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

ALLERGAN SALES, LLC,	§	
	§	
Plaintiff,	§	
	§	
v.	§	CASE NO. 2:12-CV-00207-JRG
	§	
SANDOZ., INC., et al.,	§	
	§	
Defendants.	§	
	§	

MEMORANDUM OPINION AND ORDER

Before the Court are Plaintiff Allergan Sales, LLC's Opening Claim Construction Brief (Dkt. No. 113), Defendants' Response (Dkt. No. 127), and Plaintiff's Reply (Dkt. No. 139), concerning the '890 patent.

Also before the Court are Plaintiff's Opening Claim Construction Brief (Dkt. No. 145), Defendants' Response (Dkt. No. 148), and Plaintiff's Reply (Dkt. No. 151), concerning the '409 patent.

The Court held a hearing on June 28, 2013.

I. BACKGROUND

This is a case brought by Plaintiff under the provisions of the Hatch-Waxman Act, alleging that Defendants' applications seeking approval to market generic versions of Plaintiffs' Combigan® product, and Defendants' proposed products, infringe United States Patent Nos. 8,133,890 ("the '890 patent") and 8,354,409 ("the '409 patent). The '890 patent, titled "Combination of Brimonidine and Timolol for Topical Ophthalmic Use," issued on March 13, 2012. The '409 patent bears the same title, and issued on January 15, 2013. In general, both the '890 and '409 patents concern methods of treating a patient exhibiting elevated intraocular pressure associated with diseases such as glaucoma or ocular hypertension with a composition comprising both brimonidine and timolol.

Other patents from the same family as the '890 and '409 patents were previously construed by Judge T. John Ward of this Court in a prior litigation involving the same parties to this litigation. *Allergan, Inc. v. Sandoz, Inc., et al,* No. 2:09-CV-97-TJW, 2011 WL 1599049 (E.D. Tex. April 27, 2011). The Court issued its findings of fact and conclusions of law in the prior case on August 22, 2011, finding that Defendants' generic versions of Combigan® infringe the asserted claims of those related patents, and that those patents are not invalid. *Allergan, Inc. v. Sandoz, Inc., et al,* 818 F. Supp. 2d 974 (Ed. 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. The Federal Circuit, however, upheld the validity of claim 4 of U.S. Patent No. 7,030,149.[1] The Federal Circuit also affirmed the Court's

[1] Because the '149 Patent expires on the same day as two other patents at issue in that case, U.S. Patent Nos. 7,320,976, and 7,642,258, and because as a result of the Federal Circuit's affirmance of claim 4 of the '149

construction of the term "administered in separate compositions" to require that serial administration of brimonidine and timolol be compared to the administration of those drugs in a fixed combination product.

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

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patent, Defendants will be unable to market their generic versions of Combigan® until the expiration of the '149 patent, the Federal Circuit did not address the validity of those two other patents.

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

being 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 in the '890 patent:

Term	Agreed Construction
"an affected eye"	"an eye exhibiting elevated intraocular pressure"
"about"	"approximately"
"% w/v"	"ratio of the weight of the ingredient in question divided by the total volume of the solution, with this ration expressed as a percentage"

"using"	"administering"
"the composition"	"the single composition"

(Dkt. No. 89, 3/11/2013 Joint Claim Construction and Prehearing Statement, at 1.)

There are no agreed to constructions for the '409 patent. (Dkt. No. 144, 5/30/13 Joint Claim Construction and Prehearing Statement at 1.)

IV. CONSTRUCTION OF DISPUTED TERMS IN THE '890 and '409 PATENTS

a. "brimonidine"

Plaintiff's Proposed Construction	Defendants' Proposed Construction
"brimonidine tartrate"	"brimonidine free base or brimonidine tartrate"

(Dkt. No. 89, 3/11/2013 Joint Claim Construction and Prehearing Statement, Ex. A at 1); (Dkt. No. 144, 5/30/13 Joint Claim Construction and Prehearing Statement at 1-2.)

i. The Parties' Positions

Plaintiff submits that the term "brimonidine" should be construed to mean "brimonidine tartrate." In support of its position, plaintiff 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. '890 Patent at 1:52-67. Plaintiff further argues that brimonidine tartrate is the form of brimonidine used in Examples 1 and 2 of the '890 patent, and that the patentee and the Patent Office used the two terms interchangeably. Plaintiff also cites this Court's prior construction of the term "brimonidine" as "brimonidine tartrate" in *Allergan, Inc. v. Sandoz, Inc., et al*, No. 2:09-CV-97-TJW, 2011 WL 1599049 (E.D. Tex. April 27, 2011). Plaintiff argues that the Court should construe the same term in related patents in the same way, but does not suggest that either this Court or Defendants are bound by or estopped by that prior ruling.

Plaintiff also argues that since claims 2-7 of the '890 patent were disclaimed as improper dependent claims, those claims are not available as support for claim construction, citing *Vectra Fitness, Inc. v. TNWK Corp.*, 162 F.3d 1379, 1383 (Fed. Cir. 1998) and *Genetics Institute, LLC v. Novartis Vaccines and Diagnostics, Inc.*, 655 F.3d 1291, 1299 (Fed. Cir. 2011) for the proposition that the disclaimer of claims 2-7 means that these claims should be treated as if they "never existed." Therefore, according to Plaintiff, the doctrine of claim differentiation does not apply, and the disclaimed claim language cannot be used to construe the still extant claims.

Defendants respond that the patent applicants used the term "brimonidine" to include both the specified salt and free base forms in the prosecuted claims of the patent. Defendants also expressly rely on disclaimed claims 2, 4, 5 and 7, each of which depend from claim 1 of the '890 patent. For example, disclaimed claims 2 and 4 read in pertinent part, "wherein the brimonidine is selected from the group consisting of brimonidine tartrate and brimonidine free base." Disclaimed claims 5 and 7 similarly defined and limited the "brimonidine" of claim 1, although to "brimonidine tartrate" alone. Defendants argue that the doctrine of claim differentiation applies, creating a presumption that the term "brimonidine" includes brimonidine tartrate and free base. Defendants further argue that the prosecution history of the '890 patent supports their construction, because during prosecution the patent applicants included dependent claims defining "brimonidine" as including both "brimonidine tartrate" and "brimonidine free base." *See, e.g.*, Dkt. No. 127, Defendants' Responsive Claim Construction Brief Exs. 29, 30, 31, 32, and 33.

ii. Analysis

The '890 patent[2] states that "[b]rimonidine is an alpha adrenergic agonist represented by the following formula;" it then provides a chemical structure for brimonidine tartrate. Dkt. No. 113, Ex. 1 at col. 1, lines 52-65. The patent specification goes on to state that the "chemical name for brimonidine is 5-Bromo-6-(2-imidazolidinylideneamino) quinoxaline L-tartrate." *Id.* at col. 1, lines 66-67. 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, 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 Computer Entertainment America, LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012).

Plaintiff argues that the description set forth above is such an express definition. However, the Court does not find that the language used to clearly rise to the level of lexicography. Therefore, the Court finds that the cited language does not meet the "exacting" standard to limit the understanding of one skilled in the art of the term "brimonidine" only to "brimonidine tartrate." *See, e.g., 3M Innovative Properties Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1369, 1371 (Fed.Cir.2004) (patentee acted as its own lexicographer when the specification stated: "'Multiple embossed' means two or more embossing patterns are superimposed on the web to create a complex pattern of differing depths of embossing.");

[2] Unless otherwise stated, the Court provides citations to the '890 patent specification. The '409 patent shares the same specification.

Astrazeneca AB v. Mutual Pharm. Co., 384 F.3d 1333, 1339 (Fed.Cir.2004) ("The solubilizers suitable according to the invention are defined below.").

Plaintiff also argues that because brimonidine tartrate is the form of brimonidine used in examples 1 and 2 of the '890 patent, the claims should be limited.[3] However, the use of brimonidine tartrate in the specification examples does not require the Court to adopt Plaintiff's construction. *See Aventis Pharma S.A. v. Hospira,, Inc.,* 675 F.3d 1324, 1330 (Fed. Cir. 2012) (it is not enough that the only embodiments, or all of the embodiments, contain a particular limitation to limit a claim term beyond its ordinary meaning). Particular embodiments appearing in the specification will generally not be read in to 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 is well established that "as a general rule claims of a patent are not limited to the preferred embodiment … or to the examples listed within the patent specification." *Glaxo Wellcome, Inc. v. Andrx Pharmaceuticals, Inc.,* 344 F.3d 1226, 1233 (2003). Moreover, "when a claim term has an accepted scientific meaning, that meaning is generally not subject to restriction to the specific examples in the specification." *Id.* Here, the term "brimonidine" has an accepted scientific meaning; it refers to a chemical compound with a certain formula and structure, and is not limited to the tartrate salt. This is further shown by the specification, which states that "[b]rimonidine is disclosed in U.S. Patent No. 3,890,319." Col. 1, line 41. U.S. Patent No. 3,890,319 describes the preparation of brimonidine as including both its salt and free base forms. *See* Dkt. No. 127, Defendants' Responsive Claim Construction Brief Ex. 25, at col. 1, lines 16-49 (compounds are those of the general formula represented, including their

[3] The patentees clearly knew how to write the words "brimonidine tartrate" when they wanted to, as they did throughout the specification. While Plaintiff argues that the two terms "brimonidine" and "brimonidine tartrate" are used interchangeably, the prosecution history, as discussed below, shows that the patentees' understanding of the terms was different.

pharmaceutically acceptable acid addition salts). Thus, the plain and ordinary meaning of brimonidine encompasses brimonidine free base and brimonidine tartrate.[4]

The prosecution history supports the Court's construction. A patentee's statements during prosecution are relevant to claim interpretation. *See Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1350 (Fed. Cir. 2004). During prosecution, the patentees cancelled then pending claims 1-24 and presented new claims 25-47. Dkt. No. 127, Defendants' Responsive Claim Construction Brief Ex. 29. Claim 27 read "A method according to claim 26, wherein the brimonidine is selected from the group consisting of brimonidine tartrate and brimonidine free base." New claim 29 presented similar language: "wherein the brimonidine is selected from the group consisting of brimonidine tartrate and brimonidine free base." *See also id.* Exs. 30, 31, 32, and 33. The prosecution history thus, at a minimum, strongly suggests that the patentees clearly understood the term "brimonidine" to encompass at least brimonidine tartrate and brimonidine free base. *See, e.g., 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).[5] Similarly, applying the

[4] Plaintiff's position regarding the construction of brimonidine is also undercut by its argument that the Court should construe "timolol" to mean "timolol free base." Plaintiff offers 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 descriptions of both chemical compounds in the patent specification and their usage in the patent claims is substantially similar, and the Court discerns no clear reason why the two compounds should be construed in such different manners.

[5] Defendants also cite to the prosecution of a pending patent application from the same patent family as the '890 and '409 patents, Patent Application Serial No. 13/727,106. Dkt. No. 148 at 8-9. There, on April 16, 2013, after Allergan's disclaimer of claims 2-7 of the '890 patent, Allergan filed a preliminary amendment. Id. Ex. 6. In that amendment, the applicants amended claim 1 to read in relevant part "A pharmaceutical composition for reduction of intraocular pressure comprising brimonidine tartrate …" (underlining indicates amended claim language). Plaintiff responds that this amendment is irrelevant to construction of the term brimonidine in the '409 patent (and also presumably, in the '890 patent), arguing that Defendants cite only to cases holding that prosecution of other related issued patents can be relevant to claim construction. However, whether this pending patent prosecution is intrinsic or extrinsic evidence (and the Court need not decide which), at a minimum it provides some evidence regarding the patentee's understanding of the term "brimonidine," *i.e.*, that the term is not necessarily limited to "brimonidine tartrate."

principles of claim differentiation[6] to the claims presented during prosecution also suggests that the term "brimonidine" is not limited to "brimonidine tartrate." *See American Med. Sys., Inc. v. Biolitec, Inc.*, 618 F.3d 1354, 1360 (Fed. Cir. 2010); *Phillips*, 415 F.3 at 1315.

While it is true that the patentees ultimately disclaimed claims 2-7 of the '890 patent, that disclaimer did not and could not erase the prosecution history record of the '890 patent. Indeed, Plaintiff admitted at oral argument that the prosecution history presenting those claims is still available, despite the disclaimer, as evidence that can be consulted by the Court during claim construction.[7] (Dkt. No. 158, 6/28/2013 Markman Tr. at 13-14). *Vectra,* cited by Plaintiff for the proposition that disclaimed claims 2-7 should be treated as if they "never existed," stands equally for the proposition that the "public is entitled to rely on the public record of a patent, in determining the scope of the patent's claims." *Vectra*, 162 F.3d at 1384. That public record includes the patent prosecution history. In that case, Vectra attempted to argue that it could recapture subject matter that was narrower than its disclaimed claims, but broader than the surviving claims. As explained by the Federal Circuit, such "partial recapture would effectively render disclaimers a nullity" and the "public could never rely on the scope of the non-disclaimed

[6] Because claims 2-7 were disclaimed, the Court does not apply the presumption raised by claim differentiation. Rather, the Court simply finds the principles of the doctrine of claim differentiation to be instructive here.

[7] Plaintiff argues that claims 2-7 were disclaimed as improper dependent claims that were, accordingly, invalid. Defendants respond that the disclaimer was simply a litigation tactic by Plaintiff attempting to redefine the scope of the patent claims. The Court notes that the PTO, which accords claim terms their broadest reasonable construction during prosecution, allowed claims 2-7 to issue. Therefore, it follows that the PTO believed claims 2-7 were not improper dependent claims, and that the term "brimonidine" was broad enough according to the PTO to encompass both brimonidine free base and brimonidine tartrate. The breadth of the construction that the PTO must have accorded the term "brimonidine" to permit claims 2-7 to issue undermines Plaintiff's claim construction argument. *See Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1347 (Fed. Cir. 2001) ("we may presume that the examiner gave the terms in the proposed claim their "broadest reasonable interpretation consistent with the specification," since he was obliged to do so").

claims." *Id.* Similarly here, the public is entitled to rely on the clear and unambiguous prosecution history demonstrating the patentees' understanding of the term "brimonidine."[8]

The Court is mindful that in prior litigation between the same parties concerning related patents, Judge Ward of this Court construed "brimonidine" to mean "brimonidine tartrate." *Allergan, Inc. v. Sandoz, Inc*., No. 2:09-CV-97-TJW, 2011 WL 1599049 (E.D. Tex. April 27, 2011). However, in that case "brimonidine tartrate" was a construction agreed to by the parties and adopted by Judge Ward. In contrast, claim construction of this term in the present case is hotly contested.[9] The Court has fully considered Judge Ward's prior opinion, but for all of the reasons stated above and based on the record in this case, reaches a different conclusion.

The Court construes the term "brimonidine" according to its plain and ordinary scientific meaning: the chemical compound brimonidine, including its free base and tartrate salt forms.

b. "timolol"

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

(Dkt. No. 89, 3/11/2013 Joint Claim Construction and Prehearing Statement, Ex. A at 3); . (Dkt. No. 144, 5/30/13 Joint Claim Construction and Prehearing Statement at 1-2.).

i. The Parties' Positions

Plaintiff submits that the term "timolol" should be construed to mean "timolol free base." Plaintiff argues that the 0.5% w/v limitation supports this interpretation, as the 0.5% concentration corresponds to the amount of timolol free base used in the combination of the

[8] *Genetics Institute*, also cited by Plaintiff, is silent as to the impact of disclaimer on the prosecution history.

[9] As noted above, Plaintiff does not argue that Defendants are bound by the Court's prior construction or the fact that it was an agreed to construction. Instead, Plaintiff notes that Defendants did not appeal the Court's prior construction of brimonidine, but does not explain how Defendants could have appealed an agreed to construction. The Federal Circuit did not consider the construction of "brimonidine" in its opinion.

claimed methods. Plaintiff further argues that the patent specification defines timolol as timolol free base, by virtue of its use in the patent examples.

Defendants respond that now disclaimed claims 3, 4, 6 and 7, demonstrate that "timolol" means at least "timolol free base, timolol tartrate, or timolol maleate." Defendants further argue that the patent specification refers broadly to both timolol maleate and timolol free base, and that the prosecution history, in which they defined the term "timolol" in dependent claims as including timolol tartrate, maleate, and/or free base.[10] Dkt. No. 127, Defendants' Responsive Claim Construction Brief Exs. 29, 30, 31, 32, and 33.

ii. Analysis

The '890 patent states that "[t]imolol is a beta adrenergic agent represented by the following formula," presenting the chemical structure of timolol maleate. Dkt. No. 113, Ex. 1 at col. 2, lines 1-18. While Plaintiff 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." This inconsistency in argument undermines Plaintiff's positions regarding the construction of both "timolol" and "brimonidine."

Plaintiff 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. While this may be true, Plaintiff's arguments regarding the construction of brimonidine and timolol are again inconsistent. The claims similarly use the term "0.2% w/v brimonidine," yet Plaintiff argues that the term "brimonidine" must be interpreted as only "brimonidine tartrate." This inconsistency again undermines Plaintiff's positions for both compounds. While brimonidine and timolol are different terms,

[10] Plaintiff notes that the patent specification makes no mention of timolol tartrate.

they are both chemical compounds, and this Court discerns no compelling reason why the two terms should be interpreted in the different manners suggested by Plaintiff. If Plaintiff is correct that the use of the "%w/v" limitation in the claims provides the context for claim construction, it should do so equally for both brimonidine and timolol. Accordingly, the "%w/v" limitation supports an interpretation that construes brimonidine and timolol consistently to include at least their free base forms.[11]

Plaintiff further argues that the patent examples define timolol as limited to timolol free base. Yet, the specification also references timolol maleate and there is no clear disclaimer of such coverage in either the patent specification or prosecution history. Moreover, as explained above, particular embodiments appearing in the specification will generally not be 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); *Glaxo Wellcome, Inc. v. Andrx Pharmaceuticals, Inc.*, 344 F.3d 1226, 1233 (2003). Indeed, "when a claim term has an accepted scientific meaning, that meaning is generally not subject to restriction to the specific examples in the specification." *Glaxo*, 344 F.3d at 1233. The term "timolol" has an accepted scientific meaning; therefore, the Court accords the term its plain and ordinary meaning.

As with the term "brimonidine," the prosecution history supports the Court's construction. A patentee's statements during prosecution are relevant to claim interpretation.

[11] During the prosecution of a pending patent application from the same patent family as the '890 and '409 patents, Patent Application Serial No. 13/727,106, Dkt. No. 148 at 8-9, applicants filed a preliminary amendment. *Id.* Ex. 6. Amended claim 1 recites a pharmaceutical composition "comprising brimonidine tartrate at a concentration of about 0.2% w/v and timolol at a concentration of about 0.5% w/v …" New claim 8 then recites "[t]he composition of claim 1, wherein timolol is timolol maleate and is present at a concentration of 0.68% w/v." Thus, during prosecution of this currently pending patent application, the patentee continues to advance positions that are at odds with those the Plaintiff advances here—namely that timolol includes only the "free base" form of the compound. Yet, during this pending prosecution of the related patent, the patentee continues to advocate for claims that require a construction of "timolol" that includes "timolol maleate." Whether this record is intrinsic or extrinsic evidence, it at a minimum impacts the credibility of Plaintiff's argument regarding the construction of "timolol" and demonstrates, to some extent, that the patentee's understanding of "timolol" encompasses not only the free base, but also the maleate salt.

See Microsoft Corp. v. Multi-Tech Sys., Inc., 357 F.3d 1340, 1350 (Fed. Cir. 2004). During prosecution, the patentees cancelled then pending claims 1-24 and presented new claims 25-47. Dkt. No. 127, Defendants' Responsive Claim Construction Brief Ex. 29. Claim 28 read "A method according to claim 26, wherein the timolol is selected from the group consisting of timolol tartrate, timolol maleate, and timolol free base." New claim 29 presented similar language. *See also id.* Exs. 30, 31, 32, and 33. The prosecution history thus, at a minimum, strongly suggests that the patentees clearly understood the term "timolol" to encompass each of these forms. *See e.g., 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). For the same reasons stated above regarding "brimonidine," the Court finds that this prosecution history was not erased by the disclaimer of claims 2-7 of the '890 patent. The public is entitled to rely on the clear and unambiguous prosecution history demonstrating the patentees' understanding of the term "timolol."

Judge Ward previously construed the term "timolol" in the related litigation to mean "timolol free base." *Allergan, Inc. v. Sandoz, Inc.*, No. 2:09-CV-97-TJW, 2011 WL 1599049 (E.D. Tex. April 27, 2011). However, like the previous construction of "brimonidine," Judge Ward adopted a construction of "timolol" to which all the parties essentially agreed. This Court has fully considered Judge Ward's prior opinion, and for all of the reasons stated above and based on the record in this case, reaches a different conclusion.

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

c. "as compared to brimonidine in the absence of timolol"

Plaintiff's Proposed Construction	Defendants' Proposed Construction
The term does not require construction, but if the Court chooses to construe the term, it should construe it to have its plain and ordinary meaning	"not in a fixed composition with timolol"

(Dkt. No. 89, 3/11/2013 Joint Claim Construction and Prehearing Statement, Ex. A at 5).

i. The Parties' Positions

Plaintiff submits that this term in the '890 patent claims should be given its plain and ordinary meaning. Plaintiff argues that the term refers to a comparison between using the combination formulation (0.2% brimonidine and 0.5% timolol) and brimonidine monotherapy. Plaintiff further explains that by brimonidine monotherapy, it means the FDA approved regimen of 0.2% brimonidine monotherapy administered three times a day, as described in the patent specification. According to Plaintiff, this is the comparison made in the examples in the patent specification.

Defendants respond that the proper comparison is between the use of the combination formulation and the administration of brimonidine, as long as the brimonidine is not administered in the same composition as timolol. In other words, Defendants argue that the comparison is broader than with brimonidine alone, "as on its face it can include the administration of brimonidine along with active ingredients other than timolol." Defendants further argue that nothing in the claims or the patent requires that the comparison be limited to 0.2% brimonidine monotherapy administered three times a day.

ii. Analysis

The starting point for claim construction is the language of the claims themselves. In pertinent part, that language in claim 1 of the '890 patent reads: "wherein said method [using the

brimonidine/timolol combination product] results in a lower incidence of one or more adverse events, as compared to brimonidine in the absence of timolol." Plaintiff argues that the claimed comparison means that the method results in a lower incidence of one or more adverse events as compared to a patient to who is only administered brimonidine. Defendants argue that the claimed comparison should be conducted as compared to a patient who has not taken timolol in a fixed combination with brimonidine (*e.g.,* the claimed combination). While not a model of clarity, the use of the term "in the absence of timolol" does more naturally suggest that the patient has not received timolol at all, either in fixed combination or serially with brimonidine. This does not, however, answer the question of whether the claimed comparison is to brimonidine monotherapy or to include brimonidine administered with another drug. Nor does it answer whether, as Plaintiff suggests, such monotherapy is limited to the FDA approved regimen of thrice-daily administration with 0.2% w/v brimonidine.

Patent claims are part of a "fully integrated written instrument." *Markman*, 52 F.3d at 978. The specification is "always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1313, quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Here, the patent specification does not use the term "as compared to brimonidine in the absence of timolol." The patent specification does explain, however: "The Combination administered BID demonstrated a favorable safety profile that was comparable to Timolol BID and better than Brimonidine TID with regard to the incidence of adverse events and discontinuations due to adverse events." Dkt. No. 113, Ex. 1 at col. 8, lines 61-65. Thus, it was the comparison with brimonidine monotherapy (Brimonidine TID) that resulted in a lower incidence of adverse events for the combination product—the only such disclosure in the patent specification. Accordingly,

this discussion strongly suggests that the claimed comparison should be to brimonidine monotherapy.[12]

Therefore, the Court construes the term "as compared to brimonidine in the absence of timolol" to mean **"as compared to brimonidine monotherapy."**[13] The Court declines, however, to limit such monotherapy to a thrice-daily regimen with 0.2% w/v brimonidine. The fact that the patentee chose to use the term "0.2% w/v brimonidine" in one clause of the patent claim, but did not use the same term in describing the comparator product, is strong evidence that the brimonidine of the comparator product is not limited to 0.2% w/v brimonidine. *See, e.g.*, *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). Moreover, the patentee could have defined the brimonidine monotherapy to be thrice-daily, as it did in the '409 patent, discussed in further detail below. The patentee did not. Therefore, the Court will not read that limitation into the claim language.

[12] While the patent specification also refers to certain advantages of the combination product versus the serial administration of brimonidine and timolol, such serial administration would not be "in the absence of timolol."

[13] At oral argument, Defendants submitted that the concentration of brimonidine would encompass only "known concentrations of brimonidine, and further that such known concentrations would have been between 0.08% and 0.5%." Dkt. No. 158 at 56-57. The record evidence does show that there were a variety of brimonidine concentrations between 0.08% and 0.5% that were known to those skilled in the art. The Court has not, however, been asked to apply such an interpretation to the term "brimonidine monotherapy." If such term becomes relevant in the litigation, the Court may revisit this issue.

d. "as compared to the administration of brimonidine three times a day without the concurrent administration of timolol"

Plaintiff's Proposed Construction	Defendants' Proposed Construction
The term does not require construction, but if the Court chooses to construe the term, it should construe it to have its plain and ordinary meaning	"as compared to the administration of brimonidine three times a day without the administration of timolol at the same time as the brimonidine"

i. The Parties' Positions

Plaintiff submits that this term in the '409 patent should be given its plain and ordinary meaning "in light of the intrinsic record." According to Plaintiff, that record requires comparing administration of the combination product to the administration of 0.2% w/v brimonidine monotherapy. Plaintiff alleges that its proposed construction reflects the fact that the claims were drafted to cover the unexpected result of solving the side effects associated with thrice daily 0.2% w/v brimonidine monotherapy. Plaintiff argues that this is the most natural reading of asserted claims 12 through 21 of the '409 patent. Plaintiff also asserts that this is the only comparison explicitly described in the patent specification.

Defendants assert that the claim language itself places no explicit limitation on the concentration of brimonidine to which the combination product is compared. Defendants argue that at the time of the invention of the '409 patent, one skilled in the art would have known that brimonidine could be administered in different concentrations, and accordingly, that the comparator product of the claim is not limited to a specific concentration of brimonidine. Defendants further assert that the dictionary definition of the term "concurrent" means "at the same time," and therefore, that only the administration of timolol "at the same time" as brimonidine is excluded by the language "without the concurrent administration of timolol." In other words, Defendants argue that the claimed comparator regimen includes one where timolol

and brimonidine are administered separately to a patient, including administration five minutes apart.[14] Finally, Defendants similarly argue that the term "without timolol" does not mean "without timolol or anything else." Rather, according to defendants, the claim language means that drugs other than brimonidine can also be used in the comparator treatment—that it is not limited to brimonidine monotherapy.

ii. Analysis

The starting point for claim construction is the language of the claims themselves. In pertinent part, that language in claims 12-21 of the '409 patent reads: "wherein the method results in a lower incidence of [named side effect] as compared to administration of brimonidine three times a day without the concurrent administration of timolol." The absence of a percent w/v limitation together with the use of the term "brimonidine" in these claims is compelling evidence that the "administration of brimonidine three times a day" is not limited to 0.2% w/v brimonidine, particularly where claim 1 of the '409 patent specifically includes such a limitation for the combination product. Accordingly, the Court declines to read into the claims that particular limitation.

As to the term "without concurrent administration of timolol," the Court notes that the patent specification does not use the term "concurrent administration."[15] Defendants argue that the use of the term "concurrent" excludes only the administration of the two drugs (brimonidine

[14] Plaintiff counters that in the field of ophthalmic medicine, concurrent treatments are not given at the "same time," as a patient must wait a certain amount of time, typically at least five minutes between administering drops of different drugs to the eye, lest the second drop wash out the medicine from the first drop, citing to deposition testimony and briefing in prior litigation between the parties. Dkt. No. 151 at 5.

[15] Plaintiff asserts that in the field of ophthalmic medicine the terms "adjunctive," "serial," "concomitant," and "concurrent" administration are synonymous. Dkt. No. 151 at 5, fn. 4. Plaintiff further asserts that Defendants "appear to agree that these terms have the same meaning." *Id.* In fact, Defendants do not appear to agree that the terms have the same meaning, instead stating: "The distinctions between concurrent, adjunctive, serial or concurrent administrations have not been at issue or otherwise important in this litigation until now. There is uncertainty as to the differences among the various terms used by Allergan throughout the prosecution history." Dkt. No. 148 at 14. The Court need not, however, determine whether each of these terms are synonymous and makes no such finding, one way or the other.

and timolol) at the same time, and that administration of the two drugs five minutes apart is not excluded.[16] Put another way, Defendants' interpretation seemingly excludes only the circumstance when drops of two or more different drugs are placed in the patient's eye at the exact same time. This does not, however, comport with the patent specification:

> Moreover, it has been found that adequate lowering of intraocular pressure has been obtained when administering the compositions of this invention twice a day as compared to the FDA-approved regiment wherein brimonidine ophthalmic solution, i.e., Alphagan® ophthalmic solution is administered three times a day and timolol ophthalmic solution, i.e., Timoptic® ophthalmic solution is administered twice a day. This results in the exposure of the patient to 67% and 50% of benzalkonium chloride, with the compositions of this invention, as compared to the administration of Alphagan® and Timoptic®, respectively. In FDA-approved adjunctive therapy, wherein Alphagan® and Timoptic® are serially administered, the patient is exposed to almost three times the concentration of benzalkonium chloride as compared to the administrations of the compositions of this invention twice a day.

Dkt. No. 147, Ex. 1 at col. 2, line 57 to col. 3, line 5.

Thus, the patent specification clearly describes a serial treatment of brimonidine and timolol in which the patient is being administered brimonidine three times a day and timolol twice daily. The patient is being treated with both drugs at the same time. It is logical that one skilled in the art would understand that such a patient is receiving "concurrent administration" of timolol and brimonidine. Patent claims are part of a "fully integrated written instrument." *Markman*, 52 F.3d at 978. The specification is "always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1313, quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Thus, consistent with the patent specification, the Court does not read the term

[16] Defendants' construction also begs the question of how much time can pass between the "administration" of brimonidine and another drug. Would the administration of brimonidine and another drug one minute apart be "at the same time"? Ten seconds apart? The lack of clarity to Defendants' construction does not support its proposed construction.

"without the concurrent administration of timolol" as "without the administration of timolol at the same time" as brimonidine.

Rather, the Court finds that consistent with the specification, the term "without the concurrent administration of timolol" means brimonidine monotherapy. The claims require that the claimed comparison results in a lower incidence of particular enumerated side effects for the combination product as compared to the administration of brimonidine three times a day. The patent specification explains that the patentee conducted tests in which the combination brimonidine/timolol product administered twice-daily was compared to brimonidine monotherapy administered three times a day: "The Combination administered BID demonstrated a favorable safety profile that was comparable to Timolol BID and better than Brimonidine TID with regard to the incidence of adverse events and discontinuations due to adverse events." Dkt. No. 147, Ex. 1 at col. 8, lines 55-60. Thus, it was the comparison with brimonidine monotherapy that resulted in a lower incidence of the enumerated adverse events for the combination product. Accordingly, the patent specification strongly suggests that the claimed comparison should be to brimonidine monotherapy.

Therefore, the Court construes the term "as compared to the administration of brimonidine three times a day without the concurrent administration of timolol" to mean **"as compared to brimonidine monotherapy administered three times a day."** The Court declines, however, to limit such monotherapy to that with 0.2%w/v brimonidine.

V. CONCLUSION

The Court adopts the constructions set forth in this opinion for the disputed terms of the '890 patent and '409 patents. The parties are ordered that they may not refer, directly or indirectly, to each other's claim construction positions in the presence of the jury. Likewise, the parties are ordered to refrain from mentioning any portion of this opinion, other than the actual definitions adopted by the Court, in the presence of the jury. Any reference to claim construction proceedings is limited to informing the jury of the definitions adopted by the Court.

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 David Folsom, the mediator appointed in this case. 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 on this

Sep 4, 2013

RODNEY GILSTRAP
UNITED STATES DISTRICT JUDGE