IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GALDERMA LABORATORIES L.P., GALDERMA S.A., and NESTLÉ SKIN HEALTH S.A., Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	Civil Action No. 1:19-cv-351-RGA

MEMORANDUM OPINION

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ANDREWS, U.S. DISTRICT JUDGE:

Presently before the Court is the issue of claim construction of a term in U.S. Patent No. 10,206,939 ("the '939 patent"). The Court has considered the Parties' Joint Claim Construction Brief. (D.I. 36).

I. BACKGROUND

Plaintiff filed the instant action on February 19, 2019, alleging infringement of the '939 patent. (D.I. 1). The patent relates to methods and compositions for topical treatment of rosacea with ivermectin. The parties dispute a term recited in claims 8, 9, 20, 21, and 22 of the '939 patent. (D.I. 36 at 1–2).

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) (internal quotation marks 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) (alteration in original). 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, 977–80 (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 (internal quotation marks omitted).

"[T]he words of a claim are generally 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, i.e., as of the effective filing date of the patent application." *Id.* at 1312–13 (citations and internal quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). "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 (internal quotation marks omitted). 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 and internal quotation marks omitted).

III. CONSTRUCTION OF DISPUTED TERMS

A. The '939 Patent

1. "wherein the subject has no adverse reaction, [wherein/and] the adverse reaction is skin burning sensation or skin irritation"

a. *Plaintiffs' proposed construction*: "wherein the treatment results in a low incidence of skin burning sensation or skin irritation"

b. *Defendant's proposed construction*: "wherein the pharmaceutical composition is well tolerated with a low incidence of skin burning sensation or skin irritation"

c. *Court's construction*: "wherein the treatment results in a low incidence of skin burning sensation or skin irritation"

The parties agree that "no adverse reaction" means "low incidence of skin burning sensation or skin irritation." (D.I. 36 at 1–2). But the parties disagree on two remaining issues. The first is whether the claims require that there is "no adverse reaction" to the treatment or that there is "no adverse reaction" to the composition. The second issue is whether the construction of the claims requires the additional limitation of "well tolerated."

Regarding the first issue, Plaintiffs argue that because all claims that recite the disputed language are directed to a method claim, that method must be the "method of treating" rosacea. (*Id.* at 4, 9–10). Defendant counters that because the method requires the topical application of the 1% ivermectin composition, it must be that the low incidence of skin burning or skin irritation results from the composition rather than the treatment. (*Id.* at 6–7, 11–12). I agree with Plaintiffs. The claims recite a method of treatment. While the composition of the ivermectin is a part of that treatment, the claims are not directed to only that part, but rather the

method of treatment as a whole. Thus, the claims must be construed to mean that there is no "adverse reaction" to the treatment.

Turning to the second issue, Plaintiffs argue that adding the limitation "well tolerated" is improper because the claims do not mention tolerance and the "tolerance parameters" are separate "safety assessments" from "adverse events." (*Id.* at 5–6, 10–11). Defendant responds that since the "specification discusses burning and irritation in both the context of adverse events *and* tolerability," the phrase "well tolerated" must also be included in the construction for context. (*Id.* at 7, 12–13).

I disagree with Defendant. The inclusion of "well tolerated" in the construction is unnecessary and would be an improper additional limitation. While courts must read claims in light of the specification, they may not simply import limitations from the specification into the claims. *Prima Tek II, L.L.C. v. Polypap, S.A.R.L.*, 318 F.3d 1143, 1148 (Fed. Cir. 2003). Here, the "claims themselves do not expressly provide for [the 'well tolerated'] limitation," as there is no mention of tolerance in the claims, and it would be improper to read this limitation into them. *Scriptgen Pharm., Inc. v. 3-Dimensional Pharm., Inc.*, 79 F. Supp. 2d 409, 418–19 (D. Del. 1999). The parties have already agreed that "no adverse reaction" means "low incidence of skin burning sensation or skin irritation." Applying the conclusion from the first issue, the claim term only requires that there is a low incidence of skin burning sensation or skin irritation as a result of the treatment. Thus, the addition of the "well tolerated" limitation would be improper.

Therefore, I construe "wherein the subject has no adverse reaction, [wherein/and] the adverse reaction is skin burning sensation or skin irritation" to mean "wherein the treatment results in a low incidence of skin burning sensation or skin irritation."

IV. CONCLUSION

Within five days the parties shall submit a proposed order consistent with this Memorandum Opinion suitable for submission to the jury.