United States District Court

EASTERN DISTRICT OF TEXAS
TYLER DIVISION

ALLERGAN, INC.	§	
	§	
v.	§	**Case No. 6:11-cv-441**
	§	
SANDOZ INC., ET AL.	§	

MEMORANDUM OPINION AND ORDER

This claim construction order construes the disputed claim terms of U.S. Patent No. 7,851,504 ('504 patent) entitled "Enhanced Bimatoprost Opthalmic Solution."[1] On September 27, 2012, the Court held a claim construction hearing to construe the disputed terms. For the following reasons, the Court adopts the constructions set forth below.

I. BACKGROUND

This is a patent infringement action filed pursuant to the Hatch-Waxman Act. Congress passed the Hatch-Waxman Act in 1984 to promote the manufacturing of generic pharmaceuticals. See Drug Price Competition and Patent Term Restoration Act, 98 Stat. 1585 (1984); PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2574 (2011). "Under this law, 'generic drugs' can gain [Federal Drug Administration (FDA)] approval simply by showing equivalence to a reference listed drug that has already been approved by the FDA." Mensing, 131 S. Ct. at 2574. "This allows manufacturers to develop generic drugs inexpensively, without duplicating the clinical trials already performed on the equivalent brand-name drug." Id.

[1] In this infringement action, Plaintiff also asserts U.S. Patent No. 5,688,819 ('819 patent) entitled "Cyclopentane Heptanoic Acid, 2-Cycloalkyl or Arylalkyl Derivatives as Therapeutic Agents." The '819 patent was previously litigated between Plaintiff and Defendant Sandoz Inc. in the United States District Court for the District of Delaware. See Allergan, Inc. v. Barr Labs., Inc., No. 1:09-cv-333 (D. Del. filed May 7, 2009). That case has since been appealed. See Allergan, Inc. v. Barr Labs., Inc., No. 12-1040 (Fed. Cir. filed Oct. 21, 2011). Although the parties in this case dispute the construction of a claim term in the '819 patent, they agree to be bound by the appellate court's decision on the disputed term. Accordingly, the Court finds it unnecessary to consider any claim construction issues related to the '819 patent at this time.

Plaintiff Allergan, Inc. obtained FDA approval for Lumigan® 0.03% bimatoprost ophthalmic solution in 2001. In late 2010, Plaintiff obtained FDA approval for Lumigan® 0.01% bimatoprost ophthalmic solution for the reduction of elevated intraocular pressure in certain patients, including those with open angle glaucoma or ocular hypertension. The active ingredient in Lumigan® is the prostaglandin analog bimatoprost, which operates by increasing the outflow of aqueous humor from the eye.

Defendants have each filed an Abbreviated New Drug Application (ANDA) for FDA approval to market a generic version of Plaintiff's Lumigan® 0.01% bimatoprost ophthalmic solution. Defendants seek to market their generic versions prior to the expiration of the patents listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations publication (known as the Orange Book) as covering Plaintiff's Lumigan® 0.01% bimatoprost ophthalmic solution.

Defendants filed their ANDAs pursuant to a procedure called paragraph IV certification. See 21 U.S.C. § 355(j)(2)(A). Under this procedure, Defendants certified that the patents listed in the Orange Book are invalid or will not be infringed by their generic pharmaceuticals. "Such a certification constitutes an artificial act of infringement." Pozen Inc. v. PAR Pharm., Inc., 696 F.3d 1151, 1157 (Fed. Cir. 2012). Accordingly, Plaintiff filed complaints against Defendants for infringement of the '504 patent and the '819 patent.

A total of four patents are listed in the FDA's Orange Book as covering Lumigan® 0.01% bimatoprost ophthalmic solution. Of those, Plaintiff asserts the '504 patent against all Defendants and the '819 patent only against Defendant Sandoz Inc. The '504 patent is directed to the drug's formulation while the '819 patent generally relates to the use of bimatoprost to treat glaucoma.

The ‘504 patent contains three independent claims directed to compositions. Independent claim 3 of the ‘504 patent is representative:

> A composition having a pH of about 7.3 which comprises about 0.01% bimatoprost, 200 ppm benzalkonium chloride, about 0.014 citric acid monohydrate, a phosphate buffer, NaCl, and water wherein said composition is an aqueous liquid which is formulated for ophthalmic administration.

‘504 Patent at 6:26–30.

II. LEGAL STANDARD

Claim construction is a matter of law. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995). The purpose of claim construction is to resolve the meanings and technical scope of claim terms. U.S. Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1568 (Fed. Cir. 1997). When the parties dispute the scope of a claim term, “it is the court’s duty to resolve it.” *O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008).

The claims of a patent define the scope of the invention. Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1324 (Fed. Cir. 2002). They provide the “metes and bounds” of the patentee’s right to exclude. Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257 (Fed. Cir. 1989). Accordingly, claim construction begins with and “remain[s] centered on the claim language itself.” Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1116 (Fed. Cir. 2004).

Claim terms are normally given their “ordinary and customary meaning.” Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Generally, “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.” Id at 1313.

The best guide for defining a disputed term is a patent's intrinsic evidence. Teleflex, 299 F.3d at 1325. Intrinsic evidence includes the patent's specification and the prosecution history. Id.

The claims are part of the specification. Markman, 52 F.3d at 979. ."). "[T]he context in which a term is used in the asserted claim can be highly instructive." Phillips, 415 F.3d at 1314; see also Abtox, Inc. v. Exitron Corp., 122 F.3d 1019, 1023 (Fed Cir. 1997) ("[T]he language of the claim frames and ultimately resolves all issues of claim interpretation "Differences among claims can also be a useful guide in understanding the meaning of particular claim terms." Phillips, 415 F.3d at 1314.

In addition to the claims, the specification's written description is an important consideration during the claim construction process. See Vitronics Corp., 90 F.3d at 1582. The written description provides further context for claim terms and may reflect a patentee's intent to limit the scope of the claims. See Watts v. XL Sys., Inc., 232 F.3d 877, 882 (Fed. Cir. 2000). "[T]he 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 1315 (quoting Vitronics, 90 F.3d at 1582).

The specification may also resolve ambiguous claim terms "where the ordinary and accustomed meaning of the words used in the claims lack sufficient clarity to permit the scope of the claim to be ascertained from the words alone." Teleflex, Inc., 299 F.3d at 1325. For example, "[a] claim interpretation that excludes a preferred embodiment from the scope of the claim 'is rarely, if ever, correct.'" Globetrotter Software, Inc. v. Elam Computer Grp., Inc., 362 F.3d 1367, 1381 (Fed. Cir. 2004) (quoting Vitronics Corp., 90 F.3d at 1583).

But care must be taken to avoid unnecessarily reading limitations from the specification into the claims. Teleflex, 299 F.3d at 1326; see also Raytheon Co. v. Roper Corp., 724 F.2d 951, 957 (Fed. Cir. 1983) ("That claims are interpreted in light of the specification does not mean that everything expressed in the specification must be read into all the claims."). "[P]articular embodiments appearing in the written description will not be used to limit claim language that has broader effect." Innova/Pure Water, 381 F.3d at 1117; see also Phillips, 415 F.3d at 1323 ("[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments.").

The prosecution history is also part of the intrinsic evidence. Phillips, 415 F.3d at 1317. It "consists of the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent." Id. "As in the case of the specification, a patent applicant may define a term in prosecuting a patent." Home Diagnostics, Inc. v. LifeScan, Inc., 381 F.3d 1352, 1356 (Fed. Cir. 2004). Statements made during the prosecution of the patent may limit the scope of the claims. Teleflex, 299 F.3d at 1326; see *Omega Eng'g Inc. v. Raytek Corp*., 334 F.3d 1314, 1323 (Fed. Cir. 2003) (explaining that the doctrine of prosecution disclaimer "preclud[es] patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution").

Finally, the Court may rely on extrinsic evidence to aid with understanding the meaning of claim terms. Markman, 52 F.3d at 981. Extrinsic evidence includes "all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." Id. at 980. Extrinsic evidence is generally less useful or reliable, Phillips, 415 F.3d at 1317, and it should not be relied on when it contradicts the intrinsic evidence, Markman, 52 F.3d at 981.

III. DISCUSSION

The parties' dispute focuses on the meaning and scope of two phrases in the claims of the '504 patent. The parties make identical arguments with respect to both terms. Additionally, the parties agree on the construction of a number of other terms.

a. *"[A] composition . . . which comprises . . . citric acid monohydrate . . . wherein said composition is an aqueous liquid"*[2]

Disputed Claim Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
"[A] composition . . . which comprises . . . citric acid monohydrate . . . wherein said composition is an aqueous liquid"	The term does not require construction, but if the Court chooses to construe the term, it should construe it as "a composition that is an aqueous liquid in which citric acid monohydrate is one of the materials that is used to prepare the composition."	"a composition that is an aqueous liquid comprising . . . citric acid in crystalline form containing only one water molecule per molecule of citric acid, where the water molecules are incorporated into the crystals"

The dispute between the parties concentrates on the characterization of "citric acid monohydrate" in the composition. As an initial matter, the parties are in agreement that citric acid monohydrate is a crystalline substance with a lattice chemical structure containing one water molecule per citric acid molecule. Furthermore, the parties agree that when added to water, citric acid monohydrate dissociates to citric acid and water.

Turning to construction issues, Plaintiff states that the term does not require any construction. To the extent the Court finds construction necessary, Plaintiff argues that the claims only require citric acid monohydrate be an ingredient in the composition. Plaintiff contends that the claims do not command that citric acid monohydrate remain in crystalline form in the formulation. Rather, Plaintiff concludes that the citric acid monohydrate dissolves into solution because the claims require the formulation to be an aqueous liquid.

[2] The phrase "a composition . . . which comprises . . . citric acid monohydrate . . . wherein said composition is an aqueous liquid" is found in the '504 patent at claims 2 and 3.

Defendants argue that Plaintiff misinterprets the claims. Defendants allege that the claims cover a final composition rather than a recipe with a list of ingredients. Defendants believe it is appropriate to define citric acid monohydrate as remaining in crystalline form in the formulation. Defendants argue that Plaintiff's construction improperly redrafts the claims. Instead of "citric acid monohydrate" remaining a component of the formulation, Defendants argue Plaintiff is attempting to rewrite the claims as product-by-process claims.

The Court finds that Plaintiff's proposed construction is consistent with the claim language. This construction finds support in the claim language, the specification, the prosecution history, and the extrinsic evidence.

i. The Claim Language

Defendants argue that the claim language compels the adoption of Defendants' proposed construction. Defendants allege that the use of the term "composition" in the claims has a well-established meaning in patent law. Defendants rely on Exxon Chemical Patents, Inc. v. Lubrizol Corp., 64 F.3d 1553, 1558 (Fed. Cir. 1995), and PIN/NIP, Inc. v. Platte Chemical Co., 304 F.3d 1235, 1244 (Fed. Cir. 2002), to establish the broad principle that a "chemical composition exists at the moment the ingredients are mixed together. Before creation of the mixture, the ingredients exist independently." Exxon Chem. Patents, Inc., 64 F.3d at 1558; see also PIN/NIP, 304 F.3d at 1244. Defendants argue that the use of "composition" requires "specified ingredients at any time from the moment at which the ingredients are mixed together." PIN/NIP, 304 F.3d at 1244.

Although Defendants reference sound principles of claim construction, the Court does not find that they compel adoption of Defendants' proposed construction. Defendants' reliance on the proposition that a composition is "a mixture in which the components are present together at

some point in time" does not translate to requiring citric acid monohydrate to remain in crystalline form in the formulation.

Defendants' position fails to consider the term "composition" in the context of the entirety of the claim. See Abbott Labs. v. Syntron Bioresearch, Inc., 334 F.3d 1343, 1351 (Fed. Cir. 2003) ("The usage of the disputed claim terms in the context of the claims as a whole also informs the proper construction of the terms."); Phillips, 415 F.3d at 1314 ("[T]he claims themselves provide substantial guidance as to the meaning of particular claim terms."). In context, the claim language requires that "said composition is an aqueous liquid which is formulated for ophthalmic administration." '504 Patent at 6:29–30. The description that the composition is an aqueous liquid is in direct contradiction to Defendants' proposal. A person of ordinary skill in the art at the time of the invention would understand that the ordinary and customary meaning of the claim term would be that citric acid monohydrate is a component which dissolves into the aqueous based solution. See Phillips, 415 F.3d at 1313 ("The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation. That starting point is based on the well-settled understanding that inventors are typically persons skilled in the field of the invention and that patents are addressed to and intended to be read by others of skill in the pertinent art." (citations omitted)).

Although citric acid monohydrate in crystalline form is an ingredient in the mixture, a person of ordinary skill in the art would appreciate that it would be scientifically impossible for it to remain in crystalline form in an aqueous based environment. Additionally, the existence of citric acid monohydrate in crystalline form in a product for "ophthalmic administration" would be inconsistent with the understanding of a person of ordinary skill in the art that a substance

containing crystals could not be administered to the eye. Therefore, requiring a construction specifying the existence of crystalline citric acid monohydrate in an aqueous solution would be inconsistent with the entirety of the claim language.

Defendants further argue that Plaintiff's interpretation of the claims is rewriting product claims to product-by-process claims. Defendants reason that the asserted claims are directed to compositions, and not recipes for making the end product. Relying on Exxon, Defendants conclude that Plaintiff is improperly rewriting its claims because Plaintiff's construction incorporates the requirement that the composition be an aqueous solution with the components properly dissolved. See Exxon, 64 F.3d at 1563 (Plager, J., concurring).

The Court disagrees that Plaintiff is attempting to rewrite its claims. Rather, the Court finds controlling the reasoning in Norian Corp. v. Stryker Corp., 432 F.3d 1356, 1362 (Fed. Cir. 2005). In Norian, the court accepted that a solution could be defined by "the ingredients used to make the solution." Norian, 432 F.3d at 1362. The court found that the characterization of a "solution in terms of the components put into it" was a "conventional means of describing a solution." Id. The court concluded that the claims were not product-by-process claims but remained product claims "limited to the designated ingredients from which the claimed solution was made." Id. Here, the Court is confronted with the identical situation presented in Norian. In drafting its claims, Plaintiff was allowed to describe the resulting aqueous solution in terms of its ingredient parts. Therefore, the Court finds that Plaintiff's construction does not impermissibly attempt to rewrite the claims as product-by-process claims.

The claim language as a whole guides the proper construction in this case. Accordingly, the Court finds that Plaintiff's proposed construction is consistent with the ordinary and customary meaning of the claim term as understood by one of ordinary skill in the art at the time

of the invention. See Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1367 (Fed. Cir. 2003) ("Claim language generally carries the ordinary meaning of the words in their normal usage in the field of invention.").

ii. The Intrinsic Evidence

In addition to the claims, the other intrinsic evidence in this case, specifically the specification and prosecution history, supports the adoption of Plaintiff's construction.

Similar to the arguments put forth by the Defendants with respect to the claims, Defendants argue that the specification consistently refers to the invention as a composition rather than a recipe. Therefore, Defendants urge this Court to hold that this language in the specification prevents Plaintiff from introducing process elements into its proposed construction. Defendants' analysis is misguided. As previously discussed, the Court does not find that Plaintiff's construction alters the scope of the claims to product-by-process claims. The parties are actually in agreement that the claims are directed to products.

Defendants also highlight that the specification contains references to both "citric acid monohydrate" and "citric acid." Compare '504 Patent at 2:66 with '504 Patent at 3:55. Thus, Defendants argue that Plaintiff understood how to use the terms and differentiate between them. The Court finds that this argument actually undercuts Defendants' position. The fact that Plaintiff used "citric acid monohydrate" and "citric acid" interchangeably in the specification would indicate to one skilled in the art that the ultimate ingredient in the formulation is aqueous citric acid. A person of ordinary skill would recognize that the addition of citric acid monohydrate to the composition would result in aqueous citric acid. Therefore, the use of "citric acid monohydrate" to achieve the claimed formulation is permissible. See generally Phillips, 415 F.3d at 1314 (unless otherwise indicated, "claim terms are normally used consistently throughout

the patent"). In contrast, the specification contains no support for Defendants' position that citric acid monohydrate is intended to remain crystalline in the composition.

In support of its own construction, Plaintiff notes that Defendants' proposal would read out every embodiment in the best mode section of the specification because each embodiment uses "Citric Acid, Monohydrate." See '504 Patent at 2:59–3:50. Plaintiff argues that Defendants' construction requiring citric acid monohydrate to remain in crystalline form once in solution is in contradiction to the preferred embodiments, which make no similar restriction. The Court agrees that adoption of Defendants' construction would read out all of the embodiments, including the preferred embodiment, directed at claims 2 and 3. Interpreting a claim such that it would read out the preferred embodiment "is rarely, if ever, correct and would require highly persuasive evidentiary support." Vitronics, 90 F.3d at 1583. Defendants have not provided highly persuasive evidentiary support to justify its interpretation of the claim language.

Furthermore, a person skilled in the art would understand that Plaintiff's reference to both "citric acid monohydrate" and "citric acid" was not done to differentiate between the two in the composition. Plaintiff's use of "citric acid monohydrate" and "citric acid" supports the understanding that citric acid is present in the composition by means of citric acid monohydrate. See Oatey Co. v. IPS Corp., 514 F.3d 1271, 1276 (Fed. Cir. 2008) (explaining that, absent clear, unambiguous disclaimer, the court generally does "not interpret claim terms in a way that excludes embodiments disclosed in the specification"). Even in light of Plaintiff's use of both terms, a person of ordinary skill would apprehend that citric acid monohydrate would not be required to remain crystallized once in the formulation. See Phillips, 415 F.3d at 1313 ("Importantly, 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.").

The prosecution history additionally supports Plaintiff's interpretation of the claim language. The phrase "citric acid monohydrate" was added in an amendment to what became claims 2 and 3 of the '504 patent. See Doc. No. 70-22 at 3. In support of the amendment, Plaintiff pointed to "Examples 1 and 3" in the written description. Id. at 6–7. Both examples only use the phrase "citric acid," and not crystalline "citric acid monohydrate." This further demonstrates that the claims were drafted with the understanding that citric acid monohydrate is an ingredient in the composition that dissolves in solution to form citric acid.

Importantly, the prosecution history is devoid of any disclaimer of claim scope. The Defendants have not identified any section of the prosecution history where the patentee clearly and unambiguously disclaimed the embodiment where citric acid monohydrate is added to a solution such that it becomes citric acid. See Middleton, Inc. v. Minn. Mining & Mfg. Co., 311 F.3d 1384, 1388 (Fed. Cir. 2002) (requiring disclaimer to be "clear and unambiguous" in the prosecution history).

In this case, the specification and the prosecution history support the adoption of Plaintiff's proposed construction. The intrinsic record reinforces a reading that citric acid monohydrate need not remain in crystalline form in the composition.

iii. The Extrinsic Evidence

Generally, extrinsic evidence is considered "less reliable than the patent and its prosecution history in determining how to read claim terms." Phillips, 415 F.3d at 1318. "[E]xtrinsic evidence may be useful to the court, but it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence."

Id. at 1319. In this case, the Court finds that in light of the intrinsic evidence, the extrinsic evidence supports Plaintiff's construction.

In their ANDAs, Defendants describe their generic pharmaceuticals as ophthalmic solutions and list citric acid monohydrate as one of the ingredients. See Doc. No. 70-16 at 3; 70-17 at 2. In addition, Defendant Lupin Ltd.'s ANDA equates "Citric Acid Monohydrate" in its generic pharmaceutical to "Citric Acid" in Plaintiff's Lumigan® 0.01% bimatoprost ophthalmic solution. See Doc. No. 70-16 at 6. This extrinsic evidence demonstrates that a person of ordinary skill in the art would understand that "citric acid monohydrate" describes an ingredient that would be used to achieve an aqueous product containing citric acid. The extrinsic evidence, in light of the intrinsic record, supports the adoption of Plaintiff's proposed construction.

Defendants point to the sworn declaration of Mr. John Wurst, Plaintiff's prosecution attorney, as extrinsic evidence supporting their position. See Doc. No. 77-19 at 4. Defendants argue that Mr. Wurst swore to the FDA that the '504 patent did not contain any product-by-process claims. Defendants contend that Plaintiff's current construction contradicts its prior representations to the FDA. The Court disagrees. The Court finds that Mr. Wurst's declaration is consistent with Plaintiff's proposed construction. Plaintiff only argues that the claims cover a set of ingredients. Plaintiff's construction does not mandate that a particular set of steps must be completed in order to obtain the resulting composition. Accordingly, the Court finds Defendants' argument regarding the extrinsic evidence without merit.

iv. Court's Construction

In light of the claim language, the specification, the prosecution history, and the extrinsic evidence, the Court adopts Plaintiff's proposed construction. "[A] composition . . . which comprises . . . citric acid monohydrate . . . wherein said composition is an aqueous liquid" means

"a composition that is an aqueous liquid in which citric acid monohydrate is one of the materials that is used to prepare the composition."

b. *"about 0.014 citric acid monohydrate"*[3]

Disputed Claim Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
"about 0.014 citric acid monohydrate"	The term does not require construction, but if the Court chooses to construe the term, it should construe it as "approximately 0.014% citric acid monohydrate"	"approximately 0.014% (w/v) citric acid in crystalline form containing only one water molecule per molecule of citric acid, where the water molecules are incorporated into the crystals"

The parties agree that "about" means "approximately" and that "0.014" means "0.014% weight/volume." The parties' arguments regarding the remainder of the claim term are identical to those presented for the previous phrase "a composition . . . which comprises . . . citric acid monohydrate . . . wherein said composition is an aqueous liquid."

For the same reasons stated above, the Court adopts a construction consistent with Plaintiff's proposal. "[A]bout 0.014 citric acid monohydrate" means "approximately 0.014% weight/volume citric acid monohydrate."

c. Agreed Constructions

In addition to the above disputed terms, the parties have come to several agreed constructions. Based upon the joint submission of a claim construction chart, the parties agree to the construction of the following terms. These constructions are therefore adopted by the Court:

[3] The term "about 0.014 citric acid monohydrate" is found in the '504 patent at claim 3.

'504 Claim Terms	Agreed Constructions
"phosphate buffer"	No construction necessary[4]
"about 0.01% bimatoprost"	"approximately 0.01% bimatoprost"
"pH of about 7.3"	"pH of approximately 7.3"
"about 200 ppm benzalkonium chloride"	"approximately 200 ppm benzalkonium chloride"
"said composition is an aqueous liquid which is formulated for ophthalmic administration"	"said composition is an aqueous liquid that is formulated such that it can be administered topically to the eye"

IV. CONCLUSION

For the forgoing reasons, the Court adopts the constructions as set forth above, and as listed in the attached chart.

It is SO ORDERED.

SIGNED this 10th day of January, 2013.

MICHAEL H. SCHNEIDER
UNITED STATES DISTRICT JUDGE

[4] Although the parties agree that the term "phosphate buffer" requires no construction, they provide alternative constructions should the Court believe construction is necessary. The Court agrees that "phosphate buffer" needs no construction and that it should be afforded its plain and ordinary meaning.

APPENDIX A

Claim Term	Location	Court's Construction
"a composition . . . which comprises . . . citric acid monohydrate . . . wherein said composition is an aqueous liquid"	'504 Patent, Claims 2 & 3	"a composition that is an aqueous liquid in which citric acid monohydrate is one of the materials that is used to prepare the composition"
"about 0.014 citric acid monohydrate"	'504 Patent, Claim 3	"approximately 0.014% weight/volume citric acid monohydrate."
"phosphate buffer"	'504 Patent, Claims 1–3	**[Agreed]** No construction
"about 0.01% bimatoprost"	'504 Patent, Claims 1–3	**[Agreed]** "approximately 0.01% bimatoprost"
"pH of about 7.3"	'504 Patent, Claims 1–3	**[Agreed]** "pH of approximately 7.3"
"about 200 ppm benzalkonium chloride"	'504 Patent, Claims 1 & 2	**[Agreed]** "approximately 200 ppm benzalkonium chloride"
"said composition is an aqueous liquid which is formulated for ophthalmic administration"	'504 Patent, Claims 1–3	**[Agreed]** "said composition is an aqueous liquid that is formulated such that it can be administered topically to the eye"