

United States District Court,  
D. Delaware.

**LABORATORY SKIN CARE, INC., and Zahra Mansouri,**  
Plaintiffs.

v.  
**LIMITED BRANDS, INC. and Bath and Body Works, LLC,**  
Defendants.

Civil Action No. 06-601-JJF

**Feb. 11, 2009.**

**Background:** Owner filed action against competitor alleging infringement of patent pertaining to formulations for cleansing and moisturizing the skin. Court set forth to construe disputed terms.

**Holdings:** The District Court, Farnan, J., held that:

- (1) claims did not require absorption enhancer;
- (2) use of definition from online dictionary in patent claim construction was not warranted;
- (3) claim term in specification that merely explained that concentration of antimicrobial agent normally was within certain range did not have to be limited to that numerical range;
- (4) phrase, "physiologically and cosmeceutically acceptable vehicle," meant solvent, diluent, or dispersant for constituents of composition that allowed for uniform application of constituents to surface of skin at appropriate dilution; and
- (5) phrases, "effective antimicrobial lotion," "antimicrobial lotion," and "antimicrobial lotion composition," meant lotion that effectively inhibited growth of, or killed, microorganisms present on skin.

Ordered accordingly.

6,579,516. Construed.

E. Anthony Figg, Esquire; Sharon L. Davis, Esquire and C. Nichole Gifford, Esquire of Rothwell, Figg, Ernst & Manbeck PC, Washington, D.C., Josy W. Ingersoll, Esquire; Melanie K. Sharp, Esquire and Karen E. Keller, Esquire of Young Conaway Stargatt & Taylor, LLP, Wilmington, DE, for Plaintiffs Laboratory Skin Care, Inc. and Zahra Mansouri.

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***MEMORANDUM OPINION***

**FARNAN, District Judge.**

This is a patent infringement case brought by Laboratory Skin Care, LLC and Zahra Mansouri against Limited Brands, Inc. and Bath and Body Works, LLC, alleging infringement of United States Patent Nos. 6,579,516 ("the '516 patent"), which pertains to formulations for cleansing and moisturizing the skin. ( *See*, e.g., '516 patent at 1:27-32.) The parties briefed their respective positions on claim construction, and the Court conducted a Markman hearing on the disputed terms. This Memorandum Opinion provides constructions of the disputed terms.

## **BACKGROUND**

The '516 patent relates to skin care products that moisturize the skin, prevent excess drying, and prevent against infection by pathogenic microorganisms. ('516 patent at 1:18-26.) This is achieved through skin care compositions that include, in various amounts, ingredients such as an antimicrobial component, an absorption enhancer, an emollient, a sun blocking agent, an emulsifier, a surfactant, vitamins, and natural scents. ( *See* '516 patent at 4:23-10:18.) These components may be delivered to the skin by lotion bases comprising vehicles such as water or canola oil. ( *Id.* at 6:18-7:2.)

## **DISCUSSION**

### **I. The Legal Principles of Claim Construction**

[1] [2] [3] Claim construction is a question of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977-78 (Fed.Cir.1995), *aff'd*, 517 U.S. 370, 388-90, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). When construing the claims of a patent, a court considers the literal language of the claim, the patent specification and the prosecution history. *Markman*, 52 F.3d at 979. Of these sources, the specification is "always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips v. AWH Corporation*, 415 F.3d 1303, 1312-17 (Fed.Cir.2005) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996)). However, "[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed.Cir.2004) (quoting *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed.Cir.2002)).

[4] A court may consider extrinsic evidence, including expert and inventor testimony, dictionaries, and learned treatises, in order to assist it in understanding the underlying technology, the meaning of terms to one skilled in the art and how the invention works. *Phillips*, 415 F.3d at 1318-19; *Markman*, 52 F.3d at 979-80. However, extrinsic evidence is considered less reliable and less useful in claim construction than the patent and its prosecution history. *Phillips*, 415 F.3d at 1318-19 (discussing "flaws" inherent in extrinsic evidence and noting that extrinsic evidence "is unlikely to result in a reliable interpretation of a patent claim scope unless considered in the context of intrinsic evidence").

[5] [6] In addition to these fundamental claim construction principles, a court should also interpret the language in a claim by applying the ordinary and accustomed meaning of the words in the claim. *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 759 (Fed.Cir.1984). If the patent inventor clearly supplies a different meaning, however, then the claim should be interpreted according to the meaning supplied by the inventor. *Markman*, 52 F.3d at 980 (noting that patentee is free to be his own lexicographer, but emphasizing that any special definitions given to words must be clearly set forth in patent). If possible, claims should be construed to uphold validity. *In re Yamamoto*, 740 F.2d 1569, 1571 (Fed.Cir.1984).

### **II. The Meaning of the Disputed Terms**

Plaintiffs assert that Defendants infringe claims 2, 4-7, 13, and 15-18 of the '516 patent, all of which are dependent claims. However, all of the six disputed claim terms appear explicitly only in the corresponding

independent claim. An example of such an independent claim appears as follows with the disputed claim terms underlined:

1. A moisturizing composition for applying to and leaving on human skin, the composition in the form of an antimicrobial lotion composition comprising:

- (a) an amount of triclosan effective to kill microorganisms present on the skin;
- (b) an emollient present in an amount effective to moisturize the skin; and
- (c) a lotion base comprised of a physiologically and cosmeceutically acceptable vehicle

wherein said components of said lotion are present in amounts sufficient to provide an effective antimicrobial lotion.

(516 patent at 14:9-21.) All of the asserted claims include each of the six disputed claim terms through dependency.

The primary dispute among the parties is whether the claims should be understood to require an "absorption enhancer," which is a component that functions to "promote the uptake of the product by the skin." (516 patent at 4:66-5:2.) Specifically, Defendants contend that the claim terms "moisturizing composition" and "antimicrobial lotion" should both be construed to include an "absorption enhancer." According to Defendants, "the absorption enhancer, the addition of ceramic hydroxyapatite to an off-the-shelf product is what [the] invention is all about" and "the wonder drug of [the] whole invention." (D.I. 192 at 65:15-22, 68:19-22.) This is apparent from the specification, Defendants contend, because every example set forth therein includes an "absorption enhancer" and because the need for an "absorption enhancer" is "echoed from the Abstract all the way through to Example 3 of the Detailed Description of the Invention." (D.I. 145 at 15; *see also* D.I. 192 at 49:17-21.) Plaintiffs respond that the claims do not include an explicit "absorption enhancer" limitation and that an "absorption enhancer" is merely one feature of the invention that need not be included in each and every claim. (D.I. 175 at 5, 9.)

An additional core dispute among the parties is whether the claims should be construed to require a concentration of antimicrobial agent within a particular range. Based on a passage in the specification describing the "normal" concentrations of antimicrobial agent, Defendants contend that the claim terms "amount of triclosan effective to kill microorganisms present on the skin" and "antimicrobial lotion" should both be construed to require the presence of antimicrobial agent in a concentration of 0.001-5%. (D.I. 175 at 18.) Plaintiffs respond that the relevant claim limitations are common, well accepted "functional limitations" and that in these circumstances it would be inappropriate to limit the claims to a particular numerical range mentioned in the specification. ( *See* D.I. 175 at 13.)

With a few exceptions, the claim construction disputes among the parties boil down to whether a limitation should be imported into the claims from either the specification or extrinsic evidence. The party opposing such importation has generally proposed a competing construction that merely paraphrases the claim language and offers no additional insight into the meaning of the disputed term to one of skill in the art. As set forth below, in these circumstances, the Court, after resolving the actual dispute among the parties, has generally concluded that the disputed claim terms require no additional construction.

For the reasons that follow, the Court construes the disputed terms as follows:

#### **A. "Moisturizing Composition"**

Plaintiffs' Construction	Defendants' Construction
A composition that adds moisture to the skin.	A composition for use on human skin that contains an antimicrobial agent, an emollient and an absorption enhancer.

[7] Defendants contend that the term "moisturizing composition" must include (1) an antimicrobial agent, (2) an emollient, and (3) an absorption enhancer. Though Defendants' proposed construction includes three components, Defendants place the greatest emphasis on the absorption enhancer, arguing that "[t]he need for an absorption enhancer—Ms. Mansouri's 'secret ingredient'—is made particularly clear" in the specification. (D.I. 145 at 15.) Whether the term "moisturizing composition" requires the presence of an absorption enhancer appears to be the essence of the parties' dispute over this claim term.

In support of their proposed construction, Defendants point to passages in the specification that state such things as "[c]ompositions for cleaning and moisturizing the skin according to the invention comprise an antimicrobial agent, an emollient, and an absorption enhancer ...." (516 patent at 4:19-22.) As another example, Defendants note that the specification states that "[i]n particular, skin care products of the instant invention comprise an absorption enhancing material." (*Id.* at 2:20-21; *see also* D.I. 145 at 15-16 (Defendants point to other portions of the specification that refer to an "absorption enhancer").) In relying on such passages in the specification, Defendants place particular weight on the presence of the word "comprising." For instance, at the Markman hearing, Defendants argued as follows:

We also want to direct the Court's attention to their use of the term "comprise." We know you've come across that term many times, Your Honor. "Comprise" is a term of art in patent law.

And underneath you see we've provided a definition from a Federal Circuit case. "Comprising" is a term of art used in claim language, which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claims.

So our position, Your Honor, is if you're going to use "comprise," either in the claims or elsewhere in the spec, you are alerting a person reading your patent, one of skill in the art, that the list of components after the term comprise are mandatory, but does not exclude the addition of further components.

(D.I. 191 48:16-49:10; *see also* D.I. 174 at 7 (in referring to the specification, Defendants argue that "the term 'comprise' means the listed ingredients are required").) According to Defendants, any definition of "moisturizing composition" that fails to include the three components listed in their proposed construction has the additional shortcoming of excluding the preferred embodiment from the scope of the claims. (*See* D.I. 145 at 16-17.)

In response, Plaintiffs argue first and foremost that the claims simply do not include an explicit "absorption enhancer" limitation. Defendants' proposed construction, Plaintiffs contend, is nothing more than an improper attempt to import a limitation from the specification into the claims. (*See* D.I. 175 at 4-5.) Though rapid penetration of the skin through the use of an absorption enhancer is one feature of the invention, Plaintiffs contend that there are other benefits of the invention that are independent of an absorption enhancer, such as providing reduced risk of skin infections. (*See id.* at 9.) Plaintiffs urge that the claims need not contain each and every advantage set forth in the specification. Plaintiffs further note that the specification discloses an embodiment that merely requires an absorption enhancer concentration of "up to 5% w/w." Plaintiffs contend that by failing to set a floor on the absorption enhancer concentration, this example allows for an absorption enhancer concentration of 0%. (*Id.* at 10.) With the patent disclosing such an embodiment, Plaintiffs maintain that it makes little sense to construe the claims to always require an absorption enhancer. (*Id.* at 10.) With respect to the prosecution history, Plaintiffs note that the application that issued as the '516 patent originally contained claims that specifically required an absorption enhancer.

All such claims, however, were removed in favor of claims that lacked an "absorption enhancer" limitation. ( *Id.* at 10-11.) Having conscientiously removed a particular limitation from the claims, Plaintiffs contend that the claims should not now be construed to require that particular limitation.

The Court agrees with Plaintiffs that the term "moisturizing composition" should not be construed to require, among other things, an absorption enhancer. Instructive is the Federal Circuit's decision in *Golight, Inc. v. Wal-Mart Stores, Inc.*, 355 F.3d 1327 (Fed.Cir.2004). In *Golight*, the patent at issue was directed to a wireless, remote-controlled, portable search light. *Golight*, 355 F.3d at 1329. The defendant in *Golight* argued that the asserted claims required the claimed search light to be capable of rotation through 360 degrees. In support of this position, the defendant argued that the specification disclosed nothing other than search lights having this feature. *Id.* at 1331. The *Golight* defendant placed particular reliance on a passage in the specification stating that "[a] searchlight apparatus in accordance with the present invention includes a lamp unit mounted in a housing which has a motor-driven vertical drive mechanism for tilting the lamp unit in a vertical direction and a motor-driven horizontal drive mechanism for rotating the lamp unit in a horizontal direction through at least 360 degrees." *Id.* In holding that the claims did not require 360 degree rotation, the Federal Circuit explained that the specification did not contain a clear definition or disavowal of claim scope and that, although rotation through 360 degrees was a feature of the invention, it was only one such feature. There was no requirement, the Federal Circuit explained, that the patentee include every such feature of the invention in each claim. *Id.* at 1331.

Here, as in *Golight*, the Defendants, in an attempt to limit the claims, point to passages from the specification characterizing features of the invention. In particular, the Defendants draw their proposed construction for "moisturizing composition" from a portion of the specification stating that "[c]ompositions for cleansing and moisturizing the skin according to the invention comprise an antimicrobial agent, an emollient and an absorption enhancer in combinations as described below." ('516 patent at 4:19-22; D.I. 145 at 15.) Like the passage in *Golight*, this passage characterizes the "invention" as including a set of particular features. Furthermore, like the defendant in *Golight*, the Defendants in this case further argue that "every example enumerated in the specification (including the preferred embodiment) contains an absorption enhancer." (D.I. 145 at 2.)

However, just as in *Golight*, these facts do not compel the conclusion that the claims require an absorption enhancer. Indeed, the Court sees nothing in the specification constituting a clear disavowal of claim scope. In addition, like the specification in *Golight*, the specification of the '516 patent sets forth multiple features of the invention. Specifically, in addition to rapid skin penetration through the use of an absorption enhancer, the '516 patent describes the prevention of skin infections, the prevention of excess drying of the skin, and compatibility with latex gloves. ('516 patent at 1:21-26, 3:1-18.) Though some of these benefits may be heightened through the use of an absorption enhancer, it is clear from the specification that an absorption enhancer is not required to achieve them. For instance, the specification describes the absorption enhancer as a separate and distinct component from both the "Antimicrobial Component," which prevents infections, and the "Emollient," which moisturizes the skin. ( *See id.* 4:23-45 (specification's description of the "Antimicrobial Component"); *id.* at 4:46-6:14 (specification's description of the "Absorption Carrier"); 7:16-8:3 (specification's description of the "Emollient")). As the Federal Circuit explained in *Golight*, the patentee need not claim each of these components in every claim.

Notably, the claims themselves suggest an intent to claim such features in variable combinations. For instance, Claim 1 of the '516 patent, though lacking an "absorption enhancer" limitation, includes distinct limitations directed to "(a) an amount of triclosan effective to kill microorganisms" (i.e., an antimicrobial component) and "(b) an emollient." Construing the term "moisturizing composition," which appears in the preamble, to include these components would, as Plaintiffs note, render these explicitly distinct claim limitations vestigial. (D.I. 175 at 6.) The Court will not adopt such a construction.

The prosecution history provides further support for Plaintiffs' proposed construction. As Plaintiffs note, during prosecution of the '516 patent, the patentee intentionally replaced all claims that included an explicit absorption enhancer limitation with claims that lacked such a limitation. ( *Compare* D.I. 175, Exh. 2 at 30 with '516 patent at Claim 1.) In the Court's view, this is a "strong indication" that the claims as issued do not require an absorption enhancer. *See* Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 909 (Fed.Cir.2004) ("The omission of reference to a pressure jacket in many of the claims of the applications that matured into the '669 and '261 patents is a strong indication that the applicants intended those claims to reach injectors that did not use pressure jackets.").

The portions of the specification relied upon by Defendants provide an insufficient basis upon which to limit the scope of the claims. It is true that the specification is littered with statements characterizing the "invention" as including an absorption enhancer. The trouble with these statements is that they also characterize the "invention" as including a number of other components, none of which any party could reasonably contend is a requirement of the claims. For instance, in support of their position that the claims require an "absorption enhancer," Defendants point to the following passage:

In particular, the invention is concerned with formulations for cleansing and moisturizing the skin which are antimicrobial, alcohol-free, contain no animal-or petroleum-based products, have a water base, and comprise an absorption enhancer to promote rapid uptake of the formulation by the skin.

('516 patent at 1:27-32.) Notably, in their briefing, Defendants use an ellipsis to omit the portion of this passage referring to the absence of alcohol and animal-or petroleum-based products and the presence of a water base. ( *See* D.I. 174 at 7.) Thus, though Defendants contend that this passage supports the notion that the claims require an absorption enhancer, they apparently do not contend that the other things mentioned in this passage are also required by the claims.

A similar situation exists with regard to passages in the specification that use the word "comprising," which, as explained above, is a word that Defendants contend means that "the listed ingredients are required," even when the word appears only in the specification. FN1 For instance, the specification unambiguously states that "[t]he composition according to the invention also comprises a cosmetically and physiologically acceptable preparation obtained from the Aloe vera plant." (' 516 patent at 9:20-22.) Likewise, the specification explains that "[t]he composition according to the invention also comprises one or more natural scents" and that "[t]he compositions according to the invention also comprise one or more natural herbal extracts." ( *Id.* at 9:34-35, 9:46-47.) Yet, in spite of the word "comprise," no party contends that the claims require aloe vera, natural scents, and/or herbal extracts. Interestingly, with regard to an "emollient," a component that Defendants contend *is* required by the claims, the specification explains that "[c]ompositions under the invention may *optionally* comprise one or more emollients ...." (' 516 patent at 7:18-19 (emphasis added).) Thus, in the Court's view, the specification-including its passages that use the word "comprise"- simply does not provide a clear and consistent basis upon which to limit the claims.

FN1. The Court is aware of no cases, and Defendants do not cite any, standing for the proposition that the term "comprising," when used in the specification, means "the listed ingredients are required." (D.I. 174 at 7.)

As to Defendants' argument that Plaintiffs' construction would exclude the preferred embodiment, the Court finds that Defendants are misapplying the doctrine that claims should rarely be construed to exclude the preferred embodiment. Indeed, Defendants' proposed construction, if adopted, would have the effect of *limiting* the claims to the preferred embodiment, which, for the reasons set forth above, is not appropriate in this case.

Having concluded that the claims should not be limited as Defendants contend, the Court further concludes that this term requires no additional construction. In the Court's view, Plaintiffs' proposed construction adds no additional insight as to the meaning of this claim term to one of skill in the art. FN2

FN2. During the claim construction process, in particular at the Markman hearing, Defendants further argued that the claims would be invalid as anticipated and for lack of enablement unless construed to require an "absorption enhancer." ( *See, e.g.*, D.I. 145 at 16 n. 7; D.I. 192 at 46:20-47:1.) In response, Plaintiffs explained that they "appreciate the Defendants' wanting to construe [their] claims to preserve their validity, but with all due respect, [they'll] take care of [their] own validity arguments." (D.I. 192 at 70:22-71:1.) On the current record, the Court is unable to conclude that failing to construe the claims to require an "absorption enhancer" would clearly lead to the invalidity of the claims. Nevertheless, to be clear, the Court understands Plaintiffs as having waived any argument that the claims should be construed to require an "absorption enhancer."

**B. "Skin "**

Plaintiffs' Construction	Defendants' Construction
Normal, healthy skin.	The external limiting tissue layer of an animal body; especially: the 2-layered covering of a vertebrate body consisting of an outer epidermis and an inner dermis.

[8] Defendants' contend that the term "skin" is used throughout the patent "as it is generally understood" and that it should thus be construed according to a definition from the Merriam-Webster Online Dictionary. ( *See* D.I. 174 at 8.) This definition requires "skin" to be, among other things, the outer two-layer tissue of a "vertebrate body." The Court will not adopt this definition. For one thing, there is no indication that the Merriam-Webster Online Dictionary is a resource that someone of skill in the relevant art would rely upon. More importantly, the Merriam-Webster definition does not appear well supported by the specification. Indeed, in describing "skin," the specification explains that "three major tissue layers are identified," while the Merriam-Webster definition describes "skin" as only a "2-layered covering." ('516 patent at 3:51-57.) In these circumstances, the Court concludes that it would be inappropriate to rely on the Merriam-Webster Online Dictionary. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1322-1323 (Fed.Cir.2005) (quoting *Vitronics Corp. v. Conceptronc, Inc.*, 90 F.3d 1576, 1585 (Fed.Cir.1996)) (explaining that judges may consult dictionaries "so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents").

However, Defendants do not appear to contend that the limitations present in the Merriam-Webster definition are critical. ( *See* D.I. 192 at 59:4-60:5.) Rather, Defendants appear to take issue only with Plaintiffs' position that the term "skin" be limited to "normal, healthy" skin. Indeed, on reviewing the parties' briefing, the Court concludes that this is the only meaningful dispute regarding the claim term "skin." To resolve this dispute, the Court has reviewed the intrinsic evidence. Having done so, the Court concludes that the claims should not be limited to "normal, healthy" skin. As Defendants note, the specification explains that "the instant skin care composition not only helps to maintain treated skin in a healthy condition, but also promotes healing of dry, cracked, sore, or damaged skin." ('516 patent at 10:5-9.) Likewise, the specification explains that "a skin moisturizing composition, under the invention, may be applied specifically or preferentially to the point or area of a minor cut, crack, or abrasion of the skin." ( *Id.* at 3:26-31.) Describing the use of the invention with cut, cracked, abraded, dry, sore, and/or damaged skin, the Court finds that the specification confirms that the claims are not limited to "normal, healthy" skin.

Having resolved the essential dispute among the parties, the Court sees no reason to offer any additional construction for the term "skin."

### C. "Applying To And Leaving On"

Plaintiffs' Construction	Defendants' Construction
Placing in contact with or spreading on and allowing to remain on.	No construction necessary.

The parties do not appear to have an actual dispute over the meaning of this term. Both parties agree that the term should simply receive its ordinary and customary meaning. ( *See* D.I. 192 at 23:9-20; D.I. 174 at 8.) To the extent Plaintiffs proposed a construction for this term, it appears to have been in response to some early uncertainty over whether Defendants would attach some special meaning to the term. Indeed, after proposing a construction for this term in their Opening Claim Construction Brief, Plaintiffs devoted no attention to this term in their Answering Claim Construction Brief (D.I. 175) and elected not to discuss it during the Markman hearing, explaining that they "didn't think there is a dispute." ( *See* D.I. 192 at 23:9-20.) Accordingly, the Court concludes that no construction is necessary for this claim term.

### D. "Amount of Triclosan Effective To Kill Microorganisms Present On The Skin"

Plaintiffs' Construction	Defendants' Construction
An amount of triclosan that has the desired effect of killing microorganisms on the skin.	From 0.001%-5% by weight of triclosan.

[9] The dispute among the parties is whether this term should be limited to a specific numerical range mentioned in the specification. Defendants contend that the claims should be so limited because the specification explains that "[t]he antimicrobial chemical agent is normally present in an amount of from 0.001-5% by weight, preferably from 0.05-2% by weight, and more preferably from 0.1-1% by weight." ('516 patent at 4:42-45.) Plaintiffs respond that this passage only refers to the percentage by weight of "antibacterial agent in general" and does not specifically set forth particular ranges of triclosan concentrations. (D.I. 144 at 16; D.I. 175 at 13.) Defendants, however, note that no other antimicrobial component other than triclosan is mentioned in the specification, so this passage must be referring to triclosan. ( *See* D.I. 192 at 63:4-7 (Defendants argue at the Markman hearing that "[i]f that [paragraph] doesn't apply to triclosan, then what on earth does it apply to?").)

Helpful in this case is the Federal Circuit's guidance in *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1383-1384 (Fed.Cir.2003). In *Geneva*, the claim term at issue was "synergistically effective amount of clavulanic acid," which the district court found to be ambiguous. Relying on a passage in the specification stating that "[e]ach unit dose will usually contain from 50 to 500 mg," the district court construed the term to be limited to the 50 to 500 mg range. *FN3 Geneva Pharms., Inc. v. Glaxosmithkline PLC*, 213 F.Supp.2d 597, 606 (E.D.Va.2002). Concluding that the district court erred in adopting this construction, the Federal Circuit explained that " 'effective amount' is a common and generally acceptable term for pharmaceutical claims and is not ambiguous or indefinite, provided that a person of ordinary skill in the art could determine the specific amounts without undue experimentation." *Geneva*, 349 F.3d at 1383-1384 (citing *In re Halleck*, 57 C.C.P.A. 954, 422 F.2d 911, 914 (1970)). The Federal Circuit further explained that "synergistically effective amount" is a "functional limitation" that should cover all embodiments capable of achieving "therapeutic synergy," not just those in the disclosed 50 to 500 mg range. *Id.*

FN3. The district court endeavored to construe this term in the context of an obviousness-type double patenting analysis, not the typical context of a Markman hearing. Nevertheless, the Court still finds the Federal Circuit's guidance in this case to be instructive.



Here, as in Geneva, the disputed claim term is a "functional limitation" that uses the "common and generally acceptable" "effective amount" language. Furthermore, just as the specification in Geneva stated that the relevant amount was "usually" in a particular range, the specification of the ' 516 patent states only that the antimicrobial agent is "normally" within 0.001-5% by weight. The Court sees nothing further in the intrinsic evidence to more strongly suggest that the claims should be limited to a particular numerical range. Accordingly, following Geneva, the Court will not limit the claim term to 0.001 to 5% triclosan.

Indeed, the Federal Circuit has explained that "[w]hen a claim term is expressed in general descriptive words, [courts] will not ordinarily limit the term to a numerical range that may appear in the written description or in other claims." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1249 (Fed.Cir.1998). This is a principle that the Federal Circuit has repeatedly applied, FN4 and, the Court sees no reason why it should not apply here as well, particularly in light of the fact that the specification (1) does not refer to a particular antimicrobial agent and (2) merely explains that the concentration of antimicrobial agent is "normally" within a certain range.

FN4. *See, e.g., Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1358 (Fed.Cir.2006) (declining to limit the term "water-alcohol mixture" to a composition that was at least 30 percent water when the specification stated that "the amount of alcohol employed in the suspending material *may vary widely* but it *usually* forms between 0 and 70 weight percent of the suspending material, and more usually between about 30 and 50 weight percent") (emphasis in original); *Innovad, Inc. v. Microsoft Corp.*, 260 F.3d 1326, 1332-33 (Fed.Cir.2001) (holding that the term "small volume" was not limited to being smaller than 4.4 cubic inches when the specification related the term to a function and provided no specialized meaning for the term); *Brassica Protection Products LLC v. Sunrise Farms (In re Cruciferous Sprout Litig.)*, 301 F.3d 1343, 1348 (Fed.Cir.2002) (declining to construe a claim term in terms of a specific numerical limit when, among other reasons, the patent included no indication that the claim term should be so limited).

Having decided not to adopt Defendants' proposed construction, the Court must now decide whether it should adopt Plaintiffs' proposed construction. The Court concludes that Plaintiffs' proposed construction merely paraphrases the common term "effective," offering nothing to enhance the understanding of the claims to one of skill in the art. Accordingly, the Court will not adopt Plaintiffs' proposed construction either. Having resolved the essential dispute over whether this claim term should be limited to a particular range of antimicrobial agent concentrations, the Court concludes that the term requires no additional construction.

**E. "A Physiologically And Cosmeceutically Acceptable Vehicle"**

Plaintiffs' Construction	Defendants' Construction
A substance that allows for the uniform application to the skin that is suitable in appearance, scent, texture and consistency and does not irritate or damage the skin.	A solvent, diluent, or dispersant for the constituents of the composition which allows for the uniform application of the constituents to the surface of the skin at an appropriate dilution.

[10] Plaintiffs contend that Defendants' proposed construction is incomplete. Specifically, Plaintiffs contend that Defendants only define the claim term "vehicle" and neglect to give meaning to the terms "physiologically and cosmeceutically acceptable." By requiring that the substance not irritate or damage the skin and that it have suitable appearance, scent, texture, and consistency, Plaintiffs maintain that their construction gives proper meaning to these parts of the claim term. (D.I. 175 at 18.)

Both parties rely to varying degrees on the following portion of the specification for their proposed

constructions:

The compositions according to the invention also comprise a liquid, solid or semi-solid physiologically and cosmetically acceptable vehicle or carrier. A suitable vehicle, under the invention, may act variously as solvent, diluent or dispersant for the constituents of the composition, and allows for the uniform application of the constituents to the surface of the skin at an appropriate dilution. It will be apparent to the skilled artisan that the range of possible vehicles is very broad. In general, compositions according to this invention may comprise water as a vehicle, and/or at least one physiologically and cosmetically acceptable vehicle other than water.

(516 patent at 6:18-29.) Notably, this passage refers to a "cosmetically acceptable vehicle," while the claims refer to a "cosmeceutically acceptable vehicle." Nevertheless, the Court concludes that the "vehicle" described in this passage is, in fact, the same "vehicle" required by the claims. Indeed, the Court finds that this passage contains content that gives meaning to the term "cosmeceutically." Specifically, this passage explains that a "suitable vehicle under the invention ... allows for the uniform application of the constituents to the surface of the skin at an appropriate dilution." ( *Id.*) Calling for the "vehicle" to allow for application to the "skin" at an "appropriate dilution," the Court finds that this passage encompasses the concept of being "physiologically" acceptable. Likewise, requiring the "vehicle" to allow for "uniform application" to the "skin," the Court concludes that the passage also encompasses the concept of being "cosmeceutically" acceptable. Accordingly, the Court will construe the term "physiologically and cosmeceutically acceptable vehicle" to mean, as Defendants contend, "a solvent, diluent, or dispersant for the constituents of the composition that allows for the uniform application of the constituents to the surface of the skin at an appropriate dilution."

For several reasons, the Court has decided not to adopt Plaintiffs' proposed construction. First, in support of their position that the "physiologically and cosmeceutically acceptable vehicle" not irritate or damage the skin and that it have suitable appearance, scent, texture, and consistency, Plaintiffs rely exclusively on extrinsic evidence. Specifically, Plaintiffs rely entirely on the declaration of their expert, Dr. R. Randall Wickett. ( *See* D.I. 144, Exh. C at 6-7.) Though the Court has no doubt that Dr. Wickett is well-respected in his field, Dr. Wickett's declaration is unsupported by any additional evidence and his proposed constructions appear to be constructed from whole cloth. In these circumstances, the Court is unwilling to place great weight on Dr. Wickett's declaration. FN5 Second, the specification explains that "the range of possible vehicles is very broad." ( ' 516 patent at 6:24-26.) However, Plaintiffs' proposed construction introduces additional requirements pertaining to the appearance, scent, texture, and consistency of the vehicle and whether the vehicle irritates the skin. Given the specification's guidance that the range of acceptable vehicles is "broad," the Court is reluctant to introduce so many additional limitations into the claims, especially when there is no support for it in the intrinsic record. Finally, the Court is concerned that Plaintiffs' proposed construction will, rather than clarify the claims, muddy the scope of the claims, possibly leading to an unnecessary debate over whether a particular vehicle has a "suitable" scent, for instance. Accordingly, the Court concludes that Defendants' proposed construction is more appropriate.

FN5. Indeed, Plaintiffs themselves appear to place little weight on Dr. Wickett's declaration, explaining that they "don't really think expert testimony is necessary to understand what those words mean, but [they] did submit a declaration from Professor Wickett in which he explained his understanding from this vantage point of a person of ordinary skill in the art." (D.I. 192 at 39:9-18.)

#### **F. "Antimicrobial Lotion Composition," "Antimicrobial Lotion" And "Effective Antimicrobial Lotion"**

Plaintiffs' Construction	Defendants' Construction
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A lotion that effectively kills microorganisms present on the skin.

A lotion containing 0.001%-5% of an antimicrobial chemical agent and an absorption enhancer.

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[11] The dispute among the parties is whether these terms should be construed to require (1) a concentration of antimicrobial agent within a particular range and (2) an absorption enhancer. The Court addressed essentially the same issues for the claim terms "moisturizing composition" and "amount of triclosan effective to kill microorganisms on the skin." ( *See supra* Parts II.A, II.D.). For the present claim terms, Defendants rely largely on the same arguments as they did for those terms. To the extent Defendants add additional argument, they simply note that the specification explains that "[s]kin care products of the instant invention are further formulated to rapidly penetrate the skin, whereby active ingredients of the formulation are more *effective*." ('516 patent at 2:64-67 (emphasis added).) Thus, Defendants ostensibly contend that the specification correlates "effectiveness" with rapid skin penetration, which is provided by an absorption enhancer. (D.I. 145 at 19.)

For the reasons set forth above, the Court finds that these claim terms should not be construed to require either a particular concentration of antimicrobial agent or an absorption enhancer. ( *See supra* Parts II.A, II.D.) Accordingly, the Court will not adopt Defendants' proposed construction.

Plaintiffs' proposed construction adds little to the raw claim language other than a definition of the term "antimicrobial." However, the Court finds that Plaintiffs' definition of "antimicrobial" is unsatisfactory. Specifically, Plaintiffs' definition limits the term "antimicrobial" to components that "kill" microorganisms. The specification, however, supports a broader definition, explaining that "a chemical antimicrobial agent ... functions to inhibit the growth of pathogenic or potentially pathogenic bacteria and fungi, or to kill such organisms." ('516 patent at 4:26-29.) The specification further explains that the "the chemical antimicrobial agent may be bacteriostatic, bacteriocidal, fungistatic, or fungicidal in its action." ( *Id.* 4:30-31.) In line with this description, the Court shall construe the terms "antimicrobial lotion," "antimicrobial lotion composition" and "effective antimicrobial lotion" to be "a lotion that effectively inhibits the growth of or kills microorganisms present on the skin."

## CONCLUSION

For the reasons discussed, the Court has construed the disputed terms and/or phrases of the '516 patent as provided herein. An Order consistent with this Memorandum Opinion will be entered setting forth the meanings of the disputed terms and/or phrases in the '516 patent.

## ORDER

At Wilmington, this 11th day of February 2009, for the reasons discussed in the Memorandum Opinion issued this date;

IT IS HEREBY ORDERED that the following terms and/or phrases in United States Patent No. 6,579,516 ("the '516 patent") are assigned the following meanings:

1. The term "**moisturizing composition**" requires no additional construction.
2. The term "**skin**" requires no additional construction.
3. The term "**applying to and leaving on**" requires no additional construction.
4. The term "**amount of triclosan effective to kill microorganisms present on the skin**" requires no additional construction.

5. The term "**physiologically and cosmeceutically acceptable vehicle**" means "a solvent, diluent, or dispersant for the constituents of the composition that allows for the uniform application of the constituents to the surface of the skin at an appropriate dilution."

6. the terms "**effective antimicrobial lotion,**" "**antimicrobial lotion**" and "**antimicrobial lotion composition**" mean "a lotion that effectively inhibits the growth of or kills microorganisms present on the skin."

D.Del.,2009.

Laboratory Skin Care, Inc. v. Limited Brands, Inc.

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