IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GALDERMA LABORATORIES, L.P., and NESTLÉ SKIN HEALTH S.A.,	:	
Plaintiffs,	:	
	:	C.A. No. 15-232-LPS
v.	:	
ACTAVIS LABORATORIES UT, INC.,	:	
Defendant.	:	

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MEMORANDUM OPINION

June 30, 2016
Wilmington, Delaware

STARK, U.S. District Judge:

On March 12, 2015, Plaintiffs Galderma Laboratories, L.P. ("Galderma") and Nestlé Skin Health S.A. ("Nestlé") (collectively, "Plaintiffs") filed suit against Defendant Actavis Laboratories UT, Inc. ("Actavis" or "Defendant") alleging infringement of U.S. Patent Nos. 7,439,241[1] (the "'241 patent"), 8,410,102[2] (the "'102 patent"), 8,426,410[3] ("the "'410 patent"), 8,859,551[4] (the "'551 patent"), 8,513,247[5] (the "'247 patent"), and 8,513,249[6] (the "'249 patent") (collectively, "patents-in-suit"). The patents-in-suit claim compounds, formulations, methods and systems for the treatment or prevention of inflammatory skin disorders, rosacea, and erythema (a symptom of rosacea).

The parties submitted technology tutorials and claim construction briefs. (D.I. 68, 69, 71, 72, 82, 84) The Court held a claim construction hearing on May 24, 2016. (*See* D.I. 120 ("Tr."))

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[1]The '241 patent is titled "Compounds, Formulations, and Methods for Treating or Preventing Rosacea." (D.I. 1 at ¶ 7; D.I. 1 Ex. A) It issued on October 21, 2008. (*Id.*)

[2]The '102 patent is titled "Methods and Compositions for Treating or Preventing Erythema." (D.I. 1 at ¶ 9; D.I. 1 Ex. B) It issued on April 2, 2013. (*Id.*)

[3]The '410 patent is titled "Compounds, Formulations, and Methods for Treating or Preventing Inflammatory Skin Disorders." (D.I. 1 at ¶ 11; D.I. 1 Ex. C) It issued on April 23, 2013. (*Id.*)

[4]The '551 patent is titled "Compounds, Formulations, and Methods for Treating or Preventing Inflammatory Skin Disorders." (D.I. 1 at ¶ 13; D.I. 1 Ex. D) It issued on October 14, 2014. (*Id.*)

[5]The '247 patent is titled "Methods and Compositions for Safe and Effective Treatment of Erythema." (D.I. 1 at ¶ 15; D.I. 1 Ex. E) It issued on August 20, 2013. (*Id.*)

[6]The '249 patent is titled "Methods and Compositions for Safe and Effective Treatment of Erythema." (D.I. 1 at ¶ 17; D.I. 1 Ex. F) It issued on August 20, 2013. (*Id.*)

I. LEGAL STANDARDS

The ultimate question of the proper construction of a patent is a question of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015) (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-91 (1996)). "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) (internal quotation marks omitted). "[T]here is no magic formula or catechism for conducting claim construction." *Id.* at 1324. Instead, the court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." *Id.*

"[T]he words of a claim are generally given their ordinary and customary meaning . . . [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1312-13 (internal citations and quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). The patent 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." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While "the claims themselves provide substantial guidance as to the meaning of particular claim terms," the context of the surrounding words of the claim also must be considered. *Phillips*, 415 F.3d at 1314. Furthermore, "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent . . . ." *Id.* (internal citation omitted).

It is likewise true that "[d]ifferences among claims can also be a useful guide . . . . For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-15 (internal citation omitted). This "presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim." *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

It is also possible that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. It bears emphasis that "[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)) (internal quotation marks omitted).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). The prosecution history, which is "intrinsic evidence," "consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the

invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

In some cases, "the district court will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva*, 135 S. Ct. at 841. Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the meaning of a term to those of skill in the relevant art because such dictionaries "endeavor to collect the accepted meanings of terms used in various fields of science and technology." *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Id.* Nonetheless, courts must not lose sight of the fact that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* Overall, while extrinsic evidence "may be useful" to the court, it is "less reliable" than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

Finally, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *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) (quoting *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1550 (Fed. Cir. 1996)).

II. CONSTRUCTION OF THE DISPUTED TERMS

A. "redness associated with rosacea"[7]

Plaintiffs "redness (erythema) due to rosacea"
Respironics "redness related to that observed in rosacea"
Court "redness (erythema) due to rosacea"

The parties disagree about whether this limitation requires redness to be caused by rosacea. Plaintiffs' position, which is that the redness associated with rosacea must be due to rosacea, is fully supported by the intrinsic evidence. The specification makes clear that the invention of the '241 patent is aimed at addressing erythema, or redness of the face, which is symptomatic of, i.e. caused by, rosacea. *See* '241 patent at 1:35-40 ("Rosacea develops gradually starting as frequent blushing and frequent irritation of the facial skin. More advanced rosacea is characterized by a vascular stage where patients display increasingly severe erythema (abnormal redness of the skin) and telangiectasia (visible red lines due to abnormal dilatation of capillary

[7]This term appears in claim 1 of the '241 patent.

vessels and arterioles)."), 1:51-54 ("The exact pathogenesis of rosacea is unknown, . . . the pathologic process is well described. For example, erythema associated with rosacea is caused by dilation of the superficial vasculature of the face."), 18:54-55 (describing experiment on "rosacea induced erythema"). Example 9 in the specification, which involved four subjects with "rosacea (characterized by transitory erythema of the mid-facial areas and early telangiectasis)," concluded "that 0.15% brimonidine tartrate, when used in a daily morning protocol, dramatically eliminates or reduces ***redness due to rosacea***." *Id.* at 17:63-66, 18:41-43 (emphasis added). As Plaintiffs emphasize, the '241 patent is "constantly talking about treating rosacea, not other diseases." (Tr. at 13-14)

Further, during prosecution, the applicant made clear that claim 1 (then-pending claim 29) "is directed to reducing redness of the skin that is ***associated with, i.e., due to,*** all types of rosacea. Such redness, which is synonymous with erythema, may be transient or nontransient (persistent)." (D.I. 64 Ex. 9 at 4-5 (emphasis added); *see also id.* at 4 ("As presently claimed, the invention is narrowly drawn to a method for reducing a specific symptom, namely redness, that is associated with a specific condition, namely rosacea."); D.I. 64 Ex. 8 at 2, ¶ 4) A "specification's use of 'i.e.' signals an intent to define the word to which it refers," *Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1334 (Fed. Cir. 2009), and the use of this phrase in the prosecution history supports the conclusion suggested here by the specification. Indeed, in overcoming a prior art rejection, the applicant expressly distinguished the claimed invention from prior art treating redness caused by conditions other than rosacea. *See* D.I. 64 Ex. 9 at 9 ("[R]edness associated with rosacea and menopause-related flushing are distinct dermatological conditions that respond differently to therapeutics, such as clonidine."); D.I. 64 Ex. 10 at 5

("[O]ne of ordinary skill in the art could not predict that a compound used to treat one type of flushing would be effective for treatment of another type of flushing."); D.I. 64 Ex. 11 at 13 (distinguishing claims addressing "redness . . . associated with rosacea" from prior art addressing "redness associated with pain"). "Prosecution arguments like [these ones] which draw distinctions between the patented invention and the prior art are useful for determining whether the patentee intended to surrender territory, since they indicate in the inventor's own words what the invention is not." *MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1330 (Fed. Cir. 2007).

Defendant's proposed construction – which broadens the scope of the claimed invention to cover treatments for redness ***related to that observed*** in rosacea – not only lacks affirmative support in the intrinsic evidence, but also contradicts the intrinsic evidence, as it encompasses treatments for what Defendant views as the "common cause" of erythema observed in rosacea and other conditions: "dilation of the superficial vasculature." (D.I. 69 at 7) (citing '241 patent at 1:52-55) Defendant erroneously points to Example 13 as supporting its position, arguing that because it involves the use of a provocative compound called methyl nicotinate to induce erythema by causing "vasodilatory effect on the dermal vasculature," the patentee must have intended to claim treatments for erythema caused by conditions other than rosacea. (D.I. 69 at 7) (citing '241 patent at 19:20-22) However, as Plaintiffs explain, a person of ordinary skill in the art would not understand Example 13, entitled "Testing Procedure for Prevention of Redness," to be an embodiment of the invention, but rather a method for testing embodiments of the invention. (*See* D.I. 84 at 9 n.9) (citing '241 patent at 19:18-22; D.I. 84, Ex. II at 147) Defendants' expert declaration cannot alter this outcome, given the strength of the intrinsic

evidence supporting Plaintiffs' construction. *See generally Eidos Display, LLC v AU Optronics Corp.*, 779 F.3d 1360, 1365 (Fed. Cir. 2015) ("To the extent the district court considered extrinsic evidence in its claim construction order . . . that evidence is ultimately immaterial to the outcome because the intrinsic record is clear.").

Because Plaintiffs' position finds extensive support in the intrinsic evidence and reflects the plain and ordinary meaning of "redness associated with rosacea" from the perspective of a person of ordinary skill in the art, the Court will construe this term as "redness (erythema) due to rosacea."

B. "[treating rosacea and] the symptoms associated therewith"[8]

Plaintiffs "treating rosacea or at least one discernible symptom thereof"
Defendant "[treating rosacea and] symptoms including frequent blushing, frequent irritation of the facial skin, erythema, telangiectasia, papules, pustules, and rhinophyma"
Court "treating rosacea or at least one discernible symptom thereof"

The parties disagree about whether this term requires treatment of at least one symptom of rosacea or all of the symptoms of rosacea. Here, as with the previous term, the intrinsic evidence makes clear that the former view, Plaintiffs' view, is correct. The specification explains that "[i]n one embodiment, 'treatment' or 'treating' refers to an amelioration, prophylaxis, or reversal of a disease or disorder, or ***at least one discernible symptom thereof***. For example, treating an inflammatory skin disorder (e.g., rosacea) by lessening the redness of the skin." '410 patent at 23:24-28 (emphasis added). Adopting Defendant's proposed construction would

[8]This term appears in claim 1 of the '410 patent.

improperly read this embodiment out of the claim. *See Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1550 (Fed. Cir. 1996) ("[A] claim interpretation that would exclude the [invention] is rarely the correct interpretation."). Similarly, the part of the specification cited during prosecution by the applicant in support of claim 1 (then claim 33) equates treatment of rosacea with treatment of a single symptom. (*See* D.I. 64 Ex. 13 at 2, 4; D.I. 64 Ex. 32 at 9-10) Example 9 describes testing of a brimonidine topical application which "dramatically eliminates or reduces redness due to rosacea" and is "an effective daily treatment for chronic rosacea redness." '410 patent at 18:66-19:4. Notably, Example 9 only includes one example of a patient who was "symptom free" for a period of time. *See id.* at 18:36-37, 18:61-65. In light of the intrinsic evidence, a person of ordinary skill in the art would understand that "and" is used in this term to mean "or," *see Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1361-62 (Fed. Cir. 2008) (finding that use of "and" between two terms did "not require their simultaneous existence"); *see also* D.I. 84 Ex. NN (providing one definition of "and" as "reference to either or both of two alternatives"), and that, "in context, the plural can describe a universe ranging from one to some higher number, rather than requiring more than one item," *Versa Corp. v. Ag-Bag Int'l Ltd.*, 392 F.3d 1325, 1330 (Fed. Cir. 2004).

Defendant argues that this term requires treatment of ***all*** the symptoms of rosacea exhibited in the patient being treated. In support of its position, Defendant points to the "Background of the Invention," which lists seven different symptoms of rosacea and states that certain "[c]urrent treatments, which are directed to control of redness, inflammation, and skin eruptions" are inadequate because they "cannot treat all symptoms" and do "not treat the disease itself." '410 patent at 1:66-67, 2:12-27. However, the "Background of the Invention" merely

describes the state of the art, including the limitations of particular prior art treatments, and it does not purport to describe the invention itself. (*See id.* at 2:6-27)

Because Plaintiffs' proposed construction reflects the plain and ordinary meaning of "treating rosacea and the symptoms associated therewith" in light of the intrinsic evidence from the perspective of a person of ordinary skill in the art, the Court will adopt it. Accordingly, the Court will construe this term as "treating rosacea or at least one discernible symptom thereof."

C. "pharmaceutical composition"[9]

Plaintiffs No construction necessary.
Defendant "a composition comprising a pharmaceutical compound and a pharmaceutically acceptable carrier"
Court "a composition comprising a pharmaceutical compound and a pharmaceutically acceptable carrier"

While Plaintiffs contend they are unaware of any reason why this term requires construction (*see* D.I. 71 at 14-15), Defendant explains that its construction is relevant at least to the issue of "[w]hether claim 1 of the '241 patent is invalid for obviousness type double patenting over the '410 patent, which Plaintiffs have been on notice of since January 13, 2016." (D.I. 82 at 10) (citing D.I. 82 Ex. A at 28) The Court finds that construction of this term is therefore necessary, at least because the parties do not appear to agree on whether a "pharmaceutical composition" requires a pharmaceutically acceptable carrier. *See O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., Ltd.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008) ("[W]hen the

[9]This term appears in claim 1 of the '241 patent.

parties present a fundamental dispute regarding the scope of a claim term, it is the court's duty to resolve it.").

The intrinsic evidence supports Defendant's proposed construction of this term. Claim 1 refers to a method of "topically administering a pharmaceutical composition," '241 patent at 24:31-35, and although the specification does not define the term "pharmaceutical composition," it does define "topical formulation," which the specification makes clear that claim 1 is directed to. The specification provides: "The combination of a pharmaceutically acceptable topical carrier and a compound of the invention is termed a topical formulation of the invention." *Id.* at 10:16-18. The specification further explains that "[t]opical formulations of the invention are prepared by mixing a compound of the invention with a topical carrier according to well-known methods in the art . . . ." *Id.* at 10:18-21. Plaintiffs do not explain what, if anything, is wrong with Defendant's proposed construction. (*See* Tr. at 67-69) Accordingly, the Court will construe "pharmaceutical composition" as "a composition comprising a pharmaceutical compound and a pharmaceutically acceptable carrier."

D. "Wherein" and "For" Clauses

The parties disagree about whether certain terms preceded by "wherein" and "for" are limiting. The first of these, "wherein the composition acts locally in the skin," is directed to a composition. The next two terms, "for treating erythema or a symptom associated therewith in a subject" and "wherein the erythema or the symptom is facial erythema associated with rosacea," also describe composition claims. The remaining terms begin with "wherein" and describe particular pharmacokinetic profiles achieved by certain composition claims and certain method claims.

"[T]he patentability of apparatus or composition claims depends on the claimed structure, not on the use or purpose of that structure." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002); *see also In re Kao*, 639 F.3d 1057, 1070 (Fed. Cir. 2011). "To hold otherwise would allow any formulation – no matter how obvious – to become patentable merely by testing and claiming an inherent property." *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1354 (Fed. Cir. 2012). However, "statements of intended use or asserted benefits . . . may, in rare instances, limit apparatus claims, but only if the applicant clearly and unmistakably relied on those uses or benefits to distinguish prior art," or if, in the form of a preamble, they "recite[] essential structure or steps, or if [they] are necessary to give life, meaning, and vitality to the claim." *Catalina Mktg. Int'l, Inc.*, 289 F.3d at 808-09 (internal quotation marks omitted).

Similarly, claim language that "is only a statement of purpose and intended result" which "does not result in a manipulative difference in the steps of the claim" is generally not limiting. *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1376 (Fed. Cir. 2001); *see also Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371, 1378 (Fed. Cir. 2005) (finding clause that "simply describes the intended result" of following the steps in claimed method was not limiting). Thus, in general "[a] whereby [or wherein] clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited." *Minton v. Nat'l Ass'n of Sec. Dealers, Inc.*, 336 F.3d 1373, 1381 (Fed. Cir. 2003). "However, when the 'whereby' [or 'wherein'] clause states a condition that is material to patentability, it cannot be ignored in order to change the substance of the invention." *Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329-30 (Fed. Cir. 2005) (finding clause limiting where it "is more than the intended result

of a process step," "is part of the process itself," and is "integral part of the invention").

1. "wherein the composition acts locally in the skin"[10]

Plaintiffs This term is limiting.
Defendant This term is non-limiting.
Court This term is non-limiting.

This term appears in claim 3, which depends from claim 1, a method claim, and therefore incorporates claim 1's requirement for "topically administering [the composition] to the skin of a patient." '410 patent at 24:45-51. The specification makes clear that "act[ing] locally in the skin of the patient" is a result of "topically administering" the composition. *Id.* at 3:27-30 ("The compounds are delivered in a topical skin composition that insures that the compounds are effective in the skin of a patient but do not penetrate the skin in sufficient amounts to induce serious systemic side effects."). Plaintiffs do not dispute that "act[ing] locally in the skin" is a result of "topically administering" the composition. Plaintiffs' argument that this term is material to patentability because it was used to distinguish oral formulations that act centrally in the brain stem is unpersuasive, because the use of topical administration already distinguishes the claimed method from orally administered prior art, and the cited prosecution history passages say nothing about acting "locally." (*See* D.I. 64 Ex. 9 at 6-10) Because this term merely recites an inherent result of the claimed method which was not separately relied on by the patentee to distinguish the prior art, the Court will treat this term as non-limiting.

[10]This term appears in claim 3 of the '410 patent.

2. "for treating erythema or a symptom associated therewith in a subject"[11] / "wherein the erythema or the symptom is facial erythema associated with rosacea"[12]

Plaintiffs This term is limiting.
Defendant This term is non-limiting.
Court This term is non-limiting.

These terms are statements of intended use that were not used to distinguish the prior art. Contrary to Plaintiffs' view, the claims of the '247 and '249 patents were distinguished from the prior art based on the concentration of the claimed compositions and not based on their use. (*See* D.I. 64 Ex. 23 at 7-8 ("[I]n all Examples where an αadrenoceptor agonist was used for treating erythema in patients, DeJovin used a concentration of αadrenoceptor agonist less than 0.2% (w/w) . . . i.e., Alphagan P in Example 9 having 0.15% (w/w) brimonidine tartrate . . . ."), 10 ("[T]he prior art in combination does not teach or suggest a composition comprising 0.4% to 0.6% of brimonidine for topical treatment of erythema . . . .") (emphasis omitted); D.I. 64 Ex. 14 at 7-8, 10 (same)) Accordingly, the Court will construe these terms as non-limiting.

3. Pharmacokinetic Profile terms[13]

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[11]This term appears in claim 16 of the '247 patent and claim 15 of the '249 patent.

[12]This term appears in claim 23 of the '247 patent and claim 22 of the '249 patent.

[13]The specific terms addressed here are: (i) "wherein the topical administration [of the topical gel composition] results in more reduction of the erythema or the symptom compared to a vehicle control as measured by a 12 hour success profile evaluated on both Clinician's Erythema Assessment scores and Patient's Self Assessment scales without causing unacceptable drug related adverse events, and the 12 hour success profile comprises at least 1-grade improvement o the erythema or the symptom," which appears in claims 1 and 15 of the '247 patent; (ii) "wherein

Plaintiffs These terms are limiting.
Defendant These terms are non-limiting.
Court These terms are limiting.

The specifications of the '247 and '249 patents describe pharmacokinetic parameters as being integral to the claimed inventions. *See, e.g.*, '249 patent at 2:20-30, 6:8-7:14; '247 patent at 6:23-7:14. During prosecution of these patents, specific pharmacokinetic parameters were used not only to define the claimed inventions, but also to distinguish them from the prior art.

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the 12 hour success profile further comprises about 1 hour to about 8 hours of 2-grade improvement of the erythema or the symptom," which appears in claims 5 and 22 of the '247 patent; (iii) "wherein [the erythema or the symptom is facial erythema associated with rosacea, and] the 12-hour success profile comprises an effect of 1-grade improvement of the facial erythema and about 3 hours to about 6 hours of 2-grade improvement of the facial erythema," which appears in claims 6 and 23 of the '247 patent as well as in claims 6 and 22 of the '249 patent; (iv) "wherein the topical administration of the topical gel composition to a skin area affected by the erythema or the symptom results in more reduction of the erythema or the symptom compared to a vehicle control as measured by a 12 hour success profile evaluated on both Clinician's Erythema Assessment scores and Patient's Self Assessment scales without causing unacceptable drug related adverse events, and the 12 hour success profile comprises at least 1-grade improvement of the erythema or the symptom," which appears in claim 16 of the '247 patent; (v) "wherein the topical administration of the topical composition to the skin area results in more reduction of the erythema or the symptom compared to a vehicle control as measured by a 12 hour success profile evaluated on both Clinician's Erythema Assessment scores and Patient's Self Assessment scales, wherein the 12 hour success profile comprises an effect of 1-grade improvement of the erythema or the symptom and about 1 hour to about 8 hours of 2-grade improvement of the erythema or the symptom," which appears in claims 5 and 21 of the '249 patent; (vi) "wherein the topical administration effects a serum or plasma profile of brimonidine having a mean C_{max} of about 54±28 pg/mL or less and a mean $AUC_{0\text{-}24\ hr}$ of about 568±277 pg.hr/mL or less," which appears in claims 1 and 14 of the '249 patent; and (vii) "wherein the topical administration of the topical gel composition to a skin area affected by the erythema or the symptom effects a serum or plasma profile of brimonidine having a mean C_{max} of about 54±28 pg/mL or less and a mean $AUC_{0\text{-}24\ hr}$ of about 568±277 pg.hr/mL or less," which appears in claim 15 of the '249 patent.

(*See, e.g.*, D.I. 64 Ex. 24 at 9 ("The PK profile is part of the invention."), 10 ("[I]n judging the patentability of the present claims . . . , the PK profile must also be considered."), 14 ("[T]he PK profile in the present claims . . . further defines the invention."); D.I. 64 Ex. 14 at 13-14 ("None of the prior art teaches or suggests the effectiveness of the treatment recited [in dependent claims reciting various periods of 2-grade improvement of erythema.]"), 16 ("[T]he reference claims do not recite the 'wherein' clause in the present claims, which further defines the invention."); D.I. 64 Ex. 15 at 5 (same); D.I. 64 Ex. 24 at 12 (same)) Here, Defendant "has failed to show that the allegedly inherent properties add nothing to the [claims] beyond the other recited limitations and are not material to the patentability of the invention." *The Research Found. of State Univ. of N.Y.*, 723 F. Supp. 2d at 654 (internal quotation marks and citation omitted). Accordingly, the Court will construe these terms as limiting.

III. CONCLUSION

The Court will construe the disputed terms as explained above. An appropriate Order follows.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GALDERMA LABORATORIS, L.P., and NESTLÉ SKIN HEALTH S.A.,	:	
Plaintiffs,	:	
	:	C.A. No. 15-232-LPS
v.	:	
ACTAVIS LABORATORIES UT, INC.,	:	
Defendant.	:	

ORDER

At Wilmington, this **30th** day of **June, 2016**:

For the reasons set forth in the Memorandum Opinion issued this date,

IT IS HEREBY ORDERED that the disputed claim terms of U.S. Patent Nos. 7,439,241 (the "'241 patent"), 8,426,410 ("the "'410 patent"), 8,859,551 (the "'551 patent"), 8,513,247 (the "'247 patent"), and 8,513,249 (the "'249 patent") are construed follows:

Claim Term	**Court's Construction**
"redness associated with rosacea" ['241 patent, claim 1]	"redness (erythema) due to rosacea"
"[treating rosacea and] the symptoms associated therewith" ['410 patent, claim 1]	"treating rosacea or at least one discernible symptom thereof"
"pharmaceutical composition" ['214 patent, claim 1]	"a composition comprising a pharmaceutical compound and a pharmaceutically acceptable carrier"

"wherein the composition acts locally in the skin" ['410 patent, claim 3]	This term is non-limiting.
"for treating erythema or a symptom associated therewith in a subject" ['247 patent, claim 16; '249 patent, claim 15]	This term is non-limiting.
"wherein the erythema or the symptom is facial erythema associated with rosacea" ['247 patent, claim 23; '249 patent, claim 22]	This term is non-limiting.
"wherein the topical administration results in more reduction of the erythema or the symptom compared to a vehicle control as measured by a 12 hour success profile evaluated on both Clinician's Erythema Assessment scores and Patient's Self Assessment scales without causing unacceptable drug related adverse events, and the 12 hour success profile comprises at least 1-grade improvement of the erythema or the symptom" ['247 patent, claims 1 and 15]	This term is limiting.
"wherein the 12 hour success profile further comprises about 1 hour to about 8 hours of 2-grade improvement of the erythema or the symptom" ['247 patent, claims 5 and 22]	This term is limiting.

"wherein [the erythema or the symptom is facial erythema associated with rosacea, and] the 12 hour success profile comprises an effect of 1-grade improvement of the facial erythema and about 3 hours to about 6 hours of 2-grade improvement of the facial erythema" ['247 patent, claims 6 and 23; '249 patent, claims 6 and 22]	This term is limiting.
"wherein the topical administration of the topical gel composition to a skin area affected by the erythema or the symptom results in more reduction of the erythema or the symptom compared to a vehicle control as measured by a 12 hour success profile evaluated on both Clinician's Erythema Assessment scores and Patient's Self Assessment scales without causing unacceptable drug related adverse events, and the 12 hour success profile comprises at least 1-grade improvement of the erythema or the symptom" ['247 patent, claim 16]	This term is limiting.
"wherein the topical administration of the topical composition to the skin area results in more reduction of the erythema or the symptom compared to a vehicle control as measured by a 12 hour success profile evaluated on both Clinician's Erythema Assessment scores and Patient's Self Assessment scales, wherein the 12 hour success profile comprises an effect of 1-grade improvement of the erythema or the symptom and about 1 hour to about 8 hours of 2-grade improvement of the erythema or the symptom" ['249 patent, claims 5 and 21]	This term is limiting.

"wherein the topical administration effects a serum or plasma profile of brimonidine having a mean C_{max} of about 54±28 pg/mL or less and a mean $AUC_{0\text{-}24\ hr}$ of about 568±277 pg.hr/mL or less" ['249 patent, claims 1 and 14]	This term is limiting.
"wherein the topical administration of the topical gel composition to a skin area affected by the erythema or the symptom effects a serum or plasma profile of brimonidine having a mean C_{max} of about 54±28 pg/mL or less and a mean $AUC_{0\text{-}24\ hr}$ of about 568±277 pg.hr/mL or less" ['249 patent, claim 15]	This term is limiting.

HON. LEONARD P. STARK
UNITED STATES DISTRICT JUDGE