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

ALLERGAN SALES, LLC,	§	
	§	
Plaintiff,	§	
	§	
v.	§	Case No. 2:12-cv-207-JRG
	§	
SANDOZ INC., ET AL.,	§	(Lead Case)
	§	
Defendants.	§	

MEMORANDUM OPINION AND ORDER

Before the Court are Plaintiff Allergan Sales, LLC's ("Allergan") Opening Claim Construction Brief (Dkt. No. 232), Sandoz, Inc., Alcon Laboratories, Inc., Alcon Research, Ltd., and Falcon Pharmaceuticals, Ltd.'s (collectively, "Sandoz") Responsive Claim Construction Brief (Dkt. No. 235), and Allergan's Reply Claim Construction Brief (Dkt. No. 238). The Court held a hearing on March 2, 2016, to determine the proper construction of the disputed terms in this case. Having considered the parties' arguments and the claim construction briefing, the Court issues this Memorandum Opinion and Order construing the disputed terms.

I. BACKGROUND

This is a case brought by Plaintiff Allergan under the provisions of the Hatch-Waxman Act, alleging that Defendants' application for approval to market a generic version of Allergan's Combigan® product, and Defendants' proposed product, infringes United States Patent Nos. 7,030,149 ("the '149 patent"); 7,320,976 ("the '976 patent"); 7,642,258 ("the '258 patent"); and 8,748,425 ("the '425 patent"). The '149 patent, titled "Combination of Brimonidine Timolol for Topical Ophthalmic Use," issued on April 18, 2006. The '976 patent is similarly titled, "Combination of Brimonidine and Timolol for Topical Ophthalmic Use," and issued on January

22, 2008. The ’258 and ’425 patents bear the same title and issued on January 5, 2010, and June 10, 2014, respectively. In general, the patents-in-suit concern compositions comprising both brimonidine and timolol and methods of treating a patient exhibiting elevated intraocular pressure (“IOP”) associated with diseases such as glaucoma or ocular hypertension with a composition comprising both brimonidine and timolol.

The ’149, ’976, and ’258 patents were previously construed by Judge T. John Ward of this Court in a claim construction order involving the same parties to this litigation. *Allergan, Inc. v. Sandoz, Inc., et al.*, No. 2:09-cv-97, 2011 WL 1599049 (E.D. Tex. April 27, 2011) (Dkt. No. 151, “*Allergan I Markman*”). That prior litigation involving the ’149, ’976, and ’258 patents is referred to below as *Allergan I.* The Court issued its findings of fact and conclusions of law on August 22, 2011, finding that Defendants’ generic versions of Combigan® infringed the asserted claims of those patents, and that those patents are not invalid. *Allergan, Inc. v. Sandoz, Inc., et al.*, 818 F. Supp. 2d 974 (E.D. Tex. 2011). Defendants appealed the Court’s decision that the patents in that case were not invalid, and Plaintiff appealed a portion of the Court’s claim construction. On May 1, 2013, the Court of Appeals for the Federal Circuit reversed a portion of this Court’s validity decision, finding that the asserted claims of U.S. Patent No. 7,323,463 were invalid as obvious. However, the Federal Circuit upheld the validity of claim 4 of U.S. Patent No. 7,030,149.[1]

In separate litigation before this Court, Allergan also asserted two additional patents from the same family against Sandoz: U.S. Patent Nos. 8,133,890 (“the ’890 patent”) and 8,354,409 (“the ’409 patent”). *Allergan Sales, LLC v. Sandoz, Inc., et al.*, No. 2:12-cv-207 (E.D. Tex. April

[1] Because the ’149 Patent expires on the same day as two other patents at issue in that case (and this one)—the ’976 and ’258 patents—and because as a result of the Federal Circuit’s affirmance of claim 4 of the ’149 patent, Defendants would be unable to market their generic versions of Combigan® until April 19, 2022, the Federal Circuit did not address the validity of the claims of the ’976 and ’258 patents.

13, 2012). That litigation is referred to below as *Allergan II*. On September 5, 2013, this Court construed certain terms of the '890 and '409 patents following briefing and a hearing. *Allergan Sales, LLC v. Sandoz, Inc., et al.*, No. 2:12-cv-207 (E.D. Tex. Sept. 5, 2013) (Dkt. No. 171, "*Allergan II Markman*"). In so doing, the Court considered the claim construction in *Allergan I*, but reached a different construction as to the terms "brimonidine" and "timolol." *Allergan II* was stayed pending the appeal in *Allergan I*.

On January 23, 2015, Allergan received notice that Sandoz had filed an amendment to its ANDA No. 91-087. Allergan subsequently filed suit against Sandoz, alleging infringement of the '149, '976, '258 and '425 patents. *Allergan Sales, LLC v. Sandoz Inc.*, No. 2:15-cv-347 (E.D. Tex.). Following initiation of the instant litigation, the Court consolidated it with *Allergan II*.

II. LEGAL PRINCIPLES

It is understood that "[a] claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using or selling the protected invention." *Burke, Inc. v. Bruno Indep. Living Aids, Inc.*, 183 F.3d 1334, 1340 (Fed. Cir. 1999). Claim construction is clearly an issue of law for the court to decide. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970–71 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996).

To ascertain the meaning of claims, courts look to three primary sources: the claims, the specification, and the prosecution history. *Markman*, 52 F.3d at 979. The specification must contain a written description of the invention that enables one of ordinary skill in the art to make and use the invention. *Id.* A patent's claims must be read in view of the specification, of which they are a part. *Id.* For claim construction purposes, the description may act as a sort of

dictionary, which explains the invention and may define terms used in the claims. *Id.* "One purpose for examining the specification is to determine if the patentee has limited the scope of the claims." *Watts v. XL Sys., Inc.*, 232 F.3d 877, 882 (Fed. Cir. 2000).

Nonetheless, it is the function of the claims, not the specification, to set forth the limits of the patentee's invention. Otherwise, there would be no need for claims. *SRI Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985) (en banc). The patentee is free to be his own lexicographer, but any special definition given to a word must be clearly set forth in the specification. *Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384, 1388 (Fed. Cir. 1992). Although the specification may indicate that certain embodiments are preferred, particular embodiments appearing in the specification will not be read into the claims when the claim language is broader than the embodiments. *Electro Med. Sys., S.A. v. Cooper Life Sciences, Inc.*, 34 F.3d 1048, 1054 (Fed. Cir. 1994).

This Court's claim construction analysis is substantially guided by the Federal Circuit's decision in *Phillips v. AWH Corporation*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). In *Phillips*, the court set forth several guideposts that courts should follow when construing claims. In particular, the court reiterated that "the claims of a patent define the invention to which the patentee is entitled the right to exclude." 415 F.3d at 1312 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). To that end, the words used in a claim are generally given their ordinary and customary meaning. *Id.* The ordinary and customary meaning of a claim term "is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1313. This principle of patent law flows naturally from the

recognition that inventors are usually persons who are skilled in the field of the invention and that patents are addressed to, and intended to be read by, others skilled in the particular art. *Id.*

Despite the importance of claim terms, *Phillips* made clear that "the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.* Although the claims themselves may provide guidance as to the meaning of particular terms, those terms are part of "a fully integrated written instrument." *Id.* at 1315 (quoting *Markman*, 52 F.3d at 978). Thus, the *Phillips* court emphasized the specification as the primary basis for construing the claims. *Id.* at 1314–17. As the Supreme Court stated long ago, "in case of doubt or ambiguity it is proper in all cases to refer back to the descriptive portions of the specification to aid in solving the doubt or in ascertaining the true intent and meaning of the language employed in the claims." *Bates v. Coe*, 98 U.S. 31, 38 (1878). In addressing the role of the specification, the *Phillips* court quoted with approval its earlier observations from *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998):

> Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.

Phillips, 415 F.3d at 1316. Consequently, *Phillips* emphasized the important role the specification plays in the claim construction process.

The prosecution history also continues to play an important role in claim interpretation. Like the specification, the prosecution history helps to demonstrate how the inventor and the Patent and Trademark Office ("PTO") understood the patent. *Id.* at 1317. Because the file history, however, "represents an ongoing negotiation between the PTO and the applicant," it may

lack the clarity of the specification and thus be less useful in claim construction proceedings. *Id.* Nevertheless, the prosecution history is intrinsic evidence that is relevant to the determination of how the inventor understood the invention and whether the inventor limited the invention during prosecution by narrowing the scope of the claims. *Id.*; *see Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1350 (Fed. Cir. 2004) (noting that "a patentee's statements during prosecution, whether relied on by the examiner or not, are relevant to claim interpretation").

Phillips rejected any claim construction approach that sacrificed the intrinsic record in favor of extrinsic evidence, such as dictionary definitions or expert testimony. The *en banc* court condemned the suggestion made by *Texas Digital Systems, Inc. v. Telegenix, Inc.*, 308 F.3d 1193 (Fed. Cir. 2002), that a court should discern the ordinary meaning of the claim terms (through dictionaries or otherwise) before resorting to the specification for certain limited purposes. *Phillips*, 415 F.3d at 1319–24. According to *Phillips*, reliance on dictionary definitions at the expense of the specification had the effect of "focus[ing] the inquiry on the abstract meaning of words rather than on the meaning of claim terms within the context of the patent." *Id.* at 1321. *Phillips* emphasized that the patent system is based on the proposition that the claims cover only the invented subject matter. *Id.*

Phillips does not preclude all uses of dictionaries in claim construction proceedings. Instead, the court assigned dictionaries a role subordinate to the intrinsic record. In doing so, the court emphasized that claim construction issues are not resolved by any magic formula. The court did not impose any particular sequence of steps for a court to follow when it considers disputed claim language. *Id.* at 1323–25. Rather, *Phillips* held that a court must attach the appropriate weight to the intrinsic sources offered in support of a proposed claim construction, bearing in mind the general rule that the claims measure the scope of the patent grant.

III. CONSTRUCTION OF AGREED TERMS

The Court hereby adopts the following agreed to constructions:

Term	Patent Claims	Agreed Construction
"% … by weight"; "% by weight"; "% … (w/v)," "%"	'149 patent claim 4 '976 patent claim 1 '258 patent claims 1–3, 7–9 '425 patent claim 1	"ratio of the weight of the ingredient in question divided by the total volume of the solution, with this ratio expressed as a percentage"
"a single composition"	'149 patent claim 4	plain and ordinary meaning
"about"	'976 patent claim 1	"approximately"
"brimonidine tartrate"	'258 patent claim 4 '425 patent claim 1	plain and ordinary meaning
"timolol maleate"	'258 patent claim 4	plain and ordinary meaning
"timolol free base"	'425 patent claim 1	plain and ordinary meaning
"as compared to the administration of"	'425 patent claim 1	plain and ordinary meaning
"the affected eye"	'976 patent claim 1 '425 patent claim 1	"an eye exhibiting elevated intraocular pressure"

(Dkt. No. 229 at 1, "Joint Claim Construction and Prehearing Statement," Dec. 9, 2015.)

IV. CONSTRUCTION OF DISPUTED TERMS

a. "brimonidine"

Plaintiff's Proposed Construction	Defendants' Proposed Construction
"brimonidine tartrate"	"the chemical compound brimonidine, including its free base and tartrate salt forms"

(Joint Claim Construction and Prehearing Statement, Ex. A.) The term appears in claim 4 of the '149 patent, claim 1 of the '976 patent, and claims 1, 4 and 7 of the '258 patent.[2]

[2] Because the patents share a common specification, reference is made herein to the '149 patent specification.

i. The Parties' Positions

Allergan submits that the term "brimonidine" should be construed to mean "brimonidine tartrate," as it was for the same patents in *Allergan I*. *See* (*Allergan I Markman*). Allergan argues that issue preclusion bars Sandoz from now seeking a different construction of this term (and others) because Sandoz previously litigated the construction of "brimonidine" (and other terms) in these same patents and received final judgment. Allergan also argues that the patent specification expressly defines "brimonidine" as "brimonidine tartrate," providing the full chemical name for brimonidine tartrate and a chemical drawing of the compound. '149 Patent at 1:39–53. Allergan further argues that brimonidine tartrate is the form of brimonidine used in Examples 1 and 2 of the '149 patent.

Sandoz responds that issue preclusion does not bar it from now seeking a different construction of brimonidine (and other terms) because the factors required for issue preclusion are not met here. Sandoz further argues that the Court, in its discretion, should decline to find issue preclusion even if each of the required factors is found. Sandoz also argues that the Court's construction of "brimonidine" in *Allergan II* for the '890 and '409 patents as "the chemical compound brimonidine, including its free base and tartrate salt forms" should be applied here.

In support, Sandoz also points to claim 4 of the '258 patent, dependent from claim 1, which further defines the brimonidine in claim 4 as "brimonidine tartrate." Sandoz argues that under the doctrine of claim differentiation, brimonidine in claim 1 of the '258 patent (and the other independent claims) must include more than just brimonidine tartrate. *Am. Med. Sys., Inc. v. Biolitec, Inc.*, 618 F.3d 1354, 1360 (Fed. Cir. 2010). Sandoz also points to patents cited in the "Background" section of the patent specification, arguing that these prior art patents describe

brimonidine as including salt or free base forms. Finally, Sandoz argues that the prosecution history of the subsequently issued '890 patent supports its position.

ii. Analysis

1. Issue Preclusion

Under Fifth Circuit law,[3] issue preclusion applies where (1) the identical issue was previously adjudicated; (2) the issue was actually litigated; and (3) the previous determination was necessary to the decision. *Pace v. Bogalusa City Sch. Bd.*, 403 F.3d 272, 290 (5th Cir. 2005); *see also In re Freeman*, 30 F.3d 1459, 1465 (Fed. Cir. 1994).[4]

Sandoz specifically argues that issue preclusion is not appropriate in this instance because (1) the identical issue was not previously adjudicated due to the fact that the prosecution history and the accused product have changed from *Allergan I*, making this a different issue from that which was previously adjudicated; (2) the term "brimonidine" was not actually litigated due to the fact that the construction of "brimonidine" was the subject of a stipulation by the parties in *Allergan I*; and (3) the construction was not "necessary to the decision" due to the fact that the construction was not explicitly used to determine issues of validity.

Regarding the first factor, Sandoz argues that the facts before this Court are not identical to those presented during the *Allergan I Markman*, and, thus, issue preclusion would be inappropriate here. *See In re Freeman*, 30 F.3d at 1465. Specifically, Sandoz argues that changes in the prosecution history (by virtue of subsequently issued patents) and changes to its product have resulted in issues that are not identical to those in *Allergan I*.

[3] Because issue preclusion is a procedural matter, Fifth Circuit law applies here. *See Bayer AG v. Biovail Corp*., 279 F.3d 1340, 1345 (Fed. Cir. 2002).

[4] Under Federal Circuit law, the same three factors apply. A fourth factor, that there was a full and fair opportunity to litigate the issue in the previous action, is also relevant under Federal Circuit law. *Freeman*, 30 F.3d at 1465. Under that law, the Court finds that there was, in *Allergan I*, a full and fair opportunity to litigate construction of each of the four disputed terms as to which issue preclusion is alleged by Allergan.

Sandoz is correct that prosecution history plays an important role in claim interpretation. The prosecution history is intrinsic evidence relevant to determining how the inventor understood the invention and whether the inventor limited the invention during prosecution by narrowing the scope of the claims. *See Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d at 1350 (noting that "a patentee's statements during prosecution, whether relied on by the examiner or not, are relevant to claim interpretation"). In support of its argument that subsequent prosecution history is relevant to issue preclusion, Sandoz cites *Golden Bridge Tech., Inc. v. Apple Inc.*, 937 F. Supp. 2d 490, 496 (D. Del. 2013). In *Golden Bridge Tech*, however, the patents in suit underwent reexamination, canceling new claims and adding others, which occurred ***after*** the conclusion of the original litigation. *Id.* at 493, 496. Here, by contrast, the prosecution history of the '149, '258, and '976 patents did not change. Rather, Sandoz cites to the prosecution of the subsequently issued '890 patent. But, as Allergan correctly notes, the relevant portions of the '890 patent's prosecution history were available more than a year prior to the briefing and issuance of the *Allergan I* claim constructions. Therefore, with respect to the '890 patent's prosecution history, the relevant portions that were available to the parties and the Court in *Allergan I* are the same as those available to it now. In other words, the prosecution history did not change.

Furthermore, Sandoz does not provide any specific information from the prosecution history of the '409 or '425 patents that would provide a different construction of any of the disputed terms. The only evidence offered by Sandoz of the effects of the new and allegedly differing prosecution history is that this Court previously found, when construing the '890 and '409 patents, that the prosecution history of the '425 patent (which was pending at the time)

provided "some evidence regarding the patentee's understanding of the term 'brimonidine.'"[5] That evidence, cited in a footnote in the *Allergan II Markman*, was not central to that decision, and, in any event, is cumulative of the evidence from the '890 patent prosecution history. Therefore, the Court finds this argument unpersuasive.

Sandoz next argues that because its product has changed since *Allergan I*, claim construction is now a different issue than that previously decided. The change in its product is apparently to omit the word "glaucoma" from the approved uses in its proposed product label. Other than this amendment, Sandoz's product has not changed. The active ingredients, formulation and other aspects remain identical to those at issue in *Allergan I*.

The Court also finds this argument unpersuasive. Regardless of whether Sandoz's product has changed, the Federal Circuit has made clear that "[a] claim is construed in the light of the claim language, the other claims, the prior art, the prosecution history, and the specification, ***not*** in light of the accused device . . . claims are not construed 'to cover' or 'not to cover' the accused device. That procedure would make infringement a matter of judicial whim. It is only ***after*** the claims have been ***construed without reference to the accused device*** that the claims, as so construed are applied to the accused device to determine infringement." *SRI Int'l.*, 775 F.2d at 1118 (emphasis in original).

The status and contours of Sandoz's product may be "kept in mind" during claim construction but only because "it is efficient to focus on the construction of only the disputed elements or limitations of the claims. However, the construction of claims is simply a way of elaborating the normally terse claim language in order to understand and explain, but not to change, the scope of the claims." *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927

[5] The Court declined to rule in the *Allergan II Markman* whether the prosecution history of the '425 patent was intrinsic or extrinsic evidence to the construction of the '409 and '890 patents.

F.2d 1565, 1580 (Fed. Cir. 1991). Thus, the Court rejects Sandoz's argument that the change to its label makes claim construction a different issue than that decided in the *Allergan I Markman.* That this label change might provide grounds for Sandoz to dispute infringement is also irrelevant to claim construction. Claims are construed the same way for validity and infringement. *See, e.g., Source Search Techs., LLC v. LendingTree, LLC*, 588 F.3d 1063, 1075 (Fed. Cir. 2009); *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1363 (Fed. Cir. 1998). For these reasons, the first prong of issue preclusion is met here.

Sandoz next argues that because the term "brimonidine" was stipulated to by the parties in *Allergan I*, the term was not litigated as required for issue preclusion. *See In re Freeman*, 30 F.3d at 1465. Allergan argues that no "stipulation" was filed, although it admits that the parties did agree to a construction. Allergan further argues that despite that agreement, issue preclusion applies because in the *Allergan I Markman* the Court independently analyzed the evidence, and therefore, the term was litigated.

A review of the *Allergan I* record reveals that Allergan and Sandoz expressly "agreed" on the construction of the term "brimonidine." (Dkt. No. 112 in *Allergan I* at 2, "*Allergan I* Joint Claim Construction Chart," Oct. 27, 2010.) In the *Allergan I Markman*, the Court noted the parties' agreement and found the parties' proposed construction to be consistent with the intrinsic evidence. (*Allergan I Markman* at 8.) Nowhere did Sandoz argue a term contrary to Allergan's proposal, and thus there was not full briefing of this issue, nor a full hearing.

Allergan incorrectly focuses on that fact that the Court independently confirmed the construction of the term "brimonidine" in the *Allergan I Markman.* Allergan argues that this shows that the issue was actually litigated. Allergan is wrong. This requirement of issue preclusion is satisfied where "the parties to the original action ***disputed the issue*** and the trier of

fact decided it." *In re Freeman* at 1466 (emphasis added). In *Allergan I*, Sandoz and Allergan did not dispute the construction of the term "brimonidine," and, accordingly, there was no dispute that the Court decided. For this reason, the Court finds that the second prong of the doctrine of issue preclusion has not been met here. Regarding the term "brimonidine," issue preclusion is not appropriate.

As to the third prong of the test, Sandoz argues that the construction of the term "brimonidine" was not essential to judgment because the only issue tried to this court was validity. The Court, however, entered judgments on both infringement and validity. (Dkt. No. 262 in *Allergan I*, "*Allergan I* Final Judgment and Injunction," Aug. 25, 2011.) Even if validity was the only issue tried, Sandoz has not provided any evidence that the disputed terms were not relied upon and at least implicitly essential to the validity decision. Sandoz provides only the Federal Circuit's decision and alleges non-reliance on the disputed terms. This Court, however, in finding both infringement and invalidity, did not expressly state that such terms were irrelevant or non-essential. Rather, this court expressly found infringement of claims which included the term "brimonidine" and determined validity based on prior art that included teachings regarding brimonidine. *Id.*

Further, as the Federal Circuit has stated "it is important to note that the requirement that a finding be 'necessary' to a judgment does not mean that the finding must be so crucial that, without it, the judgment could not stand. Rather, the purpose of the requirement is to prevent the incidental or collateral determination of a nonessential issue from precluding reconsideration of that issue in later litigation." *Mother's Rest., Inc. v. Mama's Pizza, Inc.*, 723 F.2d 1566, 1571 (Fed. Cir. 1983). Claim construction is not incidental or non-essential to issues of validity and infringement. Indeed, it is the first step in the process of deciding those issues. The Court,

therefore, finds that the construction of the term "brimonidine" was at least implicitly essential to the judgment in *Allergan I*.

For the reasons previously stated, as to the term "brimonidine," the identical issue was previously litigated, and that term was essential to the judgment in *Allergan I*. However, because the term "brimonidine" was not actually litigated in *Allergan I*, Sandoz is not precluded from now contesting construction of that term. The Court is aware of no additional authority that requires it to apply issue preclusion to this term. *See also Tex. Instruments, Inc. v. Linear Techs. Corp.*, 182 F. Supp. 2d 580, 589 (E.D. Tex. 2002); *Blue Calypso, Inc. v. Groupon, Inc.*, 93 F. Supp. 3d 575, 583 (E.D. Tex. 2015).

2. Construction

Turning to the construction of the term "brimonidine," the '149 patent states that "[b]rimonidine is an alpha adrenergic agonist represented by the following formula," and it then provides a chemical structure for brimonidine tartrate. '149 patent at col. 1, ll. 39–50. The patent specification goes on to state that the "chemical name for brimonidine is 5-Bromo-6-(2-imidazolidinylideneamino) quinoxaline L-tartrate." '149 patent at col. 1, ll. 52–53. To act as its own lexicographer, a patentee must "clearly set forth a definition of the disputed claim term" other than its plain and ordinary meaning. *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002). It is not enough for a patentee to simply disclose a single embodiment or use a word in the same manner in all embodiments; instead, the patentee must "clearly express an intent" to redefine the term. *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1381 (Fed. Cir. 2008). The Federal Circuit has described the standard for determining whether an inventor has provided such clear intent as "exacting." *Thorner v. Sony Comput. Entm't Am., LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012).

Allergan argues that the description set forth above is such an express definition. However, in *Allergan II*, this Court found that such language in the counterpart '890 patent[6] did not clearly rise to the level of lexicography and declined to find that the cited language meets this "exacting" standard and thus limits the understanding of one skilled in the art of the term "brimonidine" only to "brimonidine tartrate." (*Allergan II Markman* at 7–13.) In addition, the prosecution history of the '890 patent demonstrated that Allergan itself did not view this as a clear definition rising to the level of lexicography. Rather, that prosecution history "at a minimum, strongly suggests that the patentees clearly understood the term 'brimonidine' to encompass at least brimonidine tartrate and brimonidine free base." (*Id.* at 11.) The Court also relied on the fact that the specification demonstrated that Allergan "knew how to write the words "brimonidine tartrate" when it wanted to use that term. (*Allergan II Markman* at 10, n.3.) It did not do so in the claims at issue here. The specification and prosecution history of the related '890 patent are strongly suggestive that the term brimonidine encompasses more than simply brimonidine tartrate.

Similarly, in the *Allergan II Markman*, the Court addressed and rejected Plaintiff's argument that, because brimonidine tartrate is the form of brimonidine used in examples 1 and 2 of the '890 patent, the claims are so limited. It did so in part because particular embodiments appearing in the specification are generally not read into the claims. *See, e.g.*, *Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 987 (Fed. Cir. 1988) (refusing to limit the term "plasticizer" to external plasticizers). It also rejected that argument because the patent specification, through citation to prior art patents, demonstrated that "brimonidine" has an accepted scientific meaning that included its salt and free base forms. (*Allergan II Markman* at

[6] The '890 patent issued from a continuation application from the patents in suit. They share the same specification and common parentage.

10–11 (citing *Glaxo Wellcome, Inc. v. Andrx Pharms., Inc.*, 344 F.3d 1226, 1233 (Fed. Cir. 2003) ("When a claim term has an accepted scientific meaning, that meaning is generally not subject to restriction to the specific examples in the specification.")).) Finally, the Court found that Allergan had offered no compelling reason why one chemical compound, brimonidine, should be interpreted as limited to a particular brimonidine salt, while another chemical compound, timolol, should be interpreted as "timolol free base." The description of both compounds in the specification and usage in the claims was substantially similar, and the Court could discern no clear reason why the two compounds should be construed in such different manners. (*Allergan II Markman* at 11, n.4.) These reasons are equally applicable here.

Sandoz also argues that the doctrine of claim differentiation further supports its construction here, citing to claim 4 of the '258 patent, which depends from claim 1. Claim 1 defines a "composition comprising 0.2% brimonidine (w/v) and 0.5% timolol (w/v) in a single composition." Claim 4 recites the "composition of claim 1 wherein brimonidine is brimonidine tartrate and timolol is timolol maleate." Under that doctrine, a dependent claim is presumed to have different scope than the claim from which it depends. *Kraft Foods, Inc. v. Int'l Trading Co.*, 203 F.3d 1362, 1366 (Fed. Cir. 2000). The doctrine is based on "the common sense notion that different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope." *Karlin Tech. Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 971–72 (Fed. Cir. 1999). "To the extent that the absence of such difference in meaning and scope would make a claim superfluous, the doctrine of claim differentiation states the presumption that the difference between claims is significant." *Tandon Corp. v. U.S. Int'l Trade Comm'n*, 831 F.2d 1017, 1023 (Fed. Cir. 1987). Here the doctrine of claim differentiation clearly raises the presumption that the term "brimonidine" as used in claim 1 of the '258 patent must have a

separate meaning than simply brimonidine tartrate. *See also Phillips*, 415 F.3d at 1314 (claims referring to steel baffles strongly implies that the term "baffles" does not inherently mean objects made of steel).

Thus, as in the *Allergan II Markman*, the Court construes the term "brimonidine" according to its plain and ordinary meaning, the chemical compound brimonidine, including both its free base and salt forms.

b. "timolol"

Plaintiff's Proposed Construction	Defendants' Proposed Construction
"timolol free base"	"timolol free base, timolol tartrate, or timolol maleate"

(Joint Claim Construction and Prehearing Statement, Ex. A at 6.) The term appears in claim 4 of the '149 patent, claim 1 of the '976 patent, and claims 1, 4 and 7 of the '258 patent.

i. The Parties' Positions

Allergan submits that the term "timolol" should be construed to mean "timolol free base," as it was for the same patents in *Allergan I*. *See* (*Allergan I Markman* at 13–16.) Allergan again argues that issue preclusion bars Sandoz from now seeking a different construction of this term. Allergan also argues that the patent specification explains that to formulate the claimed solution, timolol maleate 0.68% (w/v) is used to achieve a concentration of 0.5% timolol in the final solution, because 0.68% timolol maleate is "equivalent to 0.5% (w/v) Timolol, free base," citing to, *e.g.*, the '149 patent at Example I. Allergan further argues that using 0.5% timolol maleate would result in a final solution of less than 0.5% timolol. Accordingly, Allergan explains, the 0.5% timolol used in the claims must refer to timolol free base.

Sandoz again responds that issue preclusion does not bar it from now seeking a different construction of timolol because the factors required for issue preclusion are not met here.

Sandoz also argues that the Court's construction of "timolol" in the *Allergan II Markman* for the '890 and '409 patents as "the chemical compound timolol, including its free base, maleate salt, and tartrate salt forms" should be applied here.

In support, Sandoz again argues the doctrine of claim differentiation, and again points to claim 4 of the '258 patent, which recites that for that dependent claim, "timolol" is "timolol maleate." Sandoz points as well to the patent specification, which it says uses "timolol" to refer to both timolol maleate and free base. And, as above with the term "brimonidine," Sandoz argues that the prosecution history of the subsequent '890 patent supports it interpretation.

ii. Analysis

1. Issue Preclusion

The parties' arguments regarding issue preclusion are substantially similar to those for the term brimonidine, and the Court reaches the same conclusions here. Construction of the term "timolol" is an identical issue to that raised in *Allergan I.* The subsequent prosecution history of the '890, '409, and '425 patents does not alter that conclusion. Likewise, Sandoz's argument regarding the change to its product is unavailing with respect to the term "timolol." While in *Allergan I* the parties initially disputed construction of "timolol" as used in the claims of the '149, '976, and '463 patents (*Allergan I* Joint Claim Construction Chart at 2), Sandoz stated in its briefing that it agreed "with Allergan that the term 'timolol' as used in the '258 patent should be construed to mean 'timolol free base.'" (Dkt. No. 123 in *Allergan I* at 14, "Sandoz's *Allergan I* Claim Construction Brief," Dec. 22, 2010.) Although a separate defendant did dispute that construction and lose, making this a closer case, there was no dispute between Sandoz and Allergan that was ultimately litigated and decided. Finally, the Court finds that the construction of "timolol" was essential to the final judgment on validity and infringement, at least implicitly.

Because all of the factors required for issue preclusion are not met here, Sandoz is not precluded from seeking an alternative construction of the term "timolol."

2. Construction

The '149 patent states that "[t]imolol is a beta adrenergic agent represented by the following formula," then presenting the chemical structure of timolol maleate. '149 patent at col.1, l. 54 to col. 2, l. 5. While Allergan argues that similar language used to describe brimonidine means that brimonidine must mean "brimonidine tartrate," it does not argue that the chemical structure provided for timolol maleate also defines the term "timolol." As the Court found in the *Allergan II Markman*, this inconsistency undermines Allergan's positions regarding the construction of both "timolol" and "brimonidine."

Allergan further argues that timolol free base is the correct interpretation of "timolol" because the 0.5% w/v limitation in the claims corresponds to the amount of timolol free base used in the combination of the claimed methods. Again, as explained in the *Allergan II Markman*, while this may be the case, it does not explain the inconsistency between Allergan's constructions of brimonidine and timolol. There is no compelling reason why the two terms should be interpreted in the different manners Allergan suggests.

Moreover, as discussed above, claim 4 of the '258 patent further defines the timolol of claim 1 as including "timolol maleate." Thus, under the doctrine of claim differentiation, claim 1 of the '258 patent must be interpreted in a way that is different than, but encompasses, timolol maleate. Limiting the term "timolol" to the "free base" in claim 1 of the '258 patent would seemingly exclude salt forms, such as timolol maleate. As explained in the *Allergan II Markman*, the breadth of the term timolol is also shown by the prosecution history of the '890 patent. There Allergan presented a claim (28) reading: "A method according to claim 26,

wherein the timolol is selected from the group consisting of timolol tartrate, timolol maleate, and timolol free base."[7] This prosecution history certainly suggests that the patentees understood the term "timolol" to encompass each of these forms. *See e.g.*, *Phillips*, 415 F.3d at 1314 (use of term "steel baffles" strongly implies that "baffles" does not inherently mean objects made of steel).

Accordingly, the Court construes the term "timolol" according to its plain and ordinary meaning, the chemical compound timolol, including both its free base and salt forms.

c. "reducing the number of daily topical ophthalmic doses"

Plaintiff's Proposed Construction	Defendants' Proposed Construction
The term should be construed as it was in *Allergan I,* to have its plain and ordinary meaning.	"adjusting downward the number of daily topical ophthalmic doses"

(Joint Claim Construction and Prehearing Statement, Ex. A at 11.) The term appears in claim 4 of the '149 patent.

i. The Parties' Positions

Allergan again argues that this term was construed in *Allergan I* to be given its plain and ordinary meaning, and accordingly, Sandoz is precluded from now seeking a different construction. More specifically, according to Allergan, in *Allergan I* Sandoz argued that the term meant "reducing the number of daily ophthalmic doses from 3 to 2 times a day," that the Court rejected that argument, (*Allergan I Markman* at 2011 WL 1599049, at *17), and therefore, that issue preclusion applies.

Sandoz asserts that it is not precluded, and that consistent with the Court's prior plain meaning construction, claim 4 requires an actual reduction in the number of daily doses from

[7] As explained in *Allergan II*, that Allergan disclaimed the ultimately issued claim with the same language does not erase this prosecution history. *Allergan II* at 12, 16. As further pointed out by Sandoz, Allergan did not disclaim claim 4 of the '258 patent.

three to two times a day. In other words, Sandoz argues that the claim requires that "a person would need to *administer* the recited fixed composition twice daily to a patient who previously received brimonidine three times daily." Thus, according to Sandoz, claim 4 has two steps: first, a reducing step, and second, an administering step.

ii. Analysis

1. Issue Preclusion

For the same reasons articulated more fully above the issue here is identical to that presented in *Allergan I.* The same claim term was the subject of construction. Sandoz points to no specific prosecution history from the subsequently issued patents that is relevant to this issue. In addition, as discussed above in more detail, that Sandoz has amended its proposed label has no bearing on the issue of claim construction. While in *Allergan I* the ultimate dispute between the parties at trial and on appeal focused on validity, rather than infringement, it is "axiomatic that claims are construed the same way for both invalidity and infringement." *Source Search Techs.*, 588 F.3d at 1075. That Sandoz has amended its proposed product label does not make the construction of this term a different issue than that decided in *Allergan I*.

Unlike the terms "brimonidine" and "timolol," it is clear that Sandoz disputed, briefed, and argued construction of the term "reducing the number of daily topical ophthalmic doses." Specifically, Sandoz argued that the term should be construed to mean "reducing the number of daily ophthalmic doses from 3 to 2 times a day." The Court rejected that construction. *See* (*Allergan I Markman* at 20–24.) Therefore, the term was actually litigated for purposes of the second prong of the doctrine of issue preclusion. That Sandoz now proposes a slightly different construction from that it previously proffered is irrelevant.

Sandoz offers no unique arguments as to why the term "reducing the number of topical ophthalmic doses" was not at least implicitly essential to this Court's prior judgments on validity and infringement, or to the Federal Circuit's decision. Indeed, a review of this Court's opinion in *Allergan I* shows that reduction in daily dosing was an important factor distinguishing the claimed invention from the prior art. *Allergan I*, 818 F. Supp. 2d at 1005 (the prior art "fails to disclose a method of reducing brimonidine treatment from three times a day to twice a day by using a fixed combination"); s*ee also id.* at 1008 ("Specific to claim 4 of the '149 patent, nothing in DeSantis discloses that reducing the dose of brimonidine from three times a day to two times a day through a fixed composition of brimonidine and timolol can maintain the efficacy of the brimonidine treatment."), 1009 ("DeSantis does not disclose a method of reducing the dose of brimonidine from three times a day to two times a day without losing efficacy in the treatment of glaucoma."). Likewise, the Federal Circuit's opinion demonstrates that the reduction in daily dosing without loss of efficacy to be a key factor distinguishing claim 4 over the prior art. *Allergan*, 726 F.3d at 1293–94. Therefore, for the reasons stated previously, the Court finds this argument unpersuasive and views the construction of the term "reducing the number of topical ophthalmic doses" to be essential to the prior judgment.

Accordingly, the Court determines that as to this claim term, the issue is 1) identical to that previously adjudicated; 2) was actually litigated; and 3) was necessary to final judgment in *Allergan I*. Sandoz is therefore precluded from seeking a different construction than that set forth by the Court in *Allergan I*. *See Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 330–31 (1979) (acknowledging the broad discretion awarded to courts when applying issue preclusion). However, even if the Court had found that Sandoz was not so precluded, the Court would reach the same conclusion as in *Allergan I*.

2. Construction

In general, prior claim construction proceedings involving the same patents-in-suit are "entitled to reasoned deference under the broad principals of stare decisis and the goals articulated by the Supreme Court in *Markman*, even though stare decisis may not be applicable per se." *Maurice Mitchell Innovations, LP v. Intel Corp*., No. 2:04–cv–450, 2006 WL 1751779, at *4 (E.D. Tex. June 21, 2006) (Davis, J.); *see TQP Development, LLC v. Intuit Inc.*, No. 2:12–CV–180, 2014 WL 2810016, at *6 (E.D. Tex. June 20, 2014) (Bryson, J.) ("[P]revious claim constructions in cases involving the same patent are entitled to substantial weight, and the Court has determined that it will not depart from those constructions absent a strong reason for doing so."); *see also Teva Pharm. USA, Inc. v. Sandoz, Inc*., 135 S.Ct. 831, 839–40 (2015) ("prior cases will sometimes be binding because of issue preclusion and sometimes will serve as persuasive authority") (citation omitted). The Court nonetheless conducts an independent evaluation during claim construction proceedings. *See, e.g.*, *Texas Instruments, Inc. v. Linear Techs. Corp*., 182 F. Supp. 2d at 589–90; *Burns, Morris & Stewart Ltd. P'ship v. Masonite Int'l Corp*., 401 F. Supp. 2d 692, 697 (E.D. Tex. 2005); *Negotiated Data Sols, Inc. v. Apple, Inc*., No. 2:11–cv–390, 2012 WL 6494240, at *5 (E.D. Tex. Dec. 13, 2012).

In the *Allergan I Markman*, the Court rejected a similar argument to the one that Sandoz now makes. Even if Sandoz was not precluded from re-litigating this issue, the Court would accord its prior decision on the same disputed claim term substantial weight. In addition, nothing in the claims themselves, the patent specification, or the prosecution history requires, as Sandoz argues, "an actual reduction in the number of daily topical ophthalmic doses of 0.2% brimonidine from three to two times a day." (Dkt. No. 235 at 19, "Sandoz Responsive Claim Construction Brief," Feb. 3, 2016.) Sandoz's construction would require, in its own words, that

to practice the claimed method, "a person would need to *administer* the recited fixed composition twice daily to a patient who previously received brimonidine three times daily." *Id.* (emphasis in original). Nothing in the intrinsic evidence requires such a step or such an actual reduction.[8]

Both parties agree that the preamble to claim 4 is an actual limitation on the claim. Sandoz argues that the claim requires two steps: first, a reducing step, and second, an administering step. Allergan, on the other hand, argues that the claim requires only the single step of administering a single composition comprising brimonidine and timolol at the claimed concentrations. The claim language itself states that "said method comprises administering said 0.2% brimonidine by weight and 0.5% timolol by weight in a single composition." Nothing in the claim preamble requires more than that. Rather, the preamble provides context for the claim. As explained by Allergan, the preamble indicates that the claimed method permits a reduction in the number of daily topical ophthalmic doses of brimonidine as compared to prior art treatments. Put another way, the preamble describes the outcome of the claimed method—that the number of daily doses of brimonidine can be reduced. It thus informs the claimed method—actual reduction in doses is not a separate requirement of the claimed method.

The patent specification supports that interpretation. The specification describes the results of a clinical trial comparing the efficacy of different treatments in different patient populations. One group of patients was dosed three times a day with 0.2% brimonidine, and another twice a day with the claimed combination. Patients in the clinical trial were not first dosed with brimonidine three times a day and then switched to the combination twice daily. The combination treatment dosed twice a day is reported as being "superior" to brimonidine three

[8] Neither party cites to any portion of the prosecution history to support its interpretation of this term.

times a day "in lowering the elevated IOP of patients with glaucoma or ocular hypertension." '149 patent at col. 8, l. 65–col. 9, l. 3. The combination is also reported as having a more favorable safety profile than brimonidine dosed three times a day. '149 patent at col. 9, ll. 4–8. The claim preamble, which reads "[a] method of reducing the number of daily topical ophthalmic doses of brimonidine administered topically to an eye of a person in need thereof for the treatment of glaucoma or ocular hypertension from 3 to 2 times a day without loss of efficacy, wherein the concentration of brimonidine is 0.2% by weight" is consistent with the clinical trial and results reported in the specification. Reading an actual "reducing" step into claim 4 is inconsistent with the patent specification.

Accordingly, the Court finds that one skilled in the art would understand the term and that no construction is necessary for "reducing the number of daily topical ophthalmic doses."

d. "without loss of efficacy"

Plaintiff's Proposed Construction	Defendants' Proposed Construction
"without decrease in lowering intraocular pressure"	"without decrease in lowering intraocular pressure in the person for whom the number of administered daily doses has been reduced."

(Joint Claim Construction and Prehearing Statement, Ex. A at 12.) The term appears in claim 4 of the '149 patent.

i. The Parties' Positions

According to Allergan, this term was construed in *Allergan I Markman* and given the meaning that Sandoz articulated. Allergan states that the Federal Circuit relied heavily on this limitation in finding claim 4 not invalid as obvious. *Allergan*, 726 F.3d at 1294. Thus, Allergan submits that Sandoz is now precluded from seeking a different construction. Allergan further argues that Sandoz's interpretation reads an erroneous and improper limitation into the claim.

Sandoz argues that it is not precluded, offering the same arguments discussed above. Sandoz further argues that the claim requires a comparison in the decrease in lowering intraocular pressure on a patient by patient basis.

ii. Analysis

1. Issue preclusion

As above, the issue here is identical to that presented in *Allergan I*. The same claim term was the subject of construction. Sandoz points to no specific prosecution history from the subsequently issued patents that is relevant to this issue. As discussed above, any change to Sandoz's proposed label does not make claim construction a different issue than previously decided.

In *Allergan I*, Sandoz fully disputed, briefed, and argued the construction of the term "reducing the number of daily topical ophthalmic doses." Indeed, Sandoz argued (against a different interpretation by Allergan) that the term should be construed to mean "without decrease in lowering intraocular pressure." Sandoz's litigated construction was adopted by the Court. *See* (*Allergan I Markman* at 20–24.) It is therefore clear that the term was actually litigated and decided, meeting the second prong of issue preclusion.

Finally, as before, Sandoz does not adequately explain why the term was not at least implicitly essential to the court's prior judgments on validity and infringement. Moreover, both this Court and the Federal Circuit expressly relied on this limitation in finding that Sandoz failed to prove that claim 4 is invalid. *See, e.g.*, *Allergan*, 726 F.3d at 1293–94. Therefore, the construction of the term "without loss of efficacy" was essential to the prior judgment.

Accordingly, the Court determines that as to this claim term, the issue is 1) identical to that previously adjudicated; 2) was actually litigated; and 3) was necessary to final judgment in

Allergan I. *See In re Freeman*, 30 F.3d at 1465. Thus, Sandoz is precluded from seeking a different construction than that set forth by the Court in *Allergan I*. But even if the Court had found that Sandoz was not so precluded, the Court would still reach the same conclusion as in *Allergan I*.

2. Construction

As an initial matter, both parties agree that the term, at a minimum, means "without decrease in lowering intraocular pressure." Sandoz, however, further argues that claim 4 also requires that the IOP lowering effects are maintained in one or more individual patients treated twice daily with the brimonidine/timolol combination, as compared to IOP lowering effects in the same patient with the prior thrice daily brimonidine treatment. While Sandoz argues that this issue—whether the efficacy comparison is done on a patient by patient basis—was not addressed during claim construction in *Allergan I*, Sandoz also points to no sound reason why it did not or could not raise this argument previously. In any event, the Court's prior construction of this term is, at a minimum, entitled to substantial weight in construing the term "without loss of efficacy." The Court also finds nothing in the patent claims, specification, or prosecution history[9] that supports Sandoz's position.

The Court has already rejected Sandoz's argument that claim 4 requires a two-step process of first reducing the number of daily doses a patient actually receives, followed by a separate administration step. The Court similarly rejects the argument that claim 4 requires an actual comparison of IOP lowering on a patient by patient basis. Sandoz points to no intrinsic or extrinsic evidence requiring such a construction.

[9] Neither party cites to the prosecution history as relevant to the interpretation of this term.

As explained above, the Court finds that the claim preamble sets forth the outcome of performing the claimed single step method—that brimonidine can be dosed twice daily (as opposed to thrice) without losing efficacy. It thus informs the method, but requires no specific additional steps to be performed. The patent specification, reporting on the results of a clinical trial, is consistent with this interpretation. The specification does not compare results on an individual by individual basis. Rather, it reports on results of different treatments in different patient populations. It would be inconsistent with the intrinsic evidence to interpret claim 4 as requiring a patient-by-patient comparison of IOP lowering results.

Accordingly, the Court construes the term "without loss of efficacy" to mean "without decrease in lowering intraocular pressure."

e. "a person in need thereof"

Plaintiff's Proposed Construction	Defendants' Proposed Construction
"general class of persons to whom the patented compositions are directed, i.e., a patient population"	"a person in need of the reduction in the number of daily doses"

(Joint Claim Construction and Prehearing Statement, Ex. A at 14.) The term appears in claim 4 of the '149 patent.

i. The Parties' Positions

Allergan argues that "a person in need thereof" is directed to the general class of patients in need of treatment—in other words, patients with glaucoma or ocular hypertension. Allergan argues that the description in the specification of clinical trial results, as well as arguments made during prosecution, support its construction.

Sandoz argues that "[c]laim 4 requires that IOP lowering effects are maintained in one or more individual patients as compared to the IOP lowering effect in each of the patients with the prior three-times-daily brimonidine regimen." (Sandoz Responsive Claim Construction Brief at

20.) Thus, according to Sandoz, the "person" is one needing a reduction in the number of daily doses. As above, Sandoz argues that the claim requires a person-by-person analysis.

ii. Analysis

The Court has already rejected Sandoz's argument that the claim preamble requires a patient by patient analysis for the terms "reducing the number of daily ophthalmic doses" and "without loss of efficacy." For the same reasons, the Court rejects Sandoz's construction here. The patent specification does not speak of comparisons on a patient by patient basis, and does not provide clinical results on a patient by patient basis. Rather, it reports on and provides analysis for separate treatment groups.

Moreover, the plain claim language does not support Sandoz's argument that the "person in need thereof" is one in need of a reduction in the number of daily doses of brimonidine. Rather, it more naturally supports a reading that "a person in need thereof" refers to patients in need of treatment for glaucoma or ocular hypertension. The claim specifies that brimonidine is administered topically to a "person in need thereof for the treatment of glaucoma or ocular hypertension." Allergan's proposed definition is thus far more consistent with the specification and the plain claim language. As Allergan argues, "a person in need thereof for the treatment of glaucoma or ocular hypertension" is "directed to the general class of patients with glaucoma or ocular hypertension."

As a general rule, "a" means "one or more." *Baldwin Graphic Sys., Inc. v. Siebert, Inc*., 512 F.3d 1338, 1342–43 (Fed. Cir. 2008). "That 'a' or 'an' can mean 'one or more' is best described as a rule, rather than merely as a presumption or even a convention. . . . An exception to the general rule that 'a' or 'an' means more than one only arises where the language of the claims themselves, the specification, or the prosecution history necessitate a departure from the

rule." *Id.* Thus, according to that rule, "a person in need thereof" reads as "one or more persons in need thereof." That is also consistent with Allergan's proposed definition.

Allergan also cites *Braintree Labs., Inc. v. Novel Labs., Inc.*, 749 F.3d 1349 (Fed. Cir. 2014) and *Wyeth v. Sandoz*, 703 F. Supp. 2d 508 (E.D.N.C. 2010) as case law that should control here. The Court disagrees that they control. *Braintree* does not establish a rule that the term "a patient" (or "a person") always refers to "a general class of persons to whom the patented compositions are directed, i.e., a patient population." *Braintree*, 749 F.3d at 1357. Rather, it simply stands for the proposition that this was the appropriate construction based on the facts in that case. *Wyeth*, and its statement that "[i]n Markman opinions, all but one of the courts that have addressed the issue agree that the appropriate comparison should be based on an average taken from a group of patients" refers only to a set of cases all of which relate to the same patent, and again, was based on the unique facts of that case. The Court therefore sees no controlling case law requiring the use of the particular language used in *Braintree*.

However, the Court finds that one skilled in the art would, in this instance, understand the term "a person in need thereof" to refer to those persons in need of brimonidine for the treatment of glaucoma or ocular hypertension. Accordingly, the Court adopts the plain and ordinary meaning of "a person in need thereof" and holds that such plain and ordinary meaning would be understood by a person of ordinary skill in the art to be a "general class of persons to whom the patented compositions are directed."

f. "reduces the incidence of"

Plaintiff's Proposed Construction	Defendants' Proposed Construction
The term does not require construction, but if it does, the Court should apply its plain and ordinary meaning	"reduces the numerical instances of"

(Joint Claim Construction and Prehearing Statement, Ex. A at 17.) The term appears in claim 1 of the '425 patent.

i. The Parties' Positions

Allergan argues that no construction is necessary, but that if construction is necessary, the Court should apply the term's plain and ordinary meaning. According to Allergan, one of ordinary skill would understand the term without any further definition. Allergan further argues that a numerical limitation such as that proposed by Sandoz is improper because side effects may be reduced in either numerical occurrence or severity.

Sandoz argues that construction is necessary, and that while the words "numerical reduction" do not appear in the patent specification, the specification does set forth numerical reductions in adverse events. According to Sandoz, because the specification provides data in the form of numbers, therefore, so should the claim.

ii. Analysis

As a starting point, the claim in question reads:

> A method of treating a patient with glaucoma or ocular hypertension comprising administering twice daily to an affected eye a single composition comprising 0.2% w/v brimonidine tartrate and 0.5% w/v timolol free base, wherein said method reduces the incidence or one or more adverse events, as compared to the administration of 0.2% w/v brimonidine tartrate monotherapy three times per day wherein the adverse event is selected from the group consisting of conjunctival hyperemia, oral dryness, eye pruritis, allergic conjunctivitis, foreign body sensation, conjunctival folliculolis, and somnolence.

According to the claim, the "method reduces the incidence of one or more adverse events." No numerical limitation is set forth in the claim language itself. Sandoz argues that this is irrelevant because the patent specification does provide numerical reduction numbers (some of which are statistically significant, some of which are not) for adverse events. However, the Court is mindful that it is improper to read limitations from the specification into the claims.

Phillips, 415 F.3d at 1323. While the specification does provide a comparison of the numerical instances and percentages of the adverse events identified in the claims between treatment groups, there is no clear indication in the specification that the patentee intended to so limit the term "reduces the incidence of" only to numerical reductions.

Allergan offers that the plain meaning of the term encompasses both a reduction in severity of an adverse event, as well as numerical occurrence of such an event. Allergan also argues that the patent specification does present reductions in severity of adverse events, pointing to the '425 patent at col. 7, ll. 39–53. That paragraph discusses "serious adverse events." While these "serious adverse events" are reportedly reduced as compared to the three times a day group, it is not clear that this language relates to the severity of a particular incidence of a side effect, as opposed to the seriousness of the side effect itself. The specification at this point appears to discuss the latter, not the former. "Two patients receiving Timolol had 4 serious adverse events (emphysema in one patient; nausea, sweating and tachycardia in another) which were considered possibly related to the study drug." '425 patent, col. 7, ll. 46–49. None of these "serious adverse events" are those listed in the claim, or in the table of adverse events reported in the patent. '425 patent at col. 7, ll. 24–38. They thus appear to, regardless of their magnitude, constitute a separate class of "serious adverse events."

The specification does, however, discuss "[i]ncreases from baseline in the severity of conjunctival erythema and conjunctival follicles" and that these were statistically significantly lower with the combination as compared to the brimonidine only group. '425 patent at col. 7, l. 66–col. 8, l. 5. Thus, there is support in the specification for the fact that one skilled in the art would understand that adverse events may be reduced in both number of occurrences, as well as in the degree of the adverse event.

Sandoz also cites to an extrinsic evidence dictionary definition of "incidence" from *Stedman's Medical Dictionary* as supporting its position. (Sandoz Responsive Claim Construction Brief, Ex. 29.) That dictionary defines "incidence" as: "The extent or rate of occurrence, especially the number of new cases of a disease in a population over a period of time." Sandoz particularly points to the language in the definition regarding "number of new cases" as supporting its position that a numerical qualifier should be added. However, this extrinsic evidence actually supports a broader interpretation of "incidence" that encompasses both severity or degree (extent) and numerical (rate) occurrence, and demonstrates that one skilled in the art would so understand the term. Such an interpretation is consonant with common sense and experience as well—for example, a headache can be mild or incapacitating.

Accordingly, the Court construes the term "reduces the incidence of" as "reduces the severity and/or rate of occurrence of."

g. "a patient"

Plaintiff's Proposed Construction	Defendants' Proposed Construction
"general class of persons to whom the patented compositions are directed, i.e., a patient population"	"one or more particular patients"

(Joint Claim Construction and Prehearing Statement, Ex. A at 15.) The term appears in claim 1 of the '425 patent.

i. The parties' positions

Allergan again argues, as it did regarding the term "a person in need thereof," that the term should be construed as covering a patient population. In support, Allergan points to the specification and particularly to the clinical trial extensively discussed therein. Allergan argues that this discussion highlights that the adverse events recited in the claims of the '425 patent are among those that were analyzed during those clinical trials, and that the claimed combination of

brimonidine and timolol resulted in a lower percentage of patients experiencing these adverse events.

Sandoz agrees that a patient population is required, because the claim requires a comparison step. According to Sandoz, if the claims require a comparison step, they also require that a doctor generate comparative data for the brimonidine tartrate monotherapy.

Allergan responds that the claims do not require any actual comparison step and explains that, for certain adverse events, such a comparison would be impossible because once a patient develops an allergy to brimonidine, that compound can no longer be used to treat the patient.

ii. Analysis

As an initial matter, the Court rejects the proposition that the '425 patent claims require a separate comparison step, as suggested by Sandoz. Nothing in the claim itself, or the patent specification, requires a separate comparison step. The claim recites:

> A method of treating a patient with glaucoma or ocular hypertension comprising administering twice daily to an affected eye a single composition comprising 0.2% w/v brimonidine tartrate and 0.5% w/v timolol free base, wherein said method reduces the incidence or one or more adverse events, as compared to the administration of 0.2% w/v brimonidine tartrate monotherapy three times per day wherein the adverse event is selected from the group consisting of conjunctival hyperemia, oral dryness, eye pruritis, allergic conjunctivitis, foreign body sensation, conjunctival folliculolis, and somnolence.

The "wherein" clause begins after the method is fully defined by the claim. While both parties appear to agree that this clause defines an actual limitation on the claim, the claim does not define a multi-step process. Rather, the claimed method has a single step: administering the claimed composition twice daily to an affected eye. The "wherein" clause, much like the claim preamble discussed above, describes the outcome of the claimed method—that there are lower incidences of certain defined adverse events when the method is practiced. It thus informs the claimed method, but does not require a separate measurement step. The outcome is understood

based on the clinical data presented in the patent. As Allergan explains, the results of that clinical data show that a lower percentage of patients taking the combination brimonidine/timolol treatment twice daily experienced adverse events than those taking brimonidine monotherapy three times a day.

Turning to Sandoz's contention that the term "patient" should be interpreted as "one or more particular patients," the Court rejects that argument as well. First, Sandoz does not explain what is meant by "particular patients" and how the "one or more particular patients" are selected. Second, as this Court previously found, it is well understood that brimonidine 0.2% causes a high rate of ocular allergy and that once a patient develops such an allergy, brimonidine is no longer available as a treatment for the patient. *Allergan I*, 818 F. Supp. 2d at 979. The adverse events recited in claim 1 of the '425 patent include at least two associated with brimonidine allergy, allergic conjunctivitis and conjunctival folliculosis. These facts are undisputed by Sandoz. Thus, a particular patient developing one of these conditions could not be used to compare the adverse events associated with thrice daily brimonidine monotherapy and twice daily combination therapy. In view of these facts, the only comparison that makes sense is as between patient populations taking different therapies. And as explained above, claim 1 itself requires no separate comparison step.

For the reasons set forth above regarding the term "a person in need thereof," the Court finds that one skilled in the art would understand the term "a patient" to refer to those persons with glaucoma or ocular hypertension. Accordingly, the Court adopts the plain and ordinary meaning of "a patient" and holds that such plain and ordinary meaning would be understood by a person of ordinary skill in the art to be a "general class of persons to whom the patented compositions are directed."

h. Indefiniteness

Sandoz argues that claims 1–8 of the ’425 patent are indefinite because they fail to inform one skilled in the art about the scope of the invention with reasonable certainty. Sandoz’s argument consists of one page of attorney argument with no supporting expert testimony or other factual evidence and is insufficient to carry its burden of proving invalidity by clear and convincing evidence.

V. CONCLUSION

The Court adopts the constructions set forth in this opinion for the disputed terms of the ’149, ’976, ’258 and ’425 patents. Within thirty (30) days of the issuance of this Memorandum Opinion and Order, the parties are hereby **ORDERED**, in good faith, to mediate this case with the mediator agreed upon by the parties. As a part of such mediation, each party shall appear by counsel and by at least one corporate officer possessing sufficient authority and control to unilaterally make binding decisions for the corporation adequate to address any good faith offer or counteroffer of settlement that might arise during such mediation. Failure to do so shall be deemed by the Court as a failure to mediate in good faith and may subject that party to such sanctions as the Court deems appropriate.

So ORDERED and SIGNED this 29th day of March, 2016.

RODNEY GILSTRAP
UNITED STATES DISTRICT JUDGE