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. 1:17-cv-01783-RGA

MEMORANDUM OPINION

Jeremy A. Tigan, MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington, DE; Michael Wilson (argued), Jamil N. Alibhai (argued), Kelly P. Chen, and Chad Ray, MUNCK WILSON MANDALA, LLP, Dallas, TX.

Attorneys for Plaintiffs.

Nathan R. Hoeschen, SHAW KELLER LLP, Wilmington, DE; Leora Ben-Ami (argued) and Justin Bova, KIRKLAND & ELLIS, LLP, New York, NY; Kristen Reichenbach (argued), KIRKLAND & ELLIS, LLP, San Francisco, CA.

Attorneys for Defendant.

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ANDREWS, U.S. DISTRICT JUDGE:

Presently before the Court is the issue of claim construction of multiple terms in U.S. Patent Nos. 8,815,816 (the "'816 Patent"), 8,362,069 (the "'069 Patent"), 9,089,587 (the "'587 Patent"), 9,233,117 (the "'117 Patent"), 9,233,118 (the "'118 Patent"), and 9,782,425 (the "'425 Patent"). (D.I. 110 at 1).

The Court has considered the Parties' Joint Claim Construction Brief. (D.I. 110). The Court heard oral argument on August 22, 2018. (D.I. 120 ("Tr.")).

I. 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) (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, 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 on 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 on 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).

II. BACKGROUND

Plaintiffs assert six patents from three patent families against Defendant. (D.I. 110 at 1). The '587 Patent, the '117 Patent, the '118 Patent, and the '425 Patent are members of the Jacovella

patent family. *(Id.)*. The patents relate generally to methods and compositions for topical treatment of rosacea with ivermectin.

The parties dispute terms in claims 1 and 7 of the '069 Patent. This patent relates to "pharmaceutical compositions based on a compound of the avermectin family." ('069 Patent at 1:22-23). The following claim of the '069 Patent is representative:

> 1. A pharmaceutical/dermatological emulsion which comprises at least one fatty phase, at least one aqueous phase and at least one avermectin compound, said at least one fatty phase comprising at least one *oily solvent* other than a mineral or *plant oil*, said avermectin compound being solubilized in said at least one *oily solvent* to form an active phase, said active phase being devoid of any solvent for said avermectin compound distinct from said at least one *oily solvent*; said emulsion consisting essentially of:
>
> a *first fatty phase* which is a solvent for the at least one avermectin compound, in an amount of from 0.01% to 25% by weight, said *first fatty phase* consisting essentially of at least one *oily solvent* selected from the group consisting of diisopropyl adipate, PPG 15 stearyl ether, octyl dodecanol, C_{12}-C_{15} alkyl benzoate and mixtures thereof;
>
> a *second fatty phase* which is not a solvent for the at least one avermectin compound, in an amount of up to 20% by weight, said *second fatty phase* consisting essentially of at least one member selected from the group consisting of silicone oils, mineral oils, stearyl alcohol, cetyl alcohol, waxes, butters and mixtures thereof;
>
> at least one avermectin compound;
>
> at least one emulsifier, in an amount of 1% to 8% by weight;
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> a gelling agent, in an amount of up to 5% by weight;
>
> an aqueous phase, in an amount of from 50% to 75% by weight;
>
> and one or more additives selected from the group consisting of humectants, preservatives, anti-irritants, moisture regulators, pH regulators, osmotic pressure modifiers, UV-A and UV-B screens and antioxidants.

('069 Patent, claim 1) (disputed terms italicized).

The parties dispute terms in claims 1, 2, and 11 of the '816 Patent. This patent relates to "formulation of ivermectin into topical pharmaceutical compositions useful for the treatment of rosacea." ('816 Patent at 1:50-53). The following claim of the '816 Patent is representative:

> 1. A method for treating *rosacea*, common acne, seborrheic dermatitis, perioral dermatitis, an acneform rash, transient acantholytic dermatitis or acne necrotica

milliaris, comprising topically applying onto the affected skin area of an individual in need of such treatment, a topical pharmaceutical emulsion which comprises: a thus effective amount of ivermectin; an oily phase; at least one surfactant-emulsifier selected from the group consisting of polyoxyethylenated fatty acid esters and sorbitan esters; *a mixture of solvents and/or propenetrating agents for the ivermectin, said solvents and/or propenetrating agents being selected from the group consisting of propylene glycol, ethanol, isopropanol, butanol, N-methyl-2-pyrrolidone, DMSO, polysorbate 80, phenoxyethanol, glyceryl triacetate and oleyl alcohol*; one or more gelling agents but excluding aluminum magnesium silicate/titanium dioxide/silica; and water; *said emulsion having lamellar layers of liquid crystals* and being chemically stable over a period of 8 weeks.

('816 Patent, claim 1) (disputed terms italicized).

The parties dispute terms in claims 1, 2, 7, 8, 10, 15, 23, and 29 of the '587 Patent. This patent relates to "a method of treating inflammatory lesions of papulopustular rosacea." ('587 Patent at 2:38-40). The following claim of the '587 Patent is representative:

1. A method of treating *papulopustular rosacea* or inflammatory lesions of *rosacea* in a subject in need thereof, comprising topically administering, once daily, to a skin area affected by the *papulopustular rosacea* or the inflammatory lesions of *rosacea* a therapeutically effective amount of a pharmaceutical composition comprising about 0.1% to about 1% by weight ivermectin and a pharmaceutically acceptable carrier *to thereby obtain an onset of a significant reduction in inflammatory lesion count in the subject 2 weeks after the initial administration of the pharmaceutical composition without co-administration of another active ingredient*, wherein the subject has moderate to severe *papulopustular rosacea* or 10 or more of the inflammatory lesions before the treatment.

('587 Patent, claim 1) (disputed terms italicized).

The parties dispute terms in claims 1, 5, and 6 of the '118 Patent. This patent relates to "a method of treating inflammatory lesions of papulopustular rosacea." ('118 Patent at 2:38-40). The following claim of the '118 Patent is representative:

1. A method of treating *papulopustular rosacea* in a subject in need thereof, comprising topically administering, once daily, to a skin area affected by the *papulopustular rosacea* a therapeutically effective amount of a pharmaceutical composition comprising about 1% by weight ivermectin and a pharmaceutically acceptable carrier to thereby obtain a significant reduction in inflammatory lesion count in the subject.

('118 Patent, claim 1) (disputed terms italicized).

The parties dispute terms in claims 1, 2, 3, 4, 9, 10, 11, 13, and 17 of the '425 Patent. The '425 Patents relates to "a method of treating inflammatory lesions of papulopustular rosacea." ('425 Patent at 2:50-52). The following claim of the '425 Patent is representative:

1. A method of treating *papulopustular rosacea* in a subject in need thereof, comprising topically administering, once daily, to a skin area affected by the *papulopustular rosacea* a therapeutically effective amount of a pharmaceutical composition comprising ivermectin and a pharmaceutically acceptable carrier *without co-administration of another active pharmaceutical ingredient*, wherein the pharmaceutical composition comprises 0.5% to 1.5% by weight ivermectin.

('425 Patent, claim 1) (disputed terms italicized).

The parties agree on a construction for five additional terms. (D.I. 110 at 7-8).

III. CONSTRUCTION OF DISPUTED TERMS

1. "oily solvent"

a. *Plaintiffs' proposed construction*:

Plain and ordinary meaning, "an oil or oil-like compound that can dissolve ivermectin"

b. *Defendant's proposed construction*:

"an organic solvent not miscible with water and excluding alcohols or glycols"

c. *Court's construction*:

"organic solvent not miscible with water that can dissolve ivermectin excluding alcohols or glycols except octyl dodecanol"

This term appears in claims 1 and 7 of the '069 Patent. The parties agree that "the '069 Patent's 'oily solvent' is a solvent for the avermectin compound that is part of an oily or fatty phase of the composition." (D.I. 110 at 11, 15). The parties further agree that a POSA would understand an "oily solvent" to be "organic" and "not miscible with water." (Tr. at 15-16, 28).

However, the parties disagree on (1) the proper characteristics of an "oily solvent" to include in a construction and (2) whether alcohols and glycols were disclaimed during prosecution.

Focusing on the first point of disagreement, Defendant argues that its definition including "organic" and "not miscible with water" is consistent with the '069 Patent's specification's description of an oily solvent. (D.I. 110 at 11-12). Defendant asserts that "the '069 Patent uses [the concept of miscibility] when describing the two phases of an oil-in-water emulsion" and "the POSA would have understood 'oily solvent' to refer to a 'solvent not miscible with water.'" (*Id.* at 12). Defendant also notes that "miscibility (or immiscibility) with water is readily discernable based on chemical structure." (*Id.* at 19). Plaintiffs broadly reject Defendant's characterization of "oily solvents," saying, "Teva's two qualifiers are unnecessary . . . ." (*Id.* at 16). Considering "organic," Plaintiffs argue that this "connotes any carbon-based solvent, not just oils or oil-like compounds" and "is so broad . . . that it does nothing to clarify the term's scope." (*Id.* at 9, 15-16). Plaintiffs further argue that "not miscible with water" creates ambiguity. (*Id.* at 16).

With respect to Plaintiffs' proposed construction, Defendant argues that the term "oil-like" is not contained in the specification and is inconsistent with the '069 Patent's preferred solvent. (*Id.* at 12). Plaintiffs respond that "oil-like" encompasses "fatty alcohols and esters preferred by the inventors." (*Id.* at 15). At oral argument, Plaintiffs suggested that "oil-like" might mean "[f]atty, oily, lipophilic, or just . . . that it's going to be part of the oily phase of this emulsion." (Tr. at 14).

On the characterization of an "oily solvent," I largely agree with Defendant. As agreed by the parties, Defendant's construction accurately characterizes an "oily solvent." Plaintiffs do not provide a persuasive reason the agreed accurate construction is unhelpful. Furthermore, adopting

Plaintiffs' suggested "oil-like" construction, a term Plaintiffs admit is synonymous with "oily," does not clarify the term.

Regarding the second point of disagreement, Defendant argues that the patentees disavowed alcohols and glycols to overcome an obviousness rejection based on the Manetta prior art reference. (D.I. 110 at 13 (citing '069 Patent File History: Amendment (May 4, 2012) at 9-14 (D.I. 112 at App. 77-82)); *see also* U.S. Pat. Pub. No. 2006/0100165 ("Manetta")). Defendant argues the disclaimer is evidenced by Applicants "attribut[ing] the 'surprisingly good physical and chemical stability properties' of the claimed emulsions to a lack of alcohol or glycol." (D.I. 110 at 13 (citing '069 Patent File History: Amendment (May 4, 2012) at 12-13 (D.I. 112 at App. 78-79))).

Plaintiffs argue that the inclusion of an alcohol as a solvent in the claims of the '069 Patent precludes a finding of disclaimer. (*Id.* at 10). Defendant admits that "octyl dodecanol, a fatty alcohol" is identified "as a solvent for avermectin" in the claims and specification of the '069 Patent. (*Id.* at 14). To overcome this apparent inconsistency, Defendant states that the inclusion of octyl dodecanol "merely suggests that the patentees did not intend 'alcohol-type solvent' to include the particular fatty alcohol octyl dodecanol." (*Id.*). Defendant argues that I should find disclaimer of alcohols, except for octyl dodecanol, because the '069 Patent characterizes certain alcohols as inferior and because a fatty alcohol, oleyl alcohol, "is one of the alcohols used by the Manetta prior art." (*Id.*).

Additionally, Plaintiffs assert that "Manetta . . . describe[s] formulations using certain alcohols or glycols to solubilize ivermectin as part of the *aqueous phase* of an emulsion, whereas all claims of the '069 Patent (proposed and issued) used oily solvents that dissolved the active within *the oily phase*." (*Id.* at 17-18 (emphasis in original)). In response, Defendant points to the

argument made by the Applicants during prosecution that focuses on the solvent and makes no mention of the aqueous/oily phase distinction. (*See id.* at 18-19). For example, when directly addressing Manetta, Applicants argued, "*Manetta* repeatedly defines emulsions wherein an avermectin compound (ivermectin) is required to be solubilized in [an] alcohol or glycol solvent or the like." ('069 Patent File History: Amendment (May 4, 2012) at 10 (D.I. 112 at 78)). Defendant asserts this contrasts with "the '069 Patent's claims requir[ing] solubilizing avermectin in an 'oily solvent.'" (D.I. 110 at 19).

I agree that Applicants disclaimed alcohols and glycols during prosecution. "[A] patentee may limit the meaning of a claim term by making a clear and unmistakable disavowal of scope during prosecution. This may occur, for example, when the patentee explicitly characterizes an aspect of his invention in a specific manner to overcome prior art." *Purdue Pharma L.P. v. Endo Pharm. Inc.*, 438 F.3d 1123, 1136 (Fed. Cir. 2006) (citation omitted). The use of an "i.e." phrase is strong evidence of an Applicant's characterization or definition of her invention. *See SkinMedica, Inc. v. Histogen Inc.*, 727 F.3d 1187, 1200 (Fed. Cir. 2013) ("[A] patentee's use of 'i.e.' signals an intent to define the word to which it refers." (citation omitted)). Furthermore, "there is no principle of patent law that the scope of a surrender of subject matter during prosecution is limited to what is absolutely necessary to avoid a prior art reference that was the basis for an examiner's rejection." *Norian Corp. v. Stryker Corp.*, 432 F.3d 1356, 1361 (Fed. Cir. 2005). During prosecution the Applicants argued, "*Manetta* repeatedly defines emulsions wherein an avermectin compound (ivermectin) is required to be solubilized in [an] alcohol or glycol solvent . . ." and that "there is clearly no appreciation in *Manetta* of the surprisingly good physical and chemical stability properties resulting from solubilization . . . in . . . at least one oily solvent . . . ." ('069 Patent File History: Amendment (May 4, 2012) at 10-13 (D.I. 112 at App. 78-81)).

Furthermore, Applicants explicitly characterized the invention as distinct from Manetta in this way, stating, "*Manetta* provides neither a suggestion nor an expectation of success in doing what the inventors have done (i.e. solubilizing [an] avermectin compound in said at least one oily solvent to form an active phase as opposed to using [an] alcohol or glycol solvent, as required by *Manetta*.[ )]." (*Id.* at 12 (D.I. 112 at App. 80)). Because Manetta discloses "oleyl alcohol" (a fatty alcohol) as a solvent for ivermectin, the Applicants' statements characterizing their invention and distinguishing Manetta must be read to disclaim this class of alcohols. (*See* Manetta at [48]).

Additionally, during prosecution Applicants amended claim 1 to include a limitation that the invention was "devoid of alcohol and glycol solvent" to avoid an obviousness rejection based on Manetta. ('069 Patent File History: Amendment (Sept. 15, 2011) at 2-13 (D.I. 112 at App. 46-57)). Applicants' effort to overcome Manetta with this amendment failed. ('069 Patent File History: Office Action (Jan. 6, 2012) at 2-3 (D.I. 112 at App. 60-61)). Applicants subsequently "cancelled Claim 1 without prejudice to or disclaimer of the subject matter thereof." ('069 Patent File History: Amendment (May 4, 2012) at 9 (D.I. 112 at App. 77)). However, the Applicants' suggested limitation, in combination with the rest of the prosecution history, supports my conclusions that Applicants understood the invention as devoid of alcohols and glycols and overcame Manetta by disclaiming these compounds.

Moreover, Applicants did not reference the aqueous/oily phase distinction on which Plaintiffs now rely. In fact, the intrinsic record shows that Applicants broadly differentiated the alcohols and glycols of Manetta from the "oily solvents" described by the claims and ascribed the positive characteristics of the invention to the non-alcohol or non-glycol nature of the solvent.

Although alcohols and glycols were disclaimed as a general matter, the patentee's inclusion of octyl dodecanol in the claims of the '069 Patent provides some evidence that octyl dodecanol

was retained. Because Applicants unmistakably disavowed alcohols and glycols, while claiming octyl dodecanol, I will include this limitation in the construction.[1]

Therefore, I will construe "oily solvent" to mean "organic solvent not miscible with water that can dissolve ivermectin excluding alcohols or glycols except octyl dodecanol."

2. "plant oil"

a. *Plaintiffs' proposed construction*:

Plain and ordinary meaning, "an oil obtained from a plant"

b. *Defendant's proposed construction*:

Indefinite or "oily substance or mixture that exists in a plant, including di-isopropyl adipate"

c. *Court's construction*:

Plain and ordinary meaning, "oil obtained from a plant as differentiated from mineral, animal, or synthetically obtained oils"

This term appears in claim 1 of the '069 Patent. The parties agree that a POSA would understand that "di-isopropyl adipate" is not an oil. (Tr. at 56-57). The parties disagree as to (1) whether a POSA would understand "oil" to mean "oily," (2) whether a plant oil must be derived from a plant, and (3) whether the patentee intended to classify di-isopropyl adipate as a "plant oil" in the context of the '069 Patent.

As to the first point of disagreement, Defendant argues, "[T]he POSA would have understood 'plant oil' to refer to 'oily substance[s] or mixture[s] that exist [] in a plant.'" (D.I. 110 at 22). Plaintiffs respond, "Teva's proposed construction . . . expands the term 'oil' to include 'oily substances' *that are not oils*." (*Id.* at 24 (emphasis in original)). Plaintiffs also point out that

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[1] I gather that it does not matter to the parties whether octyl dodecanol was disclaimed.

the patentee used "oily" in the claims "when referring to claimed solvents like fatty alcohols and esters that are not oils, but the narrower term 'oil' for the excluded plant oils." (*Id.* at 25). I agree with Plaintiffs' position that "oil" and "oily" are distinct in the context of the claims. Therefore, I will not adopt Defendant's "oily" construction.

On the second point of disagreement, Defendant contends that the distinction between "plant oils" and other oils is the "technical dichotomy between substances that can only be derived in the lab and those that may also be found in nature." (*Id.* at 22). Defendant claims, "The POSA would consider the compound itself, not the source, when classifying a substance as a 'plant oil' or not." (*Id.*). Plaintiffs respond, "[A] POSA would understand the term 'plant oil' to refer to oils extracted from plants supplied commercially as excipients." (*Id.* at 25). I agree with Plaintiffs. The plain and ordinary meaning of "plant oil" refers to oils obtained from plants.

Regarding the third point of disagreement, Defendant argues, "[T]he patentee intended to classify di-isopropyl adipate as a 'plant oil' in the context of the '069 Patent." (*Id.* at 22-23). Defendant admits that di-isopropyl adipate is not an oil. (Tr. 56-57). Despite the technical inaccuracy of Defendant's proposed classification of di-isopropyl adipate, Defendant asserts that "the '069 Patent incorporates by reference the entirety of WO 2005/089806 ("WO '806")." (*Id.* at 23).[2] WO '806 lists di-isopropyl adipate among examples of "plant oils." (*Id.*). Plaintiffs respond that the patentee did not consider "plant oil" to include di-isopropyl adipate. (*Id.* at 20-21). Plaintiffs note, "[T]he specification and claims explicitly recite diisopropyl adipate as a

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[2] "Each patent, patent application, publication, text and literature article/report cited or indicated herein is hereby expressly incorporated by reference in its entirety." ('069 Patent at 19:53-55). There are at least seven references incorporated, including 1,930 pages of THE EXTRA PHARMACOPOEIA (Martindale, 29th ed. 1989). ('069 Patent at 1:46-48). I doubt that such wholesale incorporation by reference is a good practice.

preferred oily solvent." (*Id.* at 21, 26; *see also* Tr. at 58). I agree with Plaintiffs. By its plain language, the claim's inclusion of diisopropyl adipate as an example of an oily solvent negates Defendant's construction, which is solely based on one statement incorporated by reference into the specification. A POSA would understand that the specification is a better guide to the Patent's scope than an incorporated reference.

In the alternative, Defendant argues that the '069 Patent's incorporation of references with conflicting characterizations of "di-isopropyl adipate" renders the claims indefinite.[3] (D.I. 110 at 23). Defendant asserts, "If the POSA would have been uncertain as to whether di-isopropyl adipate was excluded from the 'active phase' in claim 1 because of inconsistent information regarding whether di-isopropyl adipate is a 'plant oil,' then the POSA would not have been reasonably certain as to the scope of these claims." (*Id.*). Plaintiffs respond that the POSA's understanding of di-isopropyl adipate combined with the teachings of the claims and specification overcome any doubt cast by WO '806. (*Id.* at 27). I agree with Plaintiffs. The '069 Patent's claims and specification overwhelmingly characterize "di-isopropyl adipate" as a preferred solvent, and, therefore, not a plant oil. Given this information, a POSA would understand "di-isopropyl adipate" is not a plant oil.

Therefore, I will construe "plant oil" according to its plain and ordinary meaning: "an oil obtained from a plant as differentiated from mineral, animal, or synthetically obtained oils."

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[3] Indefiniteness must be shown by clear and convincing evidence. *See Sonix Tech. Co. v. Publ'ns Int'l Ltd*, 844 F.3d 1370, 1377 (Fed. Cir. 2017).

3. "a first fatty phase which is a solvent" and "a second fatty phase which is not a solvent"

a. *Plaintiffs' proposed construction*:

A first fatty phase [which is a solvent]: one or more lipophilic compounds [which is a solvent]

A second fatty phase [which is not a solvent]: one or more lipophilic compounds [which is not a solvent]

b. *Defendant's proposed construction*:

"a first fatty phase" and "a second fatty phase" are indefinite.

Alternatively, "a first fatty phase" means "an immiscible liquid component[] of a system that is separate from the aqueous and second fatty phase, into which the avermectin is solubilized;" and

"a second fatty phase" means "an immiscible component of a system that is separate from the aqueous and first fatty phases"

c. *Court's construction*:

A first fatty phase which is a solvent: "one or more lipophilic compounds which is a solvent"

A second fatty phase which is not a solvent: "one or more lipophilic compounds which is not a solvent"

This term appears in claim 1 of the '069 Patent. Both parties agree that "the patent describes oil-in-water emulsions consisting of two 'immiscible' phases—a fatty (oily) phase and an aqueous phase." (*Id.* at 36). The parties disagree (1) whether a POSA would understand the claim to require that the two fatty phases that make up the oily phase be immiscible as to each other and (2) whether the two fatty phases render the claim indefinite.

As to the first point of disagreement, Defendant argues that "phase" means "[a]n entity of a material system which is uniform in chemical composition and physical state." (*Id.* at 31). Defendant describes "phase" in the context of an oil-in-water emulsion as "droplets of oil [that]

are separate and recognizable in the emulsion relative to the aqueous liquid in which those droplets are dispersed." (*Id.* at 30). Defendant asserts that a POSA understands this phenomenon to encompass the concept of miscibility and proposes a definition of "phase" requiring complete miscibility from the rest of a solution. (*Id.* at 31). Such a construction, Defendant concludes, would require a product covered by claim 1 of the '069 Patent to be a complex multi-phase emulsion. (*Id.* at 32, 40).

Plaintiffs counter that, as shown by many examples, the '069 Patent "uses the term 'phase' more broadly to describe various *components* of the fatty and aqueous phases." (*Id.* at 36 (emphasis in original)). According to Plaintiffs, the intrinsic record is clear on the meaning of "phase" and superior to Defendant's "abstract definition of the term 'phase' in a general chemistry dictionary." (*Id.* at 39). Plaintiffs also respond that the '069 Patent's specification provides an understanding of the "second fatty phase" consistent with its proposed construction when it "describes how to distinguish between compounds comprising each fatty phase, stating that the second fatty phase 'means a lipophilic phase which comprises one or more lipophilic compounds which are not solvents for the active agent.'" (*Id.* at 28 (quoting '069 Patent at 3:66-4:2)). Plaintiffs further note that "nothing in the specification supports Teva's position that the 'first' and 'second' fatty phases must be 'separate' and immiscible *with respect to each other*." (*Id.* at 29 (emphasis in original)). Rather, "the specification describes mixing the fatty phases together and 'incorporating' or 'introducing' the blended fatty phase into the aqueous phase to form an emulsion." (*Id.*).

I agree with Plaintiffs because the quoted portion of the specification is lexicography. The intrinsic evidence does not support Defendant's contention that the "first" and "second" fatty phases must be separate "entities" within the final emulsion. Rather, the intrinsic record is clear

that the "phases" refer to two components of the fatty phase – a component that is a solvent and a component that is not.

On the second point of disagreement, Defendant argues that, regardless of the construction I adopt, the "first" and "second" fatty phases are indefinite. (*Id.* at 33). Defendant asserts, "It is unclear whether the patentees intended to claim an 'oil-in-water emulsion' or a multi-phase composition, or whether the claim requires the emulsion to be made in a particular way." (*Id.*). The crux of Defendant's argument focuses on its assessment that "claim 1 on its face clearly describes multi-phase emulsions," and that this would be inconsistent with a POSA's understanding as well as the examples provided in the specification. (*Id.*). Plaintiffs respond that Defendant's expert agrees that a POSA would understand the final emulsion to contain a single oily phase. (*Id.* at 37). In view of Defendant's expert's agreement, Plaintiffs assert that a POSA would have "no confusion that, in the context of the '069 Patent, 'phase' refers to components of the composition having distinct functions or characteristics." (*Id.* at 37).

Defendant also supports its view of the claim and specification by identifying a patent office rejection of a similar claim during the prosecution of a different, related patent. (*Id.* at 34). Specifically, Defendant argues that because the patent examiner of U.S. Patent No. 9,592,249 (the "'249 Patent") required that the applicants clarify that the "'first' and 'second' 'fatty phases' [are] part of the 'active phase,'" this precludes construing the phrase to have such a requirement in the '069 Patent. (*Id.* at 42). Plaintiffs respond that the '249 Patent's "prosecution actually shows that Galderma is correct." (*Id.* at 38). According to Plaintiffs, "It is clear from such prosecution history that both the examiner and inventors understood and agreed that the specification discloses, and the claims relate to, emulsions in which the two-recited fatty 'phases' *are not separate and imm[i]scible* in the final emulsion." (*Id.* (emphasis in original)). That is, Plaintiffs' stance is that

the amendment adding a "comprising" limitation was simply making express an already inherent limitation. (*Id.*).

I agree with Plaintiffs. The '069 Patent describes an active phase that is made up of "one oily phase which is a solvent for the active agent" and "one fatty phase which is not a solvent for the active agent." ('069 Patent at 3:54-65). A POSA provided with the specification and claim would understand the invention to contain a fatty phase which is a solvent for the active ingredient and a fatty phase which is not a solvent for the active ingredient. Furthermore, the prosecution history of the '249 Patent, a patent extrinsic to the '069 Patent, provides at least some support for Plaintiffs' stance that a POSA's understanding of the claimed emulsion as having two distinct phases is reflected in claim 1. Because a POSA would readily understand what the claimed emulsion would look like, the language does not render the claim indefinite.

Therefore, I construe "a first fatty phase which is a solvent" to mean "one or more lipophilic compounds which is a solvent" and "a second fatty phase which is not a solvent" to mean "one or more lipophilic compounds which is not a solvent."

4. "said emulsion having lamellar layers of liquid crystals"

a. *Plaintiffs' proposed construction*:

Plain and ordinary meaning

b. *Defendant's proposed construction*:

Indefinite or "where the liquid crystals formed in the emulsion are arranged in layers/sheets that exhibit a long-range translational order along one direction, and those lamellae layers exist in sufficient concentration and number to cause the emulsion to be stable for at least 8 weeks"

c. *Court's construction*:

Plain and ordinary meaning

This term appears in the asserted claims of the '816 Patent. The parties agree "that a POSA understands both the terms 'lamellar' and 'liquid crystal.'" (D.I. 110 at 48; Tr. at 78-79). The parties dispute (1) whether the term is indefinite because it does not require a certain structure in a particular amount and (2) whether "said emulsion having lamellar layers of liquid crystals" must be present in sufficient quantities to stabilize the oil/water interface.

On the first point of disagreement, Defendant argues that the term is indefinite because "the '816 Patent provides no guidance as to how to detect or measure these structures" and does not "disclose a required concentration or otherwise instruct as to how to determine whether a particular emulsion has 'lamellar layers of liquid crystals.'" (D.I. 110 at 46). Moreover, attributing stabilization of the emulsion to the structures, Defendant argues, "The POSA would be uncertain how much is needed to infringe these claims, since small amounts may be present and undetectable, or else detectable without contributing substantially to the emulsion's stability." (*Id.* at 47). Plaintiffs respond, "The '816 Patent . . . require[s] . . . only that the emulsion has lamellar layers of liquid crystals," not that they stabilize the emulsion or be present in a specific amount. (*Id.* at 49). Furthermore, Plaintiffs argue, "[T]he POSA is aware of tools for detecting lamellar liquid crystals within an emulsion." (*Id.*).

On this point I agree with Plaintiffs. A POSA would understand what it means to have "lamellar layers of liquid crystals." The POSA is in possession of tools that can measure such structures in an emulsion. The specification need not teach a technique for measuring the presence of a structure if the technique is known in the art. Therefore, I find the term does not render the asserted claims of the '816 Patent indefinite.

On the second point of disagreement, Defendant advocates for a construction requiring "layers or sheets of liquid crystals that exhibit a long-range translational order along one direction

(i.e., in order to form each of the layers)" and that such structures provide stability to the emulsion. (*Id.* at 47). In support of imposing a stability limitation, Defendant argues that "the example compositions in the specification achieved stability for 8 to 12 weeks, and there is no other mechanism identified in the specification as providing this stability." (*Id.* at 48). Plaintiffs respond that there is no support in the specification for importing a "layers or sheets" limitation or a "causing the emulsion to be stable for 8 weeks" limitation. (*Id.* at 44-45). Plaintiffs admit ,"[A] POSA would expect the lamellar liquid crystals to contribute to the chemical stability disclosed for the inventive emulsions," but note, "the specification does not state that the lamellar liquid crystals are the sole reason that the disclosed chemical stability is achieved." (*Id.* at 51).

On this point I agree with Plaintiffs. The '816 Patent's specification does not provide support for either of Defendant's proposed limitations. Thus, a POSA, considering the specification, would not understand the crystal formations of the '816 Patent to be limited to layers or sheets extending in a single direction. Furthermore, although "lamellar layers of liquid crystals" stabilize the emulsion, the specification does not attribute the stability of the emulsion exclusively to such structures.

Therefore, I will construe "said emulsion having lamellar layers of liquid crystals" as having its plain and ordinary meaning.

5. "rosacea"

a. *Plaintiffs' proposed construction*:

> "a chronic cutaneous disorder primarily of the convexities of the central face (cheeks, chin, nose, and central forehead), encompassing various combinations of such cutaneous signs as flushing, erythema, telangiectasia, edema, papules, pustules, ocular lesions, and rhinophyma"

b. *Defendant's proposed construction*:

"a chronic inflammatory skin condition, which includes symptoms of erythema, papules, pustules, nodules, or inflammatory lesions"

c. *Court's construction*:[4]

"chronic inflammatory eruption of the nose and adjoining flush areas of the face characterized by erythema, papules, pustules, and telangiectasia"

This term appears in the asserted claims of the '816 Patent. The parties agree that the '816 Patent does not expressly define "rosacea." (*Id.* at 52-53, 55). The parties disagree whether the intrinsic record provides a definition of "rosacea."

Defendant argues for a construction drawn from U.S. Patent No. 6,133,310 ("Parks"), which is incorporated by reference into the '816 Patent. Plaintiffs argue that Defendant's construction excludes several symptoms that Parks describes such as "'telangiectasia,' 'eruption of the nose,' affected 'eye or eyelids,' and 'flushing.'" (*Id.* at 58).

Plaintiffs advocate a construction drawn from a 2002 expert committee report ("Wilkin"). (*Id.* at 53; D.I. 112 at App. 578-82). Defendant notes that Plaintiffs' draws its definition from extrinsic evidence. (D.I. 110 at 55). Defendant also argues that Plaintiffs' construction adds unnecessary complexity by including ocular symptoms. (*Id.* at 55).

I largely agree with Defendant. Parks, as part of the intrinsic record, provides the best evidence of what the patentee meant by "rosacea." (*See* '816 Patent at 2:26-40). Wilkin is

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[4] "Rosacea" and "papulopustular rosacea" (the next term) are terms of art. Both sides have proposed constructions. I am uncertain whether there is a real dispute here, as I doubt that there would be debate among medical doctors over whether a patient did or did not have rosacea or papulopustular rosacea. I am not sure there is any benefit achieved by adopting the constructions I am adopting.

extrinsic evidence and I will not consider it because the intrinsic evidence provides a clear definition. Drawing my construction directly from Parks, I construe "rosacea" as "a chronic inflammatory eruption of the nose and adjoining flush areas of the face characterized by erythema, papules, pustules, and telangiectasia." (*See* Parks at 1:4-8).

6. "papulopustular rosacea" ("PPR")

a. *Plaintiffs' proposed construction:*

"rosacea subtype 2, a chronic inflammatory disorder characterized by facial papules, pustules, and erythema"

b. *Defendant's proposed construction*:

"chronic inflammatory disorder characterized by facial papules, pustules, persistent erythema, and the presence of inflammatory infiltrates that accompany flares"

c. *Court's construction*:

"chronic inflammatory disorder characterized by facial papules, pustules, persistent erythema, and the presence of inflammatory infiltrates that accompany flares"

This term appears in the asserted claims of the '587, '118, and '425 Patents. The parties disagree (1) whether the construction should include "subtype 2" and (2) whether "inflammatory infiltrate that accompany flares" is helpful.

On the first point of disagreement, Plaintiffs argue that "all of the Jacovella Patents cite to and rely on the 2002 Wilkin report describing PPR as a subtype of rosacea." (D.I. 110 at 53). Furthermore, "the '117 Patent describes PPR as one of four rosacea subtypes." (*Id.*). Plaintiffs argue that because "the '117, '587, '425, and '118 Patents all derive from the same priority application and share many common terms, the Court 'must interpret the claims consistently across all asserted patents.'" (*Id.* at 59 (citing *SightSound Techs., LLC v. Apple Inc.*, 809 F.3d 1307, 1316 (Fed. Cir. 2015)). Defendant responds that the content of the '587 Patent's

specification controls over Wilkin because the Applicants did not incorporate Wilkin into the patent's definitions. (*Id.* at 57). Additionally, Defendant asserts, "Although the '117 patent shares a priority claim with the '587, '425, or '118 patents, these patents are not related." (*Id.* at 56).

The proper characterization of PPR symptoms presents a second point of disagreement. Defendant advocates for a construction derived fully from the specification of the '587 Patent. (*Id.* at 56). Plaintiffs respond that Defendant's "definition describes the clinical characterization of PPR (e.g., the 'presence of inflammatory infiltrates that accompany flares') and does not assist a POSA in understanding the claim term." (*Id.* at 59).

I agree with Defendant's construction. The parties agree that Defendant's proposed construction is an accurate clinical characterization of PPR. (*Id.* at 59). Furthermore, the '587 Patent's specification provides the best evidence of what the patentee meant by "papulopustular rosacea." The fact that the '117 Patent mentions PPR as a subtype of rosacea does not overcome the strength of a construction drawn directly from the '587 Patent's specification, does not establish that "subtype 2" is helpful, and does not mean that the Court is construing terms inconsistently across related patents. Drawing my construction directly from the '587 Patent, I construe "papulopustular rosacea" to mean "a chronic inflammatory disorder characterized by facial papules, pustules, persistent erythema, and the presence of inflammatory infiltrates that accompany flares."

7. **a mixture of solvents and/or propenetrating agents for the ivermectin, said solvents and/or propenetrating agents being selected from the group consisting of propylene glycol, ethanol, isopropanol, butanol, N-methyl-2-pyrrolidone, DMSO, polysorbate 80, phenoxyethanol, glyceryl triacetate and oleyl alcohol**

a. *Plaintiffs' proposed construction*:

Plain and ordinary meaning

b. *Defendant's proposed construction*:

"a mixture of solvents and/or propenetrating agents in the emulsion that must be a mixture of at least two of propylene glycol, ethanol, isopropanol, butanol, N-methyl-2-pyrrolidone, DMSO, polysorbate 80, phenoxyethanol, glyceryl triacetate and oleyl alcohol or mixtures thereof, but cannot include any other solvents and/or propenetrating agents"

c. *Court's construction*:

"a mixture of solvents and/or propenetrating agents in the emulsion that must be a mixture of at least two of propylene glycol, ethanol, isopropanol, butanol, N-methyl-2-pyrrolidone, DMSO, polysorbate 80, phenoxyethanol, glyceryl triacetate and oleyl alcohol or mixtures thereof, but cannot include any other solvents and/or propenetrating agents"

This term appears in the asserted claims of the '816 Patent. The parties agree that this phrase contains a Markush group. (*Id.* at 65, 67). The parties dispute whether the claimed "mixture of solvents" can include solvents other than those recited in the claim.

Plaintiffs argue that the claim language overcomes the "presumption that a Markush group is closed to mixtures or combinations of the recited elements." (*Id.* at 60). "If a patentee desires mixtures or combinations of the members of the Markush group, the patentee [needs] to add qualifying language while drafting the claim." *Abbott Labs. v. Baxter Pharm. Prods., Inc.*, 334 F.3d 1274, 1281 (Fed. Cir. 2003). Plaintiffs submit that "mixtures" is such qualifying language. (D.I. 110 at 60). Specifically, Plaintiffs argue that "mixtures" allows emulsions that include the named solvents plus other unnamed solvents. (D.I. 110 at 60-61). In support of this contention,

Plaintiffs cite a case construing "mixtures" outside of the context of a Markush group. (*Id.* at 61 (citing *Mars, Inc. v. H.J. Heinz Co.*, 377 F.3d 1369, 1376 (Fed. Cir. 2004))). Plaintiffs argue that *Mars* stands for the general proposition that "mixtures" are never closed to unnamed ingredients. (*Id.*).

Defendant appears to agree that the Markush presumption was overcome to a degree, but not to the extent argued by Plaintiffs. Defendant argues, "The patentees' use of the language 'selected from the group consisting of' in claims 1, 2 and 11 of the '816 Patent indicates clear intent to apply the legal effect of that phrase, which is to close the group to additional members, i.e., additional 'solvents and/or propenetrating agents.'" (*Id.* at 62). In response to Plaintiffs' argument that "mixtures" vitiates a Markush group, Defendant asserts, "[T]he word 'mixtures' inside the Markush group allows for mixtures of the listed Markush members, which Teva does not dispute. Plaintiffs' proposal, however, would open the claim to mixtures with solvents and/or propenetrating agents *not* listed in the Markush group . . . ." (*Id* at 64-65 (emphasis in original)). This, Defendant argues, "improperly changes the 'consisting of' language into 'comprising' language." (*Id.* at 65).

Plaintiffs also argue that construing the Markush group to exclude other solvents contradicts the specification. (*Id.* at 61). Specifically, Plaintiffs note that the specification describes diisopropyl adipate, a solvent for ivermectin, as "part of the 'oily phase' that may also be a solvent for ivermectin—despite not being listed in the Markush group of a 'mixture of solvents.'" (*Id.*). Defendant responds that its construction is not inconsistent with the specification. (*Id.* at 65). Rather, the specification lists diisopropyl adipate as a part of the oily phase, a different part of the mixture than the active phase described by the Markush group. (*Id.*).

I agree with Defendant. "[I]f a patent claim recites 'a member selected from the group consisting of A, B, and C,' the 'member' is presumed to be closed to alternative ingredients D, E, and F." *Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.*, 831 F.3d 1350, 1358 (Fed. Cir. 2016). Defendant's construction gives "mixtures" its proper legal effect by limiting the solvents and/or propenetrating agents but allowing additional non-solvents and/or propenetrating agents elements to be included. The "mixtures" language requires that the solvents and/or propenetrating agents contain two or more of the listed solvents and/or propenetrating agents. It therefore serves a purpose in the phrase being construed, without converting the Markush group into a comprising claim.

Therefore, I construe "a mixture of solvents and/or propenetrating agents for the ivermectin, said solvents and/or propenetrating agents being selected from the group consisting of propylene glycol, ethanol, isopropanol, butanol, N-methyl-2-pyrrolidone, DMSO, polysorbate 80, phenoxyethanol, glyceryl triacetate and oleyl alcohol" to mean "a mixture of solvents and/or propenetrating agents in the emulsion that must be a mixture of at least two of propylene glycol, ethanol, isopropanol, butanol, N-methyl-2-pyrrolidone, DMSO, polysorbate 80, phenoxyethanol, glyceryl triacetate and oleyl alcohol or mixtures thereof, but cannot include any other solvents and/or propenetrating agents."

8. "to thereby obtain an onset of a significant reduction in inflammatory lesion count in the subject 2 weeks after the initial administration of the pharmaceutical composition"

a. *Plaintiffs' proposed construction*:

Plain and ordinary meaning

b. *Defendant's proposed construction*:

Indefinite

c. *Court's construction*:

"to thereby obtain a statistically significant reduction in inflammatory lesion count at or before two weeks"[5]

This term appears in asserted claims of the '587 and '425 Patents.[6] The parties agree that "significant reduction" means "reduction/improvement that is statistically significant, not due to chance alone, which has a p-value of 0.05 or less." (D.I. 110 at 7). The parties dispute whether "onset" is amenable to construction in the context of the claims.

Defendant argues, "[I]nconsistent use of the word 'onset' coupled with an unclear and subjective plain meaning render asserted claims 1, 10, 15, and 29 of the '587 Patent and claims 4 and 13 of the '425 Patent invalid as indefinite." (*Id.* at 70). First, Defendant notes that coupling dictionary definitions of "onset" with the agreed construction of "significant reduction" "leads to a nonsensical result." (*Id.* at 71). In Defendant's view, such a dictionary-based construction would be "directed to obtaining or observing the 'beginning' of a statistically significant belief, based on past experimental results, that reduction of inflammatory lesion count will occur in another, future patient." (*Id.* at 71-72). Defendant further argues, "Ignoring the statistical nature of this phrase would . . . not save these claims" because "'onset' must still correspond to the 'beginning or start' of something." (*Id.* at 72 (emphasis omitted)). According to Defendant, the

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[5] The somewhat different phrase, "wherein an onset of a significant reduction in inflammatory lesion count in the subject is observed 2 weeks after the initial administration," should be construed similarly. ('425 Patent, claims 4, 13; '587 Patent, claims 10, 29).

[6] This is the full term in claims 1 and 15 of the '587 patent. The language that is consistent in all the asserted claims of the '587 and '425 Patents is "an onset of a significant reduction in inflammatory lesion count in the subject." I think the analysis is the same regardless of the varying language in the remaining claims.

potential "something" that might represent a "beginning or start" is subjective much like "the onset of a cold." (*Id.*). Plaintiffs respond, "A POSA would understand that the term 'onset' means the beginning or start of a detectable clinical improvement." (*Id.* at 75).

Defendant asserts, "It is also incorrect to equate the claimed 'onset' with the 'significant reduction' itself." (*Id.* at 73). This is true, Defendant argues, because, "The prosecution history and the language of the claims themselves demonstrate that the patentees intended an 'onset of a significant reduction in inflammatory lesion count' to be something different and distinct from 'a significant reduction.'" (*Id.*). As evidence, Defendant points to the relationship between independent claim 8 and dependent claim 10 where an "onset" must be "something different and discrete." (*Id.*). Additionally, Defendant urges that the prosecution history requires the distinction because Applicants added the "onset" limitation to overcome prior art. (*Id.* at 74). Plaintiffs respond that the claims were amended to add not only "onset," but also "2 weeks after initial administration." (*Id.* at 76). The patent office allowed the claims because of the unexpected nature of the early onset. (*Id.*).

I agree with Plaintiffs that the phrase does not render the claims indefinite. The '857 Patent's specification discusses how "[t]his early onset of significant effectiveness is unexpected and surprising in comparison with the conventional treatments." ('587 Patent 4:62-64). "This early onset" refers to "at two weeks after the initial treatment, about 30% ($p<0.001$) and 27.3% ($p<0.01$) median reduction of the inflammatory lesion counts . . . ." (*Id.* at 4:55-57). A POSA considering the specification, would understand that "onset . . . 2 weeks after initial administration" refers to the timing of an observable, statistically significant, clinical improvement.

Therefore, I construe "to thereby obtain an onset of a significant reduction in inflammatory lesion count in the subject 2 weeks after the initial administration of the pharmaceutical composition" to mean "to thereby obtain a statistically significant reduction in inflammatory lesion count at or before two weeks."

9. "without co-administration of another active ingredient"

a. *Plaintiffs' proposed construction*:

Plain and ordinary meaning

b. *Defendant's proposed construction*:

"without treating with any other active ingredient at any time throughout the course of therapy"

c. *Court's construction*:

"without co-administration of another active ingredient as part of the therapy"

This term appears in the asserted claims of the '587 and '425 Patents. The parties dispute whether "co-administration of another active ingredient" extends to treatment of a patient with any other active ingredient for any reason.

Defendant argues that this negative limitation should be construed to foreclose a patient taking any other medication for any reason. (*See* D.I. 110 at 82). As support for this sweeping limitation, Defendant points to clinical studies cited in the '587 Patent's specification and a dictionary describing "'coadministration' as 'giving of two or more therapeutic agents at the same time.'" (*Id.* at 81-82). Plaintiffs respond that Defendant's "construction is overly restrictive because it improperly limits the use of any active ingredient even if the active ingredient is for something other than the PPR treatment, e.g., a headache or high blood

pressure." (*Id.* at 83). Plaintiffs argue, "[T]he construction should make clear that the claims require no other treatment *for PPR* during the *ivermectin* regimen." (*Id.* (emphasis in original)).

I agree with Plaintiffs that the "without co-administration" negative limitation is not so broad as to cover all medication taken by a patient for any reason. The fact that clinical studies limit unrelated medications, as a matter of course, is not persuasive evidence of the patentee's intent regarding "without co-administration." Therefore, the term is properly construed to exclude therapeutic treatment of PPR with any other active ingredient, but not use of active ingredients for other, unrelated ailments.

Therefore, I construe "without co-administration of another active ingredient" to mean "without co-administration of another active ingredient as part of the therapy."

IV. CONCLUSION

Within five days the parties shall submit a proposed order consistent with this Memorandum Opinion.