IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GALDERMA LABORATORIES, L.P., GALDERMA S.A. and GALDERMA RESEARCH AND DEVELOPMENT, S.N.C.	:	
Plaintiffs,	:	
v.	:	C.A. No. 10-45-LPS
TOLMAR INC. and ACTAVIS MID ATLANTIC LLC,	:	UNSEALED ON FEBRUARY 16, 2012
Defendants.	:	

Jack B. Blumenfeld and Maryellen Noreika, Wilmington, Delaware, MORRIS, NICHOLS, ARSHT & TUNNELL LLP.
Charles E. Lipsey, Reston, VA; Susan H. Griffen, Howard W. Levine, and Rebecca D. Hess, Washington, DC, FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP.

Counsel for Plaintiffs.

Adam Poff, Wilmington, Delaware, YOUNG, CONAWAY, STARGATT & TAYLOR, LLP.
Jeffrey R. Gargano, Keith M. Stolte, Krista Vink Venegas, and Kevin P. Shortsle, Chicago, Illinois, MCDERMOTT WILL & EMERY LLP.

Counsel for Defendant Tolmar Inc.

Richard L. Horowitz and David E. Moore, Wilmington, Delaware, POTTER ANDERSON & CORROON LLP.
Steve H. Sklar and Gregory C. Bays, Chicago, Illinois, LEYDIG, VOIT & MAYER, LTD.

Counsel for Defendant Actavis Mid Atlantic LLC.

MEMORANDUM OPINION

February 13, 2012
Wilmington, Delaware.

Stark, U.S. District Judge:

I. INTRODUCTION

Plaintiffs Galderma Laboratories, L.P., Galderma S.A., and Galderma Research and Development, S.N.C. (collectively hereinafter "Galderma" or "Plaintiffs") have filed this patent infringement action against Defendants Tolmar, Inc. ("Tolmar") and Actavis Mid Atlantic LLC ("Actavis" and, collectively with Tolmar, "Defendants"). (D.I. 1; D.I. 44) Galderma alleges that Defendants infringe the five patents-in-suit: U.S. Patent Nos. 7,579,377 ("the '377 patent"), 7,737,181 ("the '181 patent"), 7,834,060 ("the '060 patent"), 7,838,558 ("the '558 patent"), and 7,868,044 ("the '044 patent").[1] The '377, '060, and '044 patents claim methods of treating acne using pharmaceutical compositions containing 0.3% adapalene, while the '181 and '558 patents claim pharmaceutical compositions containing 0.3% adapalene. (D.I. 92 at 7)

Presently before the Court is the matter of claim construction. Briefing on claim construction was initially completed on June 13, 2011. (D.I. 92; D.I. 95; D.I. 136; D.I. 141) The Court held a *Markman* hearing on June 29, 2011. *See* Claim Construction Hr'g Tr., June 29, 2011 (D.I. 178) (hereinafter "Tr."). Two supplemental claim construction disputes arose more recently, and briefing on these terms was completed on January 6, 2012. (D.I. 256; D.I. 258; D.I. 272; D.I. 275) Trial is scheduled to begin on March 5, 2012. (D.I. 40)

II. LEGAL STANDARDS

"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

[1]The patents-in-suit can be found in the record as exhibits to the Joint Claim Construction Chart ("JCCC") (D.I. 82).

(Fed. Cir. 2005) (internal quotation marks omitted). Construing the claims of a patent presents a question of law. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977-78 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370, 388-90 (1996). "[T]here is no magic formula or catechism for conducting claim construction." *Phillips*, 415 F.3d 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." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (internal quotation marks omitted), *aff'd*, 481 F.3d 1371 (Fed. Cir. 2007).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman*, 52 F.3d at 980. 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.*

A court also may rely on "extrinsic evidence," which "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 ordinary 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.

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). Thus, if possible, claims should be construed to uphold validity. *See In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984).

III. CONSTRUCTION OF DISPUTED TERMS

A. ***"a thus effective amount"*** ('377 patent, claims 1 & 2)
"effective amount" ('060 patent, claims 1,4, 6, 12, 17, 23, 28, and 34)

1. Plaintiffs' Construction: "an amount shown to cause improvement, in comparison to vehicle, with good tolerance (e.g., minimizing side effects)"

2. Defendants' construction: "an amount shown to cause improvement, in comparison to vehicle"

3. Court's construction: "an amount shown to cause improvement, in comparison to vehicle"

B. ***"effective for the treatment of"*** ('558 patent, claims 1, 5, and 15)

1. Plaintiffs' Construction: "shown to cause improvement, in comparison to vehicle, with good tolerance (e.g., minimizing side effects)"

2. Defendants' Construction: "shown to cause improvement, in comparison to vehicle, for treating"

3. Court's Construction: "shown to cause improvement, in comparison to vehicle, for treating"

C. ***"an anti-acne effective amount"*** ('181 patent, claim 1; '044 patent, claim 1)

1. Plaintiffs' Construction: "an amount shown to cause improvement in treating acne, in comparison to vehicle, with good tolerance (e.g., minimizing side effects)"

2. Defendants' Construction:"an amount shown to cause improvement, in comparison to vehicle, in treating an acne condition"

3. Court's Construction: "an amount shown to cause improvement, in comparison to vehicle, in treating an acne condition"

The various terms in dispute listed above present a single, common issue: whether, in the scope of the asserted claims of the patents-in-suit, the "effective" terms necessarily refer not just to the concept of therapeutic efficacy (i.e., reducing the number of lesions in one afflicted with

acne) but also to the concept of tolerance (i.e., not producing an unacceptable level of unwanted side effects). Plaintiffs assert that the terms in dispute refer to both efficacy and tolerance. Defendants counter that these terms refer only to efficacy. The Court agrees with Defendants.

Looking first at the claim language, three of the four "effective" terms modify the phrase "amount of pharmaceutical composition." In the Court's view, this does not favor either side's proposed constructions.

The Court next turns to the specification. Importantly, throughout the specification, efficacy and tolerance are treated as separate concepts. The specification states: "Specifically, it has now surprisingly been shown that, in addition to exhibiting better ***therapeutic efficacy*** compared to known compositions, the compositions according to the invention exhibit[] ***good tolerance***, comparable to those of the known compositions with a lower concentration of active principle." ('377 patent, col. 2 ll. 4-9; '060 patent, col. 2 ll. 24-29) (emphasis added) Plainly, the patent is distinguishing between "therapeutic efficacy" and "good tolerance." Likewise, the specification discloses separate tests that were performed to show effectiveness and to show tolerance. *Compare, e.g.*, '377 and '060 patents, Example 2 (describing clinical test entitled, "Effectiveness of 0.3% Adapalene Gel and Comparison with the 0.1% Adapalene Gel," reporting that "the 0.3% adapalene gel acts more rapidly than the 0.1% adapalene gel" and "produces a clearly greater therapeutic effect after 8 weeks of treatment") *with* '377 and '060 patents, Example 3 (describing clinical test entitled, "Tolerance Regarding the 0.3% Adapalene Gel," reporting that results "confirm the safety of daily use of the 0.3% adapalene gel," "which leads to the conclusion that the two gels are well-tolerated by the patients").

Plaintiffs argue that tolerance must be included in the "effective" terms because the

inventions of the patents-in-suit are pharmaceutical compounds and methods of using such compounds for treatment of acne in humans, primarily adolescents.[2] In this context, Plaintiffs continue, the invention would not be "effective" if it is not safe and well-tolerated, as otherwise patients would not comply with their prescribed treatment. Relatedly, Plaintiffs insist that the essence of their invention is therapeutic effectiveness with good tolerance, so adopting Defendants' constructions would deprive Plaintiffs of the full scope of their invention. *See Daiichi Pharm. Co., Ltd. v. Apotex, Inc.*, 380 F. Supp. 2d 478, 488 (D.N.J. 2005), *rev'd on other grounds*, 501 F.3d 1254 (Fed. Cir. 2007) (construing, in context of patent for topical method for treatment of otopathy with antibiotics, "effective to treat" as "safe and efficacious to treat," based on reasoning that "[i]t is proper to interpret terms and phrases appearing in the claim in light of the fundamental purpose and significance of the invention . . . [and] '[s]afety was a paramount concern of the inventors' of the . . . patent"); *Purdue Pharma, L.P. v. F.H. Faulding & Co.*, 48 F. Supp. 2d 420, 437 (D. Del. 1999) (holding that "effective treatment of pain" means that an individual patient is provided with pain relief without unacceptable side effects). Defendants acknowledge that "the crux of the alleged inventions relates to an increased concentration (0.3% vs. 0.1%) of the active ingredient, adapalene, in a pharmaceutical formulation used to treat acne, allegedly with no corresponding increase in side effects over the prior, lower dosage formulation." (D.I. 95 at 1)

The Court concludes that these arguments do not overcome the clear import of the specification, which is that efficacy and tolerance are different concepts in the patents-in-suit.

---

[2]The parties have agreed that "treating" or "treatment" should be given its plain and ordinary meaning. (Tr. at 21)

See Vitronics, 90 F.3d at 1582 (describing specification as "the single best guide to the meaning of a disputed term"); *see also Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 345 (1961).

Plaintiffs similarly argue that the prosecution history supports their proposed construction. They contend: "[t]he intrinsic record, including the reasons for allowance, make clear that it was this objective of the invention – improvement with good tolerance – that caused the Examiner to allow the claims." (D.I. 141 at 2) Plaintiffs rely, for example, on the Examiner's statement that "the present claims require the effective use of 0.3% adapalene, and applicant has shown through unexpected results that the particular dosage of 0.3% adapalene was more effective than 0.1% adapalene in treating acne lesions while minimizing side effects." (D.I. 92 Ex. T at 5-6) (see Tr. at 14-15) In the Court's view, however, the Examiner in this statement is distinguishing between efficacy (i.e., treating lesions) and tolerance (i.e., minimizing side effects). (*See* Tr. at 25) In this way, the Examiner's statement is consistent with the specification, and supports Defendants' proposed construction. If the "effective" terms in the context of the patents-in-suit inherently included the concept of tolerance, there would have been no reason for the Examiner (or the specification) to distinguish between the two concepts.

Accordingly, the Court will adopt Defendants' proposed construction of the "effective" terms.

D. ***"useful for the treatment of"*** ('181 patent, claims 1, 3, and 5)

1. Plaintiffs' Construction: "shown to cause improvement, in comparison to vehicle, with good tolerance (e.g., minimizing side effects)"

2. Defendants' Construction: no construction needed as the term appears only in a preamble; or, alternatively, "capable of treating"

3. Court's Construction: "capable of treating"

As an initial matter, the Court concludes this term needs to be construed, notwithstanding that it appears in the preamble of claims 1, 3, and 5 of the '181 patent. *See Poly-America, L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1309 (Fed. Cir. 2004) ("Whether to treat a preamble as a limitation is a determination resolved only on review of the entire[] . . . patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim."); *In re Paulsen*, 30 F.3d 1475, 1479 (Fed. Cir. 1994) (stating preamble is treated as claim limitation when it "breathes life and meaning into the claims and . . . is a necessary limitation to them"). The Court agrees with Plaintiffs that here "useful for the treatment of" "provides the necessary context for the claimed methods and further serves to specify the therapeutic application of the claimed methods – to treat acne – which is the fundamental purpose of the claimed invention." (D.I. 141 at 6) Additionally, "useful for the treatment of common acne" provides the antecedent basis for the claim terms "anti-acne effective amount" and "anti-acne ingredient" in claim 1 of the '181 patent. *See Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (listing, among "guideposts" for determining whether preamble is limitation, whether there is "dependence on a particular disputed preamble phrase for antecedent basis").

Resolution of the parties' dispute follows from the Court's resolution of the related

"effective amount" terms already discussed. There is no more basis for importing the concept of tolerance into the term "useful" than there was for doing so with the "effective" terms. Accordingly, the Court will construe "useful for the treatment of" to mean "capable of treating."

E. ***"pharmaceutical composition which is a gel of"*** ('377 patent, claims 1 and 2)

1. Plaintiffs' Construction: "a pharmaceutical composition in the form of a gel consisting essentially of"

2. Defendants' Construction: "a pharmaceutical composition in the form of a gel consisting of"

3. Court's Construction: "a pharmaceutical composition in the form of a gel consisting of"

The phrase "pharmaceutical composition which is a gel of" appears in claims 1 and 2 of the '377 patent and is followed by a list of ingredients. "The dispute between the parties concerns whether this list of ingredients must be ***exclusive***." (D.I. 92 at 15) In particular, the issue is whether this term should receive what Plaintiffs refer to as a "partially open construction" or, instead, the closed construction Defendants propose. Plaintiffs contend the term "allows additional ingredients that do not substantially adversely affect the advantageous properties of the invention." (Tr. at 44) To Plaintiffs, "while the claims in question do require ***all*** the listed ingredients in the specified ***amounts***, there is nothing that forbids the addition of other ingredients that do not alter the advantageous properties of the claimed formulations." (D.I. 141 at 11) By contrast, Defendants argue that, as a result of the prosecution history, the term is limited to a pharmaceutical composition in the form of a gel consisting of only the ingredients that are thereafter specifically listed in the patent. The Court agrees with Defendants.

The issue turns on the proper interpretation of the prosecution history. After the

Examiner rejected claims that used open-ended language, "comprising," the Examiner suggested that the applicants submit claims using the more restrictive ("partially open") language "consisting essentially of." However, the applicants did not take up the Examiner's suggestion. Instead, the applicants thereafter submitted claims using the closed language "which is a gel of." The claims were allowed with the language "which is a gel of."[3]

The Court agrees with Plaintiffs that "there is no basis in the intrinsic record to argue that applicants ***needed*** to include more restrictive language." (D.I. 141 at 9) (emphasis added) Defendants also agree that "[t]he applicants ***could have*** chosen to use 'consisting essentially of' language," but Defendants add, rightly, that the applicants chose not to do so. (D.I. 95 at 19) (emphasis added) The applicants' decision was one of legal consequence, as it narrowed the scope of the issued claims. *See Norian Corp. v. Stryker Corp.*, 432 F.3d 1356, 1361-62 (Fed. Cir. 2005) ("[I]t frequently happens that patentees surrender more through amendment than may have been absolutely necessary to avoid particular prior art. In such cases, we have held the patentees to the scope of what they ultimately claim, and we have not allowed them to assert that claims should be interpreted as if they had surrendered only what they had to."). Plaintiffs must live with the decisions applicants made during prosecution.

Plaintiffs are correct that the specification teaches "the pharmaceutical composition may be an aqueous gel containing ***in particular one or more*** ingredients selected from among Carbomer 940 (BF Goodrich, Carbopol 980) and propylene glycol, or a cream containing in particular one or more ingredients selected from among [a list]." (D.I. 92 at 16) (quoting '377

---

[3]*See* D.I. 82, Ex. H at GAL88591 and GAL88593; *id.* Ex. I at GAL88598; *id.* Ex. J at GAL88712, *id.* Ex. L at GAL88723-25 (allowing claim after applicant removed "comprising" and substituted "which is a gel of").

patent at col. 3 ll. 1-8) The specification continues "the invention ***may also contain*** inert additives or combinations of these additives," and goes on to list many. ('377 patent, col. 3 ll. 9-24) The specification then adds: "Of course, those skilled in the art will take care to select the optional compound(s) to be added to these compositions in such a way that the advantageous properties intrinsically associated with the present invention are not, or are not substantially, adversely affected by the envisaged addition." (*Id.* col. 3 ll. 25-30) But all of this simply shows why the applicants would likely not have been required to surrender such claim scope in order to have their claims allowed. But, again, the applicants chose not to submit such claims and, accordingly, such claims were not issued. Accordingly, again, the Court will adopt Defendants' proposed construction.

F. ***"poloxamer 124"*** ('377 patent, claims 1 and 2; '060 patent, claims 4, 15, 26, 27, and 34; '558 patent, claims 4 and 7; '181 patent, claims 2-5; '044 patent, claims 3-6, 9-12, 25-28, and 39)

1. Plaintiffs' Construction: "Synthetic block copolymer of ethylene oxide and propylene oxide; i.e., also known in the art as poloxamer 182 and the like."[4]

2. Defendants' Construction: "A block copolymer of ethylene oxide and propylene oxide having the formula [X][5] where a equals 11-12 and b equals 20-21, and having an average molecular weight between 2090 and 2360."

3. Court's Construction: "A block copolymer of ethylene oxide and propylene oxide having the formula [X] where a equals 11-12 and b equals 20-21, and having an average molecular weight between 2090 and 2360."

---

[4]At the hearing, Plaintiffs agreed to drop from their proposal the final phrase, "and the like." (Tr. at 61)

[5]The formula [X] is $HO(C_2H_4O)_a(C_3H_6O)_b(C_2H_4O)_aH$.

The primary dispute presented with respect to this term is whether "poloxamer 124" is limited to the precise block copolymer of ethylene oxide and propylene oxide having a specific formula and a specific average molecular weight, as Defendants contend, or, instead, should be more broadly understood to also include what is known in the art as "poloxamer 182," as Plaintiffs request. On this issue the Court agrees with Defendants.

Plaintiffs' sole support for their proposed construction is a statement by the Examiner that a data sheet disclosed "poloxamer 182 (i.e. also known in the art as poloxamer 124)." (D.I. 82, Ex. N at 9; *see also* D.I. 141 at 11 n.2) To assess whether the Examiner made a mistake, both parties rely on extrinsic evidence. While Plaintiffs contend "much of the extrinsic evidence is consistent with the Examiner's statement that the two terms are used interchangeably in the art" (D.I. 141 at 15), the Court agrees with Defendants that the Examiner was mistaken (D.I. 136 at 1). Although the two poloxamers plainly share many characteristics, they are not the same thing. (*See* D.I. 136 at 2-5) An inaccurate statement by the Examiner during clam construction does not override the claim language itself. *See Storage Tech. Corp. v. Cisco Sys., Inc.*, 329 F.3d 823, 832 (Fed. Cir. 2003). Fundamentally, the Court disagrees with Plaintiffs that "a reasonable competitor examining the prosecution histories of the patents-in-suit would understand that the two terms were known in the art to be interchangeable." (D.I. 141 at 14)

At the hearing, Plaintiffs explained that they do not intend their construction to be nearly as broad as Defendants allege. Plaintiffs agreed to drop the phrase "and the like" and stated they are trying to capture within the claim scope "things that would pass in trade as the same material [as poloxamer 124] but perhaps by different names and different manufacturers." (Tr. at 61) Yet the patentees sought issuance of claims including "poloxamer 124" and that is what the issued

Proposed Construction").

Plaintiffs explained at the hearing that they are "not trying to capture a genus." (Tr. at 82) Because the last phrase of their proposed construction, "and the like," might be misunderstood as an improper attempt to capture a genus, the Court will eliminate that phrase from its construction.[6]

* * *

After the parties exchanged expert reports, it became apparent that they had two additional claim construction disputes. After a teleconference, the Court directed the parties to submit supplemental briefs. The Court now addresses the new issues.[7]

H. Supplemental Dispute 1 ('060 patent, claims 5 and 24)

The dispute here can be illustrated with respect to claims 4 and 5 of the '060 patent. Independent claim 4 provides, with emphasis added:

> A method for treating common acne, comedones, polymorphous acne, nodulocystic acne, acne conglobata ***or*** secondary acne afflicting the skin of an individual in need of such treatment, comprising topically administering to said individual an effective amount of a pharmaceutical composition which is a gel consisting essentially of 0.3% by weight of adapalene, carbomer 940, disodium edentate, methyl paraben, poloxamer 124, propylene glycol, sodium hydroxide and purified water.

---

[6]Citing the Manual of Patent Examination Procedure ("MPEP"), Defendants contend that "trade names cannot be used in a patent claim to identify or describe a particular material without rendering the claim indefinite under 35 U.S.C. § 112." (D.I. 136 at 10) The Court does not reach this indefiniteness challenge at this time.

[7]Plaintiffs' motion for leave to file a surreply brief (D.I. 278) is GRANTED. The proposed brief attached as Exhibit 1 to Plaintiffs' motion is hereby deemed filed.

Then dependent claim 5 of the '060 patent provides:

> The method according to claim 4, wherein said individual is afflicted with common acne.

Plaintiffs propose that claim 5 be construed as:

> ***A method for treating common acne*** afflicting the skin of an individual in need of such treatment, comprising topically administering to said individual an effective amount of a pharmaceutical composition which is a gel consisting essentially of 0.3% by weight of adapalene, carbomer 940, disodium edentate, methyl paraben, poloxamer 124, propylene glycol, sodium hydroxide and purified water.

(D.I. 257, Ex. 1 at 1) (emphasis added)

Defendants, by contrast, propose that claim 5 be construed as:

> ***A method for treating common acne, comedones, polymorphous acne, nodulocystic acne, acne conglobata or secondary acne afflicting the skin of an individual in need of such treatment, wherein said individual is afflicted with common acne***, comprising topically administering to said individual an effective amount of a pharmaceutical composition which is a gel consisting essentially of 0.3% by weight of adapalene, carbomer 940, disodium edentate, methyl paraben, poloxamer 124, propylene glycol, sodium hydroxide and purified water.

(*Id.*) (emphasis added)

The Court will adopt Plaintiffs' proposed construction. Independent claim 4 claims a method for treating common acne ***or*** treating other conditions (which for ease of reference may be referred to as severe acne). Defendants' construction of claim 5 is based on their assertion that claim 4 "requires that the method must be effective for treating both common acne and severe forms of acne." (D.I. 258 at 3; *see also id.* at 4) Defendants do not explain why this is so and the Court does not agree with it.

Moreover, while Defendants accuse Plaintiffs of rewriting the claim language, it is, in fact, Defendants who are attempting to do so, replacing the "or" in claim 4 with "and." In their supplemental briefing, Defendants write: "Dr. Orlow [Plaintiffs' expert] has improperly rewritten claims 5 and 24 to remove the limitation 'a method for treating common acne, comedones, polymorphous acne, nodulocystic acne, acne conglobata ***and*** secondary acne afflicting the skin of an individual in need of such treatment." (D.I. 258 at 5-6) (emphasis added).

The parties agree that the "all limitations rule" requires that anything that infringes a dependent claim must also infringe the independent claim from which it depends. *See also* 35 U.S.C. § 112 ¶ 4. The Court agrees with Plaintiffs that their proposed construction complies with this rule. Under Plaintiffs' construction, claim 5 contains each of the limitations of claim 4 and renders claim 5 narrower than claim 4, because claim 5 applies only to treatment of individuals afflicted with common acne.

I. Supplemental Dispute 2 ('181 patent, claims 35 and 36; '044 patent, claims 40 and 41)

The parties' final dispute involves dependent claims 35 and 36 of the '181 patent and claims 40 and 41 of the '044 patent, all of which depend from independent claim 1 of their respective patents. Each independent claim 1 contains what both parties agree is a "Markush group."

Illustrative of this dispute are the following claims of the '181 patent (with emphasis added):

> 1. A topically applicable pharmaceutical aqueous gel composition useful for the treatment of common acne, consisting essentially of an anti-acne effective amount of 6-[3-(1-adamantyl)-4-methoxyphenyl]-2-naphthanoic acid (adapalene) of 0.3% by weight

thereof, formulated into a topically applicable, pharmaceutically acceptable aqueous gel medium therefor, wherein adapalene is the only active anti-acne ingredient in the composition and ***wherein said aqueous gel medium comprises at least one ingredient selected from the group consisting of*** carbomers, polymeric emulsifying agents, polysaccharidic biopolymers, gums, alginates, modified celluloses, starch derived products, mix of polysorbate 80 and isohexadecane and acrylamide/sodium acryloyldimethyltaurate, and mixtures thereof.

35. The topically applicable aqueous gel composition as defined by claim 1, ***wherein said aqueous gel medium comprises at least one carbomer.***

Plaintiffs propose that dependent claim 35 should be construed as:

> A topically applicable pharmaceutical aqueous gel composition useful for the treatment of common acne, consisting essentially of an anti-acne effective amount of 6-[3-(1-adamantyl)-4-methoxyphenyl]-2-naphthanoic acid (adapalene) of 0.3% by weight thereof, formulated into a topically applicable, pharmaceutically acceptable aqueous gel medium therefor, wherein adapalene is the only active anti-acne ingredient in the composition and wherein said aqueous gel medium comprises at least one carbomer.

Defendants propose instead the following construction of claim 35, with emphasis added to show the additional language requested by Defendants and opposed by Plaintiffs:

> A topically applicable pharmaceutical aqueous gel composition useful for the treatment of common acne, consisting essentially of an anti-acne effective amount of 6-[3-(1-adamantyl)-4-methoxyphenyl]-2-naphthanoic acid (adapalene) of 0.3% by weight thereof, formulated into a topically applicable, pharmaceutically acceptable aqueous gel medium therefor, wherein adapalene is the only active anti-acne ingredient in the composition and wherein said aqueous gel medium comprises at least one carbomer ***and at least one ingredient selected from the group consisting of carbomers, polymeric emulsifying agents, polysaccharidic biopolymers, gums, alginates, modified celluloses, starch derived products, mix of polysorbate 80 and isohexadecane and acrylamide/sodium acryloyldimethyltaurate, and mixtures thereof.***

Plaintiffs contend that these claims are drafted "in proper Markush format," such that dependent claim 35 selects one member of the group of ingredients from the Markush group delineated in independent claim 1. (D.I. 256 at 17) In Plaintiffs' view, Defendants' proposed construction improperly "attempt[s] to read all the members of the Markush group into the dependent claim[s]." (D.I. 256 at 3) Defendants counter that Plaintiffs attempt to read the Markush group limitation out of the dependent claims. In Defendants' view, "the central question here . . . is whether the dependent claims are written in such a way that actually do select a single limitation (*i.e.*, ingredient from the Markush group or form of acne to treat) from a list of alternative limitations set out in the independent claim, to the exclusion of the other alternative limitations." (D.I. 275 at 2)

The Court concludes that because the dependent claims are drafted to state "said aqueous gel medium comprises at least one carbomer/carbomer 940," they must be construed to ***require*** at least one carbomer/carbomer 940, but not to the exclusion of the remaining members of the Markush group. Thus, as Defendants explain in their answering brief, the aqueous gel medium of the dependent claim ***must*** have at least one carbomer/carbomer 940, but ***may*** further include one or more (or none) of the remaining members of the Markush group among its ingredients. (D.I. 275 at 3-4) In the Court's view, this outcome is best reflected by Defendants' proposed construction. Accordingly, the Court will adopt Defendants' proposed construction.[8]

---

[8]The parties' positions are not entirely clear. To the extent that Plaintiffs contend that the dependent claims require at least one carbomer/carbomer 940 to the exclusion of the other members of the Markush group, the Court disagrees, for the reasons noted by Defendants. Defendants are similarly confusing. At times Defendants describe their position as being only that the dependent claim "***must*** include carbomer and ***may*** include at least one other ingredient selected from the Markush group" (D.I. 275 at 11), but at other points they contend that somehow "the dependent claims at issue in this case must contain ***all*** of the alternative

IV. CONCLUSION

For the reasons given above, the Court will construe the terms of the patents-in-suit consistent with this Memorandum Opinion. An appropriate Order will be entered.

---

embodiments set forth in the independent claims" (D.I. 280 at 1) (emphasis added), by which Defendants seem to mean that every member of the Markush group ***must*** be present in every embodiment of every dependent claim. For the reasons explained above, the Court concludes that the dependent claims specify that the aqueous gel medium ***must*** include the at least one carbomer/carbomer 940 specifically recited in the claims, but ***may*** further include some, all, or none of the remaining members of the Markush group recited in the corresponding independent claims.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GALDERMA LABORATORIES, L.P., GALDERMA S.A. and GALDERMA RESEARCH AND DEVELOPMENT, S.N.C.	:	
Plaintiffs,	:	
v.	:	C.A. No. 10-45-LPS
TOLMAR INC. and ACTAVIS MID ATLANTIC LLC,	:	
Defendants.	:	

ORDER

At Wilmington, this 13th day of February 2012:

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

IT IS HEREBY ORDERED that the disputed claim language of U.S. Patent Nos. 7,579,377 ("the '377 patent"), 7,737,181 ("the '181 patent"), 7,834,060 ("the '060 patent"), 7,838,558 ("the '558 patent"), and 7,868,044 ("the '044 patent"), shall be construed as follows:

1. **"a thus effective amount"** and **"effective amount"** are construed to mean "an amount shown to cause improvement, in comparison to vehicle."
2. **"effective for the treatment of"** is construed to mean "shown to cause improvement, in comparison to vehicle, for treating."
3. **"an anti-acne effective amount"** is construed to mean "an amount shown to cause improvement, in comparison to vehicle, in treating an acne condition."
4. **"useful for the treatment of"** is construed to mean "capable of treating."

5. **"pharmaceutical composition which is a gel of"** is construed to mean "a pharmaceutical composition in the form of a gel consisting of."

6. **"poloxamer 124"** is construed to mean "a block copolymer of ethylene oxide and propylene oxide having the formula $HO(C_2H_4O)_a(C_3H_6O)_b(C_2H_4O)_aH$ where a equals 11-12 and b equals 20-21, and having an average molecular weight between 2090 and 2360."

7. **"carbomer 940"** is construed to mean "a high molecular weight polymer that includes acrylic acid crosslinked with allyl ethers of pentaerythritol, *i.e.*, Carbopol® 980."

8. **Claim 5 of the '060 patent** is construed to mean "a method for treating common acne afflicting the skin of an individual in need of such treatment, comprising topically administering to said individual an effective amount of a pharmaceutical composition which is a gel consisting essentially of 0.3% by weight of adapalene, carbomer 940, disodium edentate, methyl paraben, poloxamer 124, propylene glycol, sodium hydroxide and purified water."

9. **Claim 24 of the '060 patent** is construed to mean "a method for treating common acne afflicting the skin of an individual in need of such treatment, comprising topically administering to said individual an effective amount of a pharmaceutical composition which comprises 0.3% by weight of 6-[3-(1-adamantyl)-4-methoxyphenyl]-2-naphthanoic acid (adapalene) or salt thereof, as the sole active anti-acne agent, formulated into a pharmaceutically acceptable medium therefor, said composition being a gel or a cream."

10. **Claim 35 of the '181 patent** is construed to mean "a topically applicable pharmaceutical aqueous gel composition useful for the treatment of common acne, consisting essentially of an anti-acne effective amount of 6-[3-(1-adamantyl)-4-methoxyphenyl]-2-naphthanoic acid (adapalene) of 0.3% by weight thereof, formulated into a topically applicable, pharmaceutically acceptable aqueous gel medium therefor, wherein adapalene is the only active anti-acne ingredient in the composition and wherein said aqueous gel medium comprises at least one carbomer and at least one ingredient selected from the group consisting of carbomers, polymeric emulsifying agents, polysaccharidic biopolymers, gums, alginates, modified celluloses, starch derived products, mix of polysorbate 80 and isohexadecane and acrylamide/sodium acryloyldimethyltaurate, and mixtures thereof."

11. **Claim 36 of the '181 patent** is construed to mean "a topically applicable pharmaceutical aqueous gel composition useful for the treatment of common acne, consisting essentially of an anti-acne effective amount of 6-[3-(1-adamantyl)-4-methoxyphenyl]-2-naphthanoic acid (adapalene) of 0.3% by weight thereof, formulated into a topically applicable, pharmaceutically acceptable aqueous gel medium therefor, wherein adapalene is the only active anti-acne ingredient in the composition and wherein said aqueous gel medium comprises carbomer 940 and at least one ingredient selected from the group consisting of carbomers, polymeric emulsifying agents, polysaccharidic biopolymers, gums, alginates, modified celluloses, starch derived products, mix of polysorbate 80 and

isohexadecane and acrylamide/sodium acryloyldimethyltaurate, and mixtures thereof."

12. **Claim 40 of the '044 patent** is construed to mean "a method for treating acne afflicting the skin of an individual in need of such treatment, comprising topically administering to said individual a topically applicable pharmaceutical aqueous gel composition consisting essentially of an anti-acne effective amount of 6-[3-(1-adamantyl)-4-methoxyphenyl]-2-naphthanoic acid (adapalene) of 0.3% by weight thereof, formulated into a topically applicable, pharmaceutically acceptable aqueous gel medium therefor, wherein adapalene is the only active anti-acne ingredient in the composition and wherein said aqueous gel medium comprises at least one carbomer and at least one ingredient selected from the group consisting of carbomers, polymeric emulsifying agents, polysaccharidic biopolymers, gums, alginates, modified celluloses, starch derived products, mix of polysorbate 80 and isohexadecane and acrylamide/sodium acryloyldimethyltaurate, and mixtures thereof."

13. **Claim 41 of the '044 patent** is construed to mean "a method for treating acne afflicting the skin of an individual in need of such treatment, comprising topically administering to said individual a topically applicable pharmaceutical aqueous gel composition consisting essentially of an anti-acne effective amount of 6-[3-(1-adamantyl)-4-methoxyphenyl]-2-naphthanoic acid (adapalene) of 0.3% by weight thereof, formulated into a topically applicable, pharmaceutically acceptable aqueous gel medium therefor, wherein adapalene is the only active anti-acne

ingredient in the composition and wherein said aqueous gel medium comprises carbomer 940 and at least one ingredient selected from the group consisting of carbomers, polymeric emulsifying agents, polysaccharidic biopolymers, gums, alginates, modified celluloses, starch derived products, mix of polysorbate 80 and isohexadecane and acrylamide/sodium acryloyldimethyltaurate, and mixtures thereof."

IT IS FURTHER ORDERED that the Court adopts each of the constructions on which the parties have agreed. (*See* JCCC, D.I. 82 at 4; D.I. 95 at 1 n.1)

1. **"acne conglobata"** is construed to mean "severe cystic acne characterized by cystic lesions, abscesses, communicating sinuses, and thickened, nodular scars."
2. **"acne"** is construed to mean "dermatological condition selected from the group consisting of common acne, comedones, polymorphous acne, nodulocystic acne, acne conglobata, secondary acne such as solar, drug-related or occupational acne."
3. **"carbomer(s)"** is construed to mean "a polymer that includes acrylic acid crosslinked with allyl sucrose or allyl ethers of polyalcohols."
4. **"carbomer gelling agent"** is construed to mean "a polymer that includes acrylic acid crosslinked with allyl sucrose or allyl ethers of polyalcohols that in whole or in part forms the gel vehicle."

5. **"comedones"** is construed to mean "a dilated follicle passage filled with skin flakes and sebum; the primary lesion of common acne."

6. **"common acne"** is construed to mean "dermatological condition, also known as *acne vulgaris*, characterized by an eruption that includes inflammatory and/or non-inflammatory lesions such as comedones, cysts, papules, and pustules."

7. **"moderate to moderately severe intensity"** is construed to mean "an intensity between mild and severe as defined by pictorial or numeric scales such as the Leeds scale, IGA scale, or IGE scale."

8. **"nodulocystic acne"** is construed to mean "severe acne in which the predominant lesions are follicular nodules and can include follicular cysts, which can rupture and scar."

9. **"secondary acne"** is construed to mean "acne caused by exposure to extrinsic factors such as solar, drug related or occupational acne."

10. **"pharmaceutically acceptable aqueous gel [medium]"** and **"pharmaceutically acceptable aqueous gel"** are construed to mean "aqueous gel [medium] that is compatible with the other ingredients of the formulation and is suitable for topical application."

11. **"pharmaceutically acceptable medium"** is construed to mean "a medium that is compatible with the other ingredients of the formulation and is suitable for topical application."

12. **"polymorphous acne"** is construed to mean "two or more acne conditions selected from the group consisting of common acne, comedones, nodulocystic acne, acne conglobata, and secondary acne such as solar, drug-related or occupational acne."

13. **"only active anti-acne ingredient," "sole active anti-acne agent,"** and **"sole anti-acne ingredient"** are construed in accordance with their plain and ordinary meaning, as agreed by the parties.

IT IS FURTHER ORDERED that Plaintiffs' motion for leave to file a surreply brief (D.I. 278) is GRANTED. The proposed brief attached as Exhibit 1 to Plaintiffs' motion is hereby deemed filed.

UNITED STATES DISTRICT JUDGE