IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

GALDERMA LABORATORIES, L.P., GALDERMA S.A., and GALDERMA RESEARCH & DEVELOPMENT, S.N.C.,	§	
Plaintiffs,	§	
v.	§	**CIVIL ACTION NO. 3:12-CV-02038-K**
ACTAVIS MID ATLANTIC, LLC,	§	
Defendant.	§	

AMENDED *MARKMAN* MEMORANDUM OPINION AND ORDER

Before the Court are the Parties' briefs on the issue of claim construction of the patents in suit, U.S. Patent Number 7,820,186 ("the '186 Patent"), U.S. Patent Number 8,241,649 ("the '649 Patent"), U.S. Patent Number 8,071,644 ("the '644 Patent"), U.S. Patent Number 8,080,537 ("the '537 Patent"), U.S. Patent Number 8,129,362 ("the '362 Patent"), U.S. Patent Number 8,445,543 ("the '543 Patent"), U.S Patent 7,964202 "(the '202 Patent"), and U.S. Patent 8,105,618 ("the '618 Patent"). The Court conducted a *Markman* hearing and has reviewed the Parties' briefs and all related filings and evidence, including the patents in suit, the specifications, the patent prosecution histories to the extent it was submitted by the Parties, as well as the Parties' proposed claim constructions. The Court hereby construes the disputed claims according to *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995)

(en banc), *aff'd*, 517 U.S. 360 (1996).

I. Background

A. Procedural

Plaintiffs Galderma Laboratories, L.P., Galderma S.A., and Galderma Research & Developlment, S.N.C. (collectively the "Plaintiffs" or "Galderma") filed a complaint with this Court alleging infringement of the '186, '202, '618, '649, '644, '537, and '362 Patents by Defendant, Actavis Mid Atlantic, LLC (the "Defendant" or "Actavis"). Actavis subsequently filed counter claims requesting declaratory judgment regarding the validity, enforceability, and/or infringement of these same patents and of the '543 Patent. As part of this dispute, the Parties have submitted to the Court requests for construction of certain phrases of the claims of the patents in suit. Therefore, it is necessary for the Court to construe the meanings of the disputed claim language and phrases.

B. The Orsoni Patents

The '186 Patent and the '649 Patent are part of the same patent family and they disclose a unique formulation for the treatment of acne. The '186 Patent, entitled "Gel Composition for Once-Daily Treatment of Common Acne Comprising a Combination of Benzoyl Peroxide and Adapalene and/or Adapalene Salt, was issued by the USPTO on October 26, 2010. The '649 Patent, entitled "Dermatological/Cosmetic Gels Comprising at Least One Retinoid and/or Retinoid Salt and Benzoyl Peroxide," was

issued by the USPTO on August 14, 2012. The '202 Patent, entitled "Method for Treatment of Common Acne," was issued by the USPTO on June 21, 2011. The '618 Patent, entitled "Dermatological/Cosmetic Gels Comprising at Least One Retinoid Salt and/or Benzoyl Peroxide," was issued by the USPTO on January 31, 2012. Collectively these Patents are referred to as the "Orsoni" Patents because they all list Sadrine Orsoni as the primary inventor. The Court further notes that while the Plaintiffs have alleged infringement of all of the Orsoni Patents, the Parties joint claim construction chart and argument only address claims of the '186 Patent and the '649 Patent. To the extent that any of the same disputed claim terms, that are construed herein, appear in the claims of the '202 Patent or the '618 Patent, they shall be given the same meaning of the terms as construed for the '186 Patent and '649 Patent.

The Orsoni Patents disclose an invention that addresses the treatment of acne with a mixture that contains both benzoyl peroxide ("BPO") and a adapalene, a type of retinoid. '186 Patent at 3:50-4:4. The prior art discloses that both BPO and retinoids are useful for the treatment of acne. Id at 1:1-3:47. However, the prior art does not teach a formulation for the treatment of acne that contains both benzoyl peroxide and a retinoid that remains stable for a pharmaceutically useful time period. Id. BPO is a reactive agent that is susceptible to decomposition into by products that destroy the pharmaceutical matrix. Id. BPO also reacts with other active agents in formulations, such as a retinoid, which reduces the overall activity of the formulation by reducing

both the concentration of BPO and the retinoid. Id. The Orsoni Patents claim that the inventors discovered a formulation that contains both BPO and adapalene and that in this formulation both compounds have sufficient stability so that the formulation may be used as a treatment for acne. Id at 3:50-4:4.

The Orsoni Patents, specifically, claim that use of a particular gelling agent provided this unusual stability, while other gelling agents did not. Id. The specifications of the Orsoni Patents identify the possible gelling agent as being from the family of polyacrylamide gelling agents, including the mixture of sodium acryloyldimethyltaurate copolymer/isohexadecane/polysorbate 80 (also known as "Simulgel 600"); the mixture of polyacrylamide/isoparaffin C13-14/laureth-7 (also known as "Sepigel 305".); and other mixtures of polyacrylamide polymers that are used to form gels. Id. at 4:20-39. The claims of the Orsoni Patents, however, specifically indentify only acrlyamide sodium acryloyldimethyltaurate copolymer/isohexadecane/polysorbate 80 as the gelling agent for the formulation. Id at 14:39-48.

Therefore, the disclosed inventions of the Orsoni Patents, as claimed by the inventors, solve the problems caused by the instability of BPO. The inventions further provide the benefit of treating acne with a single formulation that contains both BPO and adapalene, a treatment possibility that was previously unknown. Id at 3:50-4:4.

C. The Synergy Patents

The '644 Patent, the '537 Patent, the '362 Patent, and '543 Patent represent a

different, but related, patent family from that of the Orsoni Patents. The '644 Patent, the '537 Patent, the '362 Patent, and the '543 Patent are collectively referred to as the "Synergy" Patents. Like the Orsoni Patents, the Synergy Patents disclose an invention for the treatment of acne. While the Orsoni Patents disclose a unique formulation for an acne treatment, the Synergy Patents differ in that they teach regimens for the treatment of acne. In particular, they teach that acne treatment regimens involving the simultaneous use of BPO and adapalene result in an unexpected synergistic effect. This is why the Patents are collectively referred to as the Synergy Patents.

The '644 Patent was issued by the USPTO on December 6, 2011 and is titled "Combinations of Adapalene and Benzoyl Peroxide for Treating Acne Lesions." The '537 Patent, entitled "Combinations of Adapalene and Benzoyl Peroxide for Treating Acne Lesions," was issued by the USPTO on December 26, 2011. The '362 Patent, entitled "Combination/Association of Adapalene and Benzoyl Peroxide for Treating Acne Lesions," was issued by the USPTO on March 6, 2012. The '543 Patent, entitled "Combinations of Adapalene and Benzoyl Peroxide for Treating Acne Lesions," was issued by the USPTO on May 21, 2013.

Together the Synergy Patents teach methods and regimens for the treatment of acne using the combination of BPO and adapalene. '543 Patent at 1:50-2:31. As in the Orsoni Patents, it was known in the prior art that acne treatments involving BPO alone or adapalene alone were effective treatments for the acne. However, the Patents claim

that an acne treatment regime that involves the simultaneous use of both BPO and adapalene results in a synergistic effect, that was not expected and was not known in the prior art. Id. In essence, this synergistic effect means that the efficaciousness of the combination treatment of BPO and adapalene is significantly greater than the additive effect that would be expected, based on the individual activities of BPO and adapalene. Id.

According to the inventors, the synergistic effect seen from the simultaneous use of BPO and adapalene is an unexpected and surprising result. Id. Therefore, the invention provides significant advantages over the prior art.

II. Applicable Law - Principles of Claim Construction

Claim construction is a matter of law. *See Markman*, 52 F.3d at 979. The Federal Circuit Court has held 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) (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). The Supreme Court has stated that the claims are "'of primary importance, in the effort to ascertain precisely what it is that is patented.'" *Phillips*, 415 F.3d at 1312 (quoting *Merrill v. Yeomans*, 94 U.S. 568, 570 (1876)). A court looks to three primary sources when determining the meaning of claims: (1) the claims, (2) the specification, and (3) the prosecution history. *Markman*, 52 F.3d at 979. The claims of the patent must be read in view of the specification of

which they are a part. *Id.* The specification consists of a written description of the invention which allows a person of ordinary skill in the art to make and use the invention. *Id.* This description may act as a dictionary explaining the invention and defining terms used in the claims. *Id.* Although a court should generally give such terms their ordinary meaning, a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, so long as the special definition of the term is clearly stated in the patent specification or file history. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

The court starts with the claim itself, read in light of the specification. *See Vivid Technologies, Inc. v. American Sci. & Eng'g, Inc.*, 200 F.3d 795, 804 (Fed. Cir. 1999). While the claims themselves provide significant guidance as to the meaning of a claim term, the specification is generally dispositive as "'it is the single best guide to the meaning of a disputed term.'" *Phillips*, 415 F.3d at 1314-1315 (quoting *Vitronics*, 90 F.3d at 1582). In addition to the claim language and specification, the prosecution history is often helpful in understanding the intended meaning, as well as the scope of technical terms in the claims. *See Vivid*, 200 F.3d at 804. In particular, the prosecution history is relevant in determining whether the patentee intends the language of the patent to be understood in its ordinary meaning. Using these tools, the court construes only the claims that are in controversy and only to the extent necessary to resolve the dispute. *Vivid*, 200 F.3d at 803.

The words of a claim are usually given their ordinary and customary meaning. *See Phillips*, 415 F.3d at 1312. Ordinary and customary meaning is the meaning the claim term would have to a person of ordinary skill in the art (e.g., field of the invention). *See Id.* at 1313; *Markman*, 52 F.3d at 979. A person of ordinary skill in the art would read the claim term in the context of the entire patent, including the specification, not just the particular claim where the term appears. *Phillips*, 415 F.3d at 1313. There are instances where the ordinary meaning of claim language, as a person of skill in the art would understand it, "may be readily apparent even to lay judges," thereby requiring "little more than the application of the widely accepted meaning of commonly understood words." *Phillips*, 415 F.3d at 1314. In these situations, general purpose dictionaries are useful. *Id.*

But, in many cases, the court must determine the ordinary and customary meaning of the claim terms which have a certain meaning in a field of art. *Id.* The court can look to "'those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean.'" *Id.* (quoting *Innova*, 381 F.3d at 1116). These sources can include "'the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of the technical terms, and the state of the art.'" *Id.* (quoting *Innova*, 381 F.3d at 1116).

Aside from the written description and the prosecution history, the claims

themselves also offer assistance as to the meaning of certain claim terms. *Id.* (citing *Vitronics*, 90 F.3d at 1582).

When the intrinsic evidence, that is the patent specification and prosecution history, unambiguously describes the scope of a patented invention, reliance on extrinsic evidence, which is everything outside the specification and prosecution history, is improper. *See Vitronics*, 90 F.3d at 1583. While the Court may consult extrinsic evidence to educate itself about the invention and relevant technology, it may not rely upon extrinsic evidence to reach a claim construction that is clearly at odds with a construction mandated by the intrinsic evidence. *See Key Pharm. v. Hercon Lab. Corp.*, 161 F.3d 709, 716 (Fed. Cir. 1998).

III. Construction of the Patent Claims and Terms

A. The Orsoni Patents

1. The Inventions

The Orsoni Patents, the '186 Patent and the '649 Patent, are closely related patents that disclose a unique formulation that contains both BPO and adapalene in the same formulation. '186 Patent at 3:50-4:4. The majority of the specifications of both patents are identical, with only minor changes, and the claims of both patents are very similar. The Parties have requested the Court to construe the same phrase from both Patents. Furthermore, both Parties, in their briefing and argument, have given the Court unified arguments regarding the construction of the Orsoni Patents, without

distinction between the ''186 Patent and the '649 Patent. Therefore, the Court will collectively construe the Orsoni Patents.

2. Person of Ordinary Skill in the Art

Preferably, this Court gives the words of a claim their ordinary and customary meaning; in other words, the meaning the claim term would have to a person of ordinary skill in the art. *See Phillips*, 415 F.3d at 1312-13; *Markman*, 52 F.3d at 979. A person of ordinary skill in the art would read the claim term in the context of the entire patent, not just the particular claim where the term appears. *Phillips*, 415 F.3d at 1313. The Court holds that a person of ordinary skill in the art for the Orsoni Patents is a person with a bachelor's degree in pharmacology, chemistry, or an equivalent degree with three to five years of work experience or graduate studies experience in the fields pharmaceutical formulation and/or drug development and/or drug delivery research.

3. Priority Terms Needing Construction

For the Orsoni Patents, the Parties have asked the Court to construe only the phrase "gelling agent." The Parties disagree on the meaning of this phrase, which occurs in both of the Orsoni Patents. Claim 1 of the '186 Patent reads as follows:

> "1. A physiologically acceptable aqueous gel composition for once-daily treatment of common acne comprising antiacne actives consisting of
>
> 0.1% adapalene and/or at least one pharmaceutically acceptable salt thereof,
>
> 2.5% dispersed benzoyl peroxide, and
>
> further comprising 4% acrylamide sodium acryloyldimethyltaurate copolymer/isohexadecane/polysorbate

> 80 ***gelling agent***, said percentages being based on the weight of the total aqueous gel composition." '186 Patent at 14:39-49, emphasis added.

Claim 1 of the '649 Patent reads as follows:

> "1. A physiologically acceptable aqueous gel composition for once-daily treatment of common acne comprising:
>
> 0.1% adapalene and/or at least one pharmaceutically acceptable salt thereof;
>
> 2.5% to 5% dispersed benzoyl peroxide; and
>
> 3.5% to less than 4% acrylamide sodium acryloyldimethyltaurate copolymer/isohexadecane/polysorbate 80 ***gelling agent,*** said percentages being based on the weight of the total aqueous gel composition." '649 Patent at 14:34-42, emphasis added.

4. The Parties' Requested Construction of "Gelling Agent"

Galderma, the owner of the Orsoni Patents, proposes that the meaning of gelling agent is "an agent or agents capable of giving the composition a viscosity that is sufficient to keep the adapalene and benzoyl peroxide in suspension." Joint Claim Construction Chart at 2-3. Actavis, proposes that gelling agent should be given its plain and ordinary meaning and proposes that such plain and ordinary meaning is "agent(s) within a composition that forms a gel." Id.

Galderma argues that the Court should adopt its proposed construction because the inventor's explicitly defined gelling agent in the Patents, the description of the invention in the Patent requires that the gelling agent maintain a certain viscosity, and the language of the claims themselves require that the benzoyl peroxide be in

suspension in the formulation. Plaintiffs' Opening Claim Construction Brief at 13-17. All of which, support Galderma's proposed construction that address the invention's need for the gel to maintain a certain viscosity and for the BPO to remain in suspension. Id.

In support of its first argument, that the Patents explicitly define gelling agent, Galderma points to language that occurs in the specifications of both patents. Specifically, the Patents state,

> "The expression, "pH independent gelling agent" means a gelling agent capable of giving the composition a viscosity that is sufficient to keep the retinoid and the benzoyl peroxide in suspension, even under the influence of a variation in pH caused by the release of benzoic acid by the benzoyl peroxide." '186 Patent at 4:15-19; '649 at Patent 4:15-19.

Galderma argues that the first portion of this definition of pH independent gelling agent defines gelling agent as an "agent capable of giving the composition a viscosity that is sufficient to keep the retinoid and the benzoyl peroxide in suspension." Id.

In support of Galderma's second argument, that the specifications teach the importance of the gelling agent for suspending the active ingredients in the claimed formulations, Galderma points the Court to the repeated discussion, in the Patents' specifications, about the importance of maintaining a certain viscosity of the composition and the importance of keeping the active ingredients, especially BPO, in suspension in the formulation. Plaintiffs' Opening Claim Construction Brief at 13-17.

Finally, Galderma points to the claim language itself to support its proposed

construction of gelling agent. Id. Specifically, Galderma points out that the claims require the BPO be "dispersed" in the formulation. Id. The specifications of the Patents define being "in dispersed form" as being the same as "in suspension." Id. Specifically, the Patents state "… benzoyl peroxide is more stable in water and propylene glycol when it is in suspension (i.e., in dispersed form) …" '186 Patent 2:33-35. Galderma argues that its proposed construction of gelling agent is correct because it defines a gelling agent that is required to keep the active BPO in suspension, which is also required by other claim language that requires the BPO be "dispersed." Plaintiffs' Opening Claim Construction Brief at 13-17.

Galderma further argues that Actavis' construction of gelling agent, the plain and ordinary meaning of "agent(s) within a composition that forms a gel," is incorrect because it does nothing more than rearrange the words that are being construed. Plaintiffs' Responsive Claim Construction Brief at 4. Galderma argues that to adopt such a construction is improper and it would lead to confusion of the jury. Id.

In support of Actavis' proposed construction of gelling agent, the plain and ordinary meaning of "agent(s) within a composition that forms a gel," Actavis argues that the Patents repeatedly use the phrase "gelling agent" in a very general manner that applies to all types of gelling agents, not just one that would maintain a viscosity in the formulation of this particular invention that would keep the BPO and adapalene in suspension. Defendant Actavis Mid Atlantic LLC's Opening Claim Construction Brief

at 10-11. Therefore, incorporation of the viscosity and suspension requirements, as proposed by Galderma, into the construction of gelling agent would be incorrect. Id.

In support of this argument, Actavis provides examples from the specifications where the phrase "gelling agent" is used to describe a carbomer-based gelling agent. Id. Actavis, argues that since carbomer based gelling agents are clearly not included as part of the inventions and since the Patents use the phrase "gelling agent" to describe carbomer based gelling agents, the construction of the gelling agent cannot be limited to one that is specific to the formulation that is actually claimed by the invention. Id. Furthermore, since the phrase is used in such a general manner, it should be given its plain and ordinary meaning. Id.

Actavis also argues that the patents do not explicitly and unequivocally define gelling agent, as Galderma proposes. Actavis points out that the definition that Galderma uses to support its argument, that gelling agent is defined by the Patents, is not actually a definition of "gelling agent." Id. The definition that is provided by the Patents is one of "pH independent gelling agent." Id. According to Actavis' argument, this is not an attempt to explicitly define "gelling agent;" it is merely an attempt to define a particular type of gelling agent, a "pH independent gelling agent." Id. Furthermore, Actavis argues that the repeated use of the phrase in the specifications and file wrapper in a general manner does not support the argument that the inventors explicitly defined gelling agent, as is claimed by Galderma. Id.

5. Construction of "gelling agent."

The Court is of the opinion that neither Galderma' nor Actavis' proposed constructions of the phrase "gelling agent" are quite correct. While it is the case that the Patents provide guidance as to the proper definition of gelling agent, as claimed by both Parties, neither of the proposed constructions captures the essence of the inventions that are covered by the Orsoni Patents. As Galderma has correctly pointed out in its briefing, the Federal Circuit has stated that:

> "Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The 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." *Phillips*, 415 F.3 at 1316.

However, neither of the proposed constructions of the Parties fully takes into consideration what the inventors actually invented and intended to envelop with the claims. The Orsoni Patents, in their entirety, describe a very specific invention in which a very specific formulation was invented and claimed that provided unexpected results based on what was known in the prior art. The Patents are therefore written in a way that describes that specific invention and formulation, as opposed to a broad invention and formulation that may exist in many forms. Therefore, the Court construes the phrase "gelling agent" with this in mind. The claims, specifications, and file wrapper all support a narrow interpretation of the claimed inventions and a narrow construction of

the claim language.

The Orsoni Patents do not explicitly define the phrase "gelling agent", as claimed by the Plaintiffs. Galderma points to a definition of "pH independent gelling agent" to support its argument that the inventors acted as their own lexicographer when they drafted the Orsoni Patents. An inventor may define specific words or phrases used in a patent. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

If this definition is clear and explicit, that definition should be applied to the claim, in the context of the patent. Id. This is true even if the definition that is used in the patent is contrary to what the normal accepted meaning of those words may be to a person of ordinary skill in the art or to a lay person. Id. This is not what we have in this case.

Here, the definition that is provided is one for "pH independent gelling agent," not one for "gelling agent." '186 Patent at 4:15-19; '649 Patent at 4:15-19. The Patents provide that,

> "The expression, "pH independent gelling agent" means a gelling agent capable of giving the composition a viscosity that is sufficient to keep the retinoid and the benzoyl peroxide in suspension, even under the influence of a variation in pH caused by the release of benzoic acid by the benzoyl peroxide." Id.

As stated by Actavis, this is not a definition of the general term "gelling agent." It is instead a definition of a particular type of gelling agent. The definition does provide some guidance as to what properties a pH independent gelling agent should have when

it recites the viscosity and suspension requirements of this type of gelling agent. However, that in and of itself does not clearly and unequivocally define "gelling agent," which is required for an inventor to act as a lexicographer.

Furthermore, the definition itself is not entirely clear. While it attempts to define "ph independent gelling agent," the definition merely repeats the words "gelling agent." This indicates that the real concern of the inventor in including this definition was with providing clarity as to the inventors' intentions about the definition of the pH independent portion of the phrase, not about the definition of gelling agent itself. The definition provided by the Patents includes a description that appears to present some of the desired gel properties of a pH independent gelling agent, when it recites the viscosity and suspension characteristics of a pH independent gelling agent. However, the recitation of the words "gelling agent" in the definition itself runs contrary to an understanding that the inventors were attempting to define the meaning of "gelling agent" in this definition.

The file wrapper and prosecution history also provide insight into whether or not the definition of pH independent gelling agent was intended to also define "gelling agent." The file wrapper indicates that when the patent applications were first submitted to the USPTO, they contained claims that were substantially broader than those that were eventually included in the final claim language. Specifically, the patent applications claimed formulations that included a "pH independent gelling agent."

App. ISO Defendant Actavis Mid Atlantic, LLC's Opening Claim Construction Brief at 1, 104. The claims were rejected by the USPTO; and eventually the inventors agreed to remove them from the Patents. Id at 31.

The pH independent claims were cited as unpatentable by the USPTO because they were too broad, in consideration of the nature of the invention and of the known prior art. Id at 54-61. The invention reports a very unique formulation that exhibits desirable and unexpected properties. '186 Patent at 3:50-4:4. Specifically, the use of an acrylamide sodium acryloyldimethyltaurate copolymer/isohexadecane/polysorbate 80 gelling agent in the formulation was shown to produce unexpected stability of the active ingredients. App. ISO Defendant Actavis Mid Atlantic, LLC's Opening Claim Construction Brief at 43. Furthermore, the idea of using a combined treatment therapy was not novel under the prior art. Id. at 54-61. The USPTO appears to have believed, as the Patents themselves indicate, that the unique features of this invention were specifically the use of an acrylamide sodium acryloyldimethyltaurate copolymer/isohexadecane/polysorbate 80 gelling agent and the resulting stability of the active ingredients. Id. at 66, 93, 103. Therefore, the use of "pH independent gelling agent" in the claim language was not supported by the invention and was not novel when compared to the prior art. Id. Therefore the USPTO insisted that the pH independent claims be cancelled. Id. The result was that the Patents issued with claims that only included "acrylamide sodium acryloyldimethyltaurate

copolymer/isohexadecane /polysorbate 80 gelling agent." '186 Patent at 14:39-49; '649 Patent at 14:34-42.

While the definition of pH independent gelling agent remained in the specifications of the Orsoni patents, the pH independent claims did not. While it may not have been improper to leave this definition in the specifications, the definition also appears to be no longer directly relevant to the claims as they exist in the issued Patents. The definition was necessary to clarify the meaning of the phrase "pH independent gelling agent," when this phrase was included in the claim language because the inventors desired certain properties in the formulation that would relate to the claimed pH independent invention. However, there is no indication that the inventors or USPTO intended that this definition be extended to any gelling agent that was claimed.

In contrast, the claims that were issued were much more specific as to the gelling agent that was claimed. As stated above, an "acrylamide sodium acryloyldimethyltaurate copolymer/isohexadecane/polysorbate 80 gelling agent" was the only gelling agent that was included in the claim language. Id. Since this is the only gelling agent that was claimed by the Orsoni patents and the invention is specifically linked to this gelling agent, the Court is of the opinion that any claim construction of the phrase "gelling agent" should take this into consideration. Specifically, the Court is of the opinion that the use of the phrase "gelling agent" in the claims points toward the

specifically claimed acrylamide sodium acryloyldimethyltaurate copolymer/ isohexadecane/polysorbate 80. Meaning that the acrylamide sodium acryloyldimethyltaurate copolymer/isohexadecane /polysorbate 80 is the formulation component that is used to make the formulation a gel. The "gelling agent" phrase merely points the reader to the specific claimed gelling agent.

As in the case of "pH independent gelling agent," the Patents use the phrase "acrylamide sodium acryloyldimethyltaurate copolymer/isohexadecane/polysorbate 80 gelling agent" to point out a particular gelling agent. In this case, the acrylamide sodium acryloyldimethyltaurate copolymer/isohexadecane/polysorbate 80 is the particular gelling agent that the inventors are directing the reader's attention to.

The Patents contain many examples of the use of the phrase "gelling agent" and of references to "gels." Sometimes, the usage is very specific, in that it points to a particular gelling agent. For example the Patents sometime specifically indentify gelling agents such as: "…the mixture of polyacrylamide/isoparaffin C13-14/laureth-7…" '186 Patent at 4:24-25.; "…the use of carbomers in compositions of aqueous gel… '186 Patent at 3:30-31.; "…in other gels consisting of a mixture of hydroxypropyl-cellulose and aluminum magnesium silicate…" '186 Patent at 3:39-40.. The formulation examples provided in the Patents' specifications also use the phrase "gelling" to direct the reader's attention to a particular type of gelling agent. '186 Patent at 9:30-10:65. Such examples direct the reader's attention to various types of components to the

formulations, such as the "actives," the "aqueous," and the "gelling." Id. This reference to "gelling" further specifies a particular gelling agent that is used to form that particular gel. Id.

In contrast, the Patents also refer to gels and gelling agents in a very general manner, such usage is occurs when the reference is to gels or gelling agents in general as opposed to a particular gel formulation or gelling agent. For example, the Patents provide; "Another difficulty to be overcome in preparing a composition, especially comprising benzoyl peroxide, when it is in gel form, is that the gelling agents are destabilized…" '186 Patent at 3:22-24. "There is thus still a need for a physically stable gelled composition containing benzoyl peroxide and a retinoin." '186 Patent at 3:46-47.; "According to the invention, the gel containing benzoyl peroxide and a retinoid advantageously comprises…" '186 Patent at 5:38-39.; "…the invention also relates to a pharmaceutical or cosmetic composition … in the form of an aqueous gel…" '186 Patent at 6:31-36.; and "… the introduction of the gelling agent into the mixture…) '186 Patent at 7:34-35.

Comparison of the use of the phrase "gelling agent" in the claim language to the two ways that the phrase is used in rest of the Patents, clearly indicates that the claim language "gelling agent" is simply referring to the specific type of gelling agent, in particular the acrylamide sodium acryloyldimethyltaurate copolymer/isohexadecane /polysorbate 80. It is important to make this distinction in the between the specific and

general use of the phrase "gelling agent." To give the claim language phrase a construction that incorporates the general use of the phrase would be improper. This would present the possibility of expending the clear meaning of the phrase to include gelling agents beside the particular one that was claimed. Therefore, any claim construction of the phrase "gelling agent," as used in the claims, should be particularly tied to the "acrylamide sodium acryloyldimethyltaurate copolymer/isohexadecane /polysorbate 80" of the claims. Therefore, the Court finds that it better to construe the entire phrase "acrylamide sodium acryloyldimethyltaurate copolymer/isohexadecane /polysorbate 80 gelling agent," than it is to simply construe "gelling agent."

The Patents use of the phrase "gelling agent" and reference to gels in both a general and specific manner indicates that the inventors intended nothing more than the plain and ordinary meaning of the phrase, as suggested by Actavis. However, Actavis' proposed plain and ordinary meaning of gelling agent, "agent(s) within a composition that forms a gel," does not do much more than rearrange the words of the phrase. In addition to rearranging the words, it adds that the gelling agent is within the composition. This proposed construction does nothing to help a jury understand the meaning of this phrase. Therefore the Court does not agree with Actavis' plain and ordinary meaning of gelling agent.

The Patent specifications, however, provide insight into the plain and ordinary meaning of gelling agent. The Patents state "The term "aqueous gel" means a

composition containing, in aqueous phase, a viseoelastic mass formed from **colloidal suspensions** (**gelling agent**)." '186 Patent at 4:11-14, emphasis added. This definition of aqueous gel indicates that an aqueous gel has two features. One is that the composition is in the aqueous phase, which relates to the aqueous portion of "aqueous gel." The other feature, "a viseoelastic mass formed from colloidal suspension (gelling agent)," points to the nature of the gelling agent. Furthermore, this indicates that the inventors understood the meaning gelling agent to be related to a colloidal suspension and that a person of ordinary skill in the art should also correlate a gelling agent with a colloidal suspension.

While a construction that includes "colloidal suspension" alone may confuse a jury because of the need for a scientific understanding of what a colloidal suspension actually is, the inventors also refer to a gelling agent in a much more colloquial manner. Specifically, the specifications provide that…

> "Another difficulty to be overcome in preparing a composition especially comprising benzoyl peroxide, when it is gel form, is that the **gelling agents** are destabilized by the benzoic acid released during the degradation of the bezoyl peroxide.
>
> Specifically, the **thickeners** most commonly used for formulating these compositions with benzoyl peroxide are acrylic acid polymers (Carbomer) and celluloses alone or combined with silicates. '186 Patent at C3:21-29, emphasis added.

This passage, which discusses the problems with preparing a gel containing BPO, uses the phrase "gelling agent" synonymously with "thickener." This indicates that a more

general understanding of the term "gelling agent" is simply a "thickener", as understood by the inventors and a person of ordinary skill in the art. The concept of a thickener is a concept that a jury can certainly understand. However, a construction of gelling agent the merely uses "thickener" alone may not capture the essential scientific nature of a gel. Alone, this can be interpreted too broadly so that it includes that a person of ordinary skill in the art would not consider a "gel" under a scientific definition.

The Court is of the opinion that a construction that incorporates both the scientific term, colloidal suspension, and the colloquial term, thickener, would more clearly capture the plain and ordinary meaning of "gelling agent," as used in the Orsoni Patents. Furthermore, both of these phrases are used in the Patents, who were written for a person of ordinary skill, to refer to gelling agents. Therefore, either or both may be considered a plain and ordinary meaning to a person of ordinary skill in the art. Additionally, the use of both of the concepts of a thickener and a colloidal suspension in the construction incorporates the Patents' repeated emphasis that the formulation be a gel that maintains the proper viscosity for suspension of the active ingredients, as pointed out by Galderma.

The Court is of the opinion that both Galderma's and Actavis' proposed constructions are also incorrect because they incorporate certain limitations of the invention that are already described by other claim language. If certain claim language already provides a limitation or feature of the invention, it is not necessary to construe

other portions of the claims in a way that repeat those limitations. Such a construction is at best repetitive and at worst leads to confusion.

Actavis proposes that the phrase "gelling agent" be construed to mean "agent(s) within a composition that forms a gel." However, it is already clear from other claim language that what is claimed is a composition. It is also clear that what is claimed is a gel. Therefore there is no need to further incorporate these limitations into the construction of gelling agent.

Galderma proposes that the phrase be construed as "an agent or agents capable of giving the composition a viscosity that is sufficient to keep the adapalene and benzoyl peroxide in suspension." Galderma's proposed construction requires that the agents be in suspension. As discussed above, the inventors understood that "being in suspension" is no different than being "dispersed" because the Patent specifications use the two terms synonymously, which is an argument forwarded by Galderma. The claim language already provides that the BPO is dispersed (i.e. in suspension). Therefore there is no need to further incorporate this limitation into the construction of gelling agent.

Because the phrase "gelling agent" is not specifically defined by the Patents; "gelling agent" is used in the claim language to particularly indicate a specific gelling agent; the Patent specifications use the phrase in a manner consistent with the plain and ordinary meaning; and the Patent specifications indicate that the plain and

ordinary meaning of "gelling agent" is synonymous with "thickener" and "colloidal suspension" the Court construes the phrase "acrylamide sodium acryloyldimethyltaurate copolymer/isohexadecane/polysorbate 80 gelling agent" to mean "mixture of acrylamide sodium acryloyldimethyltaurate copolymer /isohexadecane/polysorbate 80, which is the particular agent used to form a colloidal suspension and to thicken the formulation."

B. The Synergy Patents

1. The Inventions

The Synergy Patents, like the Orsoni Patents, also address inventions for the treatment of acne. However, instead of claiming a formulation for the treatment of acne, like the Orsoni Patents, the Synergy Patents claim methods and regimens for the treatment of acne. In particular the Synergy Patents, claim treatment regimens for acne that involve the simultaneous treatment of acne with BPO and adapalene. '537 Patent at 1:50-2:31.

The Patents claim, that the simultaneous treatment of acne with BPO and adapalene provides unexpected results, based on what was known in the prior art. Id. At the time of the inventions, it was known that BPO could be used to treat acne. Id. It was also known that adapalene could be used to treat acne. Id. Furthermore, based on what was known in the prior art, the mere usage of both BPO and adapalene to treat acne at the same time would not be particularly inventive. Id. However, as the Patents

claim, the combined treatment regimen is patentable because of the unexpected results obtained from the treatment. Id.

In particular, the Patents claim that the simultaneous treatment of acne with BPO and adapalene provides a completely unexpected synergistic effect. Id. Synergistic effect means that a combined treatment with two or more active agents results in significantly better results than would be expected from the simple additive effect of the use of the two active agents. Id. The Synergy Patents state that treatment of acne with BPO provides a certain result, which was known in the prior art. Id. Similarly, treatment of acne with adapalene provides a certain result, which was also known in the prior art. Id. However, the results from the combined treatment of acne with both BPO and adapalene provides unexpected beneficial results that are significantly greater than the sum of the known results of treatment with BPO and the known results of treatment with adapalene. Id.

2. Person of Ordinary Skill in the Art

Preferably, this Court gives the words of a claim their ordinary and customary meaning; in other words, the meaning the claim term would have to a person of ordinary skill in the art. *See Phillips*, 415 F.3d at 1312-13; *Markman*, 52 F.3d at 979. A person of ordinary skill in the art would read the claim term in the context of the entire patent, not just the particular claim where the term appears. *Phillips*, 415 F.3d at 1313. The Court holds that a person of ordinary skill in the art for the Synergy Patents is a

person with a bachelor's degree in pharmacology, chemistry, or an equivalent degree with three to five years of work experience or graduate studies experience in the fields of pharmaceutical formulation and/or drug development and/or drug delivery research.

3. Priority Terms Needing Construction

The Parties dispute the meaning of certain phrases within the claims of the Synergy Patents. In particular the Parties dispute the meaning of "success rate" and of "degree of success," which are both used repeatedly in the claims of the Synergy Patents. The Parties direct the Court's attention to nine instances of the phrase "success rate" or "degree of success" that occur in the Synergy Patents and require construction. Joint Claim Construction Chart. Each of these claims describes an acne treatment regimen using varying percentages of adapalene and BPO. Each claim further describes a clinical benefit limitation. The disputed phrases "success rate" and "degree of success" occur within this clinical benefit limitation, and are used to set out the claimed parameters of the clinical benefit limitation.

Claim 3 of the '644 Patent reads as follows:

> "A regimen for the therapeutic treatment of acne lesions, the regimen comprising topically applying to the skin of a subject in need of said treatment, as active ingredients, adapalene or a pharmaceutically acceptable salt thereof and benzoyl peroxide, combined at fixed does of 0.1% adapalene and 2.5% benzoyl peroxide in a single formula that delivers said active ingredients together synergistically, wherein the adapalene or pharmaceutically acceptable salt thereof and the benzoyl peroxide are the only anti-acne ingredients in said single formula, wherein said single formula is applied once daily for a period of 12 weeks, and

wherein the net clinical benefit, expressed as at least one of **success rate** and reduction in total lesion counts in a group of such subjects, at least one of weeks 1, 2, 4, 8 and 12 is numerically superior to the sum of the net clinical benefits achieved by the 0.1% adapalene alone and 2.5% benzoyl peroxide alone at least one of the corresponding time points." '644 at 10:11-27.

Claim 1 of the '537 Patent reads as follows:

"A regimen for the therapeutic treatment of acne lesions, the regimen comprising topically applying to the skin of a subject in need of said treatment, as active ingredients, adapalene or pharmaceutically acceptable salt thereof and benzoyl peroxide combined at fixed doses of 0.1% adapalene and 2.5% benzoyl peroxide in a single formula that delivers said active ingredients together, wherein the adapalene or pharmaceutically acceptable salt thereof and the benzoyl peroxide are the only anti-acne active ingredients in said single formula, wherein said single formula is applied once daily for a period of 12 weeks, and wherein the net clinical benefit, expressed as **success rate** or reduction in total lesion counts in a group of such subjects, achieved by the single formula at week 8 is synergistic and numerically superior to the net clinical benefit achieved by 0.1% adapalene alone or 2.5% benzoyl peroxide alone at week 12." '537 Patent at 18:36-51.

Claim 3 of the '537 Patent reads as follows:

"A regimen for the therapeutic treatment of acne lesions, the regimen comprising topically applying to the skin of a subject in need of said treatment, as active ingredients, adapalene or pharmaceutically acceptable salt thereof and benzoyl peroxide combined at fixed doses of 0.1% adapalene and 2.5% benzoyl peroxide in a single formula that delivers said active ingredients together, wherein the adapalene or pharmaceutically acceptable salt thereof and the benzoyl peroxide are the only anti-acne active ingredients in said single formula, wherein said single formula is applied once daily for a period of 12 weeks, and wherein

the net clinical benefit, expressed as **success rate** or reduction in total lesion counts in a group of such subjects, achieved by the single formula at week 1, 4 or 8 is synergistic and numerically superior to the net clinical benefit achieved by 0.1% adapalene alone or 2.5% benzoyl peroxide alone at week 4, 8, or 12, respectively." '537 Patent at 18:54-19:2.

Claim 1 of the '362 Patent reads as follows:

"A regimen for the therapeutic treatment of acne lesions, the regimen comprising topically applying to the skin of a subject in need of said treatment, as active ingredients, 0.1% adapalene or a pharmaceutically acceptable salt thereof and 2.5% benzoyl peroxide, combined at fixed doses in a single formula that delivers said active ingredients together synergistically to achieve, in a group of such subjects, a **degree of success** of at least about 20%, wherein the adapalene or pharmaceutically acceptable salt thereof and the benzoyl peroxide are the only anti-acne active ingredients in said single formula, wherein said single formula is applied once daily for a period of 12 weeks." '362 Patent at 9:24-36.

Claim 9 of the '362 Patent reads as follows:

"A regimen for the therapeutic treatment of acne lesions, the regimen comprising topically applying to the skin of a subject in need of said treatment, as active ingredients, o01% adapalene or a pharmaceutically acceptable salt thereof and 2.5% benzoyl peroxide, combined at fixed doses in a single formula that delivers said active ingredients together synergistically to reduce the number of total acne lesions by at least 40%, to reduce the number of non-inflammatory acne lesions by at least 40%, and to achieve in a group of such subjects, a **degree of success** of at least about 20%, wherein the adapalene or pharmaceutically acceptable salt thereof and the benzoyl peroxide are the only anti-acne active ingredients in said single formula, wherein said single formula is applied once daily for a period of 12 weeks." '362 Patent at 10:26-40.

Claim 11 of the '362 Patent reads as follows:

"The regimen for providing early onset of action in the therapeutic treatment of acne lesions, the regimen comprising topically applying to the skin of a subject in need of said treatment, as active ingredients, adapalene or a pharmaceutically acceptable salt thereof and benzoyl peroxide, combined at fixed doses of 0.1% adapalene and 2.5% benzoyl peroxide in a single formula that delivers said active ingredients together, wherein the adapalene or pharmaceutically acceptable salt thereof and the benzoyl peroxide are the only anti-acne active ingredients in said single formula, wherein said single formula applied once daily for a period of 12 weeks, and wherein the net clinical benefit, expressed as at least one of **success rate** and reduction in total lesion counts in a group of such subjects, at least one of week 1, week 2 and week 4, is numerically superior to the sum of the net clinical benefits achieved by 0.1% adapalene alone and 2.5% benzoyl peroxide alone at least one of the corresponding time points." '362 Patent at 10:43-59.

Claim 1 of the '543 Patent reads as follows"

"A regimen for the therapeutic treatment of acne lesions, the regimen comprising topically applying to the skin of a subject in need of said treatment, as active ingredients, 0.1% to 0.3% adapalene or a pharmaceutically acceptable salt thereof and 2.5% benzoyl peroxide, combined at fixed doses in a single formula that delivers said active ingredients together, wherein the adapalene or pharmaceutically acceptable salt thereof and the benzoyl peroxide are the only anti-acne active ingredients in said single formula, wherein the percentages of adapalene and benzoyl peroxide are percentages by weight relative to the total weight of said single formula, wherein said single formula is applied once daily for a period of 12 weeks, and wherein the net clinical benefit, expressed as **success rate** or reduction in total lesion counts in a group of such subjects, achieved by the single formula at week 8 is synergistic and numerically superior to the net clinical benefit achieved by the same dose

of adapalene alone or of benzoyl peroxide alone at week 12." '543 Patent at 18:44-61.

Claim 3 of the '543 Patent reads as follows:

"A regimen for the therapeutic treatment of acne lesions, the regimen comprising applying to the skin of a subject in need of said treatment, as active ingredients, 0.1% to 0.3% adapalene or a pharmaceutically acceptable salt thereof and 2.5% benzoyl peroxide, combined at fixed doses in a single formula that delivers said active ingredients together, wherein the adapalene or pharmaceutically acceptable salt thereof and the benzoyl peroxide are the only anti-acne active ingredients in said single formula, wherein the percentages of adapalene and benzoyl peroxide are percentages by weight relative to the total weight of said single formula, wherein said single formula is applied once daily for a period of 12 weeks, and wherein the net clinical benefit, expressed as **success rate** or reduction in total lesion counts in a group of such subjects, achieved by the single formula at week 1, 4 or 8 is synergistic and numerically superior to the net clinical benefit achieved by the same dose of adapalene alone or of benzoyl peroxide alone at week 4, 8 or 12, respectively." '543 Patent at 18:64-19:14.

Claim 9 of the '543 Patent reads as follows:

"A regimen for the therapeutic treatment of acne lesions, the regimen comprising topically applying to the skin of a subject in need of said treatment, as active ingredients, 0.1% to 0.3% adapalene or a pharmaceutically acceptable salt thereof and 2.5% benzoyl peroxide, combined at fixed doses in a single formula that delivers said active ingredients together synergistically to reduce the number of total acne lesions by at least 40%, to reduce the number of non-inflammatory acne lesions by at least 40%, to reduce the number of inflammatory lesions by at least 50%, and to achieve, in a group of subjects, a **degree of success** of at least 20%, wherein the adapalene or pharmaceutically acceptable salt thereof and the benzoyl peroxide are the only anti-acne active ingredients

> in said single formula, wherein the percentages of adapalene and benzoyl peroxide are percentages by weight relative to the total weight of said single formula, wherein said single formula is applied once daily for a period of 12 weeks." '543 Patent at 20:15-31.

4. The Parties' Requested Construction of "Success Rate"/"Degree of Success."

The Parties have each proposed different constructions of the disputed claims. While the Parties disagree as to the meaning of "success rate" and "degree of success;" the Parties are in agreement that the two phrases have the same meaning. The Court is in agreement with the Parties and therefore the Court will construe the phrases "success rate" and "degree of success" collectively. Furthermore, the Parties are in agreement that the meaning of the disputed phrases is the same throughout all of the Synergy Patents. The Court is in agreement with the Parties on this issue also. Therefore, the Court will collectively construe the Synergy Patents as to the meaning of "success rate"/"degree of success."

Galderma proposes that the Court should construe the disputed phrases to mean "the percentage of patients who had an IGA (Investigator's Global Assessment of "clear" or "almost clear"." Joint Claim Construction Chart. In support of its construction Galderma argues that the inventors explicitly define the meaning of success rate/degree of success. Plaintiffs' Opening Claim Construction Brief at 9-13. That in making such an explicit definition the inventors acted as their own lexicographer. Id. Therefore, the disputed phrases must be given the definition

provided by the Patents. Specifically, Galderma points to the language of the Patents that reads:

> "…the degree of success, defined as the percentage of patients considered as being "clear", i.e., the patient has no more acne lesions (neither comedones nor inflammatory lesions), reflecting an improvement in the patient's clinical condition, or "almost clear" on the evaluation scale…" '363 Patent at 7:2-6; '537 Patent at 8:13-17; '644 at Patent 7:5-10.

Galderma argues that this definition of degree of success shows the inventors' intention to act as their own lexicographer. Plaintiffs' Opening Claim Construction Brief at 9-13. It further argues that use of the phrase "degree of success" or "success rate" in other areas of the Patents reinforces the inventors' chosen definition because the use is consistent with the provided definition and it is used to measure or describe the synergistic effect of the invention, which is in essence the novelty of the invention. Id. Galderma further argues that Actavis' proposed construction is incorrect because Actavis' construction is too vague and it relies on the determination of a hypothetical dermatologist. Id.

Actavis proposes that this Court should apply the plain and ordinary meaning to the phrases "degree of success" and "success rate." Defendant Actavis Mid Atlantic LLC's Opening Claim Construction Brief at 12-15. Specifically, Actavis proposes that the plain and ordinary meaning of these phrases is "percentage of patients for which treatment is deemed successful by a physician in the field of dermatology." Id. Actavis argues that the Court should adopt this construction because there is no evidence that

the inventor's intended to act as their own lexicographer's and adopt a narrow definition of the phrases that is tied a particular assessment scale used for evaluating acne treatments. Id.

In support of this argument, Actavis points out that their were a number of evaluation scales that were used, at the time of the invention, to evaluate the effectiveness of an acne treatment and that the Patents broadly discuss the evaluation of the therapeutic effect in a manner that indicates that any number of evaluation scales could be used to determine the "degree of success" or "success rate." Id. Actavis further points out that the definition that Galderma relies on occurs under headings entitled "Example 1" and "Clinical Study Results" and that at the beginning of "Example 1" the inventors explicitly state that the example is not limiting in any way. Id, Therefore, Actavis argues, the definition provided under this example cannot be used impart these limitations into the claims. Id.

5. Construction of "Success Rate"/"Degree of Success."

Since the Parties are in dispute as to the meaning of "success rate"/"degree of success," it is necessary for the Court to construe the meaning of these phrases. The Court is of the opinion that Galderma is correct in that the inventors' provided a definition as to the meaning of the phrases. However, while it may be clear that the inventors' intended this definition to control the meaning of the phrases, the definition itself is not entirely clear. Therefore, it is necessary to provide additional clarification as

to what the inventors meant the definition to mean.

The Court agrees with Galderma that the inventor's provided a definition of the phrases that should be applied to the claim language. Furthermore, the other language of the specifications, the usage of the phrases in the specifications, and other claim language support this conclusion. The Synergy Patents all provide the following definition of degree of success:

> "…the degree of success, defined as the percentage of patients considered as being "clear", i.e., the patient has no more acne lesions (neither comedones nor inflammatory lesions), reflecting an improvement in the patient's clinical condition, or "almost clear" on the evaluation scale…" '363 Patent at 7:2-6; '537 Patent at 8:13-17; '644 Patent at 7:5-10.

It is clear that the inventor's intended to act as their own lexicographer in this matter. The phrase clearly sets out the definition of what the inventors intended the phrase to mean.

The Court first looks to the language of the claims of the Synergy Patents. The claim language is consistent with the inventors' provided definition. The use of the phrases "degree of success" and "success rate" in the Patent claims, when compared to the other evaluation criteria used in the claim language, indicate the inventors' intention to impart a specific meaning to these phrases.

As mentioned above, many of the claims of the Synergy Patents are acne treatment regimens. '537 Patent at 18:36-20:21; '644 Patent 9:27-10:29; '362 Patent 9:25-10-61. These regimens involve the treatment of acne with both adapalene and

BPO. Id. Many claims go on to include a clinical benefit limitation. Id. Some of these compare the clinical benefit of the claimed combination treatment to that of adapalene alone or BPO alone and/or require the clinical benefit to be synergistic when compared to treatments of adapalene and BPO. Id.

The disputed phrases, "success rate" and "degree of success," are one of the criteria used to define, express, and evaluate the clinical benefits that must be achieved by the treatment regimen. Id. However, the disputed phrases are only one method that the claims use to evaluate the clinical benefit. Id. Many claims also list other criteria which may be used to determine that the clinical benefit is synergistic. Id. Some claims list multiple evaluation methods within one claim. Id.

For example, Claim 9 of the '543 Patent provides combination treatment regimen should be determined "…synergistically to reduce the number of total acne lesions by at least 40%, to reduce the number of non-inflammatory acne lesions by at least 40%, to reduce the number of inflammatory lesions by at least 50%, and to achieve, in a group of subjects, a degree of success of at least 20%..." '543 Patent at 20:21-25. In this example there are four separate limitations that are applied to the clinical benefit of the treatment. Specifically, they are 1) reduce the number of total acne lesions by at least 40%, 2) reduce the number of non-inflammatory acne lesions by at least 40%, 3) reduce the number of inflammatory lesions by at least 50%, and 4) achieve, in a group of subjects, a degree of success of at least 20%.

Claim 1 of the '543 Patent provides that "…the net clinical benefit, expressed as success rate or reduction in total lesion counts … is synergistic and numerically superior to…" '543 Patent at 18:57-58. In this example there are two possible ways to determine the net clinical benefit. The first is to use the success rate. The second is to look to a reduction in total lesion counts.

Even the other claims, that do not use the disputed terms, provide some guidance as to the inventors' intention to define the disputed phrases. For example, Claim 5 of the '537 Patent simply provides that the adapalene and BPO act synergistically to "reduce the number of non-inflammatory acne lesions by at least 40%..." '543 Patent 19:10-12. Similarly, Claim 6 of the '543 Patent provides the treatment should "reduce the number of inflammatory acne lesions by at least 50%." '543 at Patent 19:24-20:1.

An examination of the treatment evaluation methods, other than the disputed "success rate" and "degree of success" evaluation methods, indicates that the inventors provided a specific evaluation criteria that must be met by the treatment. For example, reduction in total lesions, reduce the number of non-inflammatory acne lesions by at least 40%, reduction of the number of inflammatory acne lesions by at least 50% are specific methods for evaluation of the effect of the treatments.

An evaluation method that simply points to a "degree of success" or a "success rate" appears, on its face to be a very general non-specific evaluation criteria, which

would be unlike all other included criteria. However, as already stated, the specification itself provides a definition for "degree of success." Furthermore, that definition provides an evaluation method that, like all the other evaluation criteria included in the claims, is specific, i.e "clear" or "almost clear."

Because the inventors had already defined degree of success in the specifications, there was no need to repeat these specific evaluation criteria in the claims themselves. This definition is what the inventors were directing the reader's attention to in the claim language. Such an interpretation is consistent with the other specific evaluation criteria of the claims, and a person of ordinary skill in the art would understand that the claim language referred to the provided definition of "degree of success."

The use of the phrase throughout the Patent specifications is consistent with the provided definition, which further supports the determination that the inventors defined the disputed terms. As in the claim language, "degree of success" is used consistently throughout the "Example 1" of the specifications and it is not the only evaluation criteria. "Example 1" provides the definition of "degree of success" and states that this was a main efficacy criteria. '537 Patent at 8:10-20. However, the example also provides another main efficacy criteria. Id. Specifically, "the reduction of the percentage of inflammatory and non-inflammatory lesions after 12 weeks of treatment" was a different and unique evaluation method. Id.

The rest of the example continuously differentiates between the two specific

methods of evaluation of the treatment. As in the claims, the meaning of degree of success is not further described in the example. This is because it was not necessary to redefine the meaning of the phrase, as it was previously specifically defined. The example also continues to refer to degree of success as a particular specific evaluation method that is distinguished from the other main efficacy criteria. This is done in the text discussing the results of the example, in the chart showing the data of the example, and in the graph of the example. '537 Patent at 8:25-50, Fig. 4. In all cases a simple reference to "degree of success" or "success rate" was all that was needed to impart the definition's meaning to the phrase. This is identical to the use of the phrase in the claim language.

However, the definition does not in and of itself directly reference the Investigators Global Assessment scale. Galderma has proposed a construction that ties the included definition of "degree of success" to a specific evaluation method used for the treatment of acne. Specifically, Galderma asserts that the references to "clear" and "almost clear" are references to the Investigator's Global Assessment (IGA). However, the definition itself does not reference the IGA. It merely refers to "the evaluation scale." '543 Patent at 8:17.

So the question becomes whether or not the inventors were referring to the IGA evaluation scale, to some other unspecified evaluation scale or to global evaluation scales in general. In addition to the failure of the definition to refer to the IGA scale, the

'644 Patent and the '362 Patent do not refer to the IGA scale anywhere in the specifications. The '537 Patent, however, does reference the IGA in a discussion in the specifications regarding the clinical benefit of the treatments. '543 Patent at 11:53-12:6. The lack of reference to the IGA scale in the "degree of success" definitions of the Patents and the lack of reference to the IGA anywhere at all in two of the Synergy Patents creates uncertainty as to what evaluation scale the inventors were referring to in their definition of "degree of success."

Even though the definition does not explicitly state that the evaluation scale is the IGA scale, it does include detail as to the meaning of "clear." Specifically, the degree of success definition provides that "clear" means "the patient has no more acne lesions (neither comedones nor inflammatory lesions), reflecting an improvement in the patient's clinical condition." '537 Patent at 8:10-20. Unfortunately, however, the definition does not provide a similar specific meaning for "almost clear."

The IGA provides specific meaning for both "clear" and "almost clear." The IGA defines "clear" as "clear skin with no inflammatory or noninflammatory lesions." App. ISO Plaintiffs' Opening Claim Construction Brief, App. 039. The IGA defines "almost clear" as "rare noninflammatory lesions with no more than one small inflammatory lesion." Id.

Actavis points out that at the time of the invention, researchers used many methods for evaluation of the treatment of acne and that there was not a method that

was generally accepted and used by all researchers. Defendant Actavis Mid Atlantic LLC's Responsive Claim Construction Brief at 6-9. Actavis specifically points to the Cook and Pillsbury Scale, the Burke and Cunliffe Method, and the Evaluator Global Severity Scale. Id. Actavis also directs the Court's attention to a scientific article discussing the various types of evaluation methods and the lack of agreement among researchers regarding which scale should be used. App. ISO Defendant Actavis Mid Atlantic LLC's Opening Claim Construction Brief at 170-174. It is clear from this extrinsic evidence that Actavis is correct in stating that there were multiple evaluation methods available and that the research community did not consistently use one evaluation method. However, that is not the question presented here. The question is whether or not a person of ordinary skill in the art would read the Synergy Patents and understand that the inventors were pointing toward one particular evaluation scale, the IGA scale.

While the intrinsic evidence (the claims, specifications, and file wrapper) are of utmost importance in construing claim language, it is not improper to look to extrinsic evidence to help clarify ambiguity in the meaning of the claim language. The Court may consult extrinsic evidence to educate itself about the invention and relevant technology. *See Key Pharm. v. Hercon Lab. Corp.*, 161 F.3d 709, 716 (Fed. Cir. 1998). This is especially so when extrinsic evidence supports that construction that the intrinsic evidence suggests is correct. *Id.*

The extrinsic evidence shows many of the evaluation scales used to treat acne. App. ISO Defendant Actavis Mid Atlantic LLC's Opening Claim Construction Brief at 170-174. Some of these scales do not use the "clear" and "almost clear" evaluation criteria. Id. Some use designations such as "mild," which do not have any relation or correlation to the Synergy Patents' definition of degree of success. Id. Others simply use numeric lesion counts to evaluate the clinical benefit. Id.

One particularly instructive item of extrinsic evidence, is that of the Lambert Patent. The Lambert Patent shows that there are a number of possible global investigation scales that may be used to evaluate the clinical benefit of an acne treatment regimen. Id at 220. Both Galderma and Actavis argue that the Lambert Patent supports their respective proposed constructions. Plaintiffs' Responsive Claim Construction Brief at 8.; Defendant Actavis Mid Atlantic, LLC's Opening Claim Construction Brief at 12-13.

In particular, Galderma points out that the Lambert Patent uses the same severity grades that the Synnergy Patents use, clear and almost clear, to define success rate. Plaintiffs' Responsive Claim Construction Brief at 8. Galderma is correct that the inventors' intended to use "clear" and "almost clear" to define "success rate." However, Actavis points out that the Synergy Patents do not limit the use of "clear" and "almost clear" to the IGA scale. Defendant Actavis Mid Atlantic, LLC's Opening Claim Construction Brief at 12-13.

The Lambert Patent discusses the use of the clear and almost clear criteria in connection with many types of global scales. App. ISO Defendant Actavis Mid Atlantic LLC's Opening Claim Construction Brief at 220. Specifically, the Lambert Patent states that:

> "clear or almost clear skin is analyzed in a variety of ways by a treatment evaluator …, preferably a physician global evaluation, including using a Global Static Physician Score, Static physician Global Assessment, Investigator Global Evaluation, Evaluator's Global Severity Scale, or other known scale (e.g, Cook's Scale, Leeds Scale, etc.)" Id.

While this definition of clear and almost clear is not controlling in the Synergy Patents, because it is in the extrinsic record, is does provide useful insight into the Synergy Patent inventors' meaning of clear and almost clear and how a person of ordinary skill in the art would interpret the use of those phrases. In particular, the Lambert Patent lists at least six different evaluation methods, which were known in the art at the time of the inventions of the Synergy Patents, all of which can use the "clear" and "almost clear" designations to evaluate the treatment of acne. Id. The references to "clear" and "almost clear" in the Synergy Patents could possibly be referring to any one of these evaluation methods.

The Synergy Patents provide a definition of "clear." However, that definition is not word for word identical to any of the definitions of "clear" of any of the global evaluation methods, including the IGA. In addition, the definitions of clear (that were provided to the Court) used in the Synergy Patents, the IGA scale, and other methods,

all have the same essential meaning. For example, Evaluator's Global Severity Scale defines "clear" as "normal, clear skin with no evidence of acne vulgaris (App. ISO Defendant Actavis Mid Atlantic LLC's Opening Claim Construction Brief at 170-174);" the IGA defines clear as ""clear skin with no inflammatory or noninflammatory lesions." (App. ISO Plaintiffs' Opening Claim Construction Brief, App. 039.); and the Synergy Patents define clear as "the patient has no more acne lesions (neither comedones nor inflammatory lesions), reflecting an improvement in the patient's clinical condition." '543 Patent at 8:14-16. They all mean that there is no acne. Therefore, the Synergy Patent inventors could be pointing to any of these global evaluation scales when they explain the meaning of clear. It is not limited to the IGA, as proposed by Galderma. The Synergy Patents do not give a definition of "almost clear." Therefore, there is no indication that the inventors' were discussing any particular global evaluation scale when they used the phrase "almost clear" to describe degree of success.

The reference to the IGA in one of the Synergy Patents does not support a construction of "degree of success," and therefore, "clear" and "almost clear," that is tied specifically to the IGA. At least one of the Synergy Patents, specifically references the IGA scale in its specifications. However, at least two of the Synergy Patents do not make any explicit references to the IGA at all.

The Parties all agree that the meaning of "degree of success" and "success rate"

are the same and that the meaning of those phrases is consistent throughout all of the Synergy Patents. However, each of the Synergy Patents and the claim terms and definitions included within each of them must be able to stand on their own. Therefore, even if the reference to the IGA in one Synergy Patent could be used to specifically tie the inventors' meaning of "degree of success" to the IGA in that patent, the reference to the IGA in one patent cannot be linked to a term used in another patent. The Synergy Patents that do not reference the IGA must have a meaning of "success rate" and "degree of success" that is supported by the language of that particular patent. Furthermore, if the inventors' desired to connect the definition of "degree of success" to the IGA, they would have explicitly included it in all the Synergy Patents. Therefore, the reference to the IGA by one Synergy Patent does not clarify any uncertainty in the Synergy Patents.

The construction "degree of success" and "success rate" in the Synergy Patents cannot specifically tie the IGA scale to the meaning of the disputed phrases because the Synergy Patents themselves do not do so, at least two Synergy Patents do not even reference the IGA, and the meaning of the phrases, as provided by the inventors, can be referring to any number of other global evaluation scales. The only thing that is evident from the intrinsic and extrinsic record is that the inventors' intended the references to "clear" and "almost clear" to relate to a global evaluation scale that was used in the field to evaluate the acne treatment. Imposition of the IGA scale in particular onto this

meaning would improperly narrow the meaning of the phrases "clear," "almost clear," and "degree of success," which would in turn improperly narrow the meaning of the claim language.

However, because the inventors specifically defined the phrase "degree of success," any construction must include the inventors' definition of this phrase. Therefore, the Court construes "degree of success" and "success rate" to mean "the percentage of patients considered as being "clear", i.e., the patient has no more acne lesions (neither comedones nor inflammatory lesions), reflecting an improvement in the patient's clinical condition, or "almost clear," on a global evaluation scale used to evaluate the clinical effect of an acne treatment."

IV. Agreed Terms/Phrases.

The Court notes that the Parties have submitted to the Court certain claim terms and phrases that the Parties state need to be construed, but the Parties agree as to the meaning of the terms and phrases. The Court hereby adopts the agreed constructions proposed by the Parties as described in the Joint Claim Construction Chart on file with the Court.

SO ORDERED.

Signed April 16th, 2014.

Ed Kinkeade

ED KINKEADE
UNITED STATES DISTRICT JUDGE

SUMMARY CHART OF CLAIM CONSTRUCTIONS OF PRIORITY TERMS

Construction of Terms of Patent No. 7,820,186

Language of Disputed Priority Term of Claims	Plaintiffs' Proposed Construction	Defendant's Proposed Construction	Judge's Construction
Claim 1 A physiologically acceptable aqueous gel composition for once-daily treatment of common acne comprising antiacne actives consisting of 0.1% adapalene and/or at least one pharmaceutically acceptable salt thereof, 2.5% dispersed benzoyl peroxide, and further comprising 4% **acrylamide sodium acryloyldimethyltaurate copolymer/isohexadecane/polysorbate 80 gelling agent**, said percentages being based on the weight of the total aqueous gel composition.	**gelling agent** "An agent or agents capable of giving the composition a viscosity that is sufficient to keep the adapalene and the benzoyl peroxide in suspension"	**gelling agent** Plain and ordinary meaning: "Agent(s) within a composition that forms a gel."	"**acrylamide sodium acryloyldimethyltaurate copolymer/isohexadecane/polysorbate 80 gelling agent**" "mixture of acrylamide sodium acryloyldimethyltaurate copolymer /isohexadecane/polysorbate 80, which is the particular agent used to form a colloidal suspension and to thicken the formulation."

Construction of Terms of Patent No. 8,241,649

Language of Disputed Priority Term of Claims	Plaintiffs' Proposed Construction	Defendant's Proposed Construction	Judge's Construction
A physiologically acceptable aqueous gel composition for once-daily treatment of common acne comprising: 0.1% adapalene and/or at least one pharmaceutically acceptable salt thereof; 2.5% to 5% dispersed benzoyl peroxide; and 3.5% to less than 4% **acrylamide sodium acryloyldimethyltaurate copolymer/isohexadecane/polysorbate 80 gelling agent**, said percentages being based on the weight of the total aqueous gel composition."	**gelling agent** "An agent or agents capable of giving the composition a viscosity that is sufficient to keep the adapalene and the benzoyl peroxide in suspension"	**gelling agent** Plain and ordinary meaning: "Agent(s) within a composition that forms a gel."	"**acrylamide sodium acryloyldimethyltaurate copolymer/isohexadecane/polysorbate 80 gelling agent**" "mixture of acrylamide sodium acryloyldimethyltaurate copolymer /isohexadecane/polysorbate 80, which is the particular agent used to form a colloidal suspension and to thicken the formulation."

Construction of Terms of Patent No. 8,071,644

Language of Disputed Priority Term of Claims	Plaintiffs' Proposed Construction	Defendant's Proposed Construction	Judge's Construction
Claim 3 "A regimen for the therapeutic treatment of acne lesions, the regimen comprising topically applying to the skin of a subject in need of said treatment, as active ingredients, adapalene or a pharmaceutically acceptable salt thereof and benzoyl peroxide, combined at fixed does of 0.1% adapalene and 2.5% benzoyl peroxide in a single formula that delivers said active ingredients together synergistically, wherein the adapalene or pharmaceutically acceptable salt thereof and the benzoyl peroxide are the only anti-acne ingredients in said single formula,	**success rate**	**success rate**	**success rate** "The percentage of patients considered as being "clear", i.e., the patient has no more acne lesions (neither comedones nor inflammatory lesions), reflecting

wherein said single formula is applied once daily for a period of 12 weeks, and wherein the net clinical benefit, expressed as at least one of **success rate** and reduction in total lesion counts in a group of such subjects, at least one of weeks 1, 2, 4, 8 and 12 is numerically superior to the sum of the net clinical benefits achieved by the 0.1% adapalene alone and 2.5% benzoyl peroxide alone at least one of the corresponding time points.	"the percentage of patients who has and IGA (Investigator's Global Assessment) of "clear" or "almost clear."	Plain and ordinary meaning: "Percentage of patients for which treatment is deemed successful by a physician in the field of dermatology."	an improvement in the patient's clinical condition, or "almost clear," on a global evaluation scale used to evaluate the clinical effect of an acne treatment."

Construction of Terms of Patent No. 8,080,537

Language of Disputed Priority Term of Claims	Plaintiffs' Proposed Construction	Defendant's Proposed Construction	Judge's Construction
Claim 1 A regimen for the therapeutic treatment of acne lesions, the regimen comprising topically applying to the skin of a subject in need of said treatment, as active ingredients, adapalene or pharmaceutically acceptable salt thereof and benzoyl peroxide combined at fixed doses of 0.1% adapalene and 2.5% benzoyl peroxide in a single formula that delivers said active ingredients together, wherein the adapalene or pharmaceutically acceptable salt thereof and the benzoyl peroxide are the only anti-acne active ingredients in said single formula, wherein said single	**success rate** "the percentage of patients who has and IGA	**success rate** Plain and ordinary meaning: "Percentage of	**success rate** "The percentage of patients considered as being "clear", i.e., the patient has no more acne lesions (neither comedones nor inflammatory lesions), reflecting

formula is applied once daily for a period of 12 weeks, and wherein the net clinical benefit, expressed as **success rate** or reduction in total lesion counts in a group of such subjects, achieved by the single formula at week 8 is synergistic and numerically superior to the net clinical benefit achieved by 0.1% adapalene alone or 2.5% benzoyl peroxide alone at week 12.. Claim 3 A regimen for the therapeutic treatment of acne lesions, the regimen comprising topically applying to the skin of a subject in need of said treatment, as active ingredients, adapalene or pharmaceutically acceptable salt thereof and benzoyl peroxide combined	(Investigator's Global Assessment) of "clear" or "almost clear."	patients for which treatment is deemed successful by a physician in the field of dermatology."	an improvement in the patient's clinical condition, or "almost clear," on a global evaluation scale used to evaluate the clinical effect of an acne treatment."

at fixed doses of 0.1% adapalene and 2.5% benzoyl peroxide in a single formula that delivers said active ingredients together, wherein the adapalene or pharmaceutically acceptable salt thereof and the benzoyl peroxide are the only anti-acne active ingredients in said single formula, wherein said single formula is applied once daily for a period of 12 weeks, and wherein the net clinical benefit, expressed as **success rate** or reduction in total lesion counts in a group of such subjects, achieved by the single formula at week 1, 4 or 8 is synergistic and numerically superior to the net clinical benefit achieved by 0.1% adapalene alone or 2.5% benzoyl peroxide alone at week 4, 8, or 12,	**success rate** "the percentage of patients who has and IGA (Investigator's Global Assessment) of "clear" or "almost clear."	**success rate** Plain and ordinary meaning: "Percentage of patients for which treatment is deemed successful by a physician in the field of dermatology."	**success rate** "The percentage of patients considered as being "clear", i.e., the patient has no more acne lesions (neither comedones nor inflammatory lesions), reflecting an improvement in the patient's clinical condition, or "almost clear," on a global evaluation scale used to evaluate the clinical effect of an acne treatment."

respectively.			

Construction of Terms of Patent No. 8,129,362

Language of Disputed Priority Term of Claims	Plaintiffs' Proposed Construction	Defendant's Proposed Construction	Judge's Construction
Claim 1 A regimen for the therapeutic treatment of acne lesions, the regimen comprising topically applying to the skin of a subject in need of said treatment, as active ingredients, 0.1% adapalene or a pharmaceutically acceptable salt thereof and 2.5% benzoyl peroxide, combined at fixed doses in a single formula that delivers said active ingredients together synergistically to achieve, in a group of such subjects, a **degree of success** of at least about 20%, wherein the adapalene or pharmaceutically acceptable salt thereof and the benzoyl peroxide are the only anti-acne active	**degree of success** "the percentage of patients who has and IGA (Investigator's Global Assessment) of "clear" or "almost clear."	**degree of success** Plain and ordinary meaning: "Percentage of patients for which treatment is deemed successful by a physician in the field of dermatology."	**degree of success** "The percentage of patients considered as being "clear", i.e., the patient has no more acne lesions (neither comedones nor inflammatory lesions), reflecting an improvement in the patient's clinical condition, or "almost clear," on a

ingredients in said single formula, wherein said single formula is applied once daily for a period of 12 weeks." Claim 9 A regimen for the therapeutic treatment of acne lesions, the regimen comprising topically applying to the skin of a subject in need of said treatment, as active ingredients, o01% adapalene or a pharmaceutically acceptable salt thereof and 2.5% benzoyl peroxide, combined at fixed doses in a single formula that delivers said active ingredients together synergistically to reduce the number of total acne lesions by at least 40%, to reduce the number of non-inflammatory acne lesions by at least 40%, and to achieve in a group	**degree of success** "the percentage of patients who has and IGA (Investigator's Global Assessment) of "clear" or "almost clear."	**degree of success** Plain and ordinary meaning: "Percentage of patients for which treatment is deemed successful by a physician in the field of dermatology."	global evaluation scale used to evaluate the clinical effect of an acne treatment." **degree of success** "The percentage of patients considered as being "clear", i.e., the patient has no more acne lesions (neither comedones nor inflammatory lesions), reflecting an improvement in the patient's clinical

of such subjects, a **degree of success** of at least about 20%, wherein the adapalene or pharmaceutically acceptable salt thereof and the benzoyl peroxide are the only anti-acne active ingredients in said single formula, wherein said single formula is applied once daily for a period of 12 weeks. Claim 11 The regimen for providing early onset of action in the therapeutic treatment of acne lesions, the regimen comprising topically applying to the skin of a subject in need of said treatment, as active ingredients, adapalene or a pharmaceutically acceptable salt thereof and benzoyl peroxide, combined at fixed doses of 0.1% adapalene and 2.5% benzoyl	**success rate** "the percentage of patients who has and IGA	**success rate** Plain and ordinary meaning: "Percentage of	condition, or "almost clear," on a global evaluation scale used to evaluate the clinical effect of an acne treatment." **success rate** "The percentage of

peroxide in a single formula that delivers said active ingredients together, wherein the adapalene or pharmaceutically acceptable salt thereof and the benzoyl peroxide are the only anti-acne active ingredients in said single formula, wherein said single formula applied once daily for a period of 12 weeks, and wherein the net clinical benefit, expressed as at least one of **success rate** and reduction in total lesion counts in a group of such subjects, at least one of week 1, week 2 and week 4, is numerically superior to the sum of the net clinical benefits achieved by 0.1% adapalene alone and 2.5% benzoyl peroxide alone at least one of the corresponding time points..	(Investigator's Global Assessment) of "clear" or "almost clear."	patients for which treatment is deemed successful by a physician in the field of dermatology."	patients considered as being "clear", i.e., the patient has no more acne lesions (neither comedones nor inflammatory lesions), reflecting an improvement in the patient's clinical condition, or "almost clear," on a global evaluation scale used to evaluate the clinical effect of an acne treatment."

Construction of Terms of Patent No. 8,445,543

Language of Disputed Priority Term of Claims	Plaintiffs' Proposed Construction	Defendant's Proposed Construction	Judge's Construction
Claim 1 A regimen for the therapeutic treatment of acne lesions, the regimen comprising topically applying to the skin of a subject in need of said treatment, as active ingredients, 0.1% to 0.3% adapalene or a pharmaceutically acceptable salt thereof and 2.5% benzoyl peroxide, combined at fixed doses in a single formula that delivers said active ingredients together, wherein the adapalene or pharmaceutically acceptable salt thereof and the benzoyl peroxide are the only anti-acne active ingredients in said single formula, wherein the percentages of	**success rate**	**success rate**	**success rate** "The percentage of patients considered as being "clear", i.e.,

adapalene and benzoyl peroxide are percentages by weight relative to the total weight of said single formula, wherein said single formula is applied once daily for a period of 12 weeks, and wherein the net clinical benefit, expressed as **success rate** or reduction in total lesion counts in a group of such subjects, achieved by the single formula at week 8 is synergistic and numerically superior to the net clinical benefit achieved by the same dose of adapalene alone or of benzoyl peroxide alone at week 12. Claim 3 A regimen for the therapeutic treatment of acne lesions, the regimen comprising applying to the skin of a subject in need of said treatment, as	"the percentage of patients who has and IGA (Investigator's Global Assessment) of "clear" or "almost clear."	Plain and ordinary meaning: "Percentage of patients for which treatment is deemed successful by a physician in the field of dermatology."	the patient has no more acne lesions (neither comedones nor inflammatory lesions), reflecting an improvement in the patient's clinical condition, or "almost clear," on a global evaluation scale used to evaluate the clinical effect of an acne treatment."

active ingredients, 0.1% to 0.3% adapalene or a pharmaceutically acceptable salt thereof and 2.5% benzoyl peroxide, combined at fixed doses in a single formula that delivers said active ingredients together, wherein the adapalene or pharmaceutically acceptable salt thereof and the benzoyl peroxide are the only anti-acne active ingredients in said single formula, wherein the percentages of adapalene and benzoyl peroxide are percentages by weight relative to the total weight of said single formula, wherein said single formula is applied once daily for a period of 12 weeks, and wherein the net clinical benefit, expressed as **success rate** or reduction in total lesion counts in a	**success rate** "the percentage of patients who has and IGA (Investigator's Global Assessment) of "clear" or "almost clear."	**success rate** Plain and ordinary meaning: "Percentage of patients for which treatment is deemed successful by a physician in the field of dermatology."	**success rate** "The percentage of patients considered as being "clear", i.e., the patient has no more acne lesions (neither comedones nor inflammatory lesions), reflecting an improvement in the patient's clinical condition, or "almost clear," on a global evaluation scale used to evaluate the clinical effect of an acne treatment."

group of such subjects, achieved by the single formula at week 1, 4 or 8 is synergistic and numerically superior to the net clinical benefit achieved by the same dose of adapalene alone or of benzoyl peroxide alone at week 4, 8 or 12, respectively.	**degree of success**	**degree of success**	
Claim 9 A regimen for the therapeutic treatment of acne lesions, the regimen comprising topically applying to the skin of a subject in need of said treatment, as active ingredients, 0.1% to 0.3% adapalene or a pharmaceutically acceptable salt thereof and 2.5% benzoyl peroxide, combined at fixed doses in a single formula that delivers said active ingredients together synergistically to reduce the number	"the percentage of patients who has and IGA (Investigator's Global Assessment) of "clear" or "almost clear."	Plain and ordinary meaning: "Percentage of patients for which treatment is deemed successful by a physician in the field of dermatology."	**degree of success** "The percentage of patients considered as being "clear", i.e., the patient has no more acne lesions (neither comedones nor inflammatory lesions), reflecting an improvement in the patient's clinical condition, or "almost clear," on a global evaluation scale used to evaluate the clinical effect of an acne treatment."

of total acne lesions by at least 40%, to reduce the number of non-inflammatory acne lesions by at least 40%, to reduce the number of inflammatory lesions by at least 50%, and to achieve, in a group of subjects, a **degree of success** of at least 20%, wherein the adapalene or pharmaceutically acceptable salt thereof and the benzoyl peroxide are the only anti-acne active ingredients in said single formula, wherein the percentages of adapalene and benzoyl peroxide are percentages by weight relative to the total weight of said single formula, wherein said single formula is applied once daily for a period of 12 weeks.			