims 1, 5-8, 12, 14, and 19 of the '728 patent; claims 1, 4-10, and 17 of the '715 patent; claims 1, and 6-9 of the '677 patent;

claims 1, 6-10, and 15-18 of the '652 patent; claims 1, and 6-10 of the '920 patent; claims 1 and 4-8 of the '446 patent; claims 1 and 6-9 of the '399 patent; claims 1, 2, 5-14, 18-22, and 26-29 of the '335 patent; claims 11 and 14-17 of the '560 patent; claims 8 and 11-14 of the '650 patent; and claim 1, 4 and 5 of the '698 patent. (ECF No. 89 at 29 n.20.)

Plaintiffs' Proposed Construction	Defendants' Proposed Construction
No construction necessary Plain and ordinary meaning	Claim limitation and not merely a statement of intended result or effect Plain and ordinary meaning

Plaintiffs argue that the plain and ordinary meaning of "compared to" is that the claimed effect can be compared to "the expectation if the subject did not receive purified ethyl-EPA. (ECF No. 89 at 31 (emphasis added).) By contrast, Defendants argue that "compared to" requires that a practitioner make an actual comparison with another subject or population and thus that the person practicing the method of treatment make specific measurements. (ECF No. 102 at 35-36.) The Court agrees with Plaintiffs as to the plain and ordinary meaning of "compared to" and finds that the term is not a claim limitation as indicated by Defendants.

Defendants rely on the example in the specification of the '728 patent wherein the practitioner considers four measured values, specifically the "lipid parameters of at least one subject who is administered AMR101 both before and after a treatment period, and the lipid parameters of a control subject both before and after the treatment period." (Id. at 37.) However, this construction of the term would require that a practitioner of the method "conduct a clinical trial every time he treats a patient," a seemingly absurd result. (ECF No. 113 at 17.) At the Hearing, Plaintiffs relied on Allergan, Inc. v. Sandoz, Inc., No. 6:11-cv-441, 2013 WL 13141188 (E.D. Tex. Mar. 28, 2013), to argue that the clinical trials required for VASCEPA®, which are in the intrinsic evidence, would also be available to a POSA on the labeling of the product, and this

data would provide a POSA with enough context to appreciate how to perform a comparison. (ECF No. 130 at 152-153.) By performing a comparison between "what happens when the treatment is administered versus what would otherwise happen" to a second subject, "compared to" merely "defines the magnitude of the lipid effect or avoidance of the undesirable lipid effects" and not the specific method advocated for by Defendants. (*Id.* at 154.)

The Court agrees and finds that the clinical data in the intrinsic record (*see, e.g.*, ECF No. 89-20 at 13-14) supports Amarin's view of the term's plain and ordinary meaning.

IV. CONCLUSION

The Court notes that the parties made several arguments and cited to several cases not discussed above. The Court has reviewed these arguments and cases and determines that they do not warrant discussion as they do not affect the outcome of this claim construction.

DATED THIS 10th day of August 2018.

MIRANDA M. DU
UNITED STATES DISTRICT JUDGE