UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Case No. 18-cv-00997-RM-KLM

DUKE UNIVERSITY and
ALLERGAN SALES, LLC,

Plaintiffs,

v.

SANDOZ, INC.,

Defendant and Counterclaim Plaintiff.

FINAL JUDGMENT

Pursuant to Fed. R. Civ. P. 58, Final Judgment is entered as follows:

Plaintiffs Duke University ("Duke") and Allergan Sales, LLC ("Allergan") (collectively, "Plaintiffs") alleged that Defendant Sandoz, Inc. ("Sandoz") infringed Claim 30 of U.S. Patent No. 9,579,270 (the "'270 patent") under 35 U.S.C. §§ 271 (b) and (c) by selling its bimatoprost ophthalmic solution, 0.03% pursuant to its ANDA No. 202791 ("Sandoz Product") in the United States, and that Sandoz's infringement was willful.

Sandoz alleged that Claim 30 of the '270 patent is invalid for obviousness under 35 U.S.C. § 103, invalid for lack of written description under 35 U.S.C. § 112, and invalid for lack of enablement under 35 U.S.C. § 112.

On February 22, 2023, Sandoz stipulated that its sale and offer of sale, within the United States, of its bimatoprost ophthalmic solution, 0.03% pursuant to its ANDA No. 202791 ("Sandoz

Product"), during the term of '270 Patent constituted infringement of claim 30 of the '270 Patent under 35 U.S.C. §§ 271 (b) and (c), unless that claim is found invalid. D.I. 252; *see also* D.I. 287.

On March 27, 2023, the Court held a jury trial.

On March 28, 2023, the Court granted Sandoz's motion for judgment as a matter of law under FED. R. CIV. P. 50(a) as to Plaintiffs' charge of willful infringement.

On March 31, 2023, the jury returned its verdict.

Pursuant to FED. R. CIV. P. 58(b), the Clerk of the Court enters judgment that:

1. Claim 30 of the '270 patent is not invalid for obviousness under 35 U.S.C. § 103.

2. Claim 30 is not invalid for lack of written description under 35 U.S.C. § 112.

3. Claim 30 is not invalid for lack of enablement under 35 U.S.C. § 112.

4. Final judgment is entered against Sandoz on all of Plaintiffs' claims, except that as to willful infringement, final judgment is entered against Plaintiffs.

5. Damages are awarded to Duke in the amount of $1,227,172 and to Allergan in the amount of $37,772,828.

6. Consistent with the parties' agreement, Plaintiffs are awarded prejudgment interest at the weighted average prime rate for the period starting July 1, 2017 and ending on May 8, 2023 at a rate of 4.56%, compounded quarterly. As of May 8, 2023, the prejudgment interest on Allergan's share of the judgment is $11,444,942. As of May 8, 2023, the prejudgment interest on Duke's share of the judgment is $371,826.

7. Plaintiffs are awarded costs incurred in this action, to be taxed by the Clerk of the Court pursuant to Fed. R. Civ. P. 54(d)(1) and D. Colo. L.Civ.R. 54.1 and post-judgment interest pursuant to 28 U.S.C. § 1961.

8. The parties shall pay their own Colorado attorneys' fees incurred in this case.

Dated at Denver, Colorado this 22nd day of May, 2023.

BY THE COURT:
JEFFREY P. COLWELL, CLERK

s/C. Pearson, Deputy Clerk

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Senior Judge Marcia S. Krieger

Civil Action No. 18-cv-00997-MSK-KLM

DUKE UNIVERSITY, and
ALLERGAN SALES, LLC

Plaintiffs,

v.

SANDOZ, INC.,

Defendant.

OPINION AND ORDER DENYING MOTION FOR SUMMARY JUDGMENT AND MOTION TO BIFURCATE

THIS MATTER comes before the Court pursuant to the Plaintiffs' Motion to Bifurcate **(# 42)**, the Defendant's ("Sandoz") response **(# 51)**, and the Plaintiffs' reply **(# 64)**; and Sandoz's Motion for Summary Judgment **(# 47)**, the Plaintiffs' response **(# 68)**, and Sandoz's reply **(# 74)**.[1]

FACTS

The Court summarizes the pertinent facts here and elaborates as necessary in its analysis.

According to the Plaintiffs' Complaint **(# 2)**, Plaintiff Duke University ("Duke") is the owner of U.S. Patent No. 9,579,270 ("the '270 Patent"), covering "Methods for Treating Hair Loss Using Non-Naturally Occurring Prostaglandins." Duke has licensed its rights under the '270 Patent to Plaintiff Allergan Sales, LLC ("Allergan"). Allergan markets a product based on

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[1] Also pending is a motion **(# 43)** by the Plaintiffs seeking expedited consideration of the Motion to Bifurcate. Because this Order resolves the Motion to Bifurcate, the motion to expedite is denied as moot.

the '270 Patent under the brand name Latisse. Sandoz manufactures and markets its own product, a generic version of Latisse, which the Plaintiffs allege infringes on Claims 22 and 30 of the '270 Patent. Based on these facts, the Plaintiffs assert claims for induced and contributory patent infringement. Sandoz has asserted several counterclaims, some of which allege that the Plaintiffs have engaged in anticompetitive by filing previous patent infringement lawsuits, and another of which alleges patent misuse.[2]

The Plaintiffs now move **(# 42)** to bifurcate Sandoz's antitrust and patent misuse counterclaims from the patent infringement claims to stay this matter as to those counterclaims until the infringement issues have been resolved.

Separately, Sandoz moves **(# 47)** for summary judgment on all of the Plaintiffs' infringement claims, contending that those claims are precluded under the doctrine of collateral estoppel, arising from rulings made in prior infringement lawsuits between the parties.

ANALYSIS

A. Motion for Summary Judgment

To adequately address Sandoz's collateral estoppel motion, it is necessary to discuss, in some detail, the '270 Patent, its predecessors, and the history preceding this litigation. The '270 Patent describes a method for growing hair by topically applying a chemical compound known

[2] The Court notes that, although the parties engaged in considerable litigation in the Eastern District of Texas before this case was transferred here, it does not appear that Sandoz's Answer and Counterclaims appear on the docket of this action. (Nor, for that matter, do any other pertinent filings during this case's lifespan in the Eastern District of Texas.) Within 7 days of the date of this Order, the parties shall file in this Court: (i) a full docket sheet from Case No. 2:17-cv-00528-JRG in the Eastern District of Texas, from commencement of that action through the April 3, 2018 Order transferring the case; (ii) copies of all pleadings pertinent to this action that were filed in the Eastern District of Texas prior to transfer of this case; and (ii) copies of all Orders issued by the Eastern District of Texas concerning substantive matters pertinent to this action.

as a prostaglandin. Prostaglandins are molecules that bind to certain receptors on cells in a living body and change how such cells function. The human body produces a variety of prostaglandins; the general type at issue here is known as prostaglandin F or PGF. Within the general category of PGF are many variants, some naturally-occurring and some synthesized. These variants are referred to as PGF analogs. Analogs differ from one another by virtue of various molecules that can attach to base structure of the prostaglandin and which change its pharmacological properties. For example, the prostaglandin is much like a charm bracelet to which different charms can be attached at different points.

PGF analogs were the subject of research in the 1980s as a treatment for glaucoma (among other things), and by the end of the 1990s, several inventors had obtained patents covering the use of PGF analogs for glaucoma treatment. Most notably, Dr. Murray Johnstone obtained a patent for treating glaucoma via eyedrops containing a PGF analog that described using various esters, carboxylic acids, or other molecules at the "C1 location"[3] (*i.e.* a specific type of charm at a specific location on the charm bracelet), that caused the prostaglandin to bind with cells at a site called the FP receptor. Among the things Dr. Johnstone also noticed and reported in his patent application was that when the eyedrops came in contact with the skin of the eyelid – that is, when the drug was applied topically – some patients experienced increased growth and thickening of the eyelashes as a side effect. Shortly thereafter, Allergan had obtained a patent ("the '819 patent") for a glaucoma treatment that differed from Johnstone's, in that Allergan's method disclosed an amide group, rather than an acid or ester, at the C1 location. The compound in the '819 patent is known as "bimatoprost." The '819 patent did not make any

[3] The patents seem to refer to this location as R1, rather than C1. Because the *Latisse* cases use the C1 label, this Court will follow suit.

mention of topical application of bimatoprost to the skin, nor did it indicate that hair growth was a possible side effect.

Eventually, inventors realized the commercial potential of using PGF analogs to stimulate eyelash growth for cosmetic purposes. This triggered another round of patent applications specifically directed at using PGF analogs for hair growth purposes, rather than as a glaucoma treatment. Duke's assignor obtained U.S. Patent Nos. 7,388,029 ("the '029 patent") – the predecessor to the '270 Patent at issue here – and Allergan obtained another patent, both of which covered topical application of bimatoprost (among others) for the purpose of growing hair. On the strength of these patents, Allergan began marketing a bimatoprost solution for eyelash growth under the brand name Latisse. When several manufacturers obtained approval to market generic competitors to Latisse, Allergan filed the first of several patent infringement suits.

In the first suit, which the parties refer to as *Latisse I*, Allergan sued the generic drugs' manufacturers, including Sandoz, for infringement of various claims of the '029 patent. The trial court in *Latisse I* made numerous findings, but the one most germane to the dispute here concerned the generic manufacturers' arguments that the combination of the then-existing teachings of Johnstone (that topical application of PGF analogs used to treat glaucoma are known to cause eyelash growth) and the '819 patent (that bimatoprost is type of PGF analog that can effectively be used to treat glaucoma) would have allowed a person of ordinary skill in the art to reach the conclusions of the '029 patent (that topical application of bimatoprost would be an effective method to stimulate eyelash growth), such that the '029 patent would be deemed invalid as obvious.[4] *Allergan, Inc. v. Apotex, Inc.*, 2013 WL 286251 (M.D.N.C. Jan. 24, 2013).

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[4] A claim is not patentable if the differences between its teachings and the prior art are such that the subject matter as a whole would have been obvious to one with ordinary skill in the art at the time of the invention. *Ohio Willow Wood Co. v. Alps South, LLC*, 735 F.3d 1333, 1343

That trial court found that Johnstone and the '819 patent "are too limited and different from the '029 claims to make obvious the hair growth properties of the '029 compounds". The court noted that Johnstone's hair-growing compounds did not have an amide group at C1 like the '029 patent's compounds did. It further found that the '819 patent, which did disclose compounds with an amide group at C1, "does not supply the missing link" because, at the time, "C1 acids were thought to be required for activity at the FP receptor [to produce hair growth], and bimatoprost has an amide rather than an acid at the C1 position." The court stated that "bimatoprost was thought to exert activity on a receptor other than the FP receptor, and therefore was distinguishable from the Johnstone compounds."[5] The court pointed out that there were three PGF analogs being marketed as glaucoma treatments at the time, and each of the three had different hair growth side effects, with some promoting hair growth and others inhibiting it. Thus, the court found, "a person of skill in the art would not have reason to use bimatoprost as a topical hair growth agent based on bimatoprost's identity as a prostaglandin analog alone." (The court also found that objective considerations – most significantly the "unpredictable" nature of hair growth stimulators and Latisse's success and status as the only drug approved for eyelash growth – also weighed against a conclusion that the '029 patent's claims were obvious in light of Johnstone and the '819 patent.)

On appeal, the Federal Circuit reversed, holding that the asserted claims in the '029 patent were invalid as obvious. *Allergan, Inc. v. Apotex, Inc.*, 754 F.3d 952, 961 (Fed. Cir.

(Fed. Cir. 2013). The obviousness inquiry requires the court to determine: (i) the scope and content of the prior art, (ii) the differences between the prior art and the claims at issue, (iii) the level of ordinary skill in the art, and (iv) objective considerations, such as commercial success, long-felt but unresolved need, and the failure of others. *Id.*; *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1347 (Fed. Cir. 2012).

[5] *See infra.*

2014). The Federal Circuit criticized the trial court for "looking only at properties of the C1-amide group and, particularly, bimatoprost." "In doing so," the court explained, the district court "fail[ed] to take into account the full scope of the '029 patent claims," which were "not limited to compounds with a C1-amide group [but] encompasses thousands of permutations of PGF analogs, including structures with all kinds of functional groups at the C1 location, such as" acids and esters. Because the '029 patent claimed such a broad array of possible compounds, the court explained that the generic manufacturers "did not have the exacting burden of showing a reasonable expectation of success in using the narrow class of PGF analogs with C1-amide groups to treat hair loss, let along a reasonable expectation of success in using bimatoprost in particular." Rather, the manufacturers "had the burden of showing that any compounds within the broad genus claimed by the '029 patent, including those that did not have C1-amide groups, were obvious at the time of the invention."

The court went on to explain that this reasoning was "especially problematic" because the trial court had relied upon a "feature" unique to bimatoprost – it and other PGF analogs with an amide group at C1 would bind to a variant of the FP receptor found in some cells, not the "garden variety" FP receptor.[6] Although the court noted that the vast majority of the compounds disclosed in the '029 patent were those that bound to the normal FP receptor, the court noted that "Johnstone does not [ ] teach away from compounds that bind variant forms of the FP receptor." "On the contrary," the court explained, "Johnstone even provides an alternative preference for the PGF analogs that were known to have different FP receptor binding properties."

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[6] The district court's opinion does not appear to discuss "variant" FP receptors at all. This Court assumes that the district court's reference to bimatoprost activating something "other than the FP receptor" might be what the Federal Circuit's "variant FP receptor" discussion is referencing.

The court rejected a contention that "the '029 patent represents compounds that are newly isolated or synthesized over those of Johnstone," explaining that "Johnstone taught squarely towards a new utility of a finite set of already identified and isolated compounds with properties that had already been characterized" (such as in the '819 patent). Thus, explained the court "following Johnstone, there was nothing left of a chemist to do" in order to create any new compounds that would stimulate eyelash growth; all that was necessary was to appreciate the use to which the existing compounds described in Johnstone and the '819 patent could be put.

Finally, the court also rejected the district court's findings that objective considerations, such as the "unpredictable" nature of hair growth treatments weigh against a finding of obviousness. The court found that the district court incorrectly assessed the difficulty of creating an effective hair-growing drug by considering a time before Johnstone's findings were reported; once Johnstone disclosed its findings, "the general characteristics of the hair growth art ceased to be relevant [because] Johnstone taught that . . . PGF analogs that were effective glaucoma drugs could grow hair." Thus, the Federal Circuit held that the asserted claims in the '029 patent were invalid as obvious.[7]

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[7] *Latisse I* was not the only litigation involving these parties and this family of patents (although it is the only substantive ruling implicated by Sandoz's current arguments based on collateral estoppel). During the pendency of *Latisse I*, Allergan obtained patents that derived from the '029 patent and it commenced a new infringement suit (*Latisse II*) against the generic manufacturers based on those new patents. After the Federal Circuit's ruling in *Latisse I*, the manufacturers argued in *Latisse II* that the rulings in *Latisse I* operated to collaterally estop Allergan from asserting claims based on the new patents. The district court agreed and dismissed the *Latisse II* claims on collateral estoppel grounds. Allergan did not appeal.

Allergan then obtained yet another new set of patents derived from the '029 patent and commenced a third suit against the generic manufacturers (*Latisse III*). The trial court again applied collateral estoppel from *Latisse I* and dismissed the new claims, and the Federal Circuit affirmed that dismissal. *Allergan, Inc. v. Sandoz, Inc.*, 681 Fed.Appx. 955 (Fed. Cir. 2017) (*Latisse III*).

Allergan then sought to address the ruling in *Latisse I* by narrowing the scope of the '029 patent to claim only those PGF analogs that have a C1-amide group. The Patent Office granted Allergan's request, with the result being the instant '270 patent, on which Duke and Allergan now sue.

Here, Sandoz argues that Claims 22 and 30 of the '270 patent – the claims at issue here -- are substantially identical to the claims under the '029 patent at issue in *Latisse 1*. Sandoz argues that because the Federal Circuit found those claims to be invalid due to obviousness, this Court should apply the doctrine of collateral estoppel to determine obviousness and thus enter judgment in Sandoz's favor. In response, the Plaintiffs argue that the Federal Circuit's invalidation of the '029 patent was the result of that patent's breadth and the fact that it encompassed some of the same compounds that Johnstone taught, but it did not address bimatoprost, in particular. Thus, the Plaintiffs argue, the Federal Circuit's broader ruling invaliding the '029 patent does not necessarily compel the invalidation of the narrower '270 patent here.

The principles governing collateral estoppel are set forth in *Latisse III*. *Allergan, Inc. v. Sandoz, Inc.*, 681 Fed.Appx. 955 (Fed. Cir. 2017) Sandoz has the burden of showing: (i) that the issue to which preclusion is sought – whether the invention asserted in Claims 22 and 30 of the '270 patent is obvious in light of Johnstone and the '819 patent – is identical to the issue litigated in *Latisse I*; (ii) that the issue was actually determined in the prior proceeding; (iii) that the issue's determination was a critical and necessary part of the decision in the prior proceeding; (iv) that the prior judgment is final and valid; and (v) the party to be estopped had a full and fair opportunity to litigate the issue in the prior action. 681 Fed.Appx. at 959. On the first element, complete identity of the issues is not required; patent claims that use slightly different language

to describe substantially the same invention can satisfy this element if the differences between them do not materially alter the question of invalidity. *Id.* at 959-60.

Before turning to the issues, this Court pauses to note that it is not intending to, and should not be understood to, revisit the Federal Circuit's findings in *Latisse I*. Whether the Circuit Court's rulings in *Latisse I* are sound, consistent with then-existing law, or supported by the then-existing record are questions that are not before this Court today. Rather, this Court must assume that the Federal Circuit's *Latisse I* ruling was correct in both law and fact. The question for this Court is whether the obviousness issue determined in *Latisse I* is substantially the same as the issue raised by Sandoz here.

The fundamental issue determined by the Federal Circuit in *Latisse I* was whether certain claims in the '029 patent were invalidated as obvious due to a combination of the teachings of Johnstone and the '819 patent. There is no material dispute here that the claims in the current patent – the '270 patent – describe a narrower, but otherwise identical, subset of the claims in the '029 patent. In other words, both the '029 patent and the current '270 patent claim: (i) topical application, (ii) of a PGF analog, (iii) for the purpose of stimulating eyelash growth, but whereas the '029 patent described roughly a dozen possible molecules that could be placed at the C1 location – including carboxylic acid, an ester, an amide group, and so on -- the '270 patent is specific that that location can only be occupied by an amide group.

The difference in scope between the patents undercuts any argument that *Latisse I* resolved the same issue presented here. *Latisse I*'s analysis notes that the trial court considered the question of obviousness of the '029 patent only in the context of bimatoprost and concluded that the combination of Johnstone and the '819 patent did not render the use of bimatoprost as a hair growth agent obvious. The Federal Circuit disagreed, but not because it concluded that the

prior art made the use of bimatoprost obvious. Rather, the Circuit Court reversed because the '029 patent was so broad that *other* compounds it described were obvious extensions of the prior art. 754 F.3d at 962. On several occasions, the Circuit Court makes clear that it was not finding that a hair-growth claim limited to the use of bimatoprost would be considered obvious in light of Johnstone and the '819 patent. *See* 754 F.3d at 962 n. 4 ("the appellants' obviousness arguments regarding the '029 patent were [not] limited to the obviousness of bimatoprost"); at 963 (characterizing the generic manufacturer's hypothetical burden of proving obviousness based solely on bimatoprost would be "exacting" if not worse, compared to the relatively easy burden of challenging the broad '029 patent); at n. 8 (conceding that Johnstone's teachings towards "the vasodilatory compounds taught in the parent of the '819 patent" would not include bimatoprost); at 966 (suggesting that the district court's findings regarding bimatoprost's effect "is not relevant to the '029 patent's actual claimed invention," due to that patent's breadth). Without a clear indication that the Federal Circuit was specifically deciding that a claim based narrowly on the use of only bimatoprost would be invalidated as obvious by Johnstone and the '819 patent, this Court cannot conclude that the question of whether the narrow '270 patent was necessarily decided by the Federal Circuit's analysis of the broad '029 patent in *Latisse I*.[8]

Accordingly, because the Court does not find that the particular obviousness issues Sandoz raises here with regard to the '270 patent were necessarily decided by the Federal Circuit in the context of the '029 patent in *Latisse I*, the Court finds that Sandoz has not carried its

[8] This is not to say that the '270 patent will necessarily survive an obviousness challenge in this case. Portions of *Latisse I*'s obviousness analysis sweep fairly broadly, making the "gap" that must be bridged between Johnstone and the '819 patent fairly thin. And *Latisse I*'s finding that Johnstone teaches towards the use of PGF analogs that bind to the variant FP receptor narrow that gap even more. But because the question of obviousness itself is not yet before this Court, the Court need not make any findings on that point at this time.

burden of showing that the Plaintiffs are collaterally estopped by the *Latisse I* ruling. Sandoz's Motion for Summary Judgment is therefore denied.

B. Motion to bifurcate

The Plaintiffs move **(# 42)** to bifurcate Sandoz's counterclaims sounding in anticompetitive behavior and patent misuse, arguing that discovery and trial relating to those counterclaims should be stayed until the Plaintiffs' infringement claims are resolved. Although Sandoz initially opposed this motion, the parties subsequently entered into a Joint Motion to Bifurcate and Stay Discovery **(# 76)** regarding Sandoz's counterclaims, which this Court referred to the Magistrate Judge and the Magistrate Judge granted **(# 90)**. As a result, the instant Motion to Bifurcate has been rendered moot, and the Court denies it as such.

CONCLUSION

For the foregoing reasons, the Plaintiffs' Motion to Bifurcate **(# 42)** and Plaintiffs' Motion to Expedite **(# 43)** consideration of the Motion to Bifurcate are **DENIED AS MOOT**. Sandoz's Motion for Summary Judgment **(# 47)** is **DENIED**.

Dated this 18th day of September, 2019.

BY THE COURT:

Marcia S. Krieger

Marcia S. Krieger
Senior United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Judge Raymond P. Moore

Civil Action No. 18-cv-00997-RM-KLM

DUKE UNIVERSITY,
ALLERGAN SALES, LLC, and
ALLERGAN, INC.,

Plaintiff (except Allergan, Inc.) and
Counterclaim Defendants,

v.

SANDOZ, INC.,

Defendant and Counterclaim Plaintiff.

AMENDED ORDER

This matter is before the Court on the Parties' Motions in Limine to preclude certain categories of evidence and argument. Defendant Sandoz, Inc. ("Sandoz") filed its Motion in Limine No. 1—Issue Preclusion Binds Plaintiffs to a Subset of Findings About the Prior Art and Limits the Scope of Trial. (ECF No. 173.) Plaintiffs Duke University, Allergan Sales, LLC, and Allergan, Inc. ("Allergan") filed a Motion in Limine to Exclude Sandoz's Evidence Concerning Prior Litigations (ECF No. 174) and a Motion in Limine to Exclude Sandoz's Evidence of Intent at Trial (ECF No. 175). The Parties filed responses in opposition to each Motion (ECF Nos. 179, 180, 181) and replies in support of each Motion (ECF Nos. 184, 185, 186). The Court held oral arguments on all three motions on October 4, 2022. (ECF No. 198.) The Motions have now been fully briefed, and having considered the arguments of the parties, the exhibits submitted, and the pertinent case law, the Court now finds and orders as follows.

I. BACKGROUND

This case represents the fourth round of litigation between Allergan and Sandoz over a line of patents for Allergan's product, Latisse, which is used to treat hypotrichosis, a condition characterized by having an inadequate number of eyelashes. The patent at issue in this case is United States Patent No. 9,579,270 (the "'270 patent") which is entitled "Compositions and methods for treating hair loss using non-naturally occurring prostaglandins." (ECF No. 2-3, p.1.) This line of patents stretches back to 2001, and the application claims priority to an application filed in 2000. (ECF No. 166, p.18.) The patent was assigned to Duke University, which licensed the patent to Allergan Sales, LLC. (ECF No. 111, p.1.)

Latisse comprises an ophthalmic solution made with 0.03% bimatoprost, and Allergan received approval to sell it from the United States Food and Drug Administration ("FDA") in December of 2008. Sandoz makes and sells a generic version of the product, which Allergan asserts infringes on two of the '270 patent's claims, specifically claims 22 and 30. (ECF No. 166, pp.18-19.)

Allergan has sued Sandoz, along with other manufacturers of similar generic products, over this question three times before. *See Allergan, Inv. v. Apotex, Inc.*, 754 F.3d 952 (Fed. Cir. 2014) ("*Latisse I*"); *Allergan, Inc. v. Apotex, Inc.* Nos. 1:12-cv-247, 1:13-cv-16 (M.D.N.C. Jan. 14, 2015) ("*Latisse II*"); *Allergan, Inc. v. Sandoz, Inc.*, 681 F. App'x 955 (Fed. Cir. 2017) ("*Latisse III*"). To understand the current litigation, it is useful to review a brief history of this prior litigation.

In *Latisse I*, Allergan asserted that the generic manufacturers had infringed on a prior patent in this line, United States Patent Number 7,388,029 (the "'029 patent"), which addressed the treatment of hair. Sandoz and the other defendants argued that the claims in the '029 patent

were obvious based on the prior art, specifically, United States Patent Number 5,688,819 (the "'819 patent"), and a patent application, International Patent Application Number PCT/US98/02289 ("Johnstone"). The '819 patent "discloses the use of a set of selective PGF analogs, including bimatoprost," which can be used to treat glaucoma with minimal side effects. *Latisse I*, 754 F.3d at 962. Notably, bimatoprost is a type of amide. *Id.* Johnstone, on the other hand, disclosed that certain PGF analog compounds with esters or carboxylic acids (as opposed to amides) could be used to promote hair growth. *Id.* at 958, 962.

The *Latisse I* trial court concluded that the '029 patent's claims were not obvious, but a division of the Federal Circuit reversed. *Id.* at 966. The Federal Circuit noted that the "scope of the independent claims of the '029 patent encompasses thousands of permutations of PGF analogs," including carboxylic acids, alkyl carboxylates, hydroxyls, and esters, which could be used to treat hair loss. *Id.* at 962-63. Thus, it included more substances than just bimatoprost, and therefore the defendants were not required to prove that using bimatoprost, specifically, to treat hair loss was obvious based on the prior art. *Id.* at 963. Rather, they need only show "that any compounds within the broad genus claimed by the '029 patent . . . were obvious at the time of the invention." *Id.* The Court held that the defendants had met that burden, noting that the facts supported a conclusion that "a person of ordinary skill" would have a "substantial reasonable expectation of success and motivation to use PGF analogs with high pharmacological activity and structures similar to those disclosed in Johnstone to treat hair loss." *Id.* at 966. Thus, the '029 patent was invalid. *Id.* at 970.

In *Latisse II*, Allergan again brought claims of infringement on new patents in the same line. 1:12-cv-247, 1:13-cv-16 (M.D.N.C. Jan. 14, 2015) (ECF Nos. 1, 6, 55). Following the Circuit's decision in *Latisse I*, the defendants moved for judgment on the pleadings and to

dismiss, arguing that Allergan was collaterally estopped from asserting its new patents against the defendants because they "claim priority to, and the same subject matter as," the patent held invalid in *Latisse I*. *Id.* (ECF Nos. 103, 104). The trial court agreed and entered judgment in favor of the defendants, concluding that Allergan was collaterally estopped from asserting that line of patents against the defendants. *Id.* (ECF No. 114). Allergan did not appeal.

Allergan then once again filed new patents to cover the use of bimatoprost to grow eyelashes. *Latisse III*, 681 F. App'x at 957. Allergan then filed suit again against Sandoz and other defendants, and Sandoz again moved to dismiss based on collateral estoppel. *Id.* at 958. The district court granted the motion and Allergan appealed to the Federal Circuit. *Id.* at 958-59. The Circuit affirmed, concluding that the asserted claims at issue were "substantially similar" to the patents that had already been invalidated. *Id.* at 960.

Allergan filed the application for the patent at issue in this case in 2015 and the patent issued in February of 2017. (ECF Nos. 2-2, 2-3.) Sandoz received FDA approval to sell its generic version in April of 2016. (ECF No. 166, p.20.) In 2017, Allergan again filed suit against Sandoz and another defendant, this time in the Eastern District of Texas. (ECF No. 2.) That Court ultimately severed Sandoz from the other defendant and transferred the Sandoz portion of the case to this District. (ECF No. 1.)

As pertinent here, the Parties litigated a Motion for Summary Judgment before Judge Krieger. Sandoz asserted that Allergan's claims were barred by collateral estoppel, already having been resolved in *Latisse I*. (ECF No. 47.) Judge Krieger disagreed, concluding that, while the '270 patent might not ultimately survive an obviousness challenge, summary judgment was not appropriate on the basis argued by Sandoz. (ECF No. 111, p.10.) The case was ultimately transferred from Judge Krieger to this Court, and it has now been set for trial.

The Parties requested, and the Court granted, accelerated deadlines to file the three Motions in Limine now before the Court. (ECF No. 169.) The three Motions in Limine are now fully briefed and ripe for resolution.

II. LEGAL STANDARDS

A. Issue Preclusion

"Once a court has decided an issue, it is forever settled as between the parties." *B & B Hardware, Inc. v. Hargis Indus., Inc.*, 575 U.S. 138, 147 (2015) (quotation marks and citation omitted). "[A] losing litigant deserves no rematch after a defeat fairly suffered." *Id.* (quotation marks and citation omitted). Specifically, issue preclusion bars successive litigation of an issue of law or fact when "(1) the issue previously decided is identical to the present one; (2) the prior action was finally adjudicated on the merits; (3) the party against whom the doctrine is invoked was a party or in privity with a party to the previous adjudication; … (4) the party against whom the doctrine is raised had a full and fair opportunity to litigate the issue in the previous adjudication"; and (5) the litigated issue is essential to the judgment. *Keller Tank Servs. II, Inc. v. Comm'r of Internal Revenue*, 854 F.3d 1178, 1193 (10th Cir. 2017); *B & B Hardware, Inc.*, 575 U.S. at 148 (identifying factors (1), (2), and (5)).

B. Relevance and Prejudice

"The threshold inquiry in any dispute over the admissibility of evidence is whether the evidence is relevant." *Smith v. Ingersoll-Rand Co.*, 214 F.3d 1235, 1246 (10th Cir. 2000). In assessing the relevance of proffered testimony, the Court considers whether the evidence has "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401. This assessment depends on whether the proffered evidence has a sufficient logical

relationship to the issue at hand to aid the trier of fact. *Bitler v. A.O. Smith Corp.*, 400 F.3d 1227, 1234 (10th Cir. 2005) ("Evidence appropriate for one purpose, therefore, may not be relevant for a different purpose, and it is the trial court's task to make this fitness determination."). Even relevant evidence may be excluded "if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusion the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. "The proponent bears the burden of establishing admissibility." *U.S. Aviation Underwriters, Inc. v. Pilatus Bus. Aircraft, Ltd.*, 582 F.3d 1131, 1149 (10th Cir. 2009).

III. ANALYSIS

A. Sandoz's Motion in Limine No. 1—Issue Preclusion

In its only Motion in Limine, Sandoz asks the Court to "apply issue preclusion and prevent Allergan from introducing evidence and arguments that are inconsistent with and intended to disturb the Federal Circuit's prior factual findings about the prior art." (ECF No. 173.) Sandoz asserts that the Federal Circuit made four "factual findings" which this Court should adopt and to which Allergan should be bound. Specifically, Sandoz asks the Court to adopt the following findings:

> Finding 1 (content of '819 patent): The 819 patent discloses thirteen PGF analogs, including bimatoprost, that could treat glaucoma with minimal side effects.
>
> Finding 2 (content of Johnstone): Johnstone discloses using PGF analogs that could treat glaucoma with minimal side effects to grow hair, including eyelashes.
>
> Finding 3 (motivation and expectation of success): A person of ordinary skill in the art would be motivated to use the PGF analogs of the '819 patent to grow hair as taught by Johnstone, and would have a reasonable expectation of success, irrespective of whether the analogs bind to the FP receptor or a variant receptor.
>
> Finding 4 (expectation of success; predictability): At the time of the invention of the '270 patent, it was not unpredictable to use PGF analogs that could treat

glaucoma with minimal side effects to grow hair.

(ECF No. 173, pp. 3-4.) Allergan opposes the Motion and objects to the Court's application of issue preclusion as to any of these statements. (ECF No. 180.) Allergan also asserts that Judge Krieger previously resolved this question in her Order on Sandoz's Motion for Summary Judgment, and that Sandoz is seeking a second bite at the apple.

1. Law of the Case

As an initial matter, the Court addresses Allergan's argument that Judge Krieger already considered and rejected the merits of Sandoz's four factual findings. (ECF No. 180, pp.1, 6-9.) In brief, the Court disagrees. In its Motion for Summary Judgment, Sandoz asserted that this case, like *Latisse II and Latisse III*, should be barred by collateral estoppel. (ECF No. 47.) Sandoz asserted that the essential issue in this case, whether topical application of bimatoprost for eyelash growth is obvious, was already decided by the Federal Circuit in *Latisse I*. (ECF No. 47, p.2.) Judge Krieger disagreed, concluding that the scope of the claims in the '029 patent, which was at issue in *Latisse I*, were broader than those in the '270 patent, at issue here. (ECF No. 111.) She noted that the Circuit in *Latisse I* did not invalidate the '029 patent because it concluded that the use of bimatoprost was obvious. (ECF No. 111, pp.9-10.) "Rather, the Circuit Court reversed because the '029 patent was so broad that *other* compounds it described were obvious extensions of the prior art." (ECF No. 111, p.10, emphasis original.) Judge Krieger concluded that, "[w]ithout a clear indication that the Federal Circuit was specifically deciding that a claim based narrowly on the use of only bimatoprost would be invalidated as obvious by Johnstone and the '819 patent," she could not conclude that the obviousness of the "narrow '270 patent was necessarily decided by the Federal Circuit's analysis of the broad '029 patent in *Latisse I*." (ECF No. 111, p.10.)

The Court concludes that Judge Krieger's Order addressed only the claims contained in the '029 patent as compared to those contained in the '270 patent. In contrast, Sandoz's Motion in Limine asks this Court to apply issue preclusion to the scope of the prior art at issue, and to certain elements of the obviousness analysis regarding the invention at issue here. Thus, Judge Krieger did not address the issue raised here and law of the case does not preclude this Court from evaluating Sandoz's Motion on the merits.

2. Finding 1

With regard to Finding 1, Allergan argues that the request is moot because the issue is undisputed. Sandoz responds that, despite their request, Allergan declined to stipulate to the fact. (ECF No. 184.) At the hearing on the Motion, Allergan explained that its concern is that, if the Court applies issue preclusion as to Finding 1, Sandoz will seek to prevent Allergan from elaborating further about the additional teachings that can be found in the '819 patent. (ECF No. 202, p. 47.)

The Court concludes that Finding 1 meets the elements of issue preclusion. First, the issue here—the teaching of the '819 patent—is identical to that decided by the District Court and affirmed by the Federal Circuit in *Latisse I*. 754 F.3d at 962. The Federal Circuit stated "the '819 patent discloses a list of thirteen chemical compositions for 17-phenyl PGF analogs, which were like those disclosed in Johnstone in that they contain a C5-C6 double bond and have demonstrably high pharmaceutical activity in treating intraocular pressure with minimal side effects." *Id.* In other words, it discloses thirteen PGF analogs which can be used to treat glaucoma with minimal side effects. The Federal Circuit also noted that the PGF analogs disclosed by the '819 patent include bimatoprost, "which is specifically identified by its chemical structure" in that patent. *Id.* at 960.

Allergan does not dispute that *Latisse I* was finally adjudicated on the merits, that Allergan was a party to that prior action, or that it had a full and fair opportunity to litigate the issue. Finally, this fact was clearly essential to the Federal Circuit's decision in that it had been asked to determine whether the '029 patent was obvious in light of the '819 patent and the Johnstone patent. *Id.* at 961. In determining whether a patent's claims are obvious in light of prior art, the Court will consider "(i) the scope and content of the prior art; (ii) the differences between the prior art and the claims at issue; (iii) the level of ordinary skill in the field of the invention; and (iv) relevant secondary considerations including commercial success, long-felt but unsolved needs, failure of others, and unexpected results." *Id.* (citing *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966)). Finding 1 is a statement regarding the content of the prior art, and therefore was a necessary component of the Federal Circuit's analysis.

Thus, the Court concludes that issue preclusion can properly be applied with regard to Finding 1. Therefore, the Court GRANTS Sandoz's Motion in Limine as to Finding 1. The Court notes, however, that the designated fact in Finding 1 was not the only finding cited by the Federal Circuit with regard to the content of the '819 patent. For example, that court also stated that "the '819 patent's compounds contain a C1-amide group whereas Johnstone generally discloses compounds with esters or carboxylic acids at the C1 location." *Id.* at 962. While Allergan will not be permitted to introduce evidence or make argument that contradicts Finding 1, the Court will not preclude it from introducing evidence or making arguments about the other teachings of the '819 patent.

3. Finding 2

Allergan asserts that Finding 2 is "an inaccurate and incomplete characterization of Johnstone and how the Federal Circuit described it . . . ." (ECF No. 180, p.10.) Sandoz responds

that Finding 2 "is reproduced almost word-for-word from the Federal Circuit's decision in *Latisse I*." (ECF No. 184, p.9.) As Sandoz accurately quotes, the Court in *Latisse I* concluded that "Johnstone taught that PGF analogs could be used to grow hair. Indeed, Johnstone even more specifically taught that PGF analogs that were effective glaucoma drugs could grow hair." *Latisse I*, 754 F.3d at 965. Allergan is also correct, however, that the Federal Circuit also made note that "Johnstone generally discloses compounds with esters or carboxylic acids at the C1 location." The opinion went on to point out that "Johnstone did not make a general exhortation covering thousands of possibilities—its teaching focused on specific classes of compositions of PGF analogs with specifically described structures and properties . . . ." *Id.*

For the same reasons discussed with respect to Finding 1, the Court concludes that the elements of issue preclusion have been met with regard to Finding 2 except that the Court also agrees with Allergan that, as phrased, Sandoz somewhat overstates the conclusion of the Federal Circuit. The Court, therefore, GRANTS IN PART Sandoz's Motion in Limine regarding Finding 2. The Court concludes that the proper phrasing of the finding is as follows: "Johnstone discloses using PGF analogs with esters or carboxylic acids at the C1 location, which could be used to treat glaucoma with minimal side effects, could be used to grow hair, including eyelashes."

4. Findings 3 and 4

The next two Findings that Sandoz asks the Court to adopt are related, as are Allergan's responses. The Court will therefore discuss them together. In making a determination of obviousness, and applying the so-called *Graham* factors, as previously noted, one of the questions before the fact finder is the scope and content of the prior art. Part of the determination of that scope and content turns on two questions: "[1] whether a person of

ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and [2] whether there would have been a reasonable expectation of success in doing so." *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006). The "suggestion test," as the Federal Circuit has called its "motivation-to-combine inquiry," requires that the obviousness of an invention be determined without hindsight. *Id.* at 1360-61. "The motivation to combine references can not come from the invention itself." *Heidelberger Druckmaschinen AG v. Hantscho Com. Prod., Inc.*, 21 F.3d 1068, 1072 (Fed. Cir. 1994). Put another way, "[t]here must be some reason, suggestion, or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the combination. That knowledge can not come from the applicant's invention itself." *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992).

Similarly, a "reasonable expectation of success" must be judged from the perspective of one skilled in the art "at the time the invention was made . . . ." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1367 (Fed. Cir. 2007). However, "[t]his requires 'identify[ing] a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.'" *Adapt Pharma Operations Ltd. v. Teva Pharms. USA, Inc.*, 25 F.4th 1354, 1365 (Fed. Cir. 2022) (quoting *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007)). Thus, "[t]he reasonable-expectation-of-success analysis must be tied to the scope of the claimed invention." *Teva Pharms. USA, Inc. v. Corcept Therapeutics, Inc.*, 18 F.4th 1377, 1381 (Fed. Cir. 2021). In fact, as the Court stated in *Latisse I*, "failure to consider the appropriate scope of the . . . patent's claimed invention in evaluating the reasonable expectation of success and secondary considerations constitutes a legal error." *Latisse I*, 754 F.3d at 966. While the party asserting a patent's invalidity does not have to prove "[a]bsolute predictability,"

it does have to "prove a reasonable expectation of success in achieving the specific invention claimed." *Teva Pharms. USA*, 18 F.4th at 1381.

The parties disagree about the extent to which these inquiries can reference the claims at issue—that is to say, Allergan asserts that the question at issue in this case, which was not at issue in *Latisse I*, is whether a person of ordinary skill in the art would have had the motivation, and a reasonable expectation of success, to use PGF analogs with C1-amides (including bimatoprost) to grow hair. (ECF No. 180, p. 14.) Sandoz, however, argues that "the 'motivation' of a person of ordinary skill to combine prior art references, and their 'reasonable expectation of success' in doing so, must be determined in the **absence** of the challenged patent claims." (ECF No. 184, p.3, emphasis original.)

The Court concludes that the Parties are, essentially, talking past one another on this issue. It is true that the motivation to combine, and the expectation of success, cannot be found merely by noting that someone did, in fact, combine the prior art and did, likewise, succeed in making the claimed invention. The current claim is important, however, because it answers the questions "the motivation to make what?" and the "expectation of success at what?" The Federal Circuit's opinion in *Latisse I*, in fact, turns on this very issue. The Court noted that,

> Given the breadth of the ′029 patent's claimed invention, appellants did not have the exacting burden of showing a reasonable expectation of success in using the narrow class of PGF analogs with C1–amide groups to treat hair loss, let alone a reasonable expectation of success in using bimatoprost in particular. Appellants instead had the burden of showing that any compounds within the broad genus claimed by the ′029 patent, including those that did not have C1–amide groups, were obvious at the time of the invention.

Latisse I, 754 F.3d at 963. As noted in subsection A1, above, Judge Krieger already found that the scope of the '029 patent differed from that of the '270 patent. Thus, the Court in *Latisse I* did not address issues identical to the ones that will now be before the jury, and thus the elements of

issue preclusion are not met in this case. The Court therefore DENIES Sandoz's Motion with regard to findings 3 and 4.

B. Allergan's Motion in Limine to Exclude Evidence of Prior Litigations

In Allergan's first Motion in Limine it requests that the Court preclude Sandoz from introducing in evidence, or mentioning in argument, any information regarding the prior litigation between the Parties. (ECF No. 174.) Sandoz responds that the history of the prior litigation is highly relevant, as it explains Sandoz's intent regarding the alleged infringement. (ECF No. 179.) Specifically, Sandoz asserts that, as a result of the litigation history, it believed that Allergan had "thrown in the towel" on enforcing any of its Latisse-related patents. (ECF No. 179, p.5.) It believed that Allergan would no longer assert those patents against it. Sandoz also argues that the litigation history is relevant because it informed Sandoz's belief that Allergan's patent was invalid. (ECF No. 179, p.7.)

As noted, Allergan raises claims of inducing infringement, 35 U.S.C. § 271(b), and contributory infringement, 35 U.S.C. § 271(c). Those provisions provide:

> (b) Whoever actively induces infringement of a patent shall be liable as an infringer.
>
> (c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

35 U.S.C. § 271. Both subparts require that to be liable, the alleged infringer must have "knowledge of the patent in suit and knowledge of patent infringement." *Commil USA, LLC v. Cisco Systems, Inc.*, 575 U.S. 632, 639 (2015).

Furthermore, while equitable estoppel can provide a defense to a claim of infringement, in order to prove it an alleged infringer must prove that (1) the patentee, by "misleading conduct," led the alleged infringer to "reasonably infer that the patentee [did] not intend to enforce its patent against the alleged infringer;" (2) "[t]he alleged infringer relies on that conduct;" and (3) "[d]ue to its reliance, the alleged infringer will be materially prejudiced if the patentee is allowed to proceed with its claim." *A.C. Aukerman Co. v. R.L. Chaides Const. Co.*, 960 F.2d 1020, 1028 (Fed. Cir. 1992); abrogated on other grounds by *SCA Hygiene Prod. Aktiebolag v. First Quality Baby Prod., LLC*, 580 U.S. 328 (2017). The history of litigation between the parties does not qualify as a "misleading conduct" by Allergan, nor does it go to prove either of the other elements of collateral estoppel, and thus it is irrelevant to that defense. Moreover, equitable estoppel is, as the name suggests, an equitable defense that will be tried to the Court and therefore does not necessitate that the jury be exposed to information about the litigation history in this case.

A belief that a patent is invalid is relevant to a fact finder's determination of willfulness. *Eko Brands, LLC v. Adrian Rivera Maynez Enterprises*, 946 F.3d 1367, 1377 (Fed. Cir. 2020). Sandoz asserts that it "developed views about the Johnstone and '819 prior art and publicly communicated those views to Plaintiffs in the course of prior litigations." (ECF No. 205, p.5.) To the extent that Sandoz held such a belief, and that belief was not derived from the opinion of counsel or privileged communications, that evidence is admissible unless it is more prejudicial than probative. The Court concludes that the information concerning the history of litigation surrounding this line of patents invites the jury to conclude that, because Allergan has lost three prior lawsuits involving this same product, this patent is also likely invalid. As such, its introduction would be more prejudicial than it would be probative. Sandoz is correct, however,

that it is entitled to present evidence that it did not believe the '270 patent was valid, and the jury can consider that evidence when determining whether Sandoz willfully infringed on that patent. It cannot do so, however, through references to the outcome of prior litigation. The Court concludes that it is therefore appropriate to GRANT Allergan's first Motion in Limine. The Parties shall not introduce evidence of, or argument about, the history of litigation between them in front of the jury.

C. Allergan's Motion in Limine to Exclude Sandoz's Evidence of Intent

Allergan's second Motion in Limine requests that the Court exclude Sandoz's evidence of intent at trial. (ECF No. 175.) Specifically, Allergan notes that in the Pretrial Order Sandoz made clear that it intended to introduce testimony of its business executives regarding their "business understanding" with regard to whether Sandoz was entitled to "practice the methods" covered by the '270 patent. Allergan objects to this testimony because, it says, Sandoz executives gained their business understanding from their legal counsel. Allergan further notes that Sandoz asserted privilege during discovery and declined to produce evidence regarding that legal advice.

Sandoz responds that it does not intend to rely on privileged information at trial—it asserts that the executives formed their business understanding based on publicly available information, such as the history of litigation between the parties. In fact, Sandoz argues, the witnesses at issue testified during depositions that they did not know the content of any legal advice.

In order to analyze this question, the Court concludes that it is necessary first to discuss the types of testimony at issue. Allergan cites to a number of specific statements made during discovery that it finds objectionable. Those statements can be roughly categorized into three

groups: (1) statements that Allergan had "thrown in the towel" following its losses in litigation; (2) statements that the Sandoz legal department had given the go-ahead to launch their product; (3) statements regarding the outcome of the prior litigation and the then-existing procedural posture of the remaining case (which at that time was on appeal). (ECF Nos. 175; 186.) There also may be other business understandings that have not been directly addressed in the Motion and responses—for example, the executives may have had a business understanding as to why the Sandoz product was sufficiently distinct from Latisse that it did not infringe on the patent for that reason.

As Sandoz notes, "the mere fact that an attorney was involved in a communication does not automatically render the communication subject to the attorney-client privilege." *Motley v. Marathon Oil Co.*, 71 F.3d 1547, 1550–51 (10th Cir. 1995). "In order to be covered by the attorney-client privilege, a communication between a lawyer and client must relate to legal advice or strategy sought by the client." *United States v. Johnston*, 146 F.3d 785, 794 (10th Cir. 1998). The disclosure of non-privileged information during a deposition does not waive privilege. *See Kovacs v. Hershey Co.*, No. 04-CV-01881-WYD, 2006 WL 3054167, at *3 (D. Colo. Oct. 25, 2006). "The burden of establishing the applicability of a privilege rests on the party seeking to assert it," however. *Matter of Grand Jury Subpoena Duces Tecum Issued on June 9, 1982, to Custodian of Recs.*, 697 F.2d 277, 279 (10th Cir. 1983).

When, as here, a "ruling concerning waiver of the attorney-client privilege does not involve issues unique to patent law, [the Court] appl[ies] the law of the regional circuit," in this case, the Tenth Circuit. *In re Target Tech. Co. LLC*, 208 F. App'x 825, 826 (Fed. Cir. 2006). Tenth Circuit law is unsettled on this question, however. *United States v. Osage Wind, LLC*, No. 14-CV-704-GKF-JFJ, 2021 WL 149266, at *5 (N.D. Okla. Jan. 16, 2021). The Colorado

Supreme Court has concluded that when a party places in issue a confidential communication "going directly to the claim or defense, a party impliedly waives the attorney-client privilege with respect to that communication." *Mountain States Tel. & Tel. Co. v. DiFede*, 780 P.2d 533, 543 (Colo. 1989); *see also Rhone-Poulenc Rorer Inc. v. Home Indem. Co.*, 32 F.3d 851, 863 (3d Cir. 1994). Pursuant to this view of waiver, "[a]dvice is not in issue merely because it is relevant, and does not necessarily become in issue merely because the attorney's advice might affect the client's state of mind in a relevant manner. The advice of counsel is placed in issue where the client asserts a claim or defense, and attempts to prove that claim or defense by disclosing or describing an attorney client communication." *Rhone-Poulenc Rorer Inc.*, 32 F.3d at 863. Those cases reflect the more restrictive view of waiver analysis. *See Osage Wind, LLC*, 2021 WL 149266, at *5 (describing the various approaches to the waiver analysis). Other Courts have taken a more intermediate approach, concluding that an implied waiver of privilege can be established if (1) the assertion of the privilege was a result of some affirmative act, such as filing suit, by the asserting party; (2) through that affirmative act the asserting party placed the protected information at issue; and (3) application of the privilege would deny the opposing party the opportunity to access information vital to its defense. *Am. Econ. Ins. Co. v. Schoolcraft*, No. 05-CV-01870-LTB-BNB, 2007 WL 1229308, at *4 (D. Colo. Apr. 25, 2007); *see also Fed. Deposit Ins. Corp. v. Wise*, 139 F.R.D. 168, 171 (D. Colo. 1991) (same).

The Parties both acknowledge the adage that "attorney-client communications cannot be used both as a sword and a shield." *Seneca Ins. Co. v. Western Claims, Inc.*, 774 F.3d 1272, 1278 (10th Cir. 2014) (quoting *Motley v. Marathon Oil Co.*, 71 F.3d 1547, 1552 (10th Cir. 1995)). Specifically, under even the more restrictive view, a party cannot claim privilege when it defends the conduct which is the subject of the suit by relying on advice of counsel. *Motley*, 71

F.3d at 1552. And, the Court notes, a party "cannot avoid an implied waiver of the attorney-client privilege simply by avoiding the use of the words 'advice of counsel.'" *Arkansas River Power Auth. v. Babcock & Wilcox Power Generation Grp., Inc.*, No. 14-CV-00638-CMA-NYW, 2015 WL 4031846, at *7 (D. Colo. June 30, 2015); *see also id.* (noting that no "magic words" are required to effect an implied waiver, and that to rule otherwise would "elevate semantics over substance."); *Bounds v. San Lorenzo Cmty. Ditch Ass'n*, CV 09-580 BB/CG, 2011 WL 13266524, at *3 (D.N.M. July 8, 2011) ("A litigant may not allude to confidential legal advice in an attempt to bolster their own position, while claiming that they have not placed that advice at issue in the litigation or waived their privilege in maintaining attorney-client confidentiality.").

The Court concludes that the essence of the dispute here is whether any of Sandoz's executives formed their "business understanding" as a result of advice from counsel. If Sandoz's executives are, in essence, asserting that they relied on the advice of counsel and that therefore their conduct was not knowing or willful, then even under the most restrictive view of implied waiver, in the Court's view Sandoz was required to disclose the underlying communications from counsel.

> Where a party intends to rely at trial on the advice of counsel as a defense to a claim of bad faith, that advice becomes a factual issue, and opposing counsel is entitled to know not only whether such an opinion was obtained but also its content and what conduct it advised. A party who intends to rely at trial on the advice of counsel must make a full disclosure during discovery; failure to do so constitutes a waiver of the advice-of-counsel defense.

Vicinanzo v. Brunschwig & Fils, Inc., 739 F. Supp. 891, 894 (S.D.N.Y. 1990); *see also First S. Bank v. Fifth Third Bank, N.A.*, No. CIV.A. 7:10-2097-MGL, 2013 WL 1840089, at *14 (D.S.C. May 1, 2013) ("[T]o the extent Defendant later attempts to introduce at trial any evidence that it acted in good faith or in reliance on counsel, it will not be permitted to do so as Plaintiff would then be entirely deprived of the right to have pretrial discovery on matters material to the

testimony or evidence."); *Sidco Indus. Inc. v. Wimar Tahoe Corp.*, No. CIV. 91-110-FR, 1992 WL 58732, at *1 (D. Or. Mar. 19, 1992) ("if [Defendant] intends to rely on the advice-of-counsel as a defense to a claim of bad faith or wil[l]fulness, it must make a full disclosure of the discovery supporting this defense.").

The Court has reviewed the Parties' arguments and the record in this Case and concludes that several of the statements couched by Sandoz as the "business understanding" of its executives are clearly based on legal analysis. One of the obvious such statements is that made by Mr. Jorge stating that they had received a "green light" from the legal department for launching their generic product and that "from a business understanding, I'm aware that Allergan lost multiple times but eventually we got that confirmation from legal that we could launch." (ECF Nos. 181-3, p. 72; 186-4, p.252.) Sandoz executives also testified in their depositions that they believed that Allergan had "thrown in the towel" on enforcing their Latisse patents. (ECF Nos. 181-1, pp. 207, 277; 181-2, pp.206, 214.) One of the executives, Douglas Azzalina, confirmed that he gained this business understanding following a "meeting." (ECF No. 181-2, p. 207.) In the Court's view, the understanding that Allergan had decided to abandon its litigation over the Latisse patents was clearly derived from advice of counsel. Whether Allergan was "throwing in the towel" was not public information like other facts that the executives discussed, such as the fact that Allergan had already lost two lawsuits over the related patents. That Allergan was "throwing in the towel" is an opinion uniquely within the province and expertise of Sandoz's legal counsel. Thus, the Court concludes that the first two categories of testimony were derived from privileged communications and, because Sandoz did not provide discovery in support of these assertions, its witnesses will not be permitted to testify to these understandings at trial.

The third category of statements, regarding the history of litigation between Allergan and Sandoz over the same line of patents were not derived from privileged communications. They are merely statements of publicly available information. For example, the fact that Allergan had already litigated a "number of patents" and that the resolution of those suits had been in favor of Sandoz, was public information. (ECF No. 181-1, p.207.) The mere fact that an attorney may have conveyed this publicly available information to Sandoz's executives does not render the information privileged. *See Motley*, 71 F.3d at 1550–51; *Johnston*, 146 F.3d at 794.

That is not the end of the analysis, however, for this third category of statement. The Court has already concluded, in Section B, above, that the Parties may not discuss, or introduce evidence of, the history of litigation in front of the jury. This third category of business understanding relates entirely to that history. Thus, while the Court concludes that it is not privileged, it will nevertheless be excluded.

The Court does not, it notes, restrict Sandoz from offering testimony from its executives regarding other relevant matters. For example, executives noted that Allergan had withdrawn a patent, which was public information. (ECF No. 181-2, p.215.) Furthermore, if the executives possessed a business understanding that their generic product differed in a significant way from Latisse, and thus would not violate Allergan's patent, Sandoz can introduce evidence to that effect. Sandoz executives also certainly can testify to factors such as the complexity of the supply chain in order to explain their decision to launch the generic product. Thus, the Court GRANTS IN PART Allergan's Motion in Limine to Exclude Sandoz's Evidence of Intent.

The court also notes that, as Sandoz argues, and Allergan agrees, Allergan cannot point to Sandoz's failure to present evidence of advice it received from counsel to argue that Sandoz acted willfully or that Sandoz intended to induce infringement of the '270 patent. 35 U.S.C.

§ 298. Sandoz is entitled to merely deny willfulness and to hold Allergan to its burden of proving otherwise. The Court notes that if Allergan attempts to argue that Sandoz acted willfully either based on a failure to obtain the advice of counsel or to present evidence of such advice at trial, the Court may conclude that the door has been opened to additional testimony on these issues from the Sandoz executives.

D. Equitable Claims and Defenses

As previously noted, several issues in this case will come directly to the Court for resolution. In making its decisions the Court may permit the Parties to introduce some of the evidence it has otherwise excluded in this Order. At that time the Court can resolve any issues surrounding privilege on a question-by-question basis.

IV. CONCLUSION

Based on the foregoing analysis and all the files, records, and proceedings herein, and in accordance with the foregoing, the Court ORDERS:

1. That Sandoz's Motion in Limine (ECF No. 173) is **GRANTED** with respect to Finding 1, **GRANTED IN PART** with respect to Finding 2, and **DENIED** with respect to Findings 3 and 4;
2. That Allergan's Motion in Limine to Exclude Evidence of Prior Litigations (ECF No. 174) is **GRANTED**; and

3. That Allergan's Motion in Limine to Exclude Sandoz's Evidence of Intent (ECF No. 175) is **GRANTED IN PART**.

DATED this 15th day of February, 2023.

BY THE COURT:

RAYMOND P. MOORE
United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Senior Judge Raymond P. Moore

Civil Action No. 18-cv-00997-RM-KLM

DUKE UNIVERSITY and
ALLERGAN SALES, LLC,

Plaintiffs,

v.

SANDOZ, INC.,

Defendant.

ORDER

This matter is before the Court on two motions, both filed by Defendant Sandoz, Inc. ("Sandoz"). The first is a Motion for Judgment as a Matter of Law Under Rule 50. (ECF No. 330.) The Second is a Motion for a New Trial Under Rule 59. (ECF No. 331.) Plaintiffs Duke University and Allergan Sales, LLC (together, "Allergan"), responded (ECF Nos. 338, 339) and Sandoz filed Replies (ECF No. 340, 342). Both Motions have now been fully briefed.

I. LEGAL STANDARDS

A. Fed. R. Civ. P. 59(a)

Grounds for granting relief under Fed. R. Civ. P. 59 include (1) an intervening change in the controlling law, (2) new evidence previously unavailable, and (3) the need to correct clear error or prevent manifest injustice. *Monge v. RG Petro-Mach. (Grp.) Co.*, 701 F.3d 598, 611 (10th Cir. 2012). But such a motion "cannot be used to expand a judgment to encompass new

issues which could have been raised prior to issuance of the judgment." *Sprint Nextel Corp. v. Middle Man, Inc.*, 822 F.3d 524, 536 (10th Cir. 2016) (quotation omitted).

B. Fed. R. Civ. P. 50(b)(3)

"Rule 50 of the Federal Rules of Civil Procedure provides the process for challenging the sufficiency of the evidence in a civil jury trial." *Mountain Dudes v. Split Rock Holdings, Inc.*, 946 F.3d 1122, 1128 (10th Cir. 2019). "Judgment as a matter of law under Rule 50 is appropriate only if the evidence points but one way and is susceptible to no reasonable inferences which may support the nonmoving party's position." *Id.* at 1129 (quotation omitted). "Judgment as a matter of law is cautiously and sparingly granted and then only when the court is certain the evidence conclusively favors one party such that reasonable people could not arrive at a contrary verdict." *Id.* at 1130 (brackets and quotation omitted). This Court does not make credibility determinations or weigh the evidence, and all reasonable inferences are drawn in favor of the nonmoving party. *See Stroup v. United Airlines, Inc.*, 26 F.4th 1147, 1156 (10th Cir. 2022). This is because "it is the sole province of the jury to appraise credibility, draw inferences, determine the weight to be given testimony and to resolve conflicts in the facts." *Id.* (quotation omitted).

In the specific context of a patent case in which the moving party bears the burden of proving invalidity, that party "must show that no reasonable jury could have failed to conclude that [the invalidity defense] had been established by clear and convincing evidence." *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1353 (Fed. Cir. 2003). To prevail, Sandoz must demonstrate that reasonable people could not have arrived at the verdict reached in this case.

II. BACKGROUND

The history of this litigation has been set forth at length, both in prior orders of this Court and in decisions from courts in other jurisdictions. Thus, the Court will only summarize those facts which are pertinent here.

This case represents the fourth round of litigation between Allergan and Sandoz over a line of patents for Allergan's product, Latisse, which is used to treat hypotrichosis, a condition characterized by having an inadequate number of eyelashes. The patent at issue in this case is United States Patent No. 9,579,270 (the "'270 patent") which is entitled "Compositions and methods for treating hair loss using non-naturally occurring prostaglandins." (ECF No. 2-3, p.1.) This line of patents stretches back to 2001, and the application claims priority to an application filed in 2000. (ECF No. 166, p.18.) The patent was assigned to Duke University, which licensed the patent to Allergan Sales, LLC. (ECF No. 111, p.1.) Sandoz makes and sells a generic version of the product, which Allergan asserts infringes on the '270 patent's claim 30. (ECF No. 166, pp.18-19.)

Allergan has sued Sandoz, along with other manufacturers of similar generic products, over this question three times before. *See Allergan, Inv. v. Apotex, Inc.*, 754 F.3d 952 (Fed. Cir. 2014) ("*Latisse I*"); *Allergan, Inc. v. Apotex, Inc.* Nos. 1:12-cv-247, 1:13-cv-16 (M.D.N.C. Jan. 14, 2015) ("*Latisse II*"); *Allergan, Inc. v. Sandoz, Inc.*, 681 F. App'x 955 (Fed. Cir. 2017) ("*Latisse III*"). For the purposes of this Order, the only pertinent decision is that in *Latisse I*.

In *Latisse I*, Allergan asserted that the generic manufacturers had infringed on a prior patent in this line, United States Patent Number 7,388,029 (the "'029 patent"), which addressed the treatment of hair. Sandoz and the other defendants argued that the claims in the '029 patent were obvious based on the prior art, specifically, United States Patent Number 5,688,819 (the

"'819 patent"), and a patent application, International Patent Application Number PCT/US98/02289 ("Johnstone"). The '819 patent "discloses the use of a set of selective PGF analogs, including bimatoprost," which can be used to treat glaucoma with minimal side effects. *Latisse I*, 754 F.3d at 962. Notably, bimatoprost is a type of amide. *Id.* Johnstone, on the other hand, disclosed that certain PGF analog compounds with esters or carboxylic acids (as opposed to amides) could be used to promote hair growth. *Id.* at 958, 962.

The *Latisse I* trial court concluded that the '029 patent's claims were not obvious, but a division of the Federal Circuit reversed. *Id.* at 966. The Federal Circuit noted that the "scope of the independent claims of the '029 patent encompasses thousands of permutations of PGF analogs," including carboxylic acids, alkyl carboxylates, hydroxyls, and esters, which could be used to treat hair loss. *Id.* at 962-63. Thus, it included more substances than just bimatoprost, and therefore the defendants were not required to prove that using bimatoprost, specifically, to treat hair loss was obvious based on the prior art. *Id.* at 963. Rather, they needed only show "that any compounds within the broad genus claimed by the '029 patent . . . were obvious at the time of the invention." *Id.* The Federal Circuit held that the defendants had met that burden, noting that the facts supported a conclusion that "a person of ordinary skill" ("POSA") would have a "substantial reasonable expectation of success and motivation to use PGF analogs with high pharmacological activity and structures similar to those disclosed in Johnstone to treat hair loss." *Id.* at 966. Thus, the '029 patent was invalid. *Id.* at 970.

Allergan filed the application for the patent at issue in this case in 2015 and the patent issued in February of 2017. (ECF Nos. 2-2, 2-3.) Sandoz received FDA approval to sell its generic version in April of 2016. (ECF No. 166, p.20.) In 2017, Allergan again filed suit against Sandoz. (ECF No. 2.)

As pertinent here, the Parties litigated a Motion for Summary Judgment before Judge Krieger. Sandoz asserted that Allergan's claims were barred by collateral estoppel, already having been resolved in *Latisse I*. (ECF No. 47.) Judge Krieger disagreed, concluding that, while the '270 patent might not ultimately survive an obviousness challenge, summary judgment was not appropriate on the basis argued by Sandoz. (ECF No. 111, p.10.) The case was ultimately transferred from Judge Krieger to this Court, and the case was set for trial.

Before trial, the Parties filed several Motions in Limine, including one that is again pertinent to this Order. That Motion, filed by Sandoz, asked this Court to apply issue preclusion to "prevent Allergan from introducing evidence and arguments that are inconsistent with and intended to disturb the Federal Circuit's prior factual findings about the prior art." (ECF No. 173.) In the Motion, Sandoz asserted that the Federal Circuit had made four factual findings that this Court should adopt, and about which Allergan should be precluded from rearguing. Specifically,

> Finding 1 (content of '819 patent): The 819 patent discloses thirteen PGF analogs, including bimatoprost, that could treat glaucoma with minimal side effects.
>
> Finding 2 (content of Johnstone): Johnstone discloses using PGF analogs that could treat glaucoma with minimal side effects to grow hair, including eyelashes.
>
> Finding 3 (motivation and expectation of success): A person of ordinary skill in the art would be motivated to use the PGF analogs of the '819 patent to grow hair as taught by Johnstone, and would have a reasonable expectation of success, irrespective of whether the analogs bind to the FP receptor or a variant receptor.
>
> Finding 4 (expectation of success; predictability): At the time of the invention of the '270 patent, it was not unpredictable to use PGF analogs that could treat glaucoma with minimal side effects to grow hair.

(ECF No. 173, pp. 3-4.) The Court ultimately granted the Motion in part and denied it in part. (ECF No. 234.) The Court granted Sandoz's Motion in Limine with regard to Finding 1. It also

granted the Motion in part with regard to Finding 2, modifying it slightly to read "Johnstone discloses using PGF analogs with esters or carboxylic acids at the C1 location, which could be used to treat glaucoma with minimal side effects, could be used to grow hair, including eyelashes." The Court denied Sandoz's Motion with regard to Findings 3 and 4, concluding that the issues addressed by the Court in *Latisse I* were not identical to those raised in this case, and that therefore the elements of issue preclusion were not met as to Findings 3 and 4.

The case proceeded to trial. Before the trial started, the Parties stipulated that, *if* the '270 patent was valid, Sandoz had infringed upon it. (ECF No. 287.) Following a five-day trial, a jury ultimately returned a verdict in favor of Allergan. (ECF No. 314.) The jury concluded that Sandoz had not proven, by clear and convincing evidence, that the '270 patent was invalid due to obviousness, due to lack of adequate written description, or for lack of enablement. The Court therefore entered judgment in favor of Allergan. (ECF 323.) Sandoz then filed its two post-trial Motions.

III. ANALYSIS

A. New Trial

In support of its request for a new trial, Sandoz contends that the Court erred by denying in part its Motion in Limine in which it asked the Court to apply issue preclusion as to four facts that Sandoz asserted were decided by the Federal Circuit in *Latisse I*. (ECF No. 173.) More specifically, Sandoz argues that the Court mistakenly made its decision about Facts 3 and 4 (the expectation of success and motivation to combine) with reference to the current patent '270 and Claim 30. (ECF No. 331, p.7.) Sandoz points the Court to authority that states that it is "necessary for the decisionmaker ***forget*** what he or she has been taught at trial about *the claimed invention*." *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983)

(emphasis added by Defendant); *see also, e.g. DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006); *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007). Thus, Sandoz contends that the factfinder must evaluate motivations and expectations of success of a POSA without reference to the challenged patent claim.

Allergan, meanwhile, responds by pointing the Court to authority holding that "[t]he reasonable-expectation-of-success analysis must be tied to the scope of the claimed invention." *Teva Pharms. USA, Inc. v. Corcept Therapeutics, Inc.*, 18 F.4th 1377, 1381 (Fed. Cir. 2021). Allergan notes that, in *Teva Pharms.*, the Federal Circuit cited its own holding in *Latisse I* for the proposition that the failure to consider the scope of the challenged patent's claimed invention when evaluating the reasonable expectation of success would constitute a legal error. 18 F.4th at 1381 (quoting *Latisse I*, 754 F.3d at 966).

As the Court previously explained in its Order on the Parties' Motions in Limine (ECF No. 234), it disagrees with Sandoz's reading of the case law. The Court can agree with Sandoz, that the interpretation of the *scope and content* of the prior art is determined independently of any reference to the challenged invention. *DyStar Textilfarben GmbH*, 464 F.3d at 1360 (noting that the factfinder must consider what the prior art teaches, whether it teaches away from the claimed invention, and whether it motivates the combination of teachings from different references). The Court concludes, however, that the nature of the claimed invention is critical to making the determination regarding *the motivation to combine and the reasonable expectation of success*. *See Teva Pharms.*, 18 F.4th at 1381; *DyStar Textilfarben GmbH*, 464 F.3d at 1360-61. Those cases, cited by Sandoz itself, explain that it is appropriate to require a demonstration that POSA would have had a motivation to combine the prior art to create the *claimed invention*.

DyStar Textilfarben GmbH, 464 F.3d at 1360. Furthermore, the party challenging the validity of the current invention must demonstrate that a POSA would have had a reasonable expectation of success for the *current invention*. *Teva Pharms.*, 18 F.4th at 1381 ("The Board did not err by requiring Teva to show a reasonable expectation of success for a specific mifepristone dosage. The reasonable-expectation-of-success analysis must be tied to the scope of the claimed invention.").

Thus, while the Court agrees that the Federal Circuit previously considered and made findings as to the teachings of the prior art that are again at issue here, the Court cannot agree with Sandoz that those previous findings must have a preclusive effect as to the motivation to combine and the expectation of success regarding Claim 30 in *this* case. Because the Court disagrees with the premise of Sandoz's argument, it cannot conclude that Sandoz is entitled to a new trial.

B. Judgment as a Matter of Law

In support of its request for judgment as a matter of law, Sandoz makes three arguments. (ECF No. 330.) Sandoz contends that a reasonable jury could only have concluded that: (1) the written specification in '270 is inadequate because it fails to sufficiently describe and disclose Claim 30; (2) Claim 30 fails to enable a POSA to practice the full scope of the claim; and (3) Claim 30 is invalid for obviousness. The Court will address these arguments in turn.

1. Written Specification

Sandoz first argues that no reasonable jury could have concluded that the '270 patent adequately described its invention. Specifically, Sandoz asserts that Allergan's patent fails to adequately describe the invention because it fails to describe a single claimed compound. Sandoz points out that specification encompasses billions of compounds but that Claim 30

requires a specific subset of those compounds and that no claimed compound is identified in the specification. Sandoz also claims that the specification fails to disclose the claimed efficacy for any compound in Claim 30. Sandoz argues that all of these deficits lead to an inadequate written specification because it "fails to disclose or direct a POSA to the claimed [compounds] that are effective in growing hair, let alone all types of hair on all types of mammals as claimed." (ECF No. 330, p.8.)

Allergan counters that the written description is adequate because it makes it reasonably clear to a POSA what the invention is. (ECF No. 339, p.2.) More specifically, Allergan argues that the '270 patent discloses the structural features common to the genus, such that a POSA could visualize or recognize members of that genus. Specifically, Allergan states that the common features are (1) a prostaglandin hairpin structure; (2) an unsubstituted phenyl ring at the omega end; and (3) amides at the action end. Allergan points to at least some testimony from the experts at trial to the effect that a POSA would be able to visualize and/or recognize the members of the genus.

In the Court's instructions to the jury, the jurors were asked to decide whether the '270 patent met the written description requirement. (ECF No. 308, p.33, Instruction No. 28.) The instruction told the jury that it needed to decide whether the specification described "the full scope of the claimed invention, including each element thereof, expressly or inherently." (Id.) The instruction also informed the jury that the written description in the specification "does not have to be in the exact words of the claim," but that the requirement could be satisfied by "any combination of words, structures, figures, diagrams, formulas, etc. contained in the patent specification." (Id.) "Adequate written description does not require either examples or an actual reduction to practice of the claimed invention." (Id.) The jury was directed to consider whether

the description identified any structural features common to the genus and specifically whether a POSA could visualize or recognize the claimed invention. The Court instructed the jury that, to find the written description inadequate, the jury would need to conclude that Sandoz proved, "by clear and convincing evidence that a person having ordinary skill in the field reading the patent specification as of the effective filing date of March 31, 2000 would not have recognized that it describes the full scope of the invention as finally claimed in claim 30." (Id.)

The jury apparently concluded that Sandoz failed to meet that burden of proof, and that there was insufficient evidence to permit it to conclude that a POSA would have been unable to visualize or recognize a member of the genus. Sandoz asserts that no reasonable jury could have so concluded. (ECF No. 330, pp.4-8.) Sandoz also characterizes portions of its argument as demonstrating the inadequacy of the written description as a matter of law. (Id. pp.8-14.) The Court is unpersuaded.

Sandoz points to evidence it asserts demonstrates that the written description was inadequate because (1) it didn't identify a single claimed compound; (2) it didn't guide a POSA on how to select among the described compounds; (3) it didn't disclose or exemplify hair growth examples involving the claimed compounds; and (4) it didn't disclose the efficacy for growing hair on other mammals. (ECF No. 330, pp.4-8.) Allergan, meanwhile, points to evidence that a POSA would be able to "readily understand and visualize the prostaglandin hairpin structure," and visualize each of the 13 options for the "action end" of the amides. (ECF No. 339, pp.3-6.) It further contends that the evidence supported a conclusion that it was unnecessary to select among the various compounds because no evidence demonstrated that the minor differences between the chemical structures would impact the ability to grow hair. (Id.)

As the jury instruction, (to which Sandoz agreed), states, neither examples nor a reduction to practice are required in order to provide an adequate written description. (ECF No. 308, p.33.) The jury was required to decide whether the full scope of the invention was set out in the specification, and it apparently concluded that it was. The Court notes that the fact that Sandoz's characterization of the evidence, which differs from Allergan's characterization, if believed would require a different result, does not alter the fact that the jury apparently believed Allergan's evidence, or mean that this Court should overturn the jury's verdict.

Furthermore, Sandoz repeatedly asserts that certain evidence was insufficient as a matter of law, but the Court is again unpersuaded that a different result is required. To the extent that Sandoz characterizes evidence as "legally insufficient," it forgets where the burden of proof lies. Sandoz itself had the burden to prove its affirmative defense, and to do so by clear and convincing evidence. *Boehringer*, 320 F.3d at 1353. Now, when asking this Court to enter judgment as a matter of law, it is Sandoz's burden to demonstrate that no reasonable jury could have concluded that Sandoz failed to meet its burden by clear and convincing evidence. In the Court's view, Sandoz has failed to make such a demonstration to this Court.

2. Enablement

Sandoz next argues that the '270 patent is invalid because it fails to enable a POSA to make and use the claimed invention. (ECF No. 330, p.14.) Sandoz argues that an invention is not enabled if "random trial-and-error discovery" is required to determine which compounds would successfully grow hair and it says that, in this case, there is no guidance in the specification that would indicate which compounds would be successful. (Id.) Sandoz also asserts that Allergan has admitted such testing would be required. (Id. p.15.) It argues that the specification provides no starting point from which a POSA could proceed. (Id. p.16.)

Allergan responds that the evidence allowed the jury to conclude that a POSA would be able to make every compound of the invention. (ECF No. 339, p.14.) It further argues that the evidence permitted the conclusion that the specification "describes each of the claimed compounds as suitable for growing hair." (Id.) And Allergan notes that a specification doesn't fail to enable, simply because a POSA must undertake some experimentation to make and use the invention—only a need for *undue* experimentation requires a finding of a lack of enablement. (Id. p.16.)

As set forth in the jury instructions, a specification enables an invention if it includes "a sufficiently full and clear description to have allowed a person of ordinary skill in the field of the patent to make and use the full scope of the claimed invention as of the effective filing date, here March 31, 2000, without undue experimentation." (ECF No. 308, p.35.) The Supreme Court has explained that "a specification [is not] necessarily inadequate just because it leaves the skilled artist to engage in some measure of adaptation or testing." *Amgen Inc. v. Sanofi*, 598 U.S. 594, 611 (2023). Rather, a specification may require a "reasonable amount of experimentation to make and use a patented invention." *Id.* at 612. The question of "[w]hat is reasonable in any case will depend on the nature of the invention and the underlying art." *Id.* In this case, the jury was asked to determine whether the experimentation was "undue." (Id.) The jury was presented with evidence from both Parties, and it apparently credited Allergan's evidence because it concluded that the patent was not invalid for lack of enablement. (ECF No. 314, p.2.) The Court again concludes that, although the jury could have credited Sandoz's evidence and reached the opposite conclusion, it did not act unreasonably in deciding as it did.

3. Obviousness

Sandoz's final argument in support of its Motion for Judgment as a Matter of Law is that the jury's verdict on the question of obviousness was "not supported by a legally sufficient evidentiary basis." (ECF No. 330, p.19.) More specifically, Sandoz argues that the prior art taught every limitation of Claim 30. Furthermore, it asserts that no reasonable jury could have found a lack of motivation to combine or the absence of a reasonable expectation of success. In essence, Sandoz claims that Johnstone taught that *any* of the class of compounds at issue, 17-phenyl $PGF_{2\alpha}$ derivatives, possessing high pharmacological activity and minimal side effects, could reasonably be expected to effectively treat hair loss. (Id. p.21.) It argues that the differences between esters, acids, and amides are irrelevant. (Id. p.24.)

Allergan responds that there were more promising avenues for the treatment of hair loss at the time the inventors discovered the utility of bimatoprost for that purpose. (ECF No. 339, p.21.) Allergan also contends that no prior art taught the use of amides for growing hair and that, in fact, the science at the time suggested that amides would not be effective for that purpose. (Id., pp.22, 24.) Allergan finally asserts that the prior art never made a link between intraocular pressure and hair growth. (Id. p.27.)

In its Reply, Sandoz points out that the existence of other promising avenues for hair growth is irrelevant to the obviousness of *this* method. (ECF No. 342, p.14.) Sandoz again argues that "the unrebutted evidence" showed that POSA would have understood the differences between an acid, an ester, or an amide was irrelevant. (Id. p.16.) Sandoz also asserts that the prior art was "agnostic" as to whether amides could be used to grow hair (id. p.16) and strenuously disagrees with Allergan's claim that the prior art never linked the treatment of intraocular pressure and hair growth (id. p.19).

Once again, the Court accepts that, if believed, Sandoz's characterization of the evidence would have required a different result. Nevertheless, Allergan presented contrary evidence and the jury apparently credited Allergan's characterization and believed Allergan's account. As set forth above, both Parties make extensive arguments regarding the science and chemistry involved in the making and use of this invention. Those arguments merely serve to reinforce the Court's conclusion that the dispute here is evidentiary. And the Court concludes that, drawing all reasonable inferences in favor of Allergan, as the non-moving party, adequate evidence supports the jury's decision. Thus, the Court cannot conclude that it is compelled to overturn the jury's verdict in this case.

IV. CONCLUSION

Therefore, both Motions (ECF Nos. 330, 331) are DENIED.

DATED this 21st day of September, 2023.

BY THE COURT:

RAYMOND P. MOORE
Senior United States District Judge