**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

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| IN RE: CIPRODEX | ) | Civil Action No:<br>15-cv-5756 (PGS)(DEA)<br><br>**MEMORANDUM**<br>**AND**<br>**ORDER** |

**SHERIDAN, U.S.D.J.**

This matter comes before the Court on a Second Amended Joint Claim Construction and Prehearing Statement (hereinafter "Joint Claim Construction") regarding U.S. Patent Nos. 6,284,804 ("the '804 patent"), 6,359,016 ("the '016 patent") and 9,402,805 ("the '805 patent") (collectively "Patents-in-Suit"). The Joint Claim Construction is submitted by Plaintiffs Alcon Pharmaceuticals Ltd., Alcon Laboratories, Inc., and Alcon Research, Ltd. (collectively "Alcon" or "Plaintiffs") and Defendants Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "DRL"), Par Pharmaceutical Inc. ("Par"), and Watson Laboratories, Inc. ("Watson") (DRL, Par, and Watson are collectively referred to as "Defendants"), pursuant to L. Pat. R. 4.3. (*See* D.I. 84)

The '804 and the '016 patents are directed towards topical suspension formulations containing ciprofloxacin and dexamethasone. Whereas, the '805 patent is directed towards methods of treating middle ear infections using aqueous suspension formulations containing ciprofloxacin and dexamethasone. Ciprodex®, a brand name pharmaceutical drug for treating middle ear infections (otitis media) in children with ear tubes, as well as outer ear infections (otitis externa) in children and adults, includes ciprofloxacin and dexamethasone as the active ingredients.

In order to market and sell Ciprodex®, Alcon listed the Patents-in-Suit in the Food and Drug Association's ("FDA") Approved Drug Products with Therapeutic Equivalence Applications, commonly known as the Orange Book. *See* 21 U.S.C. § 355(B)(1). Thereafter, Defendants filed an Abbreviated New Drug Application ("ANDA") with the FDA in order to seek approval to market a generic version of Ciprodex®. *See* 21 U.S.C. § 355(j)(1). Accordingly, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), Alcon initiated this suit against Defendants because Defendants' request to market the generic version of Ciprodex® is done prior to the expiration of the Patents-in-Suit.

On February 23, 2017, a stipulation and order staying the litigation between Plaintiffs and Defendant Watson was entered on the record. (*See* D.I. 100) Thereafter, on April 3, 2017, another stipulation and order was entered on the record between Plaintiffs and Defendant Par regarding Par's ANDA filings constituting an act of infringement of the '805 patent, and that Par will not assert any defense of non-infringement as to the '805 patent in this suit. (*See* D.I. 114)

As such, the remaining disputed claim terms between Plaintiffs and Defendant DRL include—"A topically administrable suspension composition intended for application to the eye, ear or nose," as recited in claim 1 of the '804 patent; "A topically administrable aqueous suspension composition intended for application to the eye, ear or nose," as recited in claims 1, 2 and 3 of the '016 patent; and "Treating a Human Patient," as recited in claim 1 of the '805 patent.

On May 8, 2017, pursuant to L. Pat. R. 4.6, a *Markman* hearing was conducted before the Court for the aforementioned terms. These terms are construed below.

## BACKGROUND

Ciprodex® is an FDA approved pharmaceutical product that includes two active ingredients—ciproflaxcin and dexamethasone. Ciprofloxacin is an antibiotic that treats infections caused by bacteria. And, dexamethasone is a steroid that reduces the actions of chemicals in the body that cause inflammation.

### I. *The Patent Family*

The Patents-In-Suit include the ’804 patent, the ’016 patent and the ’805 patent. The ’016 patent is a continuation[1] of the ’804 patent, and as such shares the same specification and inventive entity as the ’804 patent. Both, the ’804 and the ’016 patents, are directed towards suspension formulations containing dexamethasone and ciprofloxacin. The formulation contains a nonionic polymer, a nonionic surfactant and an ionic tonicity agent. The formulations are physically stable and easily re-suspended, and are intended for topical application to the eye, ear or nose. (*See* Abstract of the ’804 patent and the ’016 patent).

The only difference between the ’804 patent and the ’016 patent is the claimed subject matter. The ’804 patent includes one (1) claim directed to a composition that is intended for application to the eye, ear or nose. Whereas, the ’016 patent includes five (5) claims, wherein claims 1, 2 and 3 are in independent form, and claims 4 and 5 depend from claim 3.

The ’804 and the ’016 patents disclose a formulation that comprises two active agents—corticosteroids (dexamethasone) and antibiotic (ciprofloxacin). (*See* the ’804 patent[2], col. 2, ll. 1-

[1] *See* Manual of Patent Examining Procedure (“MPEP”) 201.07. (“A continuation application is an application for the invention(s) disclosed in a prior-filed co-pending non-provisional application […]. The disclosure presented in the continuation *must not include* any subject matter which would constitute *new matter* if submitted as an amendment to the parent application.”).

[2] Hereinafter, when referring to the specification of the ’804 patent, it is understood that the ’016 patent recites the same disclosure because the disclosures of the two patents are identical. The Court will differentiate the citations between the ’804 patent and the ’016 patent where necessary.

5) Dexmathasone can be present in any ophthalmic or optically acceptable form having poor water solubility such that the resulting formulation is a suspension formulation. Whereas, ciprofloxacin can also be present in any ophthalmic or optically acceptable form such that the ciprofloxacin ingredient is in solution in the final formulation. (*See Id.* at col. 2, ll. 10-20) In addition to these aforementioned active ingredients, the suspension formulations also contain—sodium chloride as an ionic tonicity agent, a nonionic polymer, a nonionic surfactant, a quaternary ammonium halide as a preservative, a chelating agent, and boric acid. (*See Id.* at col. 2, ll. 30—col. 3, ll. 11) The resultant suspension formulation has a desired pH of 4.5 and an average particle (mean volume basis) of the dexamethasone ingredient to be less than 10 µm (micro-meters) to avoid irritation or discomfort to the user. (*See Id.* at col. 3, ll. 10-25)

The ’804 patent discloses the different methods of forming this suspension formulation; and the different formulations A-E that were tested for resuspension time in accelerated and real-time settling studies. (*See Id.* at col. 4) The result of these studies illustrated that the suspension formulation can be preserved such that it meets both the United States Pharmacopeia (USP) and the European Pharmacopia (Ph. Eur.) minimum preservative requirements for ophthalmic and otic formulations. (*See Id.* at col. 6, ll. 25-30)

With respect to the ’805 patent, issued on August 2, 2016, it is a separate and distinct patent from the ’804 patent and the ’016 patent because the ’805 patent is not a continuation, divisional or a continuation-in-part application of either the ’804 patent or the ’016 patent. As such, the ’805 patent does not share the same disclosure as the ’804 and the ’016 patents. The earliest priority date of the ’805 patent potentially dates back to September 21, 2001, from provisional application number 60/323,951. (*See* Front Cover of the ’805 patent)

The ’805 patent is directed towards method of treating middle ear infections in humans having an open tympanic membrane[3] by using aqueous suspension formulations, which contain dexamethasone and ciprofloxacin. (*See* Abstract of the ’805 patent)

The method of treatment includes topical application of a fixed combination of ciprofloxacin and dexamethasone as an adequate suspension product. Generally, the dosage regimen includes applying the suspension product twice a day. Each application involving administering three or four drops into the ear canal, and preferably pumping the tragus[4] to force product through the opening in the tympanic membrane, and in effect to the site of the infection/inflammation in the middle ear. (*See* the ’805 patent, col. 2, ll. 20-30)

The ’805 patent discloses that in addition to the active agents—ciprofloxacin and dexamethasone—the suspension formulations include a tonicity agent. The tonicity agent may be ionic (e.g., NaCl) or nonionic (e.g., mannitol); however, NaCl is preferred as the tonicity agent. (*Id.* at col. 3, ll. 25-33)

Studies of Ciprodex® were conducted on pediatric patients with acute otitis media with tympanostomy tubes. The studies indicated that this drug, which was administered twice a day in pediatric patients, was safe and tolerated well. (*Id.* at col. 15, ll. 15-20) The ’805 patent includes twenty-two (22) claims, wherein claim 1 is an independent claim. Claim 1 is a method claim for treating a human patient, which includes the steps of—(i) diagnosing the patient having otitis

[3] *See* Body Maps, “Tympanic membrane” (“The tympanic membrane is a vital component of the human ear, and is more commonly known as the eardrum. It is a thin, circular layer of tissue that marks the point between the middle ear and the external ear. It is approximately 0.1 mm [millimeter] thick, 8 to 10 mm in diameter, and has a mass weight of around 14 mg [milligram]. Despite this diminutive size and mass, the tympanic membrane is extremely tough and flexible, and difficult to damage beyond repair.”), *available at* http://www.healthline.com/human-body-maps/tympanic-membrane (last visited May 22, 2017).

[4] *See* Merriam-Webster Dictionary, “Tragus” (“the prominence in front of the external opening of the outer ear”), *available at* https://www.merriam-webster.com/dictionary/tragus (last visited May 22, 2017).

media and an open tympanic membrane, and (ii) topically applying into the ear canal of the patients ear an aqueous suspension composition. (*Id.* at col. 15, ll. 50-62)

## II. *Declaration of Dr. Michael Crowley, Dr. M. Jayne Lawrence and Dr. Soham Roy*

Dr. Crowley, on behalf of Alcon, has provided opinion concerning the meaning of certain claim terms in the Patents-in-Suit. (*See* Declaration of Crowley ("Decl. of Crowley") at ¶ 1; D.I. 54-9). Dr. Crowley notes that the preamble[5] of the '804 patent, a term in dispute, which includes the term "suspension composition" means a liquid formulation in which one or more active ingredients are in suspension. (*Id.* at ¶ 44). That is, without the active ingredients being in suspension, no person skilled in the art would refer to a formulation as a "suspension composition." (*Id.*)

With regards to "suspension", Dr. Crowley notes that in chemistry, a suspension is defined as a two-phase system in which an un-dissolved compound is dispersed in a solid, liquid or a gas vehicle. In pharmaceuticals, Dr. Crowley notes, this term refers to solid particles that are dispersed within a liquid vehicle, which is generally water. (*Id.* at ¶ 13) Dr. Crowley notes that the suspension formulation must meet chemical and physical stability requirements sufficient to justify shelf life. Stability being defined as "the extent to which a product retains, within specified limits, and throughout its period of storage and use (i.e., its shelf life) […]." (*Id.* at ¶ 14, *citing United States Pharmacopeia* (23rd edition 1995) ("1995 USP")) Most pharmaceutical products have a shelf life of at least two (2) years. (*Id.* at ¶ 15)

A physical stability of a suspension formulation refers to the stability of the physical aspects of the composition, including—appearance, pH, viscosity, dissolution and particle size distribution for undissolved components. The size distribution of undissolved particles must

[5] *See* Claim 1 of the '804 patent at col. 8, ll. 17-18 ("A topically administrable suspension composition intended for application to the eye, ear or nose).

remain the same for the shelf life of the suspension. (*Id.* at ¶ 16) A pharmaceutical suspension is acceptable even if it settles during its shelf life, so long as it is easily re-suspendible and homogeneous for a long duration to administer a uniform dose. (*Id.* at ¶ 17)

Conversely, the composition would be unacceptable if over time, the particles start to clump together and settle in a loose structure, or form a dense sediment on the bottom of the container, known as "caking." (*Id.* at ¶ 18) Dr. Crowley notes that this is unacceptable as it prevents an administration of a uniform dose of the active ingredient and reduces the potential shelf-life of the suspension formulation. (*Id.* at ¶ 19) As such, absent such physical stability and easily re-dispersibility, the FDA would not have approved this drug. (*Id.* at ¶ 21)

Dr. Lawrence, on behalf of Defendant Watson Laboratories, Inc., has also provided opinion concerning the meaning of certain claim terms in the Patents-in-Suit. (*See* Declaration of M. Jayne Lawrence ("Decl. of Lawrence") at ¶ 12; D.I. 55-1)

Regarding the preamble of the '804, Dr. Lawrence notes that one skilled in the art would recognize that the asserted claims recite a list of specific ingredients with specific proportions, which includes pharmaceutical ingredients with pharmaceutical excipients. (*See* Decl. of Lawrence at ¶ 70) Further, Dr. Lawrence notes that the preamble of the'804—does not give additional meaning to the pharmaceutical compositions, does not add any structure to the claimed invention, and one could omit reading the preamble and still have the same complete understanding of the pharmaceutical compositions. (*Id.* at ¶ 72) Dr. Lawrence cautions that Actavis' proposed addition of "with at least one active ingredient in suspension" to the preamble is redundant and misleading because one skilled in the art would recognize that the particular claimed compositions are directed to two specific drugs—dexamethasone and ciprofloxacin—and not at least one active ingredient in suspension. (*Id.* at ¶ 77)

Lastly, Dr. Soham Roy, on behalf of Alcon, provides his opinion on the disputed claim term "treating a human patient" as recited in the preamble of claim 1 of the '805 patent. (Declaration of Dr. Soham Roy ("Decl. of Roy") at ¶ 1; D.I. 94) Dr. Roy notes that the term "treating" in the aforementioned claim term includes an *intent* requirement, such that the composition must be administered or the procedure must be performed with an intent to cause a therapeutic benefit in the subject. (*See* Decl. of Roy at ¶ 21) In other words, "treating a human patient" is directed towards a procedure that the composition must be performed 'for the purpose' of effecting a therapeutic improvement in the patient. (*Id.* at ¶ 25) Dr. Roy further states, "a treatment is always administered with the *intent* to cause a therapeutic effect in a human patient." (*Id.* at ¶ 29) As such, intent being a 'critical component' of this term. (*Id.* at ¶ 26)

**STANDARD OF REVIEW**

"It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting *Innova/Pure Water Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). Claim construction determines the correct claim scope, and is a determination exclusively for the court as a matter of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978-79 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). The focus in construing disputed terms in claim language "is on the objective test of what one of ordinary skill in the art at the time of the invention would have understood the term[s] to mean." *Id.* at 986.

To determine the meaning of the claims, courts start by considering the intrinsic evidence. *Phillips*, 415 F.3d at 1313; *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 861 (Fed. Cir. 2004); *Bell Atl. Network Servs., Inc. v. Covad Comms. Group, Inc.*, 262 F.3d 1258, 1267 (Fed. Cir.

2001). The intrinsic evidence includes the claims themselves, the specification, and the prosecution history. *Phillips*, 415 F.3d at 1314; *C.R. Bard, Inc.*, 388 F.3d at 861.

The claims themselves provide substantial guidance in determining the meaning of particular claim terms. *Phillips*, 415 F.3d at 1314. First, the context in which a term is used in the asserted claim can be very instructive. *Id.* Other asserted or non-asserted claims can aid in determining the claim's meaning because claim terms are normally used consistently throughout a patent. *Id.* Differences among claims can also assist in understanding a term's meaning. *Id.* For example, when a dependent claim adds a limitation, there is a presumption that the independent claim does not include that limitation. *Id.* at 1314-15.

"[C]laims 'must be read in view of the specification of which they are a part.'" *Id.* at 1315 (quoting *Markman*, 52 F.3d at 979). "[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.'" *Id.* (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). This is true because a patentee may define his own terms, give a claim term a different meaning than the term would otherwise possess, or disclaim or disavow the claim scope. *Id.* at 1316. In these circumstances, the inventor's lexicography governs. *Id.* The specification may also resolve the meaning of 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. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002). But, "[a]lthough the specification may aid the court in interpreting the meaning of disputed claim language, particular embodiments and examples appearing in the specification will not generally be read into the claims." *Comark Commc'ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed. Cir. 1998) (quoting *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560,

1571 (Fed. Cir. 1988)); *also see Phillips*, 415 F.3d at 1323 ("although 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 another tool to supply the proper context for claim construction. It "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips*, 415 F.3d at 1317.

"Extrinsic evidence consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. Although extrinsic evidence can be useful, it is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" *Phillips*, 415 F.3d at 1317 (quoting *C.R. Bard, Inc.*, 388 F.3d at 862).

Dictionaries and treatises may aid a court in understanding the underlying technology and the manner in which one skilled in the art might use claim terms, but dictionaries and treatises may provide definitions that are too broad or may not be indicative of how the term is used in the patent. *Id.* at 1318. Similarly, expert testimony may aid a court in understanding the underlying technology and determining the particular meaning of a term in the pertinent field, but an expert's conclusory, unsupported assertions as to a term's definition are entirely unhelpful to a court. *Id.*

Generally, extrinsic evidence is "less reliable than the patent and its prosecution history in determining how to read claim terms." *Id.* The Supreme Court recently explained the role of extrinsic evidence in claim construction:

> In some cases, however, the district court will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period. . . . In cases where those subsidiary facts are in dispute, courts will need to make subsidiary factual findings about that extrinsic evidence. These are the "evidentiary underpinnings" of claim construction that we discussed in *Markman*, and this subsidiary fact finding must be reviewed for clear error on appeal.

*Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S.Ct. 831, 841 (2015).

Overall, in construing the claims, "[t]he judge's task is not to decide which of the adversaries is correct. Instead, the judge must independently assess the claims, the specification, and if necessary the prosecution history and relevant extrinsic evidence, and declare the meaning of the claims." *Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1556 (Fed. Cir. 1995).

## ANALYSIS

The Court will now construe the disputed claim terms as listed in the Patents-in-Suit.

A. "A topically administrable [aqueous][6] suspension composition intended for application to the eye, ear or nose," as recited claim 1 of the '804 patent and in claims 1, 2 and 3 of the '016 patent.

| Claim Term | Plaintiffs' Proposed Construction | Defendants' Proposed Construction |
|---|---|---|
| "A topically administrable [aqueous] suspension composition intended for application to the eye, ear or nose" | "A pharmaceutical composition, with at least one active ingredient in suspension, suitable for topical administration to the eye, ear or nose, including that the composition is physically stable and easily re-suspended." | The preamble is not limiting and does not require construction.<br><br>To the extent the preamble is determined to require construction, it should be given its plain and ordinary meaning, "a topically administrable aqueous suspension composition intended for application to the eye, ear or nose." |

[6] The term "aqueous" only appears in preamble of claims 1, 2 and 3 of the '016 patent. The parties do not dispute that the term "aqueous" alters their proposed construction of the disputed claim term. (*See* Pl.'s Opening Br. at 5; D.I. 54; Def.'s Opening Br. at 16; D.I. 55).

Representative Claim 1 of the ’804 patent recites,

> 1. **A topically administrable suspension composition intended for application to the eye, ear or nose** consisting essentially of
> a) 0.1% (wt.) dexamethasone alcohol;
> b) 0.35% (wt.) ciprofloxacin hydrochloride, monohydrate;
> c) NaCI in an amount sufficient to cause the composition to have an osmolality of about 250-350 mOsm;
> d) 0.2% (wt.) hydroxyethyl cellulose;
> e) 0.05% (wt.) tyloxapol;
> f) a buffer comprising sodium acetate and acetic acid;
> g) 0.01% (wt.) benzalkonium chloride;
> h) 0.01% (wt.) edetate disodium;
> i) 0.6% (wt.) boric acid; and
> wherein the composition has a pH of 4.5±0.2.

Defendant DRL essentially argues that this Court should not construe the aforementioned preamble of the ’804 patent because—(i) it does not carry any patentable weight; (ii) the terms in the preamble are not construed as claim limitations; and (iii) the preamble is merely an introductory statements of purpose and intended result. (*See* Def.’s Opening Br. at 17-20; D.I. 55) In addition, DRL asserts that Alcon’s proposed construction should not be adopted because it avoids ‘chemical stability’ and ‘microbiological stability’ requirements, something which Alcon’s expert, Dr. Crowley, indicated is required for the suspension composition to be able to be re-suspended. (*See* Def.’s Responsive Br. at 22; D.I. 73 (internal citations omitted)).

Additionally, in a letter dated June 13, 2017, DRL indicated that pursuant to the amended L. Pat. R. 4.2(a), the proposed plain and ordinary meaning of the disputed claim term provides “no confusion, uncertainty or lack of clarity about DRL’s claim construction.” (*See* Def. DRL’s Letter, dated June 13, 2017). DRL further indicates that it “will ***not*** later seek to define any claim terms differently, and rests on its submissions.” (*Id.*; emphasis in original).

The “preamble” of a claim is the introductory portion of the claim that describes the invention in more general terms and typically appears before the transition term “comprising”.

*Nexans Inc. v. General Cable Technologies Corp.*, 630 F.Supp.2d 499, 506 (E.D. Pa. 2008). The determination of whether a preamble limits a claim is made on a case-by-case basis in light of the facts in each case. As such, there is no standard that determines when a preamble should be construed as a claim limitation. *Corning Glass Works v. Sumitomo Elec., U.S.A. Inc.,* 868 F.2d 1251, 1257 (Fed. Cir. 1989). Generally, there is a presumption against reading preamble language as a claim limitation because after the transition "a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use of the invention" or "to give context for what is being described in the body of the claim." *Symantec Corp. v. Computer Assocs. Int'l, Inc.*, 522 F.3d 1279, 1288 (Fed. Cir. 2008).

There are some exceptions which negate the above presumption. For instance, "[i]f the claim preamble, when read in the context of the entire claim, recites limitation of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305-1306 (Fed. Cir. 1999); *also see In re: Cruciferous Sprout Litigation,* 301 F.3d 1343, 1347 (Fed. Cir. 2002). Additionally, a "[c]lear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art may indicate that the preamble is a claim limitation because the preamble is used to define the claimed invention." *In re: Cruciferous Sprout Litigation,* 301 F.3d at 1347; *also see Metabolite Labs., Inc. v. Corp. of Am. Holdings*, 370 F.3d 1354, 1358-62 (Fed. Cir. 2004).

Further, one way for a preamble to "give meaning" to a claim is provide an antecedent basis for a term in the body of the claim. *Sanofi v. Lupin Atlantis Holdings S.A.*, 2016 WL 5842327, *2 (D. Del. 2016) (*citing Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 952 (Fed. Cir. 2006). "[W]hen the limitations in the body of the claim rely upon and derive antecedent basis from the

preamble, then the preamble may act as a necessary component of the claimed invention." *Id.* (internal quotation marks omitted). "[D]ependence on a particular disputed preamble phrase for antecedent basis may limit claim scope because it indicates a reliance on both the preamble and claim body to define the claimed invention." *Catalina Marketing Int'l, Inc. v. Coolsavings.coms, Inc.*, 289 F.3d 801, 808 (*citing Bell Communications Research, Inc. v. Vitalink Communications Corp.,* 55 F.3d 615, 620 (Fed. Cir. 1995). "[W]hen the claim drafter chooses to use *both* the preamble and the body to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one the patent protects." *Bell Comms.*, 55 F.3d at 620. Likewise, when the preamble is essential to understand limitations or terms in the claim body, the preamble limits claim scope. *Pitney Bowes,* 182 F.3d at 1306.

Here, the Court finds that the preamble carries patentable weight and should be construed as a claim limitation. The preamble recites in-part, "suspension composition." The word "composition" is recited twice in the body of the claim as "*the* composition." (*See* the '804 patent, col. 8, ll. 24, 33) In patent law, it is widely understood that the recitation of the term "the" or "said" before a feature indicates to a reader that the feature following these terms has been introduced prior in the claim language. And, as such, recitation of "the" or "said" feature simply indicates that a new feature is not being introduced in the claim. Instead, reference to an earlier recited feature is being made in order to avoid any indefiniteness rejection by the patent examiner under pre-AIA ("America Invents Act") 35 U.S.C. § 112, second paragraph, or AIA 35 U.S.C. § 112, ¶ 2.[7]

[7] *See* MPEP 2173.06(e) "Lack of Antecedent Basis" ("A claim is indefinite when it contains words or phrases whose meaning is unclear. *In re Packard*, 751 F.3d 1307, 1314 (Fed. Cir. 2014). The lack of clarity could arise where a claim refers to "said lever" or "the lever," where the claim contains no earlier recitation or limitation of a lever and where it would be unclear as to what element the limitation was making reference. Similarly, if two different levers are recited earlier in the claim, the recitation of "said lever" in the same or subsequent claim would be unclear where it is uncertain which of the two levers was intended. A claim which refers to "said aluminum lever," but recites only "a lever" earlier in the claim, is indefinite because it is uncertain as to the lever to which reference is made.").

Accordingly, by reciting "the composition" in the body of the claim, it is evident that it is referring to the "suspension composition," recited in the preamble of the claim. Granted, the drafter could have been more precise reciting "the suspension composition" or even "the topically administrable suspension composition," in the body of the claim, to avoid any ambiguity; nevertheless, the Court finds that "the composition" in the body of the claim depends on the preamble phrase (suspension composition) as an antecedent basis. *See Catalina,* 289 F.3d at 808. Same analysis applies to claims 1, 2 and 3 of the '016 patent.

As such, the Court finds that preamble of claim 1 of the '804 patent and the preamble of claims 1, 2 and 3 of the '016 patent are 'necessary to give life, meaning, and vitality' to the aforementioned claims, and thereby carry patentable weight that are to be construed as claim limitations.

Next, the Court considers the proposed construction of the aforementioned claim term. Generally, claim terms are "given their ordinary and customary meaning," which 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." *See Phillips,* 415 F.3d at 1303. In reading the aforementioned claim term, the Court finds that one skilled in the art would understand the meaning of the term at the time of the invention.

With respect to "suspension composition" in particular, the Court notes that Dr. Crowley, in his declaration, indicated that the composition needs to be physically and chemically stable such that even if solid particles settle during the shelf life of the composition, the composition is easily re-suspendible and homogeneous for a long duration in order to administer a uniform dose. (*See* Decl. of Crowley at ¶¶ 13, 17)

The Court notes that including features such as "physically stable and easily re-suspendible," as suggested by Alcon, in construing the aforementioned claim term, is unnecessary as one skilled in the art, in light of the specification, would understand the ordinary and customary meaning. *See Markman*, 52 F.3d at 979 ("[C]laims 'must be read in view of the specification of which they are a part.'") Moreover, if the Court adopted Alcon's proposed construction, or included characteristics such as physical stability and re-suspension to define the disputed claim term, then the Court would be committing the cardinal sin of incorporating limitations from the specification into the claim. *See Phillips*, 415 F.3d at 1323 ("although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments.")

In *AstraZeneca LP v. Breath Ltd.*, the court found that the term "'suspension' requires no construction and should be accorded its plain meaning, 'a liquid in which solid particles are dispersed but undissolved.'" 2013 U.S. Dist. LEXIS 49375, 21-22. In addition, the court in *Glaxo Wellcome v. Genentech, Inc.,* found that "composition" was a common enough word entitled to ordinary comprehension. *See* 136 F. Supp. 2d 316, 334-35 (D. Del. 2001). The court found in *Genentech* the construction for "composition" to mean "a combination of two or more substances." *Id*.

Accordingly, the Court determines that the term, "topically administrable [aqueous] suspension composition intended for application to the eye, ear or nose," as recited claim 1 of the '804 patent and preamble of claims 1, 2 and 3 of the '016 patent is to be given its plain, ordinary and customary meaning, which is—"topically administering a combination of two or more substances in which solid particles are dispersed, but undissolved, which is intended for application to the eye, ear or nose."

**B. "Treating a Human Patent," as recited in claim 1 of the '805 patent.**

| Claim Term | Plaintiffs' Proposed Construction | Defendants' Proposed Construction |
|---|---|---|
| "Treating a Human Patent" | "intending to cause a therapeutic improvement in a human patient" | The preamble is not limiting and does not require construction.<br><br>To the extent the preamble is determined to require construction, it should be given its plain and ordinary meaning, "a method of treating a human patient comprising the steps of…" |

Claim 1 of the '805 patent recites,

> 1. A method of **treating a human patient** comprising the steps of:
>
> (a) diagnosing the patient as having otitis media and an open tympanic membrane and/or having acute otitis externa in at least one ear; and
>
> (b) topically applying into the ear canal of the patients ear an aqueous suspension composition containing a combination of ciprofloxacin and dexamethasone, wherein the composition comprises a) 0.01-0.5% (wt.) dexamethasone; b) 0.1-0.4% (wt.) ciprofloxacin; c) 0.1-0.9% (wt.) tonicity agent; d) 0.01-0.2% (wt.) of a nonionic surfactant; and e) a buffer; wherein three or four drops of the aqueous suspension composition are administered to the patients ear twice a day, and wherein each drop is 30-35 μL.

Defendant DRL asserts that "treating a human patient," as recited in claim 1 of the '805 patent, should not be construed for reasons similar to the ones discussed above under the first claim term. (*See* Def.'s Opening Br. at 20-23; D.I. 87) In support, Defendant DRL cites to *Sanofi-Aventis U.S. LLC v. Fresenius Kabi USA, LLC*, 2016 WL 5898627, *5 (D.N.J. Oct. 7, 2016), where this Court found that the preamble phrases "a method for treating" and a "method of increasing the

survival of" merely stated the purpose of the claimed invention," and thus were not limiting. (*See* Def.'s Opening Br. at 23; D.I. 87).

The Court does not find Defendant DRL's arguments persuasive, and determines that "treating a human patient," as recited in claim 1 of the '805 patent, carries patentable weight, and is not merely an introductory statement of purpose and intended result. Unlike, the preamble construed by the Court in *Sanofi-Aventis,* the preamble term "treating a human patient" in the instant case is recited in the body of the claim. This was not the case in the preamble construed in *Sanofi-Aventis. See Sanofi-Aventis*, 2016 WL at *4-5. Claim 1 of the '805 patent recites "the patient" three (3) times in the body of the claim. Again, because the word "the" precedes the word "patient," it is apparent that it is referring to "a human patient" recited in the preamble of claim 1 to ensure proper antecedent basis; and not introducing a new or second patient. Moreover, "the patient" is further recited in claims 16 and 22; indicating a reliance on both the preamble and the claim body to define the claim scope. *Catalina,* 289 F.3d at 808.

Similarly, the word "treating" is also recited in dependent claims 19, 20 and 21. In these dependent claims, the method of treating is further limited. That is, under claim 1 the method of treating included two steps—(i) diagnosing the patient, and (ii) topically applying. Thereafter, under the aforementioned dependent claims, additional steps to the method have been included. That is, in addition to the diagnosing and topically applying, the treating also includes the steps of treating otorrhea, treating acute otitis externa, and treating granulation tissue, respectively.

As such, the Court finds that preamble of claim 1 of the '805 patent is 'necessary to give life, meaning, and vitality' to the aforementioned claims, and thereby carry patentable weight that are to be construed as claim limitations.

Next, the Court considers the proposed construction of the aforementioned claim term. Generally, claim terms are "given their ordinary and customary meaning," which 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." *Phillips*, 415 F.3d at 1303. In reading the aforementioned disputed claim term, the Court finds that one skilled in the art would understand the meaning of the term at the time of the invention.

The Court has reviewed Alcon's proposed construction of "intending to cause a therapeutic improvement in a human patient" in construing the preamble of claim 1 of the '805 patent. Alcon relies on extrinsic evidence, and dependent claims 19-21, to advance the position that claim 1 requires 'intent' to cause a therapeutic improvement. (*See* Pl.'s Opening Br. at 11; D.I. 88) The Court does not find Alcon's proposed construction persuasive because it appears to unnecessarily complicate the meaning of a term that has a well understood ordinary and customary meaning.

In *Novartis Pharms. Corp. v. Actavis, Inc.*, Novartis alleged that Actavis was infringing on its patented method for "treating iron overload" in patients with excess metal present in their bodies. 2013 U.S. Dist. LEXIS 165317 (D. Del. 2013). The court in *Novartis* was persuaded that the term "treating" should be afforded its plain and ordinary meaning in its construction; and therefore adopted "attempting to cause a therapeutic improvement in" as the proper construction for the term "treating." *Id.* at 33-34 and 41.

The Court determines that the ordinary meaning of the claim term, "treating a human patient," as understood by a person of ordinary skill in the art, is readily apparent to the Court, and claim construction "involves little more than the application of the widely accepted meaning of commonly understood words." *Phillips*, 415 F.3d at 1314.

Accordingly, the Court determines that the term, "treating a human patient," as recited in the preamble of claim 1 of the '805 patent is to be given its plain, ordinary and customary meaning, which is—"attempting to cause a therapeutic improvement in a human patient."

**ORDER**

IT IS on this 27th day of June, 2017,

**ORDERED** that "topically administrable suspension composition intended for application to the eye, ear or nose," as recited in the preamble of claim 1 of the 6,284,804 patent is to be given its plain, ordinary and customary meaning, which is—"topically administering a combination of two or more substances in which solid particles are dispersed, but undissolved, which is intended for application to the eye, ear or nose"; it is further

**ORDERED** that "topically administrable aqueous suspension composition intended for application to the eye, ear or nose," as recited in the preamble of claims 1, 2 and 3 of the 6,359,016 patent is to be given its plain, ordinary and customary meaning, which is—"topically administering a combination of two or more substances in which solid particles are dispersed, but undissolved, which is intended for application to the eye, ear or nose"; and it is further

**ORDERED** that "treating a human patient," as recited in the preamble of claim 1 of the 9,402,805 patent is to be given its plain, ordinary and customary meaning, which is—"attempting to cause a therapeutic improvement in a human patient".

*s/Peter G. Sheridan*
PETER G. SHERIDAN, U.S.D.J.