UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

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AMARIN PHARMA, INC., *et al.*, Plaintiffs, v. WEST-WARD PHARMACEUTICALS INTERNATIONAL LIMITED, *et al.*, Defendants.	Case No. 2:16-cv-02525-MMD-NJK ORDER

I. SUMMARY

This is a consolidated patent infringement case brought under the Hatch-Waxman Act where Plaintiffs Amarin Pharma, Inc., and Amarin Pharmaceuticals Ireland Limited seek to prevent Defendants West-Ward Pharmaceuticals International Limited ("West-Ward"), Hikma Pharmaceuticals USA Inc. ("Hikma"), and Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "DRL") from launching generic competitor drugs to Plaintiffs' drug Vascepa. Before the Court are: (1) Plaintiffs' motion for partial summary judgment as to certain of Defendants' affirmative defenses and counterclaims (ECF No. 234 ("Plaintiffs' Motion")); (2) Defendants' motion for summary judgment as to non-infringement (ECF No. 236 ("Defendants' Motion")); and (3) motions to seal related to these motions (ECF Nos. 235, 246, 254, 261, 265).[1] As further explained below, the Court will grant Defendants' Motion as to Plaintiffs' contributory infringement theory, but deny it as to Plaintiffs' inducement theory. The Court will grant Plaintiffs' Motion to the extent it

[1]The Court has reviewed the various responses, replies and other documents associated with these motions. (ECF Nos. 240, 247, 251, 252, 255, 262, 263, 264.) The Court also notes the parties requested oral argument, but those requests are denied because the Court finds oral argument unnecessary. *See* LR 78-1.

seeks to prevent Defendants from asserting a written description defense at trial, but deny it as moot as to the other challenged defenses and counterclaims because Defendants have withdrawn them. The Court will also mostly grant the pending motions to seal that accompanied the briefing on these motions, but will direct further briefing as to why certain exhibits should be sealed.

II. BACKGROUND

A. The Hatch-Waxman Act

"The Hatch-Waxman Act amended the Federal Food, Drug, and Cosmetic Act and the patent laws to enable generic drugs to be more easily approved and to respond to loss of effective patent life resulting from the requirement that drug products require premarket testing and then must undergo FDA review, actions that consume significant portions of a patent term." *Vanda Pharm. Inc. v. W.-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1126 (Fed. Cir. 2018) (citation omitted). The Hatch-Waxman Act strikes a balance between the competing public policy interests of encouraging the development of innovative new drugs, while also enabling competitors to bring low-cost generic drugs to market. *See id*.

As relevant here, the Hatch-Waxman Act, specifically 35 U.S.C. § 271(e)(2)(A) ("Section 271(e)(2)"), also created an artificial act of patent infringement—the filing of an Abbreviated New Drug Application ("ANDA") if the brand-name drug is still patent-protected. *See Vanda*, 887 F.3d at 1122, 1126. ANDAs allow generic drug companies to get Food and Drug Administration ("FDA") approval to bring generic drugs that are bioequivalent to already approved brand-name drugs to market without undergoing the extensive testing and certification new drugs must undergo before the FDA will allow them to be sold to the public. *See AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1045-46 (Fed. Cir. 2010). ANDAs may be filed under certain circumstances, such as where the patents covering a brand-name drug have expired, or, as here, when the generic drug manufacturer files a certification with its ANDA under 21 U.S.C. § 355(j)(2)(A)(vii)(IV)

("Paragraph IV Certification"), stating that the applicable patents are either invalid or not infringed by the generic competitor drug. *See Vanda*, 887 F.3d at 1122.

B. The Parties' Dispute[2]

Plaintiffs market a drug called "Vascepa[, which] is a pharmaceutical comprised of a highly purified omega-3 fatty acid called ethyl-eicosapentaenoic acid ["EPA"]." (ECF No. 234 at 8.) "Vascepa is indicated 'as an adjunct to diet to reduce triglyceride ("TG") levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia.'" (*Id.*) Severe hypertriglyceridemia puts patients at risk of developing pancreatitis. (*Id.*) Plaintiffs own a family of related patents sharing the same specification that purportedly cover Vascepa.

Defendants filed ANDAs including Paragraph IV Certifications based on Plaintiffs' drug Vascepa. (*See, e.g.*, ECF No. 1 at 1-6.) ANDAs must include the proposed labelling that will accompany the generic drug—and that labelling must generally be substantially the same as the labelling that accompanies the brand-name drug. *See AstraZeneca*, 633 F.3d at 1045-46. Here, Defendants' proposed labelling is materially indistinguishable from Plaintiffs' labelling. (ECF Nos. 252 at 15, 245 (sealed).) Defendants also did not seek to omit anything from Plaintiffs' labelling. (ECF No. 252 at 15.)

Defendants' filing of ANDAs allowed Plaintiff to sue them under Section 271(e)(2) in an attempt to block Defendants from bringing their competitor drugs to market. Plaintiffs allege Defendants infringe certain of the group of Vascepa-related patents' claims. Plaintiffs specifically assert infringement of "Claims 1, 13, and 16 of [U.S. Patent No. 8,293,728 ("the '728 Patent")], Claim 14 of [U.S. Patent No. 8,318,715 ("the '715 patent")], Claims 1, 7, and 8 of U.S. Patent No. 8,357,677 ("the '677 Patent"), Claims 1, 7, and 8 of U.S. Patent No. 8,367,652 ("the '652 Patent"), Claims 4, 7, and 17 of U.S. Patent No. 8,431,560 ("the '560 Patent"), and Claims 1 and 5 of U.S. Patent No. 8,518,929 ("the '929 Patent")." (ECF No. 234 at 8 (collectively, "the Asserted Claims").) These patents all cover

[2]Plaintiffs originally brought four separate lawsuits against Defendants in this district, but those suits were consolidated into this case. (ECF No. 91.)

a method of treating hypertriglyceridemia using EPA. *See, e.g.*, the '728 Patent. Plaintiffs allege that Defendants either induce infringement of, or contributorily infringe, the Asserted Claims because Defendants cannot directly infringe them—as method claims, they can only be infringed if a doctor were to treat a patient using one of Defendants' ANDA drugs in line with Defendants' labelling in a way that infringes the Asserted Claims. (ECF No. 236 at 13.)

Plaintiffs and Defendants agree about key elements of the Asserted Claims. Most notably, they agree that all 15 of the Asserted Claims "require[] administering icosapent [another name for EPA] to a patient with severe hypertriglyceridemia (TG ≥500 mg/dL) for at least 12 weeks." (ECF No. 252 at 12-13 (internal quotation marks and emphasis omitted).) Further, they agree that "fourteen of the asserted claims further require at least one of the following effects: (i) a reduction in triglycerides that is statistically significant or of at least about 10%, 20%, or 25%; (ii) no increase, no substantial increase, no statistically significant increase, or no more than 5% increase in LDL-C levels; or (iii) a reduction in apolipoprotein B." (*Id.* at 13 (internal quotation marks and punctuation omitted) (the "Other Health Benefit Claims").) The parties also agree that "[f]our asserted claims require that the patient not receive concurrent lipid altering therapy, e.g., a statin." (*Id*. (internal quotation marks omitted) (the "Excluding Statins Claims").)

The Court already construed certain disputed terms within the Asserted Claims. (ECF No. 135 (the "Claim Construction Order").) The parties attended a settlement conference after the Court issued the Claim Construction Order, but the parties did not reach a settlement. (ECF No. 150.) This case is set for a bench trial scheduled to start January 13, 2020. (ECF No. 213.)

III. LEGAL STANDARD

"The purpose of summary judgment is to avoid unnecessary trials when there is no dispute as to the facts before the court." *Nw. Motorcycle Ass'n v. U.S. Dep't of Agric*., 18 F.3d 1468, 1471 (9th Cir. 1994). Summary judgment is appropriate when the pleadings,

the discovery and disclosure materials on file, and any affidavits "show there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 330 (1986). An issue is "genuine" if there is a sufficient evidentiary basis on which a reasonable fact-finder could find for the nonmoving party and a dispute is "material" if it could affect the outcome of the suit under the governing law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-49 (1986). Where reasonable minds could differ on the material facts at issue, however, summary judgment is not appropriate. *See id.* at 250-51. "The amount of evidence necessary to raise a genuine issue of material fact is enough 'to require a jury or judge to resolve the parties' differing versions of the truth at trial.'" *Aydin Corp. v. Loral Corp.*, 718 F.2d 897, 902 (9th Cir. 1983) (*quoting First Nat'l Bank v. Cities Service Co*., 391 U.S. 253, 288-89 (1968)). In evaluating a summary judgment motion, a court views all facts and draws all inferences in the light most favorable to the nonmoving party. *See Kaiser Cement Corp. v. Fishbach & Moore, Inc.*, 793 F.2d 1100, 1103 (9th Cir. 1986).

The moving party bears the burden of showing that there are no genuine issues of material fact. *See Zoslaw v. MCA Distrib. Corp.*, 693 F.2d 870, 883 (9th Cir. 1982). Once the moving party satisfies Rule 56's requirements, the burden shifts to the party resisting the motion to "set forth specific facts showing that there is a genuine issue for trial." *Anderson*, 477 U.S. at 256. The nonmoving party "may not rely on denials in the pleadings but must produce specific evidence, through affidavits or admissible discovery material, to show that the dispute exists," *Bhan v. NME Hosps., Inc.*, 929 F.2d 1404, 1409 (9th Cir. 1991), and "must do more than simply show that there is some metaphysical doubt as to the material facts." *Orr v. Bank of Am.*, 285 F.3d 764, 783 (9th Cir. 2002) (internal citations omitted). "The mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient." *Anderson*, 477 U.S. at 252.

Further, "when parties submit cross-motions for summary judgment, '[e]ach motion must be considered on its own merits.'" *Fair Hous. Council of Riverside Cty., Inc. v.*

Riverside Two, 249 F.3d 1132, 1136 (9th Cir. 2001) (quoting *William W. Schwarzer, et al.*, *The Analysis and Decision of Summary Judgment Motions*, 139 F.R.D. 441, 499 (Feb. 1992)) (citations omitted). "In fulfilling its duty to review each cross-motion separately, the court must review the evidence submitted in support of each cross-motion." *Id.*

IV. DEFENDANTS' MOTION (ECF NO. 236)

Defendants seek summary judgment that they do not infringe any of the Asserted Claims. (ECF No. 236.) Defendants' lead arguments apply to all of the Asserted Claims, though Defendants also make arguments that apply to only a subset of the Asserted Claims—one set of arguments applies to the Other Health Benefits Claims, and the other applies to the Excluding Statins Claims. But while these arguments differ in application, they are very similar in substance. Defendants basically argue as to inducement that their proposed labelling does not encourage prescribing doctors to infringe the Asserted Claims, and argue as to contributory infringement that their proposed generic drugs may be used in substantial, non-infringing ways. (*Id*.) The Court addresses these arguments as to the Asserted Claims—and subsets of those claims—below, after first describing the applicable legal framework.

A. Legal Framework for Establishing Infringement

"Infringement is a two-step inquiry, in which a court must first construe disputed claim terms, and then compare the properly construed claims to the accused device." *Nazomi Commc'ns, Inc. v. Arm Holdings, PLC*, 403 F.3d 1364, 1367-68 (Fed. Cir. 2005) (citation omitted). The first step as to Plaintiffs' allegations that Defendants' proposed products as they will be prescribed infringe the Asserted Claims is already complete—the Court has construed the disputed claim terms. (ECF No. 135.) Plaintiffs bear the burden of persuasion as to infringement and must therefore prove all facts necessary to support their infringement claim. *See Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 571 U.S. 191, 198 (2014) ("It is well established that the burden of proving infringement generally

rests upon the patentee."). Further, "[i]nfringement is a question of fact." *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1040 (Fed. Cir. 2016) (citation omitted).

"Since the ultimate burden of proving infringement rests with the patentee, an accused infringer seeking summary judgment of noninfringement may meet its initial responsibility either by providing evidence that would preclude a finding of infringement, or by showing that the evidence on file fails to establish a material issue of fact essential to the patentee's case." *Novartis Corp. v. Ben Venue Labs., Inc.*, 271 F.3d 1043, 1046 (Fed. Cir. 2001) (citation omitted). "Summary judgment of noninfringement may only be granted if, after viewing the alleged facts in the light most favorable to the nonmovant and drawing all justifiable inferences in the nonmovant's favor, there is no genuine issue whether the accused device is encompassed by the patent claims." *Id*.

As noted *supra*, Plaintiffs assert two related but distinct infringement theories in this case—inducement and contributory infringement—that are both considered indirect infringement theories. (ECF No. 252 at 7.) The Court briefly describes below the requirements for finding liability under both an inducement and contributory infringement theory.

In this type of Hatch-Waxman Act patent litigation, where Defendants have filed ANDAs, the question of whether Defendants may be held liable for inducing infringement turns on whether Defendants "have the specific intent, based on the contents of their proposed labels, to encourage physicians to use their proposed ANDA products" in a way that infringes the Asserted Claims. *Grunenthal GMBH v. Alkem Labs. Ltd.*, 919 F.3d 1333, 1339 (Fed. Cir. 2019) (citation omitted). In other words, the Court must ask "whether the label encourages, recommends, or promotes infringement." *Id.* (citation omitted). And because the Asserted Claims are method claims, the "pertinent question is whether the proposed label instructs users to perform the patented method." *Id.* (citation omitted).

The test for contributory infringement is different. A defendant contributorily infringes a method patent when the defendant: (1) knows its product is "made or especially

adapted for use in an infringement of" that method patent; and (2) the product is "*not* a staple article or commodity of commerce *suitable for substantial non-infringing use*." *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1327 (Fed. Cir. 2009) (citing 35 U.S.C. § 271(c)) (emphasis in original). "[N]on-infringing uses are substantial when they are not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental." *Id.* (citation omitted). Thus, and as especially relevant to Defendants' Motion, contributory infringement can turn on whether there are substantial non-infringing uses, while inducement does not.

B. 12 Week Limitation That Applies to All Asserted Claims

Defendants first direct their arguments at the claim limitation admittedly present in all 15 of the Asserted Claims, which "requires administering icosapent [another name for EPA] to a patient with severe hypertriglyceridemia (TG ≥500 mg/dL) for at least 12 weeks." (ECF Nos. 236 at 14, 252 at 12-13 (internal quotation marks omitted).) The Court first addresses the parties' arguments regarding this 12 week claim limitation as to inducement, and then contributory infringement.

1. Inducement

Defendants argue they will not induce infringement of the Asserted Claims because their proposed labelling, which mirrors Plaintiffs', does not encourage doctors to prescribe the drug for at least 12 weeks. (ECF No. 236 at 14-19.) Plaintiffs respond that the labelling does encourage doctors to prescribe the drugs for at least 12 weeks, primarily because the reported clinical results included in the labelling state that the clinical trial establishing Vascepa's effectiveness lasted for 12 weeks, further pointing to expert testimony supporting Plaintiffs' view that a doctor reading the labelling would understand she should prescribe the drug to patients for at least 12 weeks. (ECF No. 252 at 17-26.) Plaintiffs further argue that disregarding this expert testimony at the summary judgment stage would be improper. (*Id.* at 26.) The Court agrees with Plaintiffs on that point.

Where, as here, there is expert testimony not inconsistent with the proposed labelling supporting the view that a doctor would understand she should prescribe the drug for at least 12 weeks, it would be inappropriate to disregard that expert testimony to grant Defendants summary judgment. Doing so would be tantamount to weighing the evidence or making credibility determinations, which the Court cannot do in considering summary judgment.

That said, whether Defendants' proposed labelling would induce doctors to prescribe their proposed drugs for 12 weeks or more is a close call because the proposed labelling does not have much to say about the duration of treatment. (*See generally* ECF No. 245.) Plaintiffs point to only three instances in the 10 pages of labelling[3] that relate to the duration of treatment: (1) the clinical studies section of the labelling describes a clinical trial (the "MARINE Trial") in which patients were enrolled for 12 weeks (ECF No. 245 at 8-9; (2) the nonclinical toxicology section of the labelling describes two studies done in rats and mice, one that lasted 2 years and the other that lasted 6 months (*id.* at 8); and the patient information section says "[d]o not change your dose or stop taking VASCEPA without talking to your doctor" (*id.* at 11). (ECF No. 252 at 14-18.) None of these instances explicitly tell doctors they should prescribe the drug for at least 12 weeks. Further, the indications and usage section of the labelling, which both begins the labelling and is the section one would expect to contain explicit instructions, does not specify a duration of treatment. (ECF No. 245 at 4.)

However, Plaintiffs persuasively argue that no treating physician would view the labelling in a vacuum—rather, they would bring their own knowledge and experience to bear on the labelling in deciding the duration of treatment. (ECF No. 252 at 17-18.) Plaintiffs also make the related argument that doctors know severe hypertriglyceridemia is a chronic condition requiring indefinite treatment. (*Id.* at 18.) Therefore, Plaintiffs argue,

[3]Again, Defendants' proposed labelling does not differ from Plaintiffs' proposed labelling in any material way.

doctors would understand the labelling as requiring treatment for more than 12 weeks. (*Id.* at 17-26.) The Court finds this argument intuitively persuasive—chronic conditions require indefinite treatment. *See Sanofi v. Glenmark Pharm. Inc.*, USA, 204 F. Supp. 3d 665, 684 (D. Del. 2016), ***aff'd sub nom. Sanofi v. Watson Labs. Inc.***, 875 F.3d 636 (Fed. Cir. 2017) (finding after bench trial that the defendants' labels induced infringement because of "the description of the long-term treatment involved in the ATHENA trial in Defendants' labels, additional clues in the labels that suggest long-term treatment, and the experts' testimony that prescribing physicians generally intend to treat patients with dronedarone for longer than 12 months[.]"). And more importantly, Plaintiffs support these arguments with expert testimony. (ECF No. 252 at 17-26.) Plaintiffs' proffered expert testimony creates a genuine issue of material fact inappropriate for resolution at summary judgment as to "whether the label encourages, recommends, or promotes infringement." *Grunenthal*, 919 F.3d at 1339; *see also Bio Tech. Gen. Corp. v. Duramed Pharm., Inc.*, 325 F.3d 1356, 1361 (Fed. Cir. 2003) (reversing grant of summary judgment of noninfringement in part on an inducement theory in part because the district court had disregarded expert testimony while explaining that the evidence necessary to survive summary judgment need not be extensive provided it is uncontradicted).

Defendants primarily rely on *Takeda Pharm. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 632 (Fed. Cir. 2015) to argue that Plaintiffs' proffered expert testimony is insufficient to show inducement because the proposed labelling lacks specific statements that encourage or will inevitably lead to infringement.[4] (ECF No. 262 at 8-9.) The Court is

[4]The Court has reviewed Defendants' supplemental authority (ECF No. 273-1), *HZNP Medicines LLC v. Actavis Laboratories UT, Inc.*, — F.3d. —, 2019 WL 5076226, *15-18 (Fed. Cir. Oct. 10, 2019), and finds it does not change the Court's ruling on inducement here. The asserted claims in *HZNP Medicines* required patients to: (1) apply a medicated lotion; (2) wait for it to dry; then (3) apply sunscreen or bugspray to the same area. *See id.* at *16. But the labelling at issue merely warned users to let the medicated lotion dry before applying sunscreen or bugspray. *See id.* at *15-*16. Similar to *Takeda*, the expert testimony in *HZNP Medicines* provided an implausible interpretation of the labelling in an attempt to show induced infringement of the asserted patent claims, whereas here, Plaintiffs' expert testimony offers a plausible interpretation of the labelling that suggests the Court could find induced infringement. *See id.* at *16-*18. Moreover, the

not persuaded. There is a meaningful distinction between the labelling in this case and the labelling at issue in *Takeda*, where the plaintiff argued the statement "[i]f you have a gout flare while taking [the drug], tell your healthcare provider," in the labelling induced infringement of claims directed to the treatment of acute gout flares, where the applicable labelling only otherwise stated that the drug was indicated for prophylaxis of gout. *Takeda*, 785 F.3d at 630, 632-34. Here, the clinical studies section of the labelling mentions that the study establishing the effectiveness of the Vascepa ran for 12 weeks, and the labelling is otherwise mostly silent as to treatment duration. (ECF No. 245.) Therefore, Plaintiffs' proffered expert testimony supplements a plausible interpretation of the labelling, instead of providing an explanation of the labelling not consistent with the labelling, like the expert testimony did in *Takeda*.[5] *See* 785 F.3d at 633.

2. Contributory Infringement

Defendants also argue they cannot contributorily infringe the Asserted Claims because their drugs as described in the proposed labelling are capable of the substantial non-infringing use of reducing triglycerides in less than 12 weeks. (ECF No. 236 at 19-23.) As support, Defendants point to the content of their proposed labelling, Plaintiffs' clinical data showing reductions of triglycerides peaking around four weeks, the specifications of the asserted patents claiming a reduction in triglycerides in as little as one week, concessions from Plaintiffs' infringement expert that probably 5% of his patients use Vascepa for less than 12 weeks, and that it would not be 'off-label,' or prohibited by the FDA, to prescribe Vascepa for less than 12 weeks. (*Id*.) Plaintiffs respond that this evidence does not establish a substantial non-infringing use, especially because of other

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relevant user in *HZNP Medicines* was a patient, and not, as here, a doctor. Thus, Plaintiffs' persuasive argument that a doctor would look at the clinical studies portion of the labelling because of that doctor's medical training and experience would not apply in the situation addressed in *HZNP Medicines*, where the court was considering whether a patient would infringe.

[5]*Takeda* also arose in a different procedural context, where a different legal standard governed that court's analysis. *See* 785 F.3d at 628-29, 634-35 (affirming the district court's denial of a preliminary injunction).

testimony from Plaintiffs' infringement expert showing that doctors understand hypertriglyceridemia is a chronic condition necessitating ongoing, indefinite treatment to maintain reductions in triglyceride levels. (ECF No. 252 at 35.) Plaintiffs further argue short-term (less than 12 week) treatment would be therefore be unusual and contrary to clinicians' intent in treating hypertriglyceridemia. (*Id.*)

The Court agrees with Defendants. Even if it only happens about 5% of the time, reducing triglycerides in less than 12 weeks using Defendants' ANDA drugs would not be "unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental." *Vita-Mix*, 581 F.3d at 1327; *see also In re Depomed Patent Litig.*, Case No. CV 13-4507 (CCC-MF), 2016 WL 7163647, at *69 (D.N.J. Sept. 30, 2016), *aff'd sub nom. Grunenthal*, 919 F.3d 1333 (finding after trial that a use pattern of a drug the plaintiffs' expert conceded would occur less than 5% of the time was a sufficiently substantial use to defeat a contributory infringement claim).

The material facts are undisputed as to this issue. First, it is undisputed that prescribing Defendants' potential ANDA drugs for fewer than 12 weeks is within the scope of the FDA approval reflected in Vascepa's labelling. (ECF No. 245 (providing no defined duration of treatment).) Second, Plaintiffs agree with Defendants that "the specification in the asserted patents states that TG reduction can occur in a shorter period of time than 12 weeks." (ECF No. 252 at 13.) Third, Plaintiffs also agree with Defendants that Plaintiffs' MARINE study results show that "the maximum effect on fasting TG reduction occurred by Week 4." (*Id.*) Fourth, while he explained that he would normally prescribe Vascepa for an indefinite period of time because severe hypertriglyceridemia is a chronic condition (ECF No. 252 at 15), Plaintiffs' infringement expert conceded that he treated patients with Vascepa for less than 12 weeks about 5% of the time, which is consistent with Vascepa's labelling. (ECF Nos. 252 at 35, 241 at 74-75 (sealed).) Thus, there is no real dispute that Vascepa—and therefore also Defendants' ANDA drugs—are, and can be for legitimate reasons, prescribed for fewer than 12 weeks. That means that reducing triglycerides in

less than 12 weeks using Defendants' ANDA drugs is a substantial non-infringing use of those drugs. Moreover, Plaintiffs proffer no evidence that directly contradicts any of the evidence discussed above. (ECF No. 252 at 32-36.)

The existence of this substantial non-infringing use for Defendants' ANDA drugs therefore defeats Plaintiffs' contributory infringement claim. *See Vita-Mix*, 581 F.3d at 1328 (affirming the district court's grant of summary judgment of no contributory infringement because there were substantial non-infringing uses for the accused products). Because there is no genuine dispute of material fact on this issue, the Court will grant Defendants summary judgment that they do not contributorily infringe Plaintiffs' Asserted Claims.[6]

C. Other Health Benefit Claims

Defendants next argue they will not induce infringement of the Other Health Benefit Claims because their proposed labels do not specifically encourage use of their products to achieve the claimed additional benefits. (ECF No. 236 at 24.) Plaintiffs respond that the clinical studies section of the labelling describes how the additional benefits described in this subset of claims occurred in the MARINE Trial, and proffer expert testimony to support the view that doctors would consider these results in choosing to prescribe Vascepa over other drugs—because the MARINE Trial shows they can reasonably expect a certain amount of triglyceride reduction in their patients while those patients also receive other health benefits. (ECF No. 252 at 26-31.) Thus, like the parties' arguments as to all

[6]The Court therefore need not, and does not, reach the parties' arguments as to contributory infringement of the Other Health Benefit Claims and the Excluding Statins Claims—because they are subsets of the Asserted Claims. That said, the Court notes that even Plaintiffs do not oppose Defendants' Motion to the extent it argues that Defendants do not contributorily infringe the Excluding Statins Claims. (ECF No. 252 at 32 n. 17.) Moreover, the Court is skeptical of Plaintiffs' theory that Defendants contributorily infringe the Other Health Benefits Claims because there is no real dispute that Defendants' potential ANDA drugs could be used in accordance with their proposed labels without achieving the specific effects required by those claims, and Plaintiffs' own clinical study explicitly establishes that some patients received the triglyceride reductions required by all Asserted Claims without getting the other health benefits required by the Other Health Benefits Claims—so at least some substantial non-infringing uses must exist. (ECF No. 262 at 24-25.)

Asserted Claims regarding the 12 week limitation, this dispute centers on whether the clinical studies section of the labelling would encourage doctors to infringe the Other Health Benefits Claims. And the answer again depends on whether the Court considers Plaintiffs' proffered expert testimony. At this stage, the Court must.

The Court will thus deny Defendants' motion for summary judgment of noninfringement as to Plaintiffs' inducement theory regarding the Other Health Benefits Claims because it simply cannot disregard Plaintiffs' expert testimony to the effect that doctors would look at the clinical study results in the labelling before deciding to prescribe a drug, and would prescribe that drug for its additional benefits beyond its primary indication. (*Id.* at 27.) The Court finds it more appropriate to consider expert testimony from both sides as to whether induced infringement may be inferred from the labelling at the upcoming bench trial, and resolve the meaning of the labelling at trial. *See, e.g., Grunenthal*, 919 F.3d at 1339-40 (affirming the district court's finding of no induced infringement after a bench trial while looking to expert testimony to determine the meaning of the labelling at issue). While there is no dispute that the clinical studies section of the labelling reflects the findings of the MARINE Trial that are also embedded in the Other Health Benefit Claims, a material factual dispute remains as to whether the labelling would encourage doctors to prescribe Defendants' ANDA drugs in a way that infringes the Other Health Benefits Claims. (ECF Nos. 236 at 24-25, 252 at 26-31.)

Defendants also argue that "Defendants' labels will not induce infringement of—*i.e.*, specifically encourage practicing—those claims that require controlling LDL-C and Apo B levels, uses of icosapent that are not even approved by the FDA." (ECF No. 236 at 25-27.) Defendants primarily rely on *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316 (Fed. Cir. 2012). (ECF No. 236 at 26-27.) In response, Plaintiffs point to expert testimony to the effect that the additional health benefits discussed in the Other Health Benefits Claims are merely "additional treatment effects that clinicians should expect when administering the product in accordance with the approved label to reduce triglycerides in

patients with severe hypertriglyceridemia." (ECF No. 252 at 29-30.) Plaintiffs also distinguish *Bayer* for this reason, noting the *Bayer* court contrasted its finding that the generic drug company defendants' labels did not induce infringement of Bayer's patent with a hypothetical different case where "[t]he patent does not claim a method of achieving a contraceptive effect in a patient in need of contraception in which the drug used to achieve the contraceptive effect has two generally beneficial additional effects." *Bayer*, 676 F.3d 1323. (ECF No. 252 at 30-31.)

The Court agrees with Plaintiffs. Again, the Court cannot ignore at this stage the expert testimony Plaintiffs point to indicating that a doctor who administers Vascepa with the primary purpose of reducing triglycerides, but also because there are additional benefits, would still be using Vascepa in an 'on label' way. (*Id.* at 30.) And *Bayer* does not require otherwise. The patent in *Bayer* was "narrowly focused on simultaneously achieving three effects in premenopausal or menopausal patients in need of all three effects; as the parties stipulated, the claim limitation referring to a 'patient in need thereof' means a patient with a 'perceived need for' all three effects." *Bayer*, 676 F.3d at 1323. The patents at issue here are all focused on a method for reducing triglyceride levels in a particular patient population by giving that patient a particular drug composition for at least 12 weeks. *See, e.g.*, Claim 1 of the '728 Patent. The benefits described and claimed in the Other Health Benefit Claims are merely additional benefits—nothing in the patent requires that a doctor only prescribe a drug because a patient has a perceived need for both the primary and additional benefits. Thus, the Court agrees with Plaintiffs that the patents at issue here are more similar to the hypothetical situation described for contrast in *Bayer*, than the patent claims at issue in *Bayer*. (ECF No. 252 at 30-31.)

In sum, the Court will deny Defendants summary judgment of non-infringement as to Plaintiffs' inducement infringement theory regarding the Other Health Benefits Claims.

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D. Excluding Statins Claims

Defendants' argument as to induced infringement of these four claims is similar to the arguments described above as to the Asserted Claims more broadly. (ECF No. 236 at 29-30.) Plaintiffs' response to Defendants' argument is also similar. (ECF No. 252 at 31-32.) In short, only the clinical studies section of the labeling refers to whether or not the patient was on a statin during the MARINE Trial (some were, some were not), and Plaintiffs' proffer expert testimony to the effect that doctors would interpret this to mean they could prescribe the drug to patients who were not also on a statin, while Defendants argue the labeling itself does not encourage such an interpretation. For essentially the same reasons as described above, the Court will deny Defendants summary judgment that they do not induce infringement of the Excluding Statins Claims.

V. PLAINTIFFS' MOTION (ECF NO. 234)

Plaintiffs seek to prevent Defendants from asserting any invalidity defenses at trial under 35 U.S.C. § 102 and 35 U.S.C. § 112 because Defendants have only disclosed evidence supporting Defendants' view that Plaintiffs' asserted patents are invalid as obvious under 35 U.S.C. § 103. (ECF No. 234.) Defendants counter they only seek to assert the defense that Plaintiffs Asserted Claims are invalid because they do not satisfy the written description requirement. (ECF No. 247 at 6.) The Court will therefore address below the other defenses Plaintiffs challenge in Plaintiffs' Motion before addressing the written description defense.

A. Other Challenged Defenses

Defendants write that they "are not asserting invalidity based on anticipation, enablement, or indefiniteness, so [Plaintiffs'] motion with respect to those defenses is moot." (*Id.*) The Court therefore deems these defenses (and counterclaims) withdrawn.

B. Written Description

But Defendants would still like the option of raising the written description defense (and counterclaim) at trial. (*Id.*) Plaintiffs respond that Defendants should not be allowed

to raise the written description defense because they did not raise it until their expert's reply report—that allowing Defendants to raise it now would be unfair and prejudicial. (ECF No. 264 at 4-6, 7-13.) Plaintiffs further respond that Defendants' written description defense is deficient as a matter of law. (*Id.* at 13-21.) The Court agrees it would be unfair and prejudicial to allow Defendants to assert a written description defense at trial, and declines to address the merits of Plaintiffs' argument.

One purpose of "the Federal Rules[] is to prevent unfair and prejudicial surprise[.]" *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 550-51 (Fed. Cir. 1998) (affirming the district court's decision not to allow a party to present a particular patent as a prior art reference at trial because that party did not produce the reference during the designated discovery period). Experts are normally expected to include "a complete statement of all opinions the witness will express and the basis and reasons for them" in their opening reports. Fed. R. Civ. P. 26(a)(2)(B)(i). Moreover, "an expert's rebuttal testimony may not introduce new, alternative or previously unconsidered theories." *Tuuamalemalo v. Las Vegas Metro. Police Dep't*, Case No. 2:16-cv-00619-JAD-VCF, 2017 WL 1550235, at *1 (D. Nev. Apr. 28, 2017) (denying motion to strike rebuttal expert report because it directly addressed the same subject matter of the opening report).

Failure to comply with these rules triggers Rule 37(c)(1), which provides, in pertinent part:

> If a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless.

Fed. R. Civ. P. 37(c)(1). Thus, when a party fails to timely disclose a witness or information, or supplement its disclosures, the default rule is the party cannot use the undisclosed information or witness to supply evidence on a motion, at a hearing, or at trial. *See, e.g.*, *Yeti by Molly, Ltd. v. Deckers Outdoor Corp.*, 259 F.3d 1101, 1106 (9th Cir. 2001) (describing the sanction as "self-executing"). The exception is when failure to disclose is

substantially justified or harmless. *See id.* And the court retains discretion to fashion appropriate relief in the event of a failure to disclose. *See id.* (stating that a district court has "particularly wide latitude" over its discretion to issue sanctions under Rule 37(c)(1)). "Several factors [] guide the determination of whether substantial justification and harmlessness exist, including (1) prejudice or surprise to the party against whom the evidence is offered; (2) the ability of that party to cure the prejudice; (3) the likelihood of disruption of trial; and (4) bad faith or willfulness in not timely disclosing the evidence." *Silvagni v. Wal-Mart Stores, Inc.*, 320 F.R.D. 237, 242 (D. Nev. 2017) (citations omitted).

Plaintiffs more specifically argue they would be prejudiced were Defendants allowed to assert a written description defense at trial because their experts had no opportunity to consider and rebut Defendants' expert's opinions as to written description while expert discovery was still open. (ECF No. 264 at 9-10.) Plaintiffs also note that Defendants obtained a two month extension of the deadline to exchange their opening expert report, over Plaintiffs' objection, "before committing to a final position on invalidity[,]" but Defendants' expert did not raise the written description defense in that opening report. (ECF Nos. 173 at 5, 264 at 11.) In addition, Plaintiffs argue that this late disclosure of Defendants' written description defense would disrupt their preparations for the upcoming trial were Defendants allowed to assert it. (ECF No. 264 at 12.) For these reasons, Plaintiffs argue Defendants should be precluded from asserting a written description defense at trial. (*Id.* at 12-13.) And while Plaintiffs' Motion included a condensed version of these fairness and prejudice arguments (ECF No. 234 at 15), Defendants did not respond to them (ECF No. 247).

The Court is persuaded by Plaintiffs' arguments. To start, there is no dispute that Defendants did not indicate they intended to assert a written description defense in their opening expert report as required by Fed. R. Civ. P. 26(a)(2)(B)(i). Thus, Defendants are not allowed to assert that defense at trial unless their failure to disclose was substantially justified or harmless. *See* Fed. R. Civ. P. 37(c)(1). Defendants do not even argue their

failure to disclose was substantially justified or harmless, instead focusing on the merits of a potential written description defense. (ECF No. 247.) This weighs in favor of finding it was not substantially justified or harmless.

Further, the factors outlined in *Silvagni* tip towards finding Defendants' failure to disclose was not substantially justified. *See* 320 F.R.D. at 242. The Court agrees with Plaintiffs that the late disclosure of the written description defense in Defendants' reply expert report prejudices Plaintiffs. The Court also agrees it would be difficult for Plaintiffs to cure the prejudice by moving to reopen expert discovery, and preparing a new expert report to rebut the written description defense, all while preparing for the bench trial scheduled to start in January. Moreover, the Court is concerned about potential disruption of trial, especially considering that all parties seem to agree it is important the case actually go to trial on the firm trial date it is currently set for. But all of this said, the Court will not impute any bad faith or willfulness to Defendants for their untimely disclosure of their intent to rely on the written description defense, as it sees no reason to do so. Even still, three of the four *Silvagni* factors weigh in favor of finding Defendants' late disclosure of their intent to assert the written description defense was not substantially justified or harmless. Thus, it was not. For all of these reasons, Defendants may not assert a written description defense at trial.

In sum, the Court will deny Plaintiffs' Motion as moot to the extent it attacks Defendants' anticipation, enablement, or indefiniteness defenses (and counterclaims) because Defendants have withdrawn those defenses (and counterclaims). But the Court will grant Plaintiffs' Motion to the extent necessary to make clear Defendants may not assert a written description defense at trial.

VI. MOTIONS TO SEAL

The parties filed redacted versions of their briefs and seek to seal certain exhibits—so most briefs related to the motions discussed above were accompanied by a motion to seal in accordance with LR IA 10-5.

In the Ninth Circuit there is "a strong presumption in favor of access to court records." *Foltz v. State Farm Mut. Auto. Ins. Co.*, 331 F.3d 1122, 1135 (9th Cir. 2003). To overcome this presumption, a party must articulate "compelling reasons" justifying nondisclosure, such as use of the record to gratify spite, permit public scandal, circulate libelous statements, or release trade secrets. *Kamakana v. City of Honolulu*, 447 F.3d 1172, 1179 (9th Cir. 2006). "The mere fact that the production of records may lead to a litigant's embarrassment, incrimination, or exposure to further litigation will not, without more, compel the court to seal its records." *Id*. (citation omitted).

In general, the parties seek to maintain under seal evidence designated as confidential by the parties during discovery, which they contend contains proprietary and confidential information that could subject them to commercial disadvantage were it to be made public. The Court describes the content of each of these motions to seal, in turn, below—and then provides the Court's ruling as to the motions to seal.

A. Content of the Motions

1. ECF NO. 235

In this motion to seal, Defendants seek to maintain the redactions present in Defendants' Motion, and file exhibits 2, 4, 12, 13, 14, 15, and 16 to Defendants' Motion under seal. (ECF No. 235 at 2.) The redactions in Defendants' Motion correspond to material pulled from these exhibits. Exhibits 2 and 4 are excerpts from the depositions of Plaintiffs' experts, where they "discuss nonpublic and proprietary information concerning [Plaintiffs' branded product," Exhibit 12 consists of "MARINE Study Report Excerpts," Exhibit 13 is the Vascepa label, Exhibit 14 is Hikma's proposed label, Exhibit 15 is DRL's proposed label, and Exhibit 16 is a response letter from the FDA to Plaintiffs. (*Id.* at 2; *see also* ECF No. 238 at 2.)

2. ECF No. 246

In this motion to seal, Defendants seek to maintain the redactions present in their response to Plaintiffs' Motion under seal, and file exhibits 1 and 2 to that response under

seal. (ECF No. 246 at 2.) The redactions in Defendants' response to Plaintiffs' Motion correspond to material pulled from these exhibits. Exhibit 1 consists of excerpts from the deposition of one of Plaintiffs' experts, where he discusses "nonpublic and proprietary information concerning Amarin's branded product[,]" and Exhibit 2 consists of excerpts from the reply expert report of one of Plaintiffs' experts. (*Id.*)

3. ECF No. 254

In this motion to seal, Plaintiffs seek to maintain the redactions present in their response to Defendants' Motion, along with sealing portions of Exhibit 13, and file the entirety of exhibits 5, 7, 9, and 10, under seal. (ECF No. 254 at 2.) Exhibits 5 and 7 are excerpts of expert deposition transcripts "that have been marked 'Confidential' and that discuss information Defendants have asserted constitutes competitively-sensitive information concerning Defendants' ANDA products." (*Id.* at 3.) Exhibits 9, 10, and 13 are Defendants' expert reports. (*Id.*)

4. ECF No. 261

In this motion to seal, Defendants seek to maintain the redactions present in their reply in support of Defendants' Motion, where the redactions reference discovery material that "is the type of technical and business information that is treated as confidential by pharmaceutical companies generally." (ECF No. 261 at 2.) "The disclosure of this information would reveal the confidential details of Amarin's technical and business information and would give competitors an unfair advantage, causing Amarin to suffer a commercial disadvantage." (*Id.*)

5. ECF No. 265

In this Motion to Seal, Plaintiffs seek to file under seal "the entirety of Exhibit C to the Reply Declaration of Michael N. Kennedy" filed with Plaintiffs' reply in support of Plaintiffs' Motion. (ECF No. 265 at 2.) Exhibit C consists of excerpts of the deposition transcript from one of the patents-in-suit's named inventors, has been marked confidential, and "discusses information that constitutes nonpublic competitively sensitive technical and

other confidential business information concerning Amarin's Vascepa® product." (*Id.* at 2-3.)

B. Ruling on the Motions

The Court will grant in part, and deny in part, Defendants' motion to seal the exhibits accompanying Defendants' Motion. (ECF No. 235.) The Court will grant the other pending motions to seal. More specifically, the Court will allow the parties to file under seal exhibits consisting of excerpts of expert deposition transcripts, and expert reports, in which the experts discuss "proprietary, trade secret, and technical information which warrants keeping [these exhibits] sealed." *Spectrum Pharm., Inc. v. Sandoz Inc.*, Case No. 2:12-cv-00111-GMN, 2013 WL 6896975, at *2 (D. Nev. Dec. 31, 2013). The parties may also maintain redactions in their briefs corresponding to material taken from those exhibits. That means the parties may file under seal exhibits 2 and 4 discussed in ECF No. 235, both exhibits discussed in ECF No. 246, all exhibits discussed in ECF No. 254, the redactions present in Defendants' reply in support of Defendants' Motion discussed in ECF No. 261, and the exhibit discussed in ECF No. 265.

However, the Court will direct Defendants to file a supplemental brief of not more than five pages within 10 days of the date of entry of this order providing additional argument as to why exhibits 12, 13, 14, 15, and 16 to Defendants' Motion should be filed under seal, along with the corresponding redactions. (ECF No. 235 at 2.) The Court will then give Plaintiffs 10 days to file a response (subject to the same page limit) to Defendants' supplemental brief, though no response is required. No reply will be permitted.

The Court is not convinced Defendants have articulated compelling reasons these exhibits should be filed under seal.[7] To reiterate, Exhibit 12 consists of "MARINE Study

[7]The Court notes its concern about the practice of moving to seal all potential trade secret information, especially in cases involving pharmaceuticals, where the public has an important interest in the safety and efficacy of the drugs they take. While this case is of course a patent case dealing with non-opioid drugs, the perils of the practice of arguably unthinkingly granting motions to seal materials containing purported trade secrets have

Report Excerpts," Exhibit 13 is the Vascepa label, Exhibit 14 is Hikma's proposed label, Exhibit 15 is DRL's proposed label, and Exhibit 16 is a response letter from the FDA to Plaintiffs. (ECF No. 235 at 2; *see also* ECF No. 238 at 2.) The results of the MARINE study are public. *See, e.g.*, Bays HE, Braeckman RA, Ballantyne CM, Kastelein JJ, Otvos JD, Stirtan WG, Soni PN. Icosapent ethyl, a pure EPA omega-3 fatty acid: effects on lipoprotein particle concentration and size in patients with very high triglyceride levels (the MARINE study). J Clin Lipidol. 2012 Nov-Dec;6(6):565-72. doi: 10.1016/j.jacl.2012.07.001. Epub 2012 Jul 24, *available at* https://www.ncbi.nlm.nih.gov/pubmed/23312052?dopt=Abstract. The Vascepa label is also public information. *See, e.g.*, https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/202057s019lbl.pdf. And considering that Defendants' proposed ANDA labels are virtually identical to the public Vascepa label (ECF No. 252 at 15), it seems unlikely they contain any confidential information. Finally, as to the FDA response letter, the Court finds Defendants have not yet provided compelling reasons outweighing the policy favoring access to court records that justify filing it under seal.

In sum, the motions to seal are mostly granted, subject to the exception discussed above.

VII. 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

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become apparent in products liability cases dealing with opioids, where harmful and revelatory information was kept hidden for years—information that could have been useful to the public. *See, e.g.*, Benjamin Lesser, Lisa Giron, and Jami Dowdell, *How judges added to the grim toll of opioids*, REUTERS (June 25, 2019, 1:00 PM), https://www.reuters.com/investigates/special-report/usa-courts-secrecy-judges/. The Court therefore advises the parties to judiciously deploy motions to seal, remaining mindful of the "strong presumption in favor of access to court records." *Foltz*, 331 F.3d at 1135. Moreover, the Court may reconsider its sealing decisions at trial, ordering documents or testimony unsealed if, for example, it becomes clear that evidence does not contain trade secrets.

that they do not warrant discussion as they do not affect the outcome of the motions before the Court.

It is therefore ordered that Defendants' motion for summary judgment (ECF No. 236) as to noninfringement is granted in part, and denied in part. It is granted to the extent Plaintiffs assert a contributory infringement theory, but denied to the extent Plaintiffs assert an inducement infringement theory.

It is further ordered that Plaintiff's motion for partial summary judgment (ECF No. 234) is granted in part, and denied in part as moot. It is granted to the extent Defendants may not assert a written description defense at trial, but denied as moot as to anticipation, enablement, or indefiniteness because Defendants have withdrawn these defenses and counterclaims.

It is further ordered that Defendants' Motion to Seal (ECF No. 235) is granted in part, and denied in part. It is granted as to exhibits 2 and 4 and their corresponding redactions, but denied without prejudice as to exhibits 12, 13, 14, 15, and 16 and their corresponding redactions.

It is further ordered that Defendants must file a supplemental brief or not more than five pages within 10 days of the date of entry of this order providing additional argument as to why exhibits 12, 13, 14, 15, and 16 to Defendants' Motion should be filed under seal, along with the corresponding redactions. (ECF No. 235 at 2.) These documents will remain under seal pending the Court's ruling on Defendants' supplemental brief.

It is further ordered that Plaintiffs will have 10 days to file a response to Defendants' supplemental brief, though none is required. No reply will be permitted.

It is further ordered that Defendants' Motion to Seal (ECF No. 246) is granted.

It is further ordered that Plaintiffs' Motion to Seal (ECF No. 254) is granted.

It is further ordered that Defendants' Motion to Seal (ECF No. 261) is granted.

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It is further ordered that Plaintiffs' Motion to Seal (ECF No. 265) is granted.

DATED THIS 28th day of October 2019.

MIRANDA M. DU
CHIEF UNITED STATES DISTRICT JUDGE