IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

DELCOR ASSET CORP. and MYLAN PHARMACEUTICALS INC.,

Plaintiffs,

v.

GLENMARK PHARMACEUTICALS LTD., GLENMARK PHARMACEUTICALS INC., USA, and STIEFEL WEST COAST, LLC,

Defendants.

C.A. No. 17-cv-1653-RGA

MEMORANDUM ORDER

Presently before the Court is the issue of claim construction of multiple terms in U.S. Patent Nos. 7,141,237 ("the '237 patent") and 7,374,747 ("the '747 patent"). I have considered the parties' joint claim construction brief. (D.I. 84). I heard oral argument on October 19, 2018.

I. BACKGROUND

On November 15, 2017, Delcor Asset Corp. ("Delcor") and Mylan Pharmaceuticals Inc. ("Mylan") brought this action against Glenmark Pharmaceuticals Ltd. and Glenmark Pharmaceuticals Inc., USA (collectively "Glenmark"), and Stiefel West Coast, LLC ("Stiefel") for infringement of the '237 and '747 patents. This action relates to Abbreviated New Drug Application ("ANDA") No. 210778, filed by Glenmark for approval to market a generic version of the branded product Evoclin. (D.I. 1 ¶ 1). Mylan holds the NDA on Evoclin and Delcor is the exclusive licensee of the '237 and '747 patents. (D.I. 1 ¶¶ 19–20). Stiefel owns the asserted

patents but was joined as an involuntary defendant and has taken no position on the issues in this case. (D.I. 1 ¶ 5; D.I. 84 at 8 n.4).

II. LEGAL STANDARD

"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) (citation omitted). "'[T]here is no magic formula or catechism for conducting claim construction.' Instead, the court is free to attach the appropriate weight to appropriate sources 'in light of the statutes and policies that inform patent law.'" *SoftView LLC v. Apple Inc.*, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting *Phillips*, 415 F.3d at 1324). When construing patent claims, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979–80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Of these sources, "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 1315.

"[T]he words of a claim are generally given their ordinary and customary meaning. . . . [This 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 1312–13. "[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent." *Id.* at 1321. "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314.

When a court relies solely upon the intrinsic evidence—the patent claims, the specification, and the prosecution history—the court's construction is a determination of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). The court may also make factual findings based upon consideration of extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317–19. Extrinsic evidence may assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Id.* Extrinsic evidence, however, is less reliable and less useful in claim construction than the patent and its prosecution history. *Id.*

"A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GMBH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (citation omitted).

III. PATENTS AT ISSUE

The '747 patent is a continuation of the '237 patent and the specifications are substantively identical. (D.I. 84 at 6 n.3). The '237 patent has four independent claims—claims 1, 28, 32, and 33—all of which are asserted. I believe claim 1 may be considered representative for the purposes of claim construction. The '747 patent has only one independent claim—claim 1.

Claim 1 of the '237 patent reads:

> 1. A topical delivery composition in a pressurized container, said composition comprising:
>
> up to 15% w/w of clindamycin phosphate;

from about 83% to about 97.9% w/w of a *quick-breaking foaming agent*, wherein said *quick-breaking foaming agent* comprises a C_1–C_6 alcohol, a C_{14}–C_{22} alcohol, water, and a surfactant; and

from about 2% to about 7% w/w of an aerosol propellant selected from the group consisting of a hydrocarbon, a chlorofluorocarbon, dimethyl ether, hydrofluorocarbons and a mixture thereof,

a *base*; and

wherein said composition is a quick-breaking temperature sensitive foam after release from said container.

Claim 1 of the '747 patent reads:

1. A method for treating a bacteria-mediated disease, said method comprising:

applying a quick-breaking temperature sensitive foam composition to the skin of a subject in need thereof, said composition comprising:

up to 15% w/w of clindamycin phosphate;

from about 83% to about 97.9% w/w of a *quick-breaking foaming agent*, wherein said *quick-breaking foaming agent* comprises a C_1–C_6 alcohol, a C_{14}–C_{22} alcohol, water, and a surfactant;

from about 2% to about 7% w/w of an aerosol propellant selected from the group consisting of a hydrocarbon, a chlorofluorocarbon, dimethyl ether, hydrofluorocarbons and a mixture thereof; and

a *base*, to treat said bacteria-mediated disease.

IV. CONSTRUCTION OF DISPUTED TERMS

1. "base"

a. *Plaintiffs' Proposed Construction*: Plain and ordinary meaning, *i.e.*, "a compound that has an available lone pair of electrons for forming a chemical bond"

b. *Glenmark's Proposed Construction*: "a pH adjusting agent to increase the pH and does not include propylene glycol, glycerin, ethanol, cetyl or stearyl alcohol, or polysorbate"

c. *Court's Construction*: Plain and ordinary meaning as understood by a person of ordinary skill in the art.

Glenmark seeks to add two separate limitations to its construction of "base"—a functional limitation ("pH adjusting agent to increase the pH") and a negative limitation ("does not include propylene glycol, glycerin, ethanol, cetyl or stearyl alcohol, or polysorbate"). I do not think the intrinsic evidence supports either.

To support its functional limitation, Glenmark relies on example 3 in the specification, which describes potassium hydroxide being used to adjust the composition from a "natural" pH of 4.5 to a pH of 5.0. (D.I. 84 at 23 (citing '237 patent at 15:23–41)). Example 3 does not identify potassium hydroxide as a "base," but a different portion of the specification states that "[i]n one particular embodiment, the pH adjusting agent is a base," and "[p]referably, the pH adjusting agent is potassium hydroxide." '237 patent at 6:55–61. Here, Glenmark is essentially asking the Court to read in limitations from particular embodiments, contrary to the principles of claim construction. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005). I do not think this case warrants an exception to the general rule—the specification does not make clear that the claimed invention must include certain features from the embodiments. *Compare Howmedica Osteonics Corp. v. Wright Med. Tech., Inc.*, 540 F.3d 1337, 1344–46 (Fed. Cir. 2008), *with SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1340–44 (Fed. Cir. 2001).

To support its negative limitation, Glenmark first argues that claim 1 of the '237 patent, considered with non-asserted dependent claims 10, 11, and 12, shows that "base" is a separate limitation from "emollient." *See* discussion of "emollient" *infra*. Because the dependent claims explicitly define "emollient" as including propylene glycol and glycerol, Glenmark argues that "base" cannot include those elements. (D.I. 84 at 25). Glenmark's argument relies on the assumption that "base" and "emollient" are mutually exclusive. In response, Plaintiffs argue that

"there is no blanket prohibition against a single component satisfying separately stated claim elements so long as it is capable of performing the function of both." (*See* D.I. 84 at 43 (citing *Powell v. Home Depot USA, Inc.*, 663 F.3d 1221, 1231–32 (Fed. Cir. 2011)). I think Plaintiffs are correct. Further, I do not think the plain language of the claims, including the relationship between claim 1 and dependent claim 10, requires finding "base" and "emollient" to be mutually exclusive.

Second, Glenmark argues that "the specification lists and describes the [excluded] compounds separately from 'base.'" (*Id.* at 26). Glenmark relies on table 2 in the specification, which is titled, "Some of the functions of ingredients in clindamycin phosphate compositions of the present invention," and describes several of Glenmark's excluded elements as having a "purpose" not related to pH adjustment. '237 patent at 11:30–32. I do not find Glenmark's argument persuasive. Table 2 does not classify any ingredient as a "base," and regardless, only lists "some" of the ingredients' functions.

Third, Glenmark argues that the inventors disclaimed Glenmark's excluded elements in response to a rejection of the claims as obvious over Jones (U.S. Patent Pub. No. US 2003/0118511). (D.I. 84 at 27–29). The inventors first amended their claims to include the limitation "a pH adjusting agent selected from a group consisting of an acid or a base" (D.I. 74-1, Ex. G), and then amended that limitation to just "a base" (*id.*, Ex. F). Glenmark asserts, "The examiner recognized that Jones disclosed a quick-breaking foaming agent with ethanol, cetyl and stearyl alcohol, polysorbate, propylene glycol, and a buffering agent." (D.I. 84 at 28). Therefore, Glenmark argues that the inventors disclaimed a construction of "base" that includes those elements. (D.I. 84 at 32).

I think Glenmark mischaracterizes the prosecution history. Although the examiner recognized that Jones disclosed Glenmark's excluded elements as part of its formulation (D.I. 74-1, Ex. M at 3), I do not think the inventors distinguished Jones based on those disclosures. Instead, it appears that the inventors overcame the rejection by showing that Jones did not teach the use of clindamycin phosphate, and specifically did not teach the use of clindamycin phosphate with a base, rather than a buffer. (D.I. 74-1, Ex. F at 12 ("Jones teaches the use of a buffer to stabilize the active agent[.] . . . Jones does not teach or suggest the use of an antibiotic agent, especially clindamycin phosphate, and its unique properties formulated into a foam. . . . [C]lindamycin phosphate in a traditional buffer system is degraded. However, with the addition of a base, the composition is unexpectedly stable and efficacious.")). The fact that some of the elements disclosed in Jones may also be bases is not, in itself, sufficient to show disclaimer.

Therefore, I reject Glenmark's proposed construction. I am not convinced, however, that I should adopt Plaintiffs' proposed construction. The parties' experts disagree on what a person of ordinary skill in the art would consider the plain and ordinary meaning of "base" in the present context. (*See* D.I. 85, Ex. 9 ¶¶ 15, 19–20). I believe further expert testimony is required to make a final determination. Thus, I will allow the parties to meet and confer to consider whether they wish to present testimony at a hearing prior to trial, or simply to resolve the issue at trial. The parties should inform the Court of their preferences in a joint status report.

2. "quick-breaking foaming agent"

a. *Plaintiffs' Proposed Construction*: No construction necessary. In the alternative, to the extent construction is deemed necessary: "quick-breaking foaming agent" has the meaning recited in the asserted claims, *i.e.*, "a C_1–C_6 alcohol, a C_{14}–C_{22} alcohol, water, and a surfactant."

b. *Glenmark's Proposed Construction*: "one or more alcohols, water, and a surfactant, and can include an emollient"

c. *Court's Construction*: No construction necessary.

Claim 1 of both asserted patents states: "wherein said quick-breaking foaming agent comprises a C_1–C_6 alcohol, a C_{14}–C_{22} alcohol, water, and a surfactant." At oral argument, Glenmark indicated that the purpose behind its proposed construction was to ensure that the quick-breaking foaming agent may also include an emollient, in addition to the items listed in the claims. (Markman Tr. at 36:5–17). The use of "comprises" clearly allows for additional unrecited elements. Plaintiffs do not dispute this. (*Id.* at 39:9–22, 40:6–24). Therefore, I find there is no actual dispute and no construction is necessary.

3. "emollient"

a. *Plaintiffs' Proposed Construction*: Construction is legally improper. In the alternative, and to the extent necessary: The compositions covered by the asserted claims of the '237 and '747 patents do not recite an "emollient," which would have its plain and ordinary meaning.

b. *Glenmark's Proposed Construction*: "one or more agents for softening or moisturizing, such as polyol, a mixture of polyols, propylene glycol, or glycerin"

c. *Court's Construction*: As the term is not in any asserted claim, the Court does not construe it.

The term "emollient" is not in any of the asserted claims. It appears in a series of non-asserted dependent claims:

> 10. The composition of claim 1, further comprising an *emollient*.
>
> 11. The composition of claim 10, wherein said *emollient* is a polyol.
>
> 12. The composition of claim 11, wherein said polyol is selected from the group consisting of a propylene glycol, glycerol, and a mixture thereof.

'237 patent, claims 10–12. Plaintiffs have taken the position that propylene glycol is the "base" in Glenmark's ANDA products. (D.I. 84 at 67, 69). Therefore, since claims 10 and 11 imply that propylene glycol is an "emollient," Glenmark argues construction is necessary to determine whether "emollient" has "a different and non-overlapping definition than 'base.'" (*Id.*).

I disagree. The material dispute is whether propylene glycol is a "base." That is a factual question that can be addressed at trial in light of my construction of "base." It would be superfluous to construe "emollient," especially when the term does not appear in any of the asserted claims. I think I would be rendering an advisory opinion. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy."). Therefore, I do not construe "emollient."

IT IS SO ORDERED this 31 day of October 2018.

United States District Judge