IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ALLERGAN SALES, LLC, *Plaintiff*, v. SANDOZ, INC., et al. *Defendants*.	§ § § § § § § § §	CASE NO. 2:12-CV-207-JRG **(LEAD CASE)**
ALLERGAN SALES, LLC, *Plaintiff*, v. SANDOZ, INC., et al. *Defendants*.	§ § § § § § § § §	CASE NO. 2:15-CV-347-JRG

MEMORANDUM OPINION AND ORDER

Before the Court are the competing motions for summary judgment by Plaintiff Allergan Sales, LLC ("Allergan") and Defendants Sandoz, Inc., Alcon Laboratories, Inc., Alcon Research, Ltd., and Falcon Pharmaceuticals, Ltd. (collectively "Sandoz") (Dkt. No. 277; Dkt. No. 280; Dkt. No. 281). Allergan's motion sought summary judgment that Sandoz was precluded from challenging the validity of claim 4 of U.S. Patent No. 7,030,149 ("the '149 patent") under the doctrines of issue preclusion and claim preclusion and that Sandoz's proposed ANDA product infringes claim 4 of the '149 patent (Dkt. No. 277). Sandoz filed two motions for summary judgment. Sandoz's first motion sought summary judgment that claim 4 of the '149 patent was invalid (Dkt. No. 280). Sandoz's second motion sought summary judgment of non-infringement

of claim 4 of the ’149 patent (Dkt. No. 281). The Court held a hearing on August 25, 2016 and heard oral argument on the motions. After considering the briefing and evidence, the Court finds that Allergan’s Motion for Summary Judgment (Dkt. No. 277) and Sandoz’s Motion for Summary Judgment of Invalidity of Claim 4 of the ’149 Patent (Dkt. No. 280) should be **DENIED**; however, the Court finds that Sandoz’s Motion for Summary Judgment of Non-Infringement as to Claim 4 of the ’149 Patent (Dkt. No. 281) should be **GRANTED-IN-PART** and **DENIED-IN-PART**.

I. BACKGROUND

A. Procedural History: *Allergan I, Allergan II*, and *Allergan III*

In 2007, the FDA approved Allergan’s New Drug Application for the drug Combigan, which is described as a “fixed combination” product designed to lower intraocular pressure in patients with glaucoma and ocular hypertension. (Dkt. No. 277 p. 3). Allergan has six patents alleged to cover Combigan and its administration: the ’149 patent, and U.S. Patent Nos. 7,320,976 (“the ’976 patent”), 7,642,258 (“the ’258 patent”), 8,133,890 (“the ’890 patent”), 8,354,409 (“the ’409 patent”), and 8,748,425 (“the ’425 patent”). (*Id.* at 3–4). Each of these patents is listed in the FDA-Approved Drug Products with Therapeutic Equivalence Evaluations database, commonly referred to as the “Orange Book.” (*Id.* at 4).

1. *Allergan I*

In 2008, Sandoz submitted an Abbreviated New Drug Application (“ANDA”) to the FDA seeking approval to make a generic version of Combigan (“the proposed ANDA product”). (Dkt. No. 287 p. 5). After submitting its ANDA, Sandoz sent a Paragraph IV letter to Allergan indicating that it had submitted its ANDA to the FDA. (Dkt. No. 277 p. 4). In response to Sandoz’s Paragraph IV letter, Allergan filed suit against Sandoz for infringement of the ’149,

’463, ’976, and ’258 patents. *See Allergan, Inc. v. Sandoz Inc.*, 818 F. Supp. 2d 974 (E.D. Tex. 2011) (“the *Allergan I* case”). In its Answer to Allergan’s Complaint in Allergan I, Sandoz raised affirmative defenses and counterclaims of invalidity of the asserted patents. (Dkt. No. 277 at 4; Dkt. No. 287 at 6). Sandoz also moved for summary judgment of non-infringement of claims 1 through 3 of the ’149 patent, which the Court granted. *Allergan*, 818 F. Supp. 2d at 982. Shortly before trial, Sandoz filed a stipulation of infringement that its ANDA met all of the limitations of claim 4 of the ’149 patent, claim 1 of the ’976 patent, claims 1-6 of the ’463 patent, and claims 1-9 of the ’258 patent. (2:09-cv-97, Dkt. No. 234). The case proceeded to a bench trial on the issue of invalidity of the remaining asserted claims (including claim 4 of the ’149 patent), and the Court found the claims to be infringed, based on the stipulations, and not invalid. *Allergan*, 818 F. Supp. 2d at 1031. The Court enjoined Sandoz from making, using, offering to sell, or selling the products described in the ANDA within the United States until after the latest of the expiration dates of the ’149, ’976, ’463, and ’258 patents. (2:09-cv-97, Dkt. No. 260).

Allergan and Sandoz both appealed the Court’s ruling to the Federal Circuit. *See Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286 (Fed. Cir. 2013). On appeal, the Federal Circuit reversed-in-part, finding that the asserted claims of the ’463 patent were invalid as obvious. *Id.* at 1288. However, the Federal Circuit affirmed this Court’s holding that claim 4 of the ’149 patent was not invalid, reasoning that Sandoz failed to present clear and convincing evidence that claim 4 of the ’149 patent would have been obvious. *Id.* at 1288. The Federal Circuit declined to address the claims of the ’258 and ’976 patents, explaining that ‘[t]he ’258, ’976, and ’149 patents each expire on April 19, 2022. Because we conclude that claim 4 of the ’149 patent is not

invalid, the Appellants will be unable to enter the market until that date. Accordingly, we find it unnecessary to address the claims of the '258 and '976 patents." *Id.* at 1294 n.2.[1]

2. *Allergan II*

In March of 2012, while *Allergan I* was still pending in this Court, the '890 patent issued. (Dkt. No. 1 ¶ 23). Shortly thereafter, Allergan filed suit against Sandoz alleging that Sandoz's ANDA infringed the '890 patent. (Dkt. No. 1) ("the *Allergan II* case"). On March 15, 2013, Sandoz amended its answers to add counterclaims for non-infringement and invalidity of the later-issued '409 patent, as well as non-infringement and invalidity of the '890 patent. (Dkt. No. 311 p. 6–7). *Allergan II* was ultimately consolidated with *Allergan III* to form the present action. (Dkt. No. 220).

3. *Allergan III*

While *Allergan I* was on appeal, Sandoz modified its ANDA in an effort to design around Allergan's patents. (Dkt. No. 287 p. 6). Sandoz's modifications came in the form of a label change, rather than alterations to the chemical composition of its product. (*Id.* at 7; Dkt. No. 303 p. 56). The label of the proposed ANDA product at issue in *Allergan I* indicated use of the product "in patients with glaucoma or ocular hypertension." However, Sandoz later modified its ANDA to remove the indicated use of glaucoma. (Dkt. No. 287 p. 7). As a result, Sandoz now only seeks approval for the indicated use of its product in patients with ocular hypertension. (*Id.*). After Sandoz modified its ANDA, it filed a Rule 60(b)(5) motion to modify the injunction the Court issued in *Allergan I* to permit Sandoz to make its proposed ANDA product. (2:09-cv-97, Dkt. 280). This Court denied Sandoz's Rule 60(b)(5) motion, (2:09-cv-97, Dkt. No. 308), and the Federal Circuit affirmed. *Allergan, Inc. v. Sandoz, Inc.*, 587 Fed. App'x 657 (Fed. Cir. 2014).

[1] The Federal Circuit also found no error in this Court's claim construction. *Allergan*, 726 F.3d at 1288.

On January 23, 2015, Sandoz sent a second Paragraph IV letter to Allergan, which notified Allergan of Sandoz's modified ANDA. (2:15-cv-347, Dkt. No. 1 ¶ 33–34). Following receipt of the Paragraph IV letter, Allergan again filed suit against Sandoz, this time for infringement of the '149, '976, '258, '425 patents. (2:15-cv-347, Dkt. No. 1) ("the *Allergan III* case"). As noted above, the Court then consolidated *Allergan II* and *Allergan III*. (Dkt. No. 220).

The motions presently before the Court focus solely on claim 4 of the '149 patent, and claim 4 currently lies at the heart of the dispute between the parties. Since Sandoz remains enjoined from launching its proposed ANDA product based on claim 4 of the '149 patent, the FDA will not grant final approval to make the product. Thus, Sandoz concedes, "even if this Court decides the other five contested patents in Sandoz's favor, Sandoz will only be able to launch its product if this Court determines claim 4 to be invalid or not infringed." (Dkt. No. 254-1).

The present motions address both invalidity and infringement with respect to claim 4. As a result, the Court will address the motions issue-by-issue rather than motion-by-motion. Additionally, because Allergan argues that Sandoz is precluded from challenging the validity of claim 4, both issue preclusion and claim preclusion will be addressed prior to a substantive review of invalidity.

II. LEGAL STANDARD

Summary judgment is proper when "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Under this standard, "the mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no genuine [dispute] of material fact." *Anderson v. Liberty Lobby,*

Inc., 477 U.S. 242, 247–48 (1986). The substantive law identifies the material facts, and disputes over facts that are irrelevant or unnecessary will not defeat a motion for summary judgment. *Id*. at 248. A dispute about a material fact is "genuine" when the evidence is "such that a reasonable jury could return a verdict for the nonmoving party." *Id.* Any evidence must be viewed in the light most favorable to the nonmovant. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986) (citing *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 158–59 (1970)).

The moving party has the burden to identify the basis for granting summary judgment and to supply evidence demonstrating the absence of a genuine dispute of material fact. *Celotex v. Catrett*, 477 U.S. 317, 323 (1986). If the moving party does not have the ultimate burden of persuasion at trial, the party "must either produce evidence negating an essential element of the nonmoving party's claim or defense or show that the nonmoving party does not have enough evidence of an essential element to carry its ultimate burden of persuasion at trial." *Nissan Fire & Marine Ins. Co., Ltd. v. Fritz Cos., Inc.*, 210 F.3d 1099, 1102 (9th Cir. 2000). Alternatively, if the moving party bears the ultimate burden of persuasion at trial, "it must lay out the elements of the claim, cite the facts which it believes satisfies these elements, and demonstrate why the record is so one-sided as to rule out the prospect of a finding in favor of the non-movant on the claim." *Hotel 71 Mezz Lender LLC v. Nat'l Retirement Fund*, 778 F.3d 593, 601 (7th Cir. 2015).

III. ANALYSIS

A. Issue Preclusion Does Not Bar Sandoz from Asserting Its Theories of Invalidity

In Allergan's motion for summary judgment, it argues first that issue preclusion bars Sandoz from re-arguing the validity of claim 4 of the '149 patent because invalidity is a single issue for purposes of issue preclusion. (Dkt. No. 277 at 15). This Court disagrees that issue preclusion bars Sandoz's invalidity argument.

1. Legal Standard for Issue Preclusion

Under Fifth Circuit law, four conditions must be met before issue preclusion may be applied to bar relitigation of an issue previously decided: "(1) the issue under consideration is identical to that litigated in the prior action; (2) the issue was fully and vigorously litigated in the prior action; (3) the issue was necessary to support the judgment in the prior case; and (4) there is no special circumstance that would make it unfair to apply the doctrine." *Winters v. Diamond Shamrock Chem. Co.*, 149 F.3d 387, 391 (5th Cir. 1998) (quotations omitted). Unlike its counterpart, claim preclusion, issue preclusion is "limited to matters distinctly put in issue, litigated, and determined in the former action." *Brister v. A.W.I., Inc.*, 946 F.2d 350, 354 (5th Cir. 1991).

The primary dispute here centers on whether Sandoz's new written description and enablement theories of invalidity under 35 U.S.C. § 112 are the "identical issues" that were litigated in *Allergan I*. Whether patent validity is a single issue for purposes of issue preclusion is an issue "particular to patent law," and thus Federal Circuit precedent is binding. *Evonik Degussa GmbH v. Materia Inc.*, 53 F. Supp. 3d 778, 793 (D. Del. 2014) (citing *Hallco Mfg. Co., Inc. v. Foster*, 256 F.3d 1290, 1294 (Fed. Cir. 2001)).

2. The Identical Issue Sandoz Seeks to Litigate Was Not Litigated in *Allergan I*

Allergan argues that Sandoz's invalidity theories under § 112 are precluded by this Court's decision in *Allergan I* because invalidity, including each different theory of invalidity, is a single issue for purposes of issue preclusion. (Dkt. No. 277 p. 15). Since invalidity was litigated in *Allergan I*, Allergan argues that Sandoz is precluded from raising any invalidity defense in the present action. (*Id.*). Sandoz responds by arguing that issue preclusion does not bar relitigation of invalidity because the Court's change in the construction of claim 4 prevents

application of issue preclusion for two reasons: (1) "the question of invalidity was never actually litigated under the proper claim construction" and (2) "it would be inequitable to apply the doctrine." (Dkt. No. 287 p. 11). Sandoz also argues that, regardless of the change in claim construction, issue preclusion should not bar Sandoz's validity challenge because the theories presently asserted are not the same invalidity theories litigated in *Allergan I*. (*Id.*). The Court finds Sandoz's arguments on this point to be persuasive. Application of issue preclusion to bar Sandoz from asserting new theories of invalidity under a new, broader claim construction of critical terms where new theories under § 112 are included would be inappropriate.

At the heart of this dispute are the Court's two different claim constructions of the terms "brimonidine" and "timolol." In *Allergan I*, the parties expressly agreed on the construction of these terms. (Dkt. No. 241 p. 12, 18). Under that agreement, "brimonidine" was construed as "brimonidine tartrate" and "timolol" was construed as "timolol free base." (2:09-cv-97, Dkt. No. 112 p. 2). The case proceeded to trial on Sandoz's obviousness challenge to the validity of claim 4 of the '149 patent, and this Court held that claim 4 was not invalid. *Allergan*, 818 F. Supp. 2d at 1031.

At claim construction in the present case, Allergan argued that issue preclusion barred Sandoz from seeking a different, broader construction of the terms "brimonidine" and "timolol" than that which controlled in *Allergan I*. (Dkt. No. 241 p. 8, 17). This Court rejected that argument on the basis that the constructions of "brimonidine" and "timolol" were not actually litigated in *Allergan I*, given that the parties had mutually agreed to the resulting constructions. (*Id.* at 14, 18–20). Since the construction of "brimonindine" and "timolol" was not actually litigated in *Allergan I*, one of the essential elements of issue preclusion was absent. As a result, application of the doctrine was inappropriate. (*Id.*). After reaching this conclusion, the Court

construed "brimonidine according to its plain and ordinary meaning, the chemical compound brimonidine, including both its free base and salt forms." (*Id.* at 17). Likewise, the Court construed the term "timolol according to its plain and ordinary meaning, the chemical compound timolol, including both its free base and salt forms." (*Id.* at 20). As a result, when the issues were actually disputed the Court reached a different claim construction with respect to the terms "brimonidine" and "timolol" than was reached when their construction was agreed to in *Allergan I.*

Although the Federal Circuit has not ruled on the matter, the Court recognizes that there is authority supporting Allergan's argument that, as a general proposition, invalidity is one single issue for purposes of issue preclusion. *See, e.g., VirnetX Inc v. Apple, Inc.*, No. 6:12-cv-855, slip op. at 5–6 (E.D. Tex. Aug. 8, 2014); *Evonik*, 53 F. Supp. 3d at 793–94; *Fairchild Semiconductor Corp. v. Power Integrations, Inc.*, 2015 WL 1905871, at *2 (D. Del. Apr. 23, 2015); *Crossroads Sys. (Tex.), Inc. v. Dot Hill Sys. Corp.*, 2006 WL 1544621, at *5 (W.D. Tex. May 31, 2006). As a general matter, the Court does not necessarily disagree. However, that is not to say that there is never an appropriate exception to this general rule. Indeed, Fifth Circuit precedent has established that there may be "special circumstances" in which it would be "unfair" to apply the issue preclusion doctrine. *See Winters*, 149 F.3d at 391. Whether or not invalidity is a single issue for issue preclusion purposes, this Court is satisfied that the present facts demonstrate that issue preclusion is not proper here.

First, there can be no dispute that the validity of claim 4 of the '149 patent has never been litigated under this Court's second claim construction. One of the staples of issue preclusion is that the doctrine is "limited to matters distinctly put in issue, litigated, and determined in the former action." *Brister*, 946 F.2d at 354. When analyzing whether the issue of validity has

already been litigated, it is necessary to look first at the scope of the controlling claim construction. As the Federal Circuit has recognized, "[c]laim interpretation is the first step of a validity analysis." *Scimed Life Sys. v. Johnson & Johnson*, 87 F. App'x 729, 734 (Fed. Cir. 2004). Therefore, when the scope of the claim construction changes, the issue of validity changes, and issue preclusion will not bar assertion of invalidity theories under a new claim construction. *TASER Int'l, Inc. v. Karbon Arms, LLC,* 6 F. Supp. 3d 510, 519 (D. Del. 2013) (citing 6 Annotated Patent Digest § 38:46) ("if the invalidity theories are based on different claim constructions . . . the requirement of identicality is not satisfied"). Under this framework, even if all theories of invalidity are considered to be the same issue, the change in claim construction prevents application of issue preclusion. *Id.*[2] The present case embodies this precise scenario: the Court's claim construction has materially changed and, noticeably, has enlarged from that of *Allergan I* with respect to the terms "brimonidine" and "timolol." Sandoz asserts that this change in claim construction gives rise to § 112 theories that were previously unavailable, and not litigated, under the *Allergan I* claim construction. (Dkt. No. 287 p. 18). As a result, the "identicality" requirement of issue preclusion is not present under these facts.

This Court's change in claim construction takes on an even greater degree of significance in light of the fact that Sandoz's invalidity theories in this case arise under § 112. Even courts holding that all theories of invalidity form a single issue for purposes of issue preclusion have

[2] The Court is aware that there are at least two district court opinions suggesting that even a subsequent change in claim construction will not prevent application of issue preclusion to bar relitigation of invalidity. *See, e.g., Fairchild Semiconductor Corp. v. Power Integrations, Inc.*, 2015 WL 1905871 (D. Del. April 23, 2015); *Crossroads Sys. (Tex.), Inc. v. Dot Hill Sys. Corp.*, 2006 WL 1544621, at *5 (W.D. Tex. May 31, 2006). The Court is of the opinion that the *Fairchild* case is distinguishable on its facts. In *Fairchild*, the court recognized that there was a "minor" change in claim construction. *Fairchild*, 2015 WL 1905871 at *2. The court went on to hold that this "minor" change did not create an exception to the general rule that validity is a single issue. *Id.* Importantly, even in light of the "minor" change, the court determined that the issue of validity was necessarily identical to that which was litigated in the first case because the scope of the claim narrowed rather than expanded. *Id.* Unlike Fairchild, the issue of validity here is not "necessarily identical" because here the scope of the terms has expanded. With respect to *Crossroads Sys.*, to the extent that the court may have held that a subsequent claim construction will not prevent application of issue preclusion, this Court respectfully disagrees.

recognized that when "the scope of a subsequent claim differs from that of a prior patent claim, a new issue of patent validity exists with respect to . . . 35 U.S.C. § 112." *Evonik*, 53 F. Supp. 3d at 791–92. Indeed, as the Federal Circuit has recognized, "[c]laim construction is inherent in any written description analysis." *Atl. Research Mktg. Sys., Inc. v. Troy*, 659 F.3d 1345, 1354 (Fed. Cir. 2011). Therefore, since "[a] district court must base its analysis of written description under § 112, ¶ 1 on a proper claim construction," it would be nonsensical to preclude a § 112 defense on the basis that the defense has already been litigated under a different claim construction. *See Koninklijke Philips Elecs. N.V. v. Cardiac Sci. Operating Co.*, 590 F.3d 1326, 1336 (Fed. Cir. 2010).

This case does not represent a situation wherein Sandoz is attempting to get two bites at the apple. In fact, with respect to its invalidity defenses, Sandoz has not yet had its first (and only) bite at the apple under the current claim construction. The Court is persuaded that when a subsequent and broadened claim construction gives rise to a new invalidity defense, not previously litigated, issue preclusion will not bar assertion of the new invalidity defenses. To preclude a party from asserting invalidity defenses under one particular claim construction on the basis that different theories of invalidity have previously been litigated under a different claim construction, would run completely counter to the notions of fairness which the doctrine was created to further and protect.

For the reasons stated above, the Court finds that issue preclusion does not bar Sandoz from asserting its § 112 defenses under this Court's new claim construction. Accordingly, summary judgment on this issue is improper and should be denied.

B. Claim Preclusion Does Not Bar Sandoz from Asserting its Theories of Invalidity

To say that issue preclusion does not bar Sandoz from asserting its § 112 defenses does not end the entire preclusion inquiry. Allergan further asserts that claim preclusion bars Sandoz from litigating the validity of claim 4 of the '149 patent under its § 112 theories because this case involves the "same claim" that was litigated in *Allergan I*. Here too, the Court disagrees.

1. Legal Standard for Claim Preclusion

Under Fifth Circuit law, claim preclusion applies where "(1) the parties are identical in the two actions; (2) the prior judgment was rendered by a court of competent jurisdiction; (3) there was a final judgment on the merits; and (4) the same claim or cause of action is involved in both cases." *Oreck Direct, LLC v. Dyson, Inc.*, 560 F.3d 398, 401 (5th Cir. 2009). The primary dispute between the parties with respect to claim preclusion centers on whether or not this case involves the "same claim or cause of action" as *Allergan I*.

The question of whether this case involves the same claim as *Allergan I* is "particular to patent law" and thus is governed by Federal Circuit precedent. *Hallco Mfg. Co.*, 256 F.3d at 1294. Under Federal Circuit law, [a]n assertion of invalidity of a patent by an alleged infringer is not a 'claim' but a defense to the patent owner's 'claim.'" *Foster v. Hallco Mfg. Co., Inc.*, 947 F.2d 469, 479 (Fed. Cir. 1991). "[T]he right to pursue the invalidity defense in later litigation between the parties . . . depends on whether the underlying cause of action is different from the one brought earlier, which in turn depends on whether the [products in the two cases] are essentially the same, or if any differences between them are merely colorable." *Hallco v. Foster*, 256 F.3d at 1297.

2. *Allergan I* and the Present Case do not Involve the Same "Claim"

Allergan argues that Sandoz's "design around" to remove the indicated use of glaucoma from the label of its product, which is chemically indistinguishable from the product litigated in *Allergan I*, does not make the "claim" different in this case. (Dkt. No. 277 p. 19). Sandoz responds by arguing that because the product at issue "is indicated for a different use by a different patient population as compared to the originally litigated Sandoz ANDA," the "claim" is different in this case. (Dkt. No. 287 p. 19).

The Court is persuaded that the present case involves a different claim than that which was litigated in *Allergan I*. Sandoz's section viii carve out, which omits the words "glaucoma or" from the label, indicates that it is seeking approval from the FDA to "market the generic drug for a different method of use" than the methods of use claimed in Sandoz's proposed ANDA product which was the subject of *Allergan I*. *See Novartis Pharms. Corp. v. Actavis, Inc.*, No. CIV.A. 12-366-RGA, 2012 WL 6212619, at *4 (D. Del. Dec. 5, 2012). The product in *Allergan I* indicated that it was for use in patients with "glaucoma or ocular hypertension." The elimination of one of those methods of use renders this product different from the product that was at issue in *Allergan I*, regardless of the fact that the chemical composition of the two products may be identical. *See Caraco Pharm. Laboratories, Ltd. v. Novo Nordisk A/S*, 132 S.Ct. 1670, 1681–82 (2012). Given that the product at issue is indicated for a different method of use and targeted to a different segment of the marketplace than the *Allergan I* product, the Court is satisfied that the underlying claim for infringement is different from the claim brought in *Allergan I*. *See Hallco v. Foster*, 256 F.3d at 1297. These differences are tangibly real and are more than merely colorable.

For the reasons stated above, the Court finds that claim preclusion does not bar Sandoz's assertion of its § 112 defenses. Accordingly, summary judgment on this issue is improper and the motion should be denied.

C. Invalidity

Since the Court has concluded that Sandoz is not precluded from asserting invalidity of claim 4 of the '149 patent, the Court next addresses the substance of Sandoz's invalidity arguments. Sandoz has moved for summary judgment that claim 4 of the '149 patent is invalid under § 112 for lack of an adequate written description. (Dkt. No. 280). Sandoz argues that claim 4 "covers a vast number of combinations of chemical compounds that the applicants did not invent, describe or disclose." (*Id.* at 1). According to Sandoz, the single disclosed example of a fixed combination formulation is "not representative of all possible formulations of brimonidine and timolol within the scope of claim 4." (*Id.* at 2). Allergan responds, in relevant part, by asserting that there are genuine issues of material fact as to whether the specification supports the genus covered by the "brimonidine" and "timolol" terms. (Dkt. No. 288 p. 11). The Court agrees with Allergan that issues of material fact relating to whether the specification supports the genus covered by "brimonidine" and "timolol" precludes summary judgment.

1. Legal Standard for Written Description

Section 112(a) of the Patent Act provides that "[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. § 112(a). The Federal Circuit has consistently held that this statute sets forth two separate and distinct requirements, known as "enablement" and "written description." *Ariad Pharms., Inc. v. Eli Lilly*

Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010). At issue here is whether Sandoz can carry its burden to demonstrate that there is no genuine issue of material fact that claim 4 of the '149 patent is invalid for lack of written description.

"The test for the sufficiency of the written description 'is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.'" *Vasudevan Software v. MicroStrategy, Inc.*, 782 F.3d 671, 682 (Fed. Cir. 2015) (quoting *Ariad*, 598 F.3d at 1351). "[T]he test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed." *Ariad*, 598 F.3d at 1351. Whether a patent complies with the written description requirement is a question of fact. *Id.* "A party must prove invalidity for lack of written description by clear and convincing evidence." *Vasudevan Software*, 782 F.3d at 682.

"To satisfy the written description requirement for a claimed genus, a specification must describe the claimed invention in such a way that a person of skill in the art would understand that the genus that is being claimed has been invented, not just a species of the genus." *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1124 (Fed. Cir. 2008). This requirement is met when the specification allows one skilled in the art to "visualize or recognize the identity of the members of the genus." *Regents of the Univ. of Cal. v. Eli Lilly Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997). Under Federal Circuit precedent, even a single representative embodiment can support written description of a claimed genus. *See, e.g., Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1073 (Fed. Cir. 2005); *Bilstad v. Wakalopulos*, 386 F.3d 1116, 1125–26 (Fed. Cir. 2004).

2. Sandoz is Unable to Demonstrate That No Genuine Issue of Material Fact Exists With Respect to Its Written Description Defense

In its motion for summary judgment, Sandoz argues that the Court's claim construction of the terms "brimonidine" and "timolol" renders claim 4 broader than the disclosed invention. (Dkt. No. 280 p. 6). Allergan responds by arguing that the parties disagree as to which salt forms of brimonidine and timolol are covered by claim 4 and whether the example in the specification would be representative of the various alleged salt forms of brimonidine and timolol. (Dkt. No. 288 p. 11–15). These disagreements, according to Allergan, constitute genuine disputes of material fact. The Court agrees with Allergan.

Claim 4 of the '149 patent claims a fixed combination of said 0.2% brimonidine by weight and 0.5% timolol by weight in a single composition. Under the Court's claim construction, "brimonidine" means "the chemical compound brimonidine, including both its free base and salt forms," and "timolol" means "the chemical compound timolol, including both its free base and salt forms." (Dkt. No. 241 p. 17, 20). The '149 patent contains one example of a fixed combination formulation of brimonidine and timolol and contains a clinical trial comparing the efficacy of that fixed combination with that of monotherapy with 0.2% brimonidine tartrate. (Dkt. No. 42-5 at 3:40–9:8). Sandoz argues that this is insufficient to satisfy the written description requirement given the broader construction of the terms "brimonidine" and "timolol."

In support of its argument, Sandoz's expert, Dr. Paul Laskar, asserts that "when construed to cover formulations that encompass different chemical forms of the active ingredients," claim 4 of the '149 patent "yields over 300 possible combinations of 0.2% brimonidine and 0.5% timolol." (Dkt. No. 280 at 9; Dkt. No. 280-1 ¶ 25). Dr. Laskar reaches this conclusion by relying on the prior art referenced in the '149 patent. (Dkt. No. 280 p. 9). According to Sandoz, the '149 patent discloses only one of these 300 possible combinations and

thus is invalid for lack of written description. Allergan responds with its own expert, Dr. Timothy Macdonald, who opines that under this Court's claim construction there are only six combinations of brimoninidine/timolol. (Dkt. No. 302 p. 9). Dr. Macdonald opines that there are only two pharmaceutically acceptable forms of brimonidine and three pharmaceutically acceptable forms of timolol, and thus there are only six possible combinations of those pharmaceutically acceptable forms. (*Id.*). This dispute represents a battle of the experts. As a result, there is a genuine dispute of material fact as to which forms of brimonidine and timolol are encompassed within the Court's claim construction.

Furthermore, even if claim 4 of the '149 patent yields over 300 possible combinations of brimonidine and timolol, Allergan maintains that there is still a genuine dispute over whether a person of skill in the art would find the example in the specification to be representative of these combinations. (Dkt. No. 288 p. 15). Relying on the Federal Circuit's decision in *Invitrogen*, Allergan asserts that even a single example can be representative of the hundreds of potential combinations Sandoz claims exist. (*Id.* citing *Invitrogen*, 429 F.3d at 1073). Allergan argues that Sandoz has failed to demonstrate that a person of skill in the art would not believe the example in the specification to be representative of the 17 alleged salts of brimonidine and 18 alleged salts of timolol. (*Id.*). Given that the inquiry into whether a patent complies with the written description requirement is generally a question of fact, the Court agrees that a genuine dispute exists as to whether a person of skill in the art would find the single example in the specification representative of the potential combinations of brimonidine and timolol.

Since the Court finds that there are genuine disputes of material fact as to whether claim 4 of the '149 patent is invalid for lack of written description, summary judgment on the issue of validity is inappropriate and should be denied.

D. Infringement

Allergan moved for summary judgment that that Sandoz's proposed ANDA product infringes claim 4 of the '149 patent because the product "meets every limitation of this claim." (Dkt. No. 277 p. 20). Sandoz moved for summary judgment of non-infringement, arguing both that it does not directly infringe claim 4 of the '149 patent and that it does not induce infringement of claim 4. (Dkt. No. 281 p. 1). The Court finds that as to whether Sandoz has directly infringed claim 4 of the '149 patent, summary judgment is appropriate. However, the Court finds that neither party can carry its burden to demonstrate no genuine issue of material fact exists with respect to the issue of induced infringement, and there summary judgment is appropriate and should be denied.

1. Legal Standard for Infringement

As section 271 of the Patent Act provides, "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent [], infringes the patent." 35 U.S.C. § 271(a). Assessing infringement requires two steps. First, a Court must construe the claims of the patent. *Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 418 F.3d 1326, 1340 (Fed. Cir. 2005). Second, the Court must compare the accused product to the construed claims. *Id.* "When a patentee seeks to block FDA approval of an [ANDA] under 35 U.S.C. § 271(e)(2)(A), the infringement inquiry focuses on the hypothetical infringement that would occur if the defendant's [ANDA] were approved and the defendant began to make and sell the drug." *Novartis Corp. v. Ben Venue Laboratories, Inc.*, 271 F.3d 1043, 1047 (Fed. Cir. 2001).

Section 271 of the Patent Act also sets out a patent owner's right to recover for induced infringement. Subsection (b) provides, "[w]hoever actively induces infringement of a patent shall

be liable as an infringer." 35 U.S.C. § 271(b). "[I]nducement requires that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement." *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006). Since liability under § 271(b) is premised on "purposeful, culpable expression, and conduct," a showing of mere knowledge of potential infringing uses is not sufficient to establish inducement. *MGM Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 937 (2005). In the Hatch-Waxman context, however, a proposed label that instructs users to perform the patented method "may provide evidence of [the ANDA applicant's] affirmative intent to induce infringement." *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010).

2. Summary Judgment of Non-Infringement is Appropriate as to Allergan's Claim for Direct Infringement Because There Is No Summary Judgment Evidence That Sandoz Administers the Accused Product

In its motion for summary judgment of non-infringement, Sandoz argues that because Allergan has produced no evidence that Sandoz will practice the method described in claim 4, Sandoz is entitled to summary judgment of non-infringement with respect to Allergan's claim of literal infringement. (Dkt. No. 281 p. 8). The Court agrees.

Claim 4 of patent '149 reads:

> A method of reducing the number of daily topical ophthalmic doses of brimonidine administered topically to an eye of a person in need thereof for the treatment of glaucoma or ocular hypertension from 3 to 2 times a day without loss of efficacy, wherein the concentration of brimonidine is 0.2% by weight, said method comprising *administering* said 0.2% brimonidine by weight and 0.5% timolol by weight in a single composition.

(Dkt. No. 42-5). The claim language requires the *administration* of a formulation comprising "0.2% brimonidine by weight and 0.5% timolol by weight in a single composition." Indeed, even Allergan recognized at claim construction that the claim required an administration step. (Dkt. No. 241 p. 24). In response to Sandoz's motion for summary judgment of non-infringement,

Allergan failed to produce any evidence that Sandoz has administered the formulation comprising 0.2% brimonindine by weight and 0.5% timolol by weight in a single composition.

Since the Court finds that there is no genuine dispute of material fact as to Allergan's claim for direct infringement and that judgment of non-infringement as to claim 4 of the '149 patent is appropriate and should be granted.

3. Disputes as to Genuine Issues of Material Fact Exist With Respect to Induced Infringement

As the briefing and oral argument presented on August 25, 2016, demonstrate, there are multiple genuine issues of material fact with respect to the issue of induced infringement of claim 4 of the '149 patent. Specifically, there are genuine disputes of material fact with respect to whether both Combigan and Sandoz's proposed ANDA product meet the efficacy limitation contained in claim 4 and whether Sandoz possesses the requisite specific intent to induce infringement.

Claim 4 of the '149 patent requires a formulation comprising 0.2% brimonidine by weight and 0.5% timolol by weight to be administered twice daily "without loss of efficacy" compared to three times daily dosing of 0.2% brimonidine. Sandoz argues that no one can know whether its proposed ANDA product will be sufficiently effective to meet the efficacy requirement for a patient population limited to patients with ocular hypertension. (Dkt. No. 281 p. 12). In support of this argument, Sandoz emphasizes that "none of the Allergan clinical trials involved patients suffering only from ocular hypertension." (*Id.*). Since Allergan's tests did not involve patients suffering only from ocular hypertension, and because Sandoz has conducted no tests of its own, Sandoz argues that there is no evidence that the efficacy requirement has been met.

Allergan counters by pointing to the report of its expert, Dr. Mei Sheng Duh, which Allergan claims demonstrates that "[intraocular pressure ("IOP")] lowering was equivalent for both ocular hypertension and glaucoma patients in Allergan's clinical studies." (Dkt. No. 289 p. 14). Further, Allergan argues that "Sandoz's corporate representative has acknowledged that its identical product will have the same therapeutic efficacy and clinical performance as Combigan." (*Id.*). Allergan also asserts that "Sandoz has represented to the FDA that its product will have equivalent performance to Combigan." (*Id.*). While this may be some evidence, the Court finds that there remains a genuine dispute of material fact as to whether or not Combigan and Sandoz's proposed ANDA product meets claim 4's efficacy requirement.

Additionally, there is a genuine dispute of material fact as to whether Sandoz possesses the requisite knowledge and specific intent to induce infringement. Sandoz argues that nothing about the label of its proposed ANDA product "encourages others to achieve the efficacy requirements, as required by claim 4." (Dkt. No. 281 p. 11). Sandoz also argues that because it lacks the knowledge as to whether its proposed ANDA product meets the efficacy requirement, and also lacks the knowledge as to whether its product infringes, it necessarily lacks the specific intent to induce infringement. (*Id.* at 12). Allergan responds by explaining that "Sandoz's label instructs doctors and patients to use Sandoz's product in an infringing manner" because it instructs them to "perform the claimed method." (Dkt. No. 289 p. 16). According to Allergan, "[n]othing more is required to find that Sandoz has the requisite intent to induce infringement." (*Id.*). Again, the Court concludes that there is a genuine dispute of material fact as to whether Sandoz possess the requisite knowledge and specific intent to induce infringement. Proving intent to the requisite degree necessary for summary judgment is difficult indeed. Here, Allergan falls short.

Since the Court finds that there are genuine disputes of material fact as to Allergan's claim for induced infringement, summary judgment on this issue is improper.

III. CONCLUSION

For the reasons stated above, Allergan's Motion for Summary Judgment (Dkt. No. 277) and Sandoz's Motion for Summary Judgment of Invalidity (Dkt. No. 280) are **DENIED**. However, Sandoz's Motion for Summary Judgment of Non-Infringement (Dkt. No. 281) is **GRANTED-IN-PART** as follows: Sandoz's motion is **GRANTED** with respect to Allergan's claim for direct infringement but is **DENIED** with respect to Allergan's claim for indirect infringement.

So Ordered this
Sep 30, 2016

RODNEY GILSTRAP
UNITED STATES DISTRICT JUDGE