NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BAUSCH HEALTH IRELAND LIMITED, et al., Plaintiffs, v. PADAGIS ISRAEL PHARMACEUTICALS LTD et al., Defendants.	**Civil Action No. 20-5426 (SRC) (CONSOLIDATED)** **OPINION & ORDER**

CHESLER, U.S.D.J.

This matter comes before the Court on the application for claim construction by Plaintiffs Bausch Health Ireland Limited, Bausch Health Americas Inc., and Bausch Health US, LLC (collectively, "Bausch") and Defendants Padagis Israel Pharmaceuticals LTD and Padagis US LLC (collectively, "Padagis.") These consolidated cases arise from Hatch-Waxman litigation regarding patents related to the drugs Duobrii® and Bryhali®. Padagis is a pharmaceutical company which has filed ANDA No. 214626 to produce generic versions of these products. Bausch owns U.S. Patent Nos. 8,809,307 ("the '307 patent"), 10,478,502 ("the '502 patent"), 10,251,895 ("the '895 patent"), and 10,426,787 ("the '787 patent"). The parties seek claim construction of terms in these four patents.

ANALYSIS

I. The law of claim construction

A court's determination "of patent infringement requires a two-step process: first, the

court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement." Acumed LLC v. Stryker Corp., 483 F.3d 800, 804 (Fed. Cir. 2007). "[W]hen the district court reviews only evidence intrinsic to the patent (the patent claims and specifications, along with the patent's prosecution history), the judge's determination will amount solely to a determination of law." Teva Pharms. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831, 841 (2015).

The focus of claim construction is the claim language itself:

> 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. Attending this principle, a claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'

Innova/Pure Water, Inc. v. Safari Water Filtration Sys., 381 F.3d 1111, 1115-1116 (Fed. Cir. 2004) (citations omitted).

The Federal Circuit has established this framework for the construction of claim language:

> We have frequently stated that the words of a claim 'are generally given their ordinary and customary meaning.' We have made clear, moreover, that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application. 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. . .
>
> 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. In such circumstances, general purpose dictionaries may be helpful. In many cases that give rise to litigation, however, determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art.

> Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean. Those sources include the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.

Phillips v. AWH Corp., 415 F.3d 1303, 1312-1314 (Fed. Cir. 2005) (citations omitted).

II. Claim construction of the disputed terms

A. The "synergistic reduction" terms in the '895 and '787 patents

The parties dispute the meaning of a claim term that appears in claim 1 of the '895 patent and claim 1 of the '787 patent. Claim 1 of the '895 patent is representative, with the disputed term italicized:

> A topical pharmaceutical composition for treating psoriasis the composition comprising:
>
> (a) active ingredients consisting of: (i) halobetasol propionate, at a concentration of 0.01 percent by weight of the composition; and (ii) tazarotene at a concentration of 0.045 percent by weight of the composition; and
>
> (b) a dermatologically acceptable carrier; … wherein the composition comprising the halobetasol propionate and the tazarotene at said concentrations is capable of providing synergistic efficacy and *synergistic reduction of at least an adverse event selected from the group consisting of itching, burning, and stinging, for said treating.*

Bausch proposes this construction: "a frequency of adverse events (specifically, itching, or burning and stinging) that is less than the combined frequencies of the adverse events attributable to compositions having the active ingredients individually." Padagis contends that

the meaning is indefinite[1] but, in the alternative, proposes this construction: "reduction of at least one adverse event selected from the group consisting of itching, burning, and stinging, wherein the reduction is greater than the corresponding reduction provided by each active ingredient administered individually (i.e., the reduction of the combined product must be greater than halobetasol propionate and greater than tazarotene)."

It is this Court's practice to defer considerations of patent invalidity due to indefiniteness until summary judgment or trial, which the parties in this case have acknowledged. At this juncture, this Court considers only disputes over construction of the claim terms at issue. The Court begins the analysis by dividing the term into two parts, "synergistic reduction of at least an adverse event," and "selected from the group consisting of itching, burning, and stinging."

As to the second part, the parties dispute whether there are two groups of adverse events (1: itching; 2: burning and stinging) or three groups (1: itching; 2: burning, 3: stinging.) This question is resolved easily, as the claim language uses commas to clearly indicate three groups: "synergistic reduction of at least an adverse event selected from the group consisting of itching, burning, and stinging." There is no sensible way to read this, as Bausch proposes, so as to ignore the commas and clump burning and stinging into one of two groups. Bausch relies on incorporating a characteristic of a data table, Table 13, which is in the specification and displays the adverse event data in two groups, one of which includes both burning and stinging, rather than three groups. '895 patent, col.18 l.46-col.19 l.48. Yet Bausch ignores the fact that

[1] "A patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898, 901 (2014).

the textual description of the research study that produced the data in Table 13, has the same commas:

> The percentage of patients who experienced adverse events, as indicated by itching, burning, and stinging, is much lower for those who were treated with IDP-118 than those treated with HP or Taz. The results are shown in Table 13.

'895 patent, col.16 ll.25-29. This Court interprets the claim language at issue as it is written, giving meaning to all of the commas: there are three groups of adverse events.

The question about the meaning of "synergistic reduction of an adverse event" is more challenging. This Court having now determined that there are three kinds of adverse events, the parties' proposed constructions may be rephrased as follows:

Plaintiffs:

> "a frequency of an adverse event that is less than the combined frequencies of such adverse events attributable to compositions having the active ingredients individually."

Defendants:

> "reduction of at least one adverse event wherein the reduction is greater than the corresponding reduction provided by each active ingredient administered individually (i.e., the reduction of the combined product must be greater than halobetasol propionate and greater than tazarotene)."

Both constructions propose a comparison, greater than or less than. There are two major conceptual differences between the proposed constructions: what the reduction is, and the understanding of synergistic.

Defandants' opening brief puts primary emphasis on their argument that the claim term is indefinite, and offers little analysis to support their alternative construction. Generally, Defendants offer vague assertions of consistency with particular intrinsic evidence and an analogy to runners, but little in the way of specific reasoning. Defendants' responsive brief

challenges Plaintiffs' construction but supports Defendants' proposed construction only with more vague statements. Defendants do not even acknowledge that they have proposed a very narrow construction of the claim language, much less justified this narrowing under Federal Circuit law.

1. "Reduction of at least an adverse event"

Although the parties do not focus much on the question of what is being reduced, their briefs show very different ideas about it, captured by this question: is there one reduction or three? For Plaintiffs, there is one reduction at issue, the product of a comparison of the frequency of adverse events observed in the combination therapy to those of the "expected combination (i.e., the combination of the observed effects of the individual components)."[2] (Pls.' Br. 29.) According to Plaintiffs, in order to meet the claim limitation, that comparison must demonstrate that the combination therapy produces a reduction in the frequency of an adverse event, from the level of the Expected Combination: the actual observed frequency of an adverse event produced by the combination therapy must be lower than the estimated frequency of the Expected Combination. There is only one reduction of interest in the inquiry.

Defendants' opening brief presents sharply contradictory ideas about reduction of adverse events, as they move from their indefiniteness argument to the alternative construction. Defendants first argue that a POSA would not understand the use of "synergistic" in association with "reduction of an adverse event," and state:

In the context of efficacy, each active ingredient of a drug combination will have

[2] Plaintiffs concede that they have not explained how to calculate the value of the expected combination, and contend that this is a matter to be resolved down the road, "at the appropriate stage of the case, after appropriate discovery." (Pls.' Resp. Br. at 24.) Hereinafter, this Opinion will refer to this hypothetical value as the "Expected Combination."

> some level of efficacy when administered alone, as a monotherapy. *Id.* In contrast, each active ingredient of a drug combination, when administered alone, as a monotherapy, cannot "reduce" its own adverse events. *Id.* For example, if treatment with halobetasol propionate ("HP") lotion did not cause any patients to experience itching, a person of skill would not say that HP lotion "reduces" the adverse event of itching. *See id.* Instead, the person of skill would have understood that HP lotion simply does not cause the adverse event of itching. *Id.* Therefore, a person of skill could not perform the calculations required under the common meaning of "synergistic efficacy" for a "reduction of . . . an adverse event." *Id.* ¶ 52. A person of skill would not have a baseline value against which to compare the "reduction" caused by the drug combination because the individual ingredients cannot "reduce" adverse events when administered alone. *Id.*

(Defs.' Br. 20-21.) Ten pages later, Defendants' brief proposes a construction that strongly contradicts many of the statements just quoted. (Compare Defs.' Br. 31-34.) There, suddenly, each monotherapy is said to reduce its own adverse events. Suddenly, Defendants have found that each therapy has baseline values of adverse events and there is a method to calculate the reduction of adverse events from the baseline.

Under Defendants' proposed construction, there are three reductions of interest in the inquiry. Each therapy – the combination therapy, and the two monotherapies, for a total of three – has its own reduction. Defendants' briefs explain that they mean a reduction from baseline, using frequencies of adverse events. Defendants offer this example, based on Table 13: "In the HP group, 67.7% of patients reported some level of itching at baseline, while 27.4% of patients reported some level of itching at the end of the 8-week treatment period, resulting in a 40.3% reduction from baseline." (Defs.' Br. 33-34.) Thus, Defendants propose that "reduction" here means "change from baseline," and is calculated by subtracting the adverse event frequency at the end of a particular treatment from the adverse event frequency at the start of that treatment. In the "synergistic reduction" inquiry, then, this calculation is done three times, and it is the three

calculated reductions that are compared: the reduction shown by the combination therapy must be greater than each of the reductions shown by the monotherapies.[3]

Defendants offer very little justification for this understanding of reduction, and what little justification they offer is based on appeals to common sense rather than the patent or patent law. For example, Defendants argue: "It would not benefit a patient in terms of reduction in itching, burning, or stinging if the combination product caused the patient to suffer the same or more itching, burning, or stinging than the patient would experience with either HP alone or Taz alone." (Defs.' Br. at 32.)

Defendants' construction of "reduction" has a number of problems – beyond the fact that it contradicts their initial statements on the subject –, but the most conspicuous one is the central idea that one calculates three reductions, based on the data from the inventive combination therapy as well as from the monotherapies, by subtracting the frequency of an adverse event at the end of treatment from the baseline frequency at the start. As Defendants point out, the specification describes the main clinical research study as follows:

> Clinical Efficacy was determined based on the percentage of subjects who were treatment successes.
> . . .
> To be judged as a treatment success, subjects had to show two-grade improvement in IGA from the baseline, and to have an IGA score of "clear, or almost clear" at the evaluation time.

[3] Defendants' proposed construction, then, requires that each monotherapy has a reduction of adverse events. Defendants' expert, Dr. Sauder, testified to the contrary:

> Q. Okay. So a monotherapy then can't reduce its own events, correct?
> A. Right.

(Sauder Dep. 91:9-11, Weisbruch Dec. Ex. 32.)

‘895 patent, col.14 ll.18-26. Defendants cite this in support of their interpretation, arguing that the “reduction” in adverse events should be calculated in a similar way to treatment success, but they provide no justification for this. Rather, these statements in the specification show that the patentees clearly specified when a measure was relative to the baseline, and they did not do so in describing the method with regard to adverse events.[4] The specification says only the following about the collection of the adverse events data:

> Information on reported and observed adverse events (“AEs”) was obtained at each visit.
> . . .
> Tolerability was evaluated through assessments of selected local signs and symptoms (itching, dryness, and burning/stinging).

‘895 patent, col.13 ll. 53-57. Then, when presenting the adverse events results, as already quoted, the specification states:

> The percentage of patients who experienced adverse events, as indicated by itching, burning, and stinging, is much lower for those who were treated with IDP-118 than those treated with HP or Taz. The results are shown in Table 13.

‘895 patent, col.16 ll.25-29. In contrast to the specification statements about the method by which the patentees determined clinical efficacy, the statements about adverse events say nothing about any use of the baseline frequencies.[5] Rather, the only statements say that the adverse

---

[4] Similarly, the specification also discloses a method for correcting the treatment success percentages for vehicle effect. ‘895 patent, col.15 ll.42-47. The patentees knew how to describe methods of correction of percentages, but did not describe correcting percentages of adverse events, as Defendants’ construction proposes.

[5] Defendants also cite an article (Gold et al.), co-authored by Plaintiffs’ expert Dr. Sugarman, in which it appears that the researchers performed similar research on the same pharmaceuticals and discussed skin reactions, including burning, stinging, and itching, with reference to the baseline. (Gourash Dec. Ex. 8 at 866-67.) This extrinsic evidence has no role in claim construction at this juncture. Moreover, the Court notes that, in the Gold article, the researchers did not use the phrase, “adverse events,” but rather calculated reduction from baseline of “local skin reaction scores” using mean scores, not frequencies; it appears to be significantly different

events were assessed at each visit, and the result of interest was the product of comparing the percentages of patients who experienced adverse events, for each treatment of interest.

These statements in the patent are consistent with Plaintiffs' understanding of reduction and inconsistent with Defendants.' Plaintiffs propose that the determination of "reduction of an adverse event" involves a comparison of, on one side, the percentage of patients who experienced an adverse event during treatment with the combination therapy. Even though, on the other side of the comparison, Plaintiffs put a presently unknown quantity (the Expected Combination) obtained by a presently unknown method, the part that Plaintiffs define clearly is consistent with what is written in the patent. There is nothing in the relevant statements in the patent about using the baseline to adjust the adverse events data in any way, nor that the reduction relative to baseline manifested by the combination therapy should be compared to the reductions relative to baseline manifested by the monotherapies.[6]

Defendants' proposed construction also blurs the distinction between adverse events, produced by the therapy, and symptoms of disease. While the patent does leave room for overlap in regard to itching – which is described both as adverse event as well as a characteristic of the disease of psoriasis[7] –, stinging and burning are described only as adverse events. The

---

from the concepts and method for calculating reduction of adverse events that Defendants propose here. (Id. at 867.)

[6] This is not to say that a method for determining whether a combination treatment meets the claim limitation at issue must exclude any reference to the baseline. Table 13 displays baseline adverse events data, and the Gold reference appears to calculate reduction from baseline of "local skin reaction scores." At this juncture, however, the Court finds no basis to make a narrowing construction of the claim term that limits it to any particular method of calculation – particularly a method that Defendants, ten pages earlier in their brief, argued against. During the next phase of claim construction of this term, this Court will consider questions of how to determine the value of the Expected Combination.

[7] "Psoriasis is characterized by discrete areas of skin inflammation with redness, thickening,

specification equates "adverse events" with "side effects."[8] During prosecution, the applicants, in support of the "synergistic reduction" claim language, argued: "the synergistic reduction of side effects as shown in Table 13 are unexpected and surprising." (Exhibit 19 at 10.) Perhaps the clearest statement appears in the Sugarman declaration, which the applicants submitted in support of the proposed amendment to the claim language:

> 12. In addition, although corticosteroids have been observed to reduce the severity of skin reactions when used in conjunction with tazarotene, people of ordinary skill in the art expected that such benefit required much higher corticosteroid concentrations than that of halobetasol propionate in the Invention. The only FDA approved concentration of halobetasol propionate is 0.05%, which is 5 times more than the halobetasol propionate content of the Invention. Therefore, I was surprised to see that a low concentration of 0.01% halobetasol propionate could be enough to significantly reduce the side effects of tazarotene monotherapy, as reported in Table 13 of the specification.

(Exhibit 18 at ¶ 12.) A declaration submitted by the applicant during prosecution is part of the intrinsic evidence of the prosecution history. See Cont'l Circuits LLC v. Intel Corp., 915 F.3d 788, 798 (Fed. Cir. 2019) (statements in such a declaration are "statements in the prosecution history.") It is unmistakable that the Sugarman declaration states that the inventive combination significantly reduced the side effects of the Taz monotherapy. It does not say that the combination increased the monotherapy's reduction from baseline. This is important evidence that Plaintiffs' understanding of "reduction" is correct, and that Defendants' is not.

A troubling problem with Defendants' construction is that, after having calculated the three reductions relative to baseline, one must compare the combination therapy reduction with

---

intense scaling, and in some cases, itching." '895 patent, col.1 ll.28-30.

[8] "In yet another aspect, the present invention provides a method of treating psoriasis topically with pharmaceutical composition . . . ; wherein the composition is applied once daily for more than 2 weeks, such as 4 weeks, for 6 weeks or for 8 weeks without any serious adverse events (side effects)." '895 patent, col.21 ll.11-19.

each monotherapy reduction, and the combination therapy reduction from baseline must be *greater* than each monotherapy reduction from baseline. Thus, using Defendants' model, the claims at issue require that the combination therapy must show an *increased* reduction of adverse events. The idea that the patentee made atypical use of the word "reduction," to mean "increased reduction," has no support in the patent.

This analysis is supported by the only other use in the patent of a "reduc-" word with regard to adverse events: "The need still exists for more effective and safer topical medicaments with reduced adverse effects for the management of psoriasis." '895 patent, col.2 ll.4-6. Note that, in this sentence, again, the goal is a treatment with "reduced adverse effects." Nothing here suggests that this involves *increasing* the reduction of adverse events from baseline.

2. "Synergistic"

There are significant points of agreement between the parties about the meaning of "synergistic." The parties have agreed that, in the claims at issue, the meaning of the term, "synergistic efficacy," is "more efficacious than the combined efficacies of compositions, each comprising only one of the active ingredients." The parties also agree on their understanding of synergy in the context of efficacy of drug combinations in the relevant art: "The concept of synergy is commonly used and understood in the context of the efficacy of a drug combination, and means that the efficacy of the combination is greater than the sum of the efficacies observed with treatment of either individual active ingredient." (Defs.' Br. 19-20.)

The parties also appear to agree that the full, operationalized meaning of "synergistic reduction of an adverse event" is not straightforwardly deduced by application of the concept of "synergistic efficacy" to "reduction of an adverse event." The patent specification teaches

exactly how to determine synergistic efficacy:

> As required by FDA success was defined as at least a two-grade improvement from Baseline in the IGA score and an IGA score equating to `Clear` or `Almost Clear`.
> . . .
> Actual Clinical Efficacy compared to Predicted Additive Clinical Efficacy (as a percentage of subjects achieving "Treatment Success") is shown in Table 8. The "Treatment Success" percentages for the active treatment groups (IDP-118, HP, and Taz) were corrected for vehicle effect by subtracting the actual Vehicle group results from each to determine the net Treatment Success are shown as a percentage of the number of subjects treated.
>
> The synergistic effect of IDP-118 is illustrated by comparing the clinical efficacy from IDP-118 to the predicted efficacy from combining HP and Taz (see Table 9). The control-adjusted percentage of patients who were successfully treated with IDP-118 was greater than the sum of control-adjusted percentages of patients who were successfully treated singly with HP and Taz at all evaluation times: 2 weeks of treatment, 4 weeks of treatment, 8 weeks of treatment, and 4 weeks after the completion of 8 weeks of treatment (Week 12).

‘895 patent, col.14 l.33-col.15 l.67. The specification thus teaches that the synergistic effect on efficacy is seen by comparing the clinical efficacy of the combination to the predicted efficacy from combining HP and Taz. As depicted in Table 9, the synergistic effect was shown by the fact that the control-adjusted success rate for IDP-118 was greater than the sum of the control-adjusted percentages for the monotherapies. The parties agree that the patent presents no similar clear instructions for a method to determine whether a combination treatment meets the claim limitation, “synergistic reduction of an adverse event.”

It is here that the agreement between the parties ends. Defendants argue that a method cannot be ascertained with reasonable certainty but, in the alternative, present a method. Plaintiffs argue that some aspects of the method may be inferred from the ordinary meaning of “synergistic,” but that further discovery and proceedings are needed to establish the method to be used to ascertain the value of the Expected Combination.

Plaintiffs contend that, in the claim term at issue, "synergistic" has its ordinary meaning. Plaintiffs offer the statement of their expert, Dr. Sugarman: "two active ingredients have a synergistic relationship when the overall result of the combination is greater than the additive[9] result that would otherwise be expected." (Sugarman Dec. ¶ 43.) Defendants agree that the patent, in the phrase "synergistic efficacy," applies the ordinary meaning of "synergistic," but contend that a POSA would not be able to understand "synergistic reduction of an adverse event." Defendants' expert, Dr. Sauder, agrees with this position, but accepted that "synergistic" has this common meaning:

> Q. And you agree that the common meaning of "synergistic" is that the combination product exhibits a greater effect than the combination of the effects of the combination product's individual monads, right?
>
> A. Yes.

(Sauder Dep. 81:3-8, Weisbruch Dec. Ex. 32.)

This Court concludes that the patents apply the ordinary meaning of "synergistic" to the concept of efficacy, and that the best understanding of that ordinary meaning may be inferred from this statement in the specification: "The synergistic effect of IDP-118 is illustrated by comparing the clinical efficacy from IDP-118 to the predicted efficacy from combining HP and Taz (see Table 9)." '895 patent, col.15 ll.58-60. This statement, when generalized, leads to the following principle: the synergistic effect of a combination therapy is illustrated by comparing the clinically observed [property] of the combination therapy to the predicted [property] from combining the separate components of the combination. This formulation is not materially

[9] Sugarman also explains, citing the Tallarida reference, that "additive" here does not mean the mathematical operation of addition. (Sugarman Dec. ¶ 45.)

different from the ordinary meaning of "synergistic" stated by the experts on both sides.

Moreover, this Court concludes that Plaintiffs, in their brief, have correctly applied the ordinary meaning of "synergistic," as just formulated, to "reduction of an adverse event" in the context of the patents at issue. Plaintiffs' proposed construction, however, falls a little short as an expression of their ideas and needs a little tweaking to better express them. As just stated, in regard to efficacy, the patent refers to the "predicted [performance] from combining HP and Taz." Plaintiffs' brief speaks of the "expected combination (i.e., the combination of the observed effects of the individual components)," as well as defining synergy as "a comparison of the combination product against the combined effect of the individual active ingredients." (Pls.' Br. 29, 30 n.10.) These all appear to be the same basic ideas: the actual performance of the combination therapy is compared to the expected performance, derived from the combination of the observed effects of the individual components; this is the concept of the Expected Combination. These also appear to be the same as the concepts expressed in the formulas presented on page 30 of Plaintiffs' opening brief, as further explained by Dr. Sugarman in paragraphs 62 and 63 of his declaration.

Defendants' proposed construction does not incorporate the ordinary meaning of "synergistic." Defendants' expert, Dr. Sauder, testified:

> Q. Do you agree that when the inventors wanted to describe the combination product as superior to the individual monads alone, they did not refer to the relationship as synergistic?
>
> A. Yes, I guess I would agree with that.

(Sauder Dep. 83:19-24, Weisbruch Dec. Ex. 32.) However, Defendants' proposed construction describes the combination product as superior to the individual monotherapies alone. According

to Dr. Sauder's testimony, the inventors did not describe such a relationship as synergistic. Defendants' proposed construction does not give "synergistic" a meaning consistent with its use in the patent.

Furthermore, as Plaintiffs noted, Dr. Sauder admitted that the specification does not support Defendants' construction when he stated: "the specification is silent on whether a 'synergistic reduction' requires IDP-118 to reduce an adverse event more than: (1) either HP or Taz when administered alone." (Sauder Dec. ¶ 61.) This is not a surprise; Defendants openly admit that, under their construction, as to itching, the data in Table 13 do not show a synergistic reduction by the inventive composition. (Defs.' Br. 34.) This contradicts the specification's characterization of Table 13, already quoted:

> The percentage of patients who experienced adverse events, as indicated by itching, burning, and stinging, is much lower for those who were treated with IDP-118 than those treated with HP or Taz. The results are shown in Table 13.

'895 patent, col.16 ll.25-29. While the specification does not assert that Table 13 shows "synergistic reduction" of adverse events, the applicants did so expressly during prosecution, in the amendment and response dated August 9, 2018, in which the claims at issue were amended to include the "synergistic reduction" term:

> **The Present Invention as Recited by the Claims is Unexpected and Surprising to a Person of Ordinary Skill in the Art.**
>
> Applicant submits herewith a declaration by Jeffrey Sugarman, M.D. that the achievement of clinical results, as shown in Tables 7 and 8 of the specification, as filed, showing synergistic efficacy of the combination of halobetasol propionate at 0.01% wt. and tazarotene at 0.04500 wt., and the synergistic reduction of side effects as shown in Table 13 are unexpected and surprising. Such unexpected and surprising results support the nonobviousness of the present invention as recited in each of claims 1, 8, 13-14, and 31-32.

(Weisbruch Dec. Ex. 19 at 10.) Of course, it is not impossible that the applicants were

mistaken, but it seems more likely that the fact that Defendants concede that application of their proposed construction to Table 13 fails to demonstrate a claimed feature of the invention is a red flag that Defendants' construction is wrong.

The Court concludes that the claim term at issue should be construed so as to reflect the ordinary meaning of "synergistic," and that Plaintiffs, in their brief, have correctly expressed its ordinary meaning. For the reasons explained, the Court modifies Plaintiffs' proposed construction in three ways: 1) to reflect that there are three groups of adverse events; 2) to stay truer to the original phrasing, "at least an adverse event selected from the group . . .;"[10] and 3) to better express the concept of the Expected Combination, as discussed. This Court construes "synergistic reduction of at least an adverse event selected from the group consisting of itching, burning, and stinging, for said treating" as "a frequency of at least an adverse event (selected from the group of itching, burning, and stinging) that is less than the Expected Combination, i.e., the expected frequency of said adverse event derived from combining the performances of the active ingredients as monotherapies." This construction is necessarily incomplete. A second phase of claim construction will be needed to determine and operationalize the meaning of "the Expected Combination," as used in that construction.

B. The "liquid oil component" terms in the '307 and '502 patents

The term "liquid oil component" ("LOC") appears in claims 1 and 22 of the '307 patent and claim 1 of the '502 patent. Claim 1 of the '502 patent states:

> 1. A pharmaceutical composition for topical application to the skin of an individual comprising: a *liquid oil component* comprising diethyl sebacate and a

[10] Plaintiffs' proposed construction can be read to mean that all three kinds of adverse events are somehow lumped together. The claim language clearly requires that the limitation be met in regard to only one of the three, considered separately.

> corticosteroid selected from the group consisting of halobetasol propionate, clobetasol propionate, betamethasone dipropionate, diflorasone diacetate, and fluocinonide at a concentration less than 0.05%; and an aqueous component comprising water; wherein the composition is free of white petrolatum.

Claim 1 of the '307 patent states:

> 1. A pharmaceutical composition for topical application to the skin of an individual comprising halobetasol propionate at a concentration of 0.04% or less and a *liquid oil component* comprising one or more dicarboxylic acid esters, wherein the dicarboxylic acid esters are selected from diethyl sebacate, diisopropyl adipate, and dibutyl sebacate and wherein at least 25% of the halobetasol propionate is solubilized in the *liquid oil component* at 22°C.

Plaintiffs propose this construction: "a component consisting of one or more solvents which are practically insoluble or insoluble in water and which are liquid at room temperature." Defendants contend that the term is indefinite but, in the alternative, propose this construction: "The liquid oil component includes all ingredients of the formulation that are practically insoluble or insoluble in water and which are liquid at room temperature of 22°C." While both constructions refer to being liquid at room temperature, only Defendants' construction specifies a room temperature of 22°C, but neither party contends that this makes any material difference. Instead, the material difference between the constructions is that, for Plaintiffs, LOC includes only solvents with the specified characteristics, while for Defendants, LOC includes all ingredients with the specified characteristics. The claim construction dispute, then, turns on the question of whether or not the components of LOC are limited to solvents.

Plaintiffs' construction cannot be correct because it is contrary to claim 8 of the '502 patent: "The pharmaceutical composition of claim 1, wherein the liquid oil component further comprises an emulsifying agent." In Phillips, the Federal Circuit stated:

> Quite apart from the written description and the prosecution history, the claims themselves provide substantial guidance as to the meaning of particular claim

terms. . . .

> Other claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment as to the meaning of a claim term. Because claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims.

Phillips v. AWH Corp. , 415 F.3d 1303, 1314 (Fed. Cir. 2005). Plaintiffs' proposed construction is inconsistent with the meaning of the same term in claim 8. Plaintiffs agree that the emulsifying agents in the patents are not liquid oil solvents: "Dr. Lane explained that the skilled artisan would understand that certain ingredients dissolved or partially dissolved in the liquid oil solvents (e.g., the active ingredient or emulsifying agents) may be considered part of the oil phase but not themselves liquid oil component solvents." (Pls.' Resp. Br. 22.) Because claim 8 requires that the LOC comprise an emulsifying agent, which is not a solvent, Plaintiffs' construction could not be correct in claim 8. Plaintiffs have not argued that LOC has a different meaning in claim 8; the scope of LOC must be broader than solvents.

Plaintiffs attempt to address this issue by arguing: "the phraseology of claim 8 indicates that the emulsifier is dissolved ***within*** the liquid oil component, not that an emulsifier ***is*** part of a liquid oil component solvent." The Court does not understand this distinction, which does not appear to reflect the well-established interpretation of "comprising" in Federal Circuit law: the "term 'comprising' creates a presumption that the recited elements are only a part of the device, that the claim does not exclude additional, unrecited elements." Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp., 831 F.3d 1350, 1358 (Fed. Cir. 2016). Pursuant to this principle, the use of "comprising" in claim 8 creates a presumption that an emulsifying agent is a

part of the LOC.[11] Plaintiffs have not even addressed this issue, much less rebutted that presumption.[12] Plaintiffs' argument that the emulsifying agent of claim 8 is ***not*** part of the LOC is contrary to this well-established principle. Plaintiffs have not persuasively addressed the problem that their proposed construction is inconsistent with claim 8 of the '502 patent.

Having established that the scope of LOC must be broader than Plaintiffs propose, the Court considers Defendants' argument that the scope is reflected in this statement in the specification:

> The liquid oil component of the present application includes all ingredients of the formulation that are practically insoluble or insoluble in water and which are liquid at room temperature of 22° C.

'307 patent, col.4 ll.17-20 (hereinafter, the "Specification LOC Phrase" or "the Phrase.") Defendants contend that this constitutes an explicit definition of LOC, which does not have an ordinary meaning in the art. Defendants, however, formulate no argument to persuade that the Specification LOC Phrase constitutes an explicit definition, nor do they cite any law in support: Defendants simply assert that it *is*.

This Court reads the Specification LOC Phrase as a clear and unqualified affirmative statement of an attribute of the LOC. The structure is open in the way that a claim using "comprising" is open: it states what the LOC "includes," which this Court understands to mean

---

[11] Similarly, claim 9 of the '502 patent is directed to the composition of claim 1 wherein the aqueous phase comprises an emulsifying agent. It appears that emulsifying agents may be part of the liquid oil component or the aqueous phase.

[12] Even if Plaintiffs had argued that "comprising" here did not have its ordinary meaning, they would still be unable to explain why in the '502 patent claims, the LOC sometimes comprises a solvent (as in claim 2 of the '502 patent; Plaintiffs agree mineral oil is a solvent (Pls.' Br. 17)), and sometimes does not, as they construe claim 8. Claim 2 and claim 8 are identical except for the element comprised; how would the meaning of "comprising" change?

"includes but is not limited to." It does not state comprehensively what the LOC may include, nor what the LOC requires in order to be present.

"Explicit definition," in this context, is a term of art in Federal Circuit law. The Federal Circuit has held:

> It is black letter law that a patentee can "choose to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term that could differ in scope from that which would be afforded by its ordinary meaning." *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342, 60 U.S.P.Q.2D (BNA) 1851, 1854 (Fed. Cir. 2001). "The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." *Vitronics Corp. v. Conceptronic, Inc*., 90 F.3d 1576, 1582, 39 U.S.P.Q.2D (BNA) 1573, 1577 (Fed. Cir. 1996). Where, as here, the patentee has clearly defined a claim term, that definition "usually . . . is dispositive; it is the single best guide to the meaning of a disputed term." *Id.*

Jack Guttman, Inc. v. Kopykake Enters., 302 F.3d 1352, 1360 (Fed. Cir. 2002). The Court observes that Defendants have made no reference to any of this. Under these principles, this Court inquires: with the Specification LOC Phrase, does the specification act as a dictionary defining the phrase, "liquid oil component?" Did the patentees clearly set forth an explicit definition? In the absence of any supporting argument from Defendants, this Court is not prepared to agree that, with the Specification LOC Phrase, the patentees clearly set forth an explicit definition of "liquid oil component." It is a clear statement of one general attribute of the liquid oil component, but not more.

In the context of the present claim construction dispute, however, the determination that Defendants have labeled the Specification LOC Phrase unpersuasively does not change the significance of the Phrase itself. This Court understands the Phrase to be a general and unqualified declaration of one attribute of the LOC. As such, it does "show what a person of skill in the art would have understood disputed claim language to mean," albeit only in part.

Phillips, 415 F.3d at 1314; see also Vitronics Corp. v. Conceptronic , 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("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.") Crucially, the Phrase is intrinsic evidence that demonstrates that Plaintiffs' proposed construction is incorrect and that Defendants' proposed construction is correct. The key claim construction question here is whether the scope is limited to solvents with the required characteristics or extends to all ingredients with the required characteristics, and the Phrase is intrinsic evidence that the scope of the LOC extends to all such ingredients.

Plaintiffs attempt to counter Defendants' position by pointing to Table 2 in Example 2 in the specification. Plaintiffs argue that Table 2 supports their construction, and is contrary to Defendants.' Defendants point to Table 2 in support of their argument that LOC is indefinite, and argue that Plaintiffs' proposed construction is a strategy to undermine Defendants' potential indefiniteness challenge based on Table 2. The parties have, however, some points of agreement: the parties agree that, while Table 1 includes the emulsifier sorbitan monooleate ("SMO") in formulations A through D, the data values in Table 2 do not include SMO in the liquid oil component. The parties also agree that SMO is practically insoluble or insoluble in water and liquid at room temperature of 22° C. These are undisputed facts. The question is: what role should Table 2 and these facts play in this claim construction analysis?

Defendants contend that the Phrase and Table 2 are inconsistent: SMO meets the criteria in the Phrase to be included in the LOC, but is not listed as part of the LOC in Table 2. Plaintiffs do not discuss the Phrase, but argue, in essence, that their construction must be correct because then Table 2 is correct, and that, under Defendants' construction, Table 2 has a mistake.

To further complicate the situation, Defendants contend that Table 2 conflicts with claim 8. In short, the parties have presented this Court with an interlocking puzzle involving the construction of LOC, the Phrase, Table 2, and claim 8. The Court is not presently tasked with solving every aspect of that interlocking puzzle, but merely to decide between Plaintiffs' and Defendants' construction of LOC.

Plaintiffs thus ask this Court to adopt a construction that is inconsistent with claim 8 and with the Phrase, but consistent with Table 2. Defendants ask this Court to adopt a construction that is consistent with claim 8 and with the Phrase, but inconsistent with Table 2. Neither party has proposed a construction that is problem-free, and this Court must choose between them; neither is perfect. Between the two, this Court finds that the more problematic of the two is the construction that is inconsistent with the plain language of another claim, and that the less problematic is the construction that may be inconsistent with Table 2,[13] but which is supported by the specification and consistent with Claim 8. This Court is presently tasked with deciding the claim construction dispute that the parties have put before it, not with resolving the questions around Table 2, which will be addressed if and when the parties decide to do so.

This Court finds that Defendants' proposed construction of LOC is the better of the two, and adopts it: "The liquid oil component includes all ingredients of the formulation that are

[13] At this point, that is speculation. The understanding of Table 2 likely depends on how one understands what is written about it in Example 2, which appears to involve technical matters of chemistry. If and when the time comes for Plaintiffs to explain Table 2 and Example 2, they may be able to reconcile them with this Court's construction. And adopting Plaintiffs' proposed construction would not necessarily resolve all consistency problems in the specification, since limiting the LOC to solvents would conflict with the Specification LOC Phrase anyway. Adopting Plaintiffs' proposed construction might shift which part of the specification has the conflict, but there will still be a conflict.

practically insoluble or insoluble in water and which are liquid at room temperature of 22°C."

In conclusion, the Court construes the terms at issue as follows. The "liquid oil component" includes all ingredients of the formulation that are practically insoluble or insoluble in water and which are liquid at room temperature of 22°C. "Synergistic reduction of at least an adverse event selected from the group consisting of itching, burning, and stinging, for said treating" means "a frequency of at least an adverse event (selected from the group of itching, burning, and stinging) that is less than the Expected Combination, i.e., the expected frequency of said adverse event derived from combining the performances of the active ingredients as monotherapies." A second phase of claim construction will be needed to determine and operationalize the meaning of "the Expected Combination," as used in that construction.

SO ORDERED.

s/ Stanley R. Chesler
STANLEY R. CHESLER, U.S.D.J.

Dated: November 3, 2021