United States District Court,
N.D. Texas, Fort Worth Division.

GALDERMA LABORATORIES, L.P. and S.A,
v.
ACTAVIS MID-ATLANTIC, L.L.C.

Civil Action No. 4:06-CV-471-Y

Aug. 27, 2008.

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ORDER CONSTRUING CLAIM TERMS OF UNITED STATES PATENT NO. 6,106,848

TERRY R. MEANS**, District Judge.**

This is a patent-infringement case. Galderma Laboratories, L.P., and Galderma, S.A. ("Galderma"), make and sell a lotion under the trade name "Clobex" for treating various skin conditions such as psoriasis, eczema, and dermatitis. Galderma has sued Actavis Mid-Atlantic, L.L.C. ("Actavis"), alleging infringement of its United States patent no. 6,106,848 ("the '848 patent"), the patent behind the Clobex lotion. Galderma's suit for patent infringement stems from Actavis's filing of an abbreviated new-drug application with the United States Food and Drug Administration under 21 U.S.C. s. 355. Actavis has countered, seeking a declaration that the ' 848 patent is not being infringed and that the patent is invalid. Before the Court are the parties' requests (docs.70 & 81) for construction of certain claim terms in the '848 patent. The Court has carefully considered the patent, its prosecution history, and the parties' briefs and appendices and makes the following construction of the disputed claim terms as discussed below.

I. Background

The '848 patent relates to a skin lotion that is an oil-in-water emulsion with a high glycol content, intermediate viscosity, an emulsifying system, and an active biological agent to treat the skin condition. The oil-in-water emulsion includes oil droplets dispersed in water and, because oil and water are immiscible, the lotion requires an emulsifying agent to prevent the natural separation of oil and water.

In skin lotions or creams that include a steroid as its active agent, it is advantageous for them to have a high

glycol content because the glycol promotes penetration of the steroid into the skin. At the time of Celobex's invention, lotions or creams containing a high glycol content were either thick creams that were undesirably viscous, greasy, and sticky, or they used volatile solvents that made them too fluid and limited their usefulness and application.

The inventors sought to develop a new lotion containing a high concentration of glycol but with an intermediate viscosity and a desired skin feel. The inventors determined that an emulsifying system that included an emulsifier containing an anionic amphiphilic polymer greatly facilitated the formulation of a stable oil-in-water emulsion having all of the desired characteristics, including intermediate viscosity and desired skin feel with a high glycol content. All of the disputed claim terms concern the emulsion and the emulsifiers.

II. Claim-Construction Standard

Claim construction is a matter of law. Markman v. Westview Instruments, 517 U.S. 370, 372, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). Indeed, "the construction of a patent, including terms of art within its claims, is exclusively within the province of the court" because "judges, not juries, are the better suited to find the acquired meaning of patent terms." Id. at 372, 388.

The duty of the trial judge is to determine the meaning of the claims at issue, and to instruct the jury accordingly. In the exercise of that duty, the trial judge has an independent obligation to determine the meaning of the claims, notwithstanding the views asserted by the adversary parties.

Exxon Chem. Patents v. Lubrizol Corp., 64 F.3d 1553, 1555 (Fed.Cir.1995).

In the performance of this duty, the Court is guided by several principles. At the same time, "there is no magic formula or catechism for conducting claim construction." Phillips v. AWH Corp., 415 F.3d 1303, 1324 (Fed.Cir.2005). The Court is not barred from considering any particular sources nor is the Court required to analyze the variety of sources available in any particular sequence. *Id*. But the Court must refrain from using those resources to contradict claim meaning that is unambiguous in light of the intrinsic evidence and for the Court to attach the appropriate weight to those sources in light of the statutes and policies that inform patent law. *Id*.

To that end, the Court starts by recognizing that it is a "bedrock principle" in patent law that "the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Id*. at 1312 (internal quotations and citations omitted). This is because the inventor "is required to define precisely what his invention is" and it is "unjust to the public, as well as an evasion of the law, to construe" the claims "in a manner different from the plain import of its terms." *Id*. (internal quotations and citations omitted).

Generally, the terms of a claim are given the ordinary and customary meaning that the terms would have to a person of ordinary skill in the art in question at the time of the invention. *Id*. at 1313.

It is the person of ordinary skill in the field of the invention through whose eyes the claims are construed. Such person is deemed to read the words used in the patent documents with an understanding of their meaning in the field, and to have knowledge of any special meaning and usage in the field. The inventor's words that are used to describe the invention-the inventor's lexicography-must be understood and interpreted by the court as they would be interpreted by a person in that field of technology.

Multiform Dessicants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1477 (Fed.Cir.1998). Thus, the Court should consult the same resources as would the person of ordinary skill in the art. *Id*. Those sources include "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1116 (Fed.Cir.2004).

The claims themselves in the patent can provide substantial guidance as to the meaning of particular claim terms, and the context in which the term appears in the claim can be highly instructive. Phillips, 415 F.3d at 1314. Because claim terms are frequently used in a consistent manner throughout the patent, the use of a term in one claim often will illuminate the meaning of the same term that appears in other claims. Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342 (Fed.Cir.2001). On the other hand, differences among claims can also be useful in understanding the meaning of particular claim terms. Phillips, 415 F.3d at 1315. "For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id*.

The claims of a patent do not stand alone, but are a part of a fully integrated instrument that consists principally of a specification that concludes with the claims. Markman v. Westview Instruments, 52 F.3d 967, 978-79 (Fed.Cir.1995) (*en banc*). Claims must be read in view of the specification. Phillips, 415 F.3d at 1315. The United States Court of Appeals for the Federal Circuit has long emphasized the importance of the specification in claim construction, and that court has referred to the specification as "highly relevant to the claim construction analysis." *Id*. (internal quotations and citations omitted). "Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). This close kinship between the specification and the claims "is enforced by the statutory requirement that the specification describe the claimed invention in full, clear, concise, and exact terms." Phillips, 415 F.3d at 1316; 35 U.S.C. s. 112, para. 1.

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.

Renishaw PLC v. Marposs Societa' Per Azioni, 158 F.3d 1243, 1250 (Fed.Cir.1998).

The Court may also consider the patent's prosecution history if it is in evidence. Markman, 52 F.3d at 980. The prosecution history is part of the intrinsic evidence and consists of the complete record of the proceedings before the Patent and Trademark Office ("PTO"). Phillips, 415 F.3d at 1317. The prosecution history often includes citations to prior art and provides evidence of how the PTO and the inventor understood the patent. *Id*. The prosecution history was created by the inventor when he attempted to explain and obtain the patent from the PTO, and "the patentee is held to what he declares during the prosecution of his patent." Gillespie v. Dywidag Sys. Int'l, USA, 501 F.3d 1285, 1291 (Fed.Cir.2007); Markman, 52 F.3d at 980. "Yet, because the prosecution history represents an ongoing negotiation between the PTO and the applicant" and not the final product, "it often lacks the clarity of the specification and thus is less useful for claim construction purposes." Markman, 52 F.3d at 980. Still, the prosecution history can inform on the meaning of a claim term by demonstrating how the inventor understood his invention and whether the inventor limited the invention in the course of prosecution to achieve allowance thereby making the claim scope narrower than it would otherwise be. *See* Vitronics, 90 F.3d at 1582-83.

The Court may also consider extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, and includes expert and inventor testimony, dictionaries, and learned treaties." Markman, 52 F.3d at 980. But while extrinsic evidence may be helpful, it is less significant than the intrinsic record in determining the meaning of a claim term. *See* C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 862 (Fed.Cir.2004). The Court may avail itself to dictionaries and technical dictionaries if the Court deems it helpful in determining the true meaning of a claim term. Markman, 52 F.3d at 980. Likewise, the Court may consider expert testimony if it will help the Court understand the background of the technology at issue, explain how the invention works, or assist in the Court's understanding of technical aspects of the patent in line with that of a person skilled in the art. *See* Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1308-09 (Fed.Cir.1999). An expert may also provide evidence that a particular term in the patent or in prior art has a particular meaning in the pertinent field. Phillips, 415 F.3d at 1318.

The Court should reject, however, any expert opinions that merely offer conclusory and unsupported assertions as to the definition of a claim term. *Id*. "Similarly, a court should discount any expert testimony that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent." *Id*. (internal quotations and citations omitted).

The Federal Circuit, in *Phillips,* elaborated on why extrinsic evidence is viewed with a skeptic's eye. First, it is not a part of the patent and may not have been created at the time of the patent nor for the purposes of explaining the patent's scope and meaning. Second, a publication may not be written by or for a person skilled in the relevant art. Third, expert opinions and reports are generated for litigation and may suffer from biases not present in the intrinsic evidence. Fourth, there can be endless amounts of potential extrinsic evidence and the Court could be left with the considerable task of wading through this evidence separating out that which has marginal probative value. Finally, there is a risk that undue reliance on extrinsic evidence could lead to a claim construction that is at odds with the public record thereby undermining the public-notice function of patents. "In sum, extrinsic evidence may be useful to the Court, but it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id*.

III. Analysis

The '848 patent includes twenty claims, with Claim 1 being the only independent claim. Galderma only asserts infringement of Claim 1, and all of the disputed terms appear in Claim 1. It provides:

A stable topically applicable oil-in-water emulsion which is topically applicable to skin having intermediate viscosity comprising (a) from 30% to 50% by weight relative to the total weight of said emulsion of at least one glycol, (b) *at least one emulsifying agent comprising an anionic amphiphilic polymer,* and (c) at least one biologically active agent, **wherein said anionic amphiphilic polymer is present in an amount which in the absence of another emulsifying agent results in an emulsion** having an intermediate viscosity, wherein said intermediate viscosity which ranges from 3 to 10 Pa.s (3,000 to 10,000 centipoises), measured with a Brookfield viscometer LVDV II+paddle No. 4, at a speed of 30 revolutions/minutes for thirty seconds, and at a temperature of 25 (deg.) C.(plus-or-minus sign)3 (deg.) C.

(Pls.' App. at 7-8.) The disputed terms in Claim 1 can be separated into three categories: (1) the preamble (italicized portion); (2) the emulsifying-system limitation (underlined portion); and (3) the first "wherein"

clause (bold portion).

A. The term "Stable"

Galderma contends that the term "stable" as used in Claim 1 should be construed as "[the emulsion] does not quickly separate." (Pls.' Br. at 9.) Actavis contends "stable" should be construed as "not readily altering in chemical makeup or physical state." (Def.'s Br. at 3.) The parties' dispute over the term "stable" is straightforward. Galderma argues that the term "stable" is limited to physical stability, where Actavis argues the term includes both physical and chemical stability. The extrinsic evidence cited by both parties, namely dictionary definitions of "stable" in the chemistry context, make clear that "stable" can mean both physical and chemical stability.

In Claim 1, "stable" modifies "oil-in-water emulsion" describing the oil-in-water emulsion as "stable." The specification makes clear that the invention is about producing "a stable emulsion" that has an intermediate viscosity. (Pls.' App. at 5.) More specifically, the specification teaches that "a stable emulsion is provided ... by selecting ... at least one polymeric emulsifier. The polymeric emulsifiers are in particular described by CLYMANS & BRAND in 'Cosmetics and Toiletries' (manufacture worldwide, 1995, 119-125)." (Id.)

The reference to Clymans is instructive. The particular pages cited in the patent refer to an article about polymeric emulsifiers as "an alternative to traditional emulsifiers based on stability of multi-phase systems." (Id. at 207.) In these pages, Clymans refers to the stability of an emulsion as when phase separation begins. If the emulsion begins to separate quickly, Clymans characterizes the emulsion as either unstable or of low stability. Nowhere does it refer to the chemical stability of the emulsion.

"Incorporation by reference provides a method for integrating material from various documents into a host document ... by citing such material in a manner that makes clear that the material is effectively part of the host document as if it were explicitly contained therein." Cook Biotech, Inc. v. Acell, Inc., 460 F.3d 1365, 1376 (Fed.Cir.2006). Incorporation by reference requires the host document to identify "with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents." *Id*. Whether and to what extent there has been an incorporation by reference is a question of law. *Id*.

The specific pages in Clymans that describe stable emulsion using polymeric emulsifiers has been incorporated into the patent by reference. The specification cites to specific pages in Clymans. And the specification teaches that the invention provides a stable emulsion by using an emulsifying system that has at least one polymeric emulsifier and it then refers the reader to Clymans for the particular polymeric emulsifiers. This makes clear that its reference is to emulsions that use polymeric emulsifiers and that do not suffer from quick phase separation.

Finally, there is support in the extrinsic record suggesting that a stable emulsion means preventing the physical separation of the dispersed liquid into the immiscible continuous liquid. The *Encyclopedic Dictionary of Chemical Technology,* under the definition of "emulsions," states "emulsifying agents that stabilize emulsions act by absorption to the dispersed phase .... " ENCYCLOPEDIC DICTIONARY OF CHEMICAL TECHNOLOGY 131 (1993). This refers to a stable emulsion as one where phase separation does not occur. An emulsion has also been referred to as "a significantly stable suspension of particles of liquid of a certain size within a second, immiscible liquid. The term *significantly stable* means relative to the intended use and may range from a few minutes to a few years." Milton J. Rosen, SURFACTANTS

AND INTERFACIAL PHENOMENA 304 (2d. ed.1989) (emphasis in original). Therefore, the Court concludes that "stable" as modifying "oil-in-water emulsion" is referring to the prevention of the natural separation of oil and water. Accordingly, the Court construes the term "stable" to mean **an oil-in-water emulsion where the oil and water will not separate for a significant period of time (relative to the emulsion's intended use).**

B. The Term "Oil-in-Water Emulsion"

Galderma contends that the term "oil-in-water emulsion" as used in Claim 1 means "a composition including oil dispersed in water." (Pls.' Br. at 12.) Actavis contends it means "a system consisting of oil dispersed within water whereby the oil droplets are larger than colloidal size." (Def.'s Br. at 5.) The parties agree that the construction should include oil dispersed in or within water. The parties' dispute, however, is two fold.

First, Galderma contends that its construction uses the term "composition including" and refers to the entire composition (e.g. perfumes, preservatives, and other additives). By contrast, Actavis's construction uses the term "consisting of," which, Galderma contends, is a term of art in patent law that will improperly limit the term "oil-in-water emulsion" to only oil and water.

Second, Galderma contends that its definition reflects the ordinary meaning of the term "emulsion." Galderma argues that Actavis's definition attempts to add a limitation by requiring the oil droplets be larger than colloidal size. Galderma complains that the term "colloidal" does not appear anywhere in the ' 848 patent.

Actavis contends that Galderma's construction relates to dispersions generally and not just emulsions. Actavis counters that its use of the term "consisting" in its construction enjoys no special significance beyond its lay meaning and that "consisting" is a term of art in patent law only when it is used in the claim, not in the claim construction. Actavis does not appear to be arguing that the emulsion should be limited to oil and water only. And Actavis contends that its construction is firmly anchored in the ordinary and plain meaning of emulsion.

The Court starts by noting that the patent does not define the term "emulsion" or the term "oil-in-water emulsion." The Court also notes that the parties' dispute over "a composition including" and "a system consisting" is purely semantic since Actavis has not asserted that the emulsion only contains oil and water. Even if it did, that would clearly be contradicted by the claim since it teaches that the emulsion includes, besides oil and water, a high glycol content and a biologically active agent. Thus, the only dispute is whether the oil droplets must be larger than colloidal size.

There is nothing in the '848 patent that suggests the oil droplets being dispersed in water must be of any particular size, let alone larger than colloidal size. Rather, the '848 patent discusses the oil-in-water emulsion in terms of its complete composition, its physical stability, its viscosity, and its emulsifying system used to form and stabilize the emulsion. Droplet size is not discussed and it does not appear to have any bearing on the emulsion. Moreover, Actavis concedes that the patent and its prosecution history provide no suggestion as to whether the oil droplets must be larger than colloidal size. Instead, Actavis relies on dictionary definitions to argue that its construction is the "more precise." (Def.'s Br. at 6.)

The dictionary and encyclopedic definitions provided by the parties almost uniformly define an emulsion

without requiring that the droplets being dispersed in the continuous immiscible liquid be any particular size. Actavis's strongest support is its citation to Webster, which states that "the dispersed liquid is **usually** in droplets of larger than colloidal size." WEBSTER'S NINTH NEW COLLEGIATE DICTIONARY 408 (1988) (emphasis added). Similarly, the *United States Pharmacopedia-National Formulary,* relied upon by Actavis, states, "Emulsions are two-phased systems in which one liquid is dispersed throughout another liquid **in the form of small droplets."** (Def.'s App. at 90.) (Emphasis added.) The parties agree that colloidal means over one nanometer in size, but there is no indication that "small droplets" means a droplet greater or smaller than one nanometer. Since one nanometer is one-billionth of a meter, two nanometers could still constitute a small droplet.

Requiring the oil droplets to be larger than colloidal size is a limitation that is not supported by the patent or its prosecution history, and the extrinsic evidence does not support the notion that the plain meaning of emulsion requires that the droplets dispersed into the continuous liquid be larger than colloidal size. Therefore, the Court concludes that it would be inappropriate for the construction of "oil-in-water emulsion" to contain the limitation that the oil droplets be larger than colloidal size. Accordingly, the Court construes "oil-in-water emulsion" as **a composition that includes in it oil dispersed in water.**

C. The Phrase "Stable, Topically Applicable Oil-in-Water Emulsion which is Topically Applicable to Skin"

Galderma contends that the phrase "stable, topically applicable oil-in-water emulsion which is topically applicable to skin" means "an oil-in-water emulsion that does not quickly separate and which is adapted for application to skin." (Pls.' Br. at 15.) Actavis contends it means "an oil-in-water emulsion that does not separate between the time of its manufacture and its eventual application to a patient's skin." (Def.'s Br. at 7.) The parties agree that the proper construction of this term includes a requirement that the emulsion not separate for a period of time and that it be adapted for application to the skin.

Galderma argues that Actavis's construction "is inherently flawed" because it requires the emulsion to remain stable until its application to the skin-essentially an endless shelf life. Galderma contends the claim language does not support the indefinite time component of eventual application to the skin.

Actavis points out that Claim 1 specifies that the emulsion is both stable and topically applicable. Thus, Actavis argues, "the emulsion must at least be stable until such time as the emulsion is applied to the skin ...." (Def.'s Br. at 7.) But while the Court agrees that both "stable" and "topically applicable" modify "oil-in-water emulsion," that does not imply that the claim requires the emulsion to remain stable until it is applied to the skin. Instead, it implies that there must be a stable emulsion that can be applied to skin as opposed to a stable emulsion that cannot be applied to skin.

Actavis's construction is fatally flawed. It requires the emulsion to remain stable until applied to the skin and, therefore, implies that the emulsion could potentially remain stable forever (assuming the lotion stays in its container and is never used). Galderma's construction, however, suffers from the same fatal flaw. It is equally ambiguous because it never specifies how long "quickly" is. Although Galderma's construction could imply that the emulsion will not remain stable forever, the indefiniteness of Galderma's construction that the emulsion will not separate quickly is not supported by the patent. While the patent fails to explicitly state how long the emulsion must remain stable, it does imply a more definite, though not concise, period of time in which the emulsion is to remain stable.

As indicated earlier, the Court has construed "stable" to mean an oil-in-water emulsion where the oil and water will not separate for a significant period of time (relative to the emulsion's intended use). The specification describes the invention as intended for use on the skin. Its purpose is to provide a cream that contains a high glycol content allowing maximum skin penetration of the biological agent while at the same time having an intermediate viscosity allowing for a more desirable skin feel. It is clear from the claim and the specification that the emulsion cannot separate quickly or else it would be useless as a skin cream. But it is also clear that the patent is not claiming an endless shelf life for the invention. And the Court does not believe that an ordinary person skilled in the art would read the patent as inventing a therapeutic skin cream with an endless shelf life. Undoubtedly that would have been included in the patent had there been such an invention.

The extrinsic evidence also supports the notion that the patented emulsion would have some sort of definite shelf life. The *United States Pharmacopedia-National Formulary* states that the stability "with respect to a drug dosage form, refers to the chemical and physical integrity of the dosage unit, and, when appropriate, the ability of the dosage unit to maintain protection against microbial contamination. The shelf life of the dosage form is the time lapse from initial preparation to the specified expiration date." (Def.'s App. at 86.) Even Galderma admits that its inventors would testify that the emulsion "ideally should remain stable for a period consistent with its intended use as a delivery system for the active agent." (Amend. Jt. Cl. Constr. Stmt. Ex. B. at 1.)

Therefore, the Court concludes that the construction must contain a more definite period of time than "does not quickly separate" or "does not separate between the time of its manufacture and its eventual application to ... skin." Accordingly the Court construes "stable, topically applicable oil-in-water emulsion which is topically applicable to skin" as **an oil-in-water emulsion that remains stable between its manufacture, followed by commercial distribution in due course, and the consumer's prompt and complete application to the skin as intended or directed.**

D. The Phrase "At Least One Emulsifying Agent Comprising"

Galderma contends that the phrase "at least one emulsifying agent comprising" means "an emulsifying system including one or more materials acting or co-acting to maintain an emulsion." (Pls.' Br. at 17.) Actavis contends it means "an emulsifier [that] is a surface-active substance that promotes the formation and stabilization of an emulsion." (Def.'s Br. at 9.)

Galderma argues that its construction refers to an emulsifying system that comprises of one or more materials that act together to maintain the emulsion. Galderma continues that its construction includes various materials and is not limited to surfactants. Galderma complains that Actavis's construction limits the patent to a single emulsifier and to a surface-active substance or a surfactant.

Actavis does not dispute that the patent contemplates at least one emulsifying agent and argues that the Court need only construe the term "emulsifying agent." In other words, Actavis does not dispute that the emulsion may contain more than one emulsifying agent. Actavis does, however, argue that the patent uses the term "emulsifying agent," a singular noun, and thus, "emulsifying agent" should not be construed to encompass more than one material. Actavis further counters that Galderma "has things backwards" because an emulsifying agent, it contends, "constitutes one type of surfactant ...." (Def.'s Br. at 16.)

The claim language states that the oil-in-water emulsion comprises of "at least one emulsifying agent

comprising [of] an anionic amphiphilic polymer ...." (Pl.'s App. at 8.) The claim language clearly contemplates the emulsion's containing one or more emulsifying agents. The dispute between the parties centers around whether the emulsifying agent, or each emulsifying agent if more than one are used, may contain more than one material.

The parties agree that the term "comprising" means "including the following elements but not excluding others." (Joint Cl. Const. Ex. A at 1.) That suggests the emulsifying agent includes an anionic amphiphilic polymer but does not exclude the possibility that the agent also includes other materials in its makeup. Such a construction would not be inapposite to the singular noun use of "emulsifying agent" since a single agent can include multiple materials in its makeup.

The general rule is that the same terms used throughout the patent should be construed consistently. Claim 1 uses "comprising" twice. The first time it appears, it states that the oil-in-water emulsion, which is the subject of the invention, comprises of at least one glycol, at least one emulsifying agent, and at least one biologically active agent. The parties do not dispute that the emulsion may contain other chemicals besides the glycol, emulsifying agent, and biologically active agent. In fact, Claim 2 states that the emulsion may include gelling and/or thickening agents. The second time "comprising" appears is when it is used in conjunction with the emulsifying agent.

Elsewhere in the claims, the term "comprising" is used as the parties have defined the term. In Claim 2 for example, it states that the oil-in-water emulsion as defined by Claim 1 comprises "of at least one gelling and/or thickening agent." (Pl.'s App. at 8.) And Claim 6 states that the anionic amphiphilic polymer in Claim 1 comprises of "copolymerizate of olefinically unsaturated carboxylic and C_{10}-C_{30} alkyl ester comonomers." (Id.) Clearly, if the emulsifying agent comprises of an anionic amphiphilic polymer and the anionic amphiphilic polymer may include materials in addition to copolymerizate of olefinically unsaturated carboxylic and C_{10}-C_{30} alkyl ester comonomers, then a person skilled in the art would understand that the emulsifying agent may comprise of more than one material.

Turning now to whether the term "emulsifying agent" should be limited to surfactants, the CONCISE DEFINITION OF BIOMEDICINE AND MOLECULAR BIOLOGY 411 (2nd ed.2002), defines "emulsifying agent" as a "substance capable of promoting the formation and stabilization of an emulsion." It does not limit the substance to surfactants. "Of prime importance is the capability of the emulsifying agent to promote emulsification and to maintain the stability of the emulsion for the intended shelf life of the product ." PHARMACEUTICAL DOSAGE FORMS AND DRUG DELIVERY SYSTEMS 270 (Ansel ed., 6th ed. 1995) (Pls.' App. at 292). The PHARMACEUTICAL DOSAGE FORMS AND DRUG DELIVERY SYSTEMS explains that the most prevalent theories of emulsification are surface-tension theory, oriented-wedge theory, and plastic- or interfacial-film theory. (Id.)

As the name implies, the surface-tension theory refers to surface-active agents (surfactants) that lower the interfacial tension between the two immiscible liquids. (Id.) The oriented-wedge theory involves monomolecular layers of an emulsifying agent curved around a droplet of the internal phase. (Id.) The theory is based on the "presumption that certain emulsifying agents orient themselves about and within a liquid in a manner reflective of their solubility in that particular liquid." (Id.) And "the plastic- or interfacial-film theory places the emulsifying agent at the interface between the oil and water, surrounding the droplets of the internal phase as a thin layer of film absorbed on the surface of the drops. The film prevents the contact and coalescing of the dispersed phase ..." (the oil dispersed in the water). (Id.)

As recounted earlier, the crux of the invention is the use of polymeric emulsifiers to create an emulsion that contains a high glycol content while at the same time maintaining an intermediate viscosity and a desired skin feel. The patent allows for more than one emulsifying agent and each emulsifying agent may contain more than one material in its composition. There is nothing in the patent or in the prosecution history that limits the emulsifying agent to surfactants. It may contain surfactants or it may not.

As also recounted earlier, the patent specifically refers one skilled in the art to Clymans, which more particularly describes the polymeric emulsifiers used in the invention. Clymans teaches that two characteristics of polymeric emulsifiers "are they do not form micelles and [they] do not affect the surface tension of water." (Id. at 212.) It states that "copolymerization of acrylic acid with a hydrophobic monomer ... enables the gel particles to anchor onto an oil droplet" making the oil droplet "immobilized," forming the emulsion. (Id. at 211.) A graphic depicts the gel oriented around the oil droplet. (Id.) And Clymans explains that "these emulsions are significantly different from emulsions based on traditional emulsifiers" as it has "no surface activity on the oil phase of the emulsion" and, as such, "means that novel product properties are now achievable." (Id. at 211, 213.) Among these novel properties are that the viscosity of the emulsion can be easily manipulated, the contribution of the polymer to skin sensation is low, and the polymer de-activates upon contact with the skin, increasing its water resistance. (Id. at 212-13.)

Therefore, the Court concludes that the construction of "emulsifying agent" should not be limited to surfactants. Accordingly, the Court construes "at least one emulsifying agent comprising" as meaning **an emulsifying system comprised of one or more emulsifying agents, at least one of which is comprised of one or more materials, including an anionic amphiphilic polymer.**

E. The Term "Anionic Amphiphilic Polymer"

The parties agree that "anionic" means "characterized by a negatively charged group or groups." (Joint Cl. Const. Ex. A at 1.) The parties disagree as to the construction of the terms "amphiphilic," "polymer," and, by implication, "anionic amphiphilic polymer."

1. Amphiphilic

Galderma contends "amphiphilic" means "having portions with different polarities, e.g., hydrophilic and lipophilic/hydrophobic." (Pls.' Br. at 24.) Actavis contends it means "having a polar water-soluble (or hydrophilic) group attached to a water-insoluble (or hydrophobic) hydrocarbon chain." (Def.'s Br. at 17.) The parties agree that "amphiphilic" refers to a substance that has different polarities such as hydrophilic (water-loving) and hydrophobic (water-hating). The dispute centers around Actavis's limiting of the term to a particular structure in which the hydrophobic portion is specifically a hydrocarbon chain.

Galderma argues that the term "amphiphilic" generally refers to a substance that has portions with different polarities, in this case, a hydrophilic (water-loving) and lipophilic (oil-loving)/hydrophobic (water-hating). Galderma contends that its broader definition is consistent with the examples of anionic amphiphilic polymers contained in the patent and in Clymans.

But Actavis points out that the specification describes polymeric emulsifiers composed of two types of monomers: carboxylic acids (which are hydrophilic) and C_{10}-C_{30} acrylic esters (which are hydrophobic). The acrylic esters are composed of hydrocarbons. While Galderma presents expert testimony that other polymeric emulsifiers exist without having a hydrocarbon chain, the example Galderma's expert provides,

Actavis illustrates, are nonionic; Galderma's patent only covers anionic amphiphilic polymers. This is important since *anionic modifies amphiphilic polymer just as amphiphilic modifies polymer*.

The Federal Circuit has repeatedly warned against confining claims to embodiments described in the specification. *See* Phillips v. AWH Corp., 415 F.3d 1303, 1323 (Fed.Cir.2005).

To avoid importing limitations from the specification into the claims, it is important to keep in mind that the purposes of the specification are to teach and enable those of skill in the art to make and use the invention and to provide a best mode for doing so. One of the best ways to teach a person of ordinary skill in the art how to make and use the invention is to provide an example of how to practice the invention in a particular case. Much of the time, upon reading the specification in that context, it will become clear whether the patentee is setting out specific examples of the invention to accomplish those goals, or whether the patentee instead intends for the claims and the embodiments in the specification to be strictly coextensive. The manner in which the patentee uses a term within the specification and claims usually will make the distinction apparent.

(*Id*.) (internal citations omitted). In this circumstance, however, the specification states that "a stable emulsion is provided ... by selecting ... at least one polymeric emulsifier." (Pls.' App. at 5.) The specification teaches that the polymeric emulsifiers are particularly described in Clymans and goes on to teach that the polymeric emulsifiers "are, in particular, anionic amphiphilic polymers more specifically those comprising at least one hydrophilic recurring structural unit of the unsaturated olefin carboxylic acid type, and at least one hydrophobic recurring structural unit of the C_{10}-C_{30} alkyl ester type." (*Id*.) This language tells a person of ordinary skill in the art that the claims and the embodiments in the specification are coextensive.

Both sides are able to cite to extrinsic evidence, such as dictionaries, that support their respective constructions. Since the specification and its embodiments refer to anionic amphiphilic polymers that contain a hydrocarbon chain in a way that a person ordinarily skilled in the art would understand to be coextensive with the patent's claims, and because the only examples of amphiphilic polymers supplied by Galderma are nonionic, the Court concludes that amphiphilic should be defined with the hydrocarbon chain limitation. Accordingly, the Court construes "amphiphilic" as **having a hydrophilic (water-loving) group attached to a lipophilic (oil-loving)/hydrophobic (water-hating) hydrocarbon chain .**

2. Polymer

Galderma contends "polymer" means a "substance composed of molecules having recurring structural units." (Pls.' Br. at 26.) Actavis contends it means a "substance composed of at least one macromolecule, i.e., a molecule of high relative molecular mass, the structure of which essentially comprises the multiple repetition of units derived, actually or conceptually, from molecules of low relative molecular mass (monomers)." (Def.'s Br. at 19.) The parties agree that a polymer is a substance composed of molecules that include recurring units or multiple repetition of units. Galderma contends that its construction represents the ordinary meaning of polymer while Actavis's construction incorporates additional limitations, such as size or mass, that is not supported by polymer's ordinary meaning, the patent, or the intrinsic evidence.

As both parties note, the patent does not define polymer. The dictionary definitions provided by Galderma define a polymer as a "high molecular weight substance" and a substance "made of giant molecules formed by the union of simple molecules (monomers)." CONCISE DICTIONARY OF BIOMEDICINE AND MOLECULAR BIOLOGY 880 (Pei Show Juo ed., 2nd ed.2002); MCGRAW-HILL DICTIONARY OF

SCIENTIFIC AND TECHNICAL TERMS 1635 (6th ed.2003); (Pls.' App. at 223, 248). Terms are given their ordinary meaning unless the patent explicitly states otherwise.

Galderma admits that the polymeric emulsifiers identified in its specification are very large compounds with many repeating monomeric units and that the polymers are large enough to be cross-linked. As discussed above with amphiphilic, a person of ordinary skill in the art would understand that the claims, the embodiments in the specification, and the specification are coextensive. The specification teaches that anionic amphiphilic polymers crosslinked with monomers are preferred. "Among said crosslinked polymers ..., those marketed ... under the trademarks PEMULEN TR1, PEMULEN TR2, CARBOPOL 1342, and CARBOPOL 1382 are most particularly preferred according to the present invention." (Pls.' App. at 5.) Accordingly, the Court construes "polymer" as **a substance with a high relative molecular mass and/or weight and having recurring molecular structure.**

3. Anionic Amphiphilic Polymer

Galderma contends that the term "anionic amphiphilic polymer" means "a polymer including both a negatively charged group or groups and polar and non-polar portions (e.g., hydrophilic and lipophilic/hydrophobic)." (Pls.' Br. at 27.) Actavis contends the term means "a polymer having a polar water-soluble (or hydrophilic) negatively charged group attached to a water-insoluble (or hydrophobic) hydrocarbon chain." (Def.'s Br. at 22.) Based on the parties agreed construction of "anionic" and on the Court's construction of "amphiphilic" and "polymer," the Court construes "anionic amphiphilic polymer" as **a polymer containing a negatively charged group or groups and having a water-soluble or hydrophilic (water-loving) portion attached to a water-insoluble lipophilic (oil-loving)/hydrophobic (water-hating) hydrocarbon chain .**

F. The Phrase: "Wherein Said Anionic Amphiphilic Polymer is Present in an Amount which in the Absence of Another Emulsifying Agent Results in an Emulsion"

Galderma contends that the term "wherein said anionic amphiphilic polymer is present in an amount which in the absence of another emulsifying agent results in an emulsion" means that "the 'at least one emulsifying agent' recited in clause (b) is present in an amount that, even if any emulsifier(s) within the composition other than the recited 'at least one emulsifying agent' are excluded, results in an emulsion." (Pls.' Br. at 29.) Actavis contends the term means "the emulsion includes a sufficient amount of anionic amphiphilic polymers to produce the recited emulsion and that the emulsion includes only anionic amphiphilic polymers as emulsifying agents and excludes emulsions that contain emulsifying agents other than or in addition to anionic amphiphilic polymers." (Joint Cl. Const. Ex. B at 17-18.) FN1 The dispute here is whether the claim allows for other emulsifiers that are not anionic amphiphilic polymers.

FN1. Actavis changed its proposed construction in its brief without any notice to Galderma and after the parties had exchanged proposed constructions and after the parties had filed their Joint Claim Construction Statement. The Court sustains Galderma's objection to Actavis's new proposed claim construction and its seeking to have an additional term construed: "another emulsifying agent." The Court notes, however, that its construction in this section necessarily construes the term "another emulsifying agent" as including emulsifying agents that do not contain an anionic amphiphilic polymer.

Claim 1 states that the invention is a stable oil-in-water emulsion that can be applied to the skin, is of intermediate viscosity, and, at a minimum, is comprised of at least one glycol that is 30% to 50% of the

total weight of the emulsion, at least one anionic amphiphilic polymer emulsifying agent, and at least one biologically active agent. Claim 1 further provides that the anionic amphiphilic polymer must be present in a sufficient amount that, in the absence of any other emulsifier, it will form and stabilize the emulsion with an intermediate viscosity. Thus, under the plain language of Claim 1, the emulsion must include an emulsifier that contains a sufficient amount of an anionic amphiphilic polymer to form and stabilize the emulsion, but that the emulsion may contain other emulsifiers.

The specification illustrates that the patent does not exclude the use of other emulsifiers that are not anionic amphiphilic polymers. According to the patent, "the compositions ... may comprise from 0% to 3% by weight, preferably from 0% to 2% by weight, relative to the total weight of the composition, of at least one coemulsifier which is advantageously selected from among esters of saturated and unsaturated fatty acids, which are natural or synthetic, in particular oleic acid or (iso)stearic acid ...." (Pls.' App. at 7.) These coemulsifiers are optional, but may be used in the invention and they are not or do not contain anionic amphiphilic polymers. Moreover the patent includes preferred embodiments as examples one and two that include PEG-6 isostearate as 2% of the composition and which, by itself, is not an anionic amphiphilic polymer.

Actavis does not challenge the claim language or the specification, but instead looks to the prosecution history and relies on the doctrine of prosecution disclaimer to argue that Galderma limited its invention during the prosecution of its patent to the use of only emulsifiers that are anionic amphiphilic polymers. The doctrine of prosecution disclaimer is well established and prevents a patentee from recapturing through claim interpretation specific meanings disclaimed during the prosecution of the patent. *See* Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1223 (Fed.Cir.2003). The prosecution history must show that the patentee "clearly and unambiguously" disclaimed or disavowed the proposed interpretation during the patent's prosecution to obtain claim allowance. Middleton, Inc. v. 3M Co., 311 F.3d 1384, 1388 (Fed.Cir.2002). "Indeed, by distinguishing the claimed invention over the prior art, an applicant is indicating what the claims do not cover." Spectrum Int'l v. Sterilite Corp., 164 F.3d 1372, 1378-79 (Fed.Cir.1998). "As a basic principle of claim interpretation, prosecution disclaimer promotes the public notice function of the intrinsic evidence and protects the public's reliance on definitive statements made during prosecution." Omega Eng'g, Inc., 334 F.3d at 1324.

After reviewing the prosecution history, the Court concludes that although Galderma limited its patent by distinguishing it from a prior art (a prior patent), it did not exclude the use of other emulsifiers including the use of emulsifiers that are not anionic amphiphilic polymers. During the patent's prosecution, the examiner rejected earlier versions of Claim 1 as "obvious" under a prior patent (hereinafter referred to as "the Robert patent"). The Robert patent discloses an oil-in-water emulsion using a mixture of emulsifiers. The preferred emulsifier contains a fatty-acid ester blend based on a mixture of sorbitan or sorbitol fatty-acid ester and sucrose fatty-acid ester. This emulsifier is available under the trade name Arlatone 2121. The Robert patent teaches that the oil-in-water emulsion may also include, mixed with the preferred emulsifier, emulsifiers containing polymers of acrylic acid having amphipathic properties; in other words, amphiphilic polymers. These polymeric emulsifiers are available under the trade names Carbopol 1382, Carbopol 1342, and Pemulen TR-1.

Galderma's invention also uses polymeric emulsifiers, more specifically, anionic amphiphilic polymer emulsifiers. Galderma sought to distinguish its patent from the Robert patent by amending Claim 1 to read "at least one emulsifying agent **consisting essentially of an anionic amphiphilic polymer.**" Pl.'s App. at 82-83.) Actavis admits that use of the phrase "consisting essentially of" in a patent claim "means that the

claim covers products containing the specified ingredients as well as products containing unspecified ingredients provided that the unspecified ingredients do not materially affect the basic and novel characteristics of the claimed invention." (Def.'s Br. at 27.)

Galderma explained to the examiner that "based on the amendment ..., all of the claims now require that the emulsifying agent consist essentially of an anionic amphiphilic polymer. Such a composition is not taught or suggested by the [Robert patent]." (Pl.'s App. at 84.) Galderma went on to explain that the Robert patent is distinguished from its claim because the Robert patent "necessarily comprises of a mixture of a sorbitan fatty-acid ester and a sucrose fatty-acid ester" where its claim contains "an emulsifying agent [that] consists essentially of an anionic amphiphilic polymer." (*Id*. at 86.) And Galderma further argued that the Robert patent "does not anticipate the claimed compositions ... based on the difference in the emulsifying agent" because "there is no suggestion in the Robert [patent] ... to substitute the emulsifying agent disclosed therein, which comprises [of] a mixture of a sorbitan fatty-acid ester and a sucrose fatty-acid ester, e.g., Arlatone 2121, for an emulsifying agent as in the present invention, which instead comprises a single component, i.e. an anionic amphiphilic polymer." (*Id*. at 87, 89.)

When the examiner again rejected Galderma's claim application, its agents met with the examiner and, in the summary of the meeting, the examiner wrote, "Claim permits more than 1 emulsifier; 'consisting of' still would permit >1 emulsifier. Claims limited to 1 or more anionic amphiphilic polymers, however, would be reconsidered in view of art ...." (*Id*. at 118.) Translated, the examiner's notes state that Galderma's proposed claim permits the use of more than one type emulsifier in the emulsion, and that the examiner would reconsider his rejection if Galderma proposed an amendment that limited its claim to the use of one or more emulsifying agents all of which contain anionic amphiphilic polymers.

Galderma rejected that offer and, instead, proposed an amendment that ultimately was approved as Claim 1 in this litigation. Galderma deleted the "consisting essentially of" and replaced it with "comprising," and added "wherein said anionic amphiphilic polymer is present in an amount which in the absence of another emulsifying agent results in an emulsion having an intermediate viscosity." (*Id*. at 120-21.) Galderma submitted the amendment "to expedite allowance," and explained that "the prior art does not suggest that an amphiphilic anionic polymer could be used as an emulsifier in a composition as claimed ...." (*Id*.) Moreover, the amended language did not limit the claim to only emulsifiers containing anionic amphiphilic polymers.

Based on this prosecution history, the Court concludes that Galderma did not disclaim the use of other emulsifying agents that are not anionic amphiphilic polymers but, rather, it limited the use of those other emulsifying agents such that if used, they would not materially affect or alter the emulsion. This reading of the prosecution history is supported by the claim language, the specification, and the embodiments since the use of other emulsifying agents such as PEG-6 is restricted to no more than 2% to 3% of the total weight of the emulsion.

Accordingly, the Court construes "Wherein said anionic amphiphilic polymer is present in an amount which in the absence of another emulsifying agent results in an emulsion" to mean that **the emulsion must contain at least one emulsifying agent that contains an anionic amphiphilic polymer in an amount sufficient to form and stabilize the emulsion to the exclusion of any other emulsifying agent and that, if the emulsion should contain an additional emulsifying agent that does not contain an anionic amphiphilic polymer, it may only be present in an amount that will not materially affect or alter the emulsion.**

IV. Conclusion

For the reasons stated above, the jury shall be instructed in accordance with the Court's construction of the disputed claim terms in the '848 patent. FN2

FN2. Actavis has also requested that the Court construe the term "polymeric emulsifier." This term appears in Claims 5 and is relevant to Claims 7-10. It does not appear in Claim 1, which is the subject of this litigation. Galderma contends that the term "polymeric emulsion" used in Claim 5 and the term "said emulsion" used in Claims 9 and 10 are mistakes and should be corrected. Galderma states, however, that it "does not intend to assert infringement of Claims 5 and 7-10" and, thus, "the Court need not correct those claims or construe" them. (Pl.'s Br. at 9, n. 40.) Galderma informs the Court that it "expressly reserves the right to later correct the 848 patent, including before the PTO." (Id.) Since Galderma has asserted that it will not seek an infringement claim against Actavis for infringement of Claims 5 and 7 through 10 and since Actavis has not persuaded the Court that construction of "polymeric emulsifier" is necessary to the determination of infringement of Claim 1, the Court will not construe that term.

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