IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDICIS PHARMACEUTICAL CORPORATION, and DOW PHARMACEUTICAL SCIENCES, INC.,	)	
Plaintiffs,	)	
v.	)	Civ. Action No. 11-409-LPS-CJB
ACTAVIS MID ATLANTIC LLC,	)	
Defendant.	)	

REPORT AND RECOMMENDATION

In this Hatch-Waxman action filed by Plaintiffs Medicis Pharmaceutical Corporation ("Medicis") and Dow Pharmaceutical Sciences, Inc. ("Dow Pharma") (collectively, "Plaintiffs") against Defendant Actavis Mid Atlantic LLC ("Defendant"), Plaintiffs allege infringement of U.S. Patent No. 6,387,383 ("the '383 patent"). Presently before the Court is the matter of claim construction. I recommend that the District Court adopt the constructions as set forth below.

I. BACKGROUND

A. The Parties

Medicis is a Delaware corporation with its principal place of business in Scottsdale, Arizona. (D.I. 63 at ¶ 1) Medicis is a pharmaceutical company whose branded products are used primarily for the treatment of dermatological and podiatric ailments. (*Id.*) Dow is a California corporation, founded by Dr. Gordon J. Dow, which is engaged in the business of research, development, and sale of pharmaceutical products. (D.I. 63 at ¶ 2; D.I. 77 at 6, ¶ 3) Defendant Actavis is a Delaware limited liability company with its principal place of business in New

Jersey. (D.I. 77 at 6, ¶ 1) Actavis is part of one of the world's largest generic pharmaceutical companies. (D.I. 79 at 2)

B. The '383 Patent

The '383 patent is entitled "Topical Low-Viscosity Gel Composition," and was issued on May 14, 2002. (D.I. 51, ex. B)[1] The '383 patent lists three inventors: Gordon J. Dow, Robert W. Lathrop, and Debra A. Dow. (*Id.*) Dow Pharma is the sole assignee of the '383 patent, and Medicis is its exclusive licensee. (D.I. 63 at ¶ 8) The '383 patent is based on U.S. Appl. No. 09/632,508 which was filed on August 3, 2000. ('383 patent) The '383 patent contains fifty-nine claims, three of which (claims 1, 18, and 37) are independent. (*Id.*, col. 19:42–24:14)

The '383 patent relates a topical gel composition for use in the treatment of skin diseases and disorders, such as acne vulgaris, and to methods of administering and preparing that composition.[2] (*Id.*, col. 1:7–9) The '383 patent identifies a number of different active agents (to be used either alone or in combination) for acne treatment, including antibiotics, corticosteriods, retinoids, anti-inflammatory imidazoles, and non-steroidal anti-inflammatory agents ("NSAIDs"). (*Id.*, col. 3:11–18) But the focus of the '383 patent is not on active pharmaceutical ingredients. Instead, the crux of the invention is a purportedly novel, low-viscosity "delivery system" for

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[1] The '383 patent appears several times on the docket, including as an exhibit to the parties' Joint Claim Construction Chart. (D.I. 51, ex. B) Further citations will simply be to the "'383 patent."

[2] This three-fold nature of the invention of the '383 patent is reflected by the three independent claims. Claim 1 is directed to various gel compositions, claim 18 recites methods of treating skin disorders using those compositions, and claim 37 describes a method of preparing the compositions.

these active ingredients.[3] (*Id.*, col. 2:57) This low-viscosity delivery system is provided through the use of a "lightly cross-linked polyacrylic acid polymer[]," which has a low viscosity relative to its concentration in aqueous solutions. (*Id.*, col. 4:30–35, 46–47) The low viscosity of the overall gel composition offers two principal advantages: (1) more appealing cosmetic characteristics, such as a reduction in a "sticky" feel or residue; and (2) more accurate application through improved flow and pourability. (*Id.*, col. 4:17–20; 13:18–23; *see also id.*, col. 7:12–14 (noting that "tests have shown that the less viscous material is cosmetically more elegant and [results in] more regular use"))

C. Procedural Posture

This case arises out of Defendant's submission of Abbreviated New Drug Application ("ANDA") No. 202-564 to the United States Food and Drug Administration, which seeks approval to market a generic version of Ziana®, a brand-name drug. (D.I. 63 at ¶ 12) Medicis is the owner of approved New Drug Application No. 050802, which covers Ziana®. (*Id.* at ¶ 10) Ziana® is a gel with two active ingredients—clindamycin phosphate and tretinoin—that is used to treat skin diseases, including acne vulgaris. (*Id.*) Medicis has listed the '383 patent and U.S. Reissue Patent No. 41,134 ("the '134 patent") in the Orange Book as covering its Ziana® gel. (D.I. 1 at ¶ 14; D.I. 63 at ¶ 11) The '134 patent, which is owned by Alyzan Inc. ("Alyzan") and exclusively licensed to Medicis, was originally asserted against Defendant. (*See* D.I. 1, Count II) However, the parties stipulated to a dismissal of all claims relating to the '134 patent, and, as a

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[3] Viscosity is a property that describes the resistance of a fluid to flow. *See, e.g.*, The Physics Hypertextbook, http://physics.info/viscosity/ (last visited June 11, 2012). The higher the viscosity of a material, measured in centipoise ("cP"), the more resistant it is to flow. *Id.* By way of illustration, water at room temperature has a viscosity of 1 cP, honey has a viscosity of 10,000 cP, and sour cream has a viscosity of 100,000 cP. *Id.*

result, Alyzan was dismissed from this action without prejudice. (D.I. 50)

After the dismissal of Alyzan, Plaintiffs filed their First Amended Complaint for Patent Infringement, which includes infringement allegations based solely on the '383 patent. (D.I. 63) Defendant timely answered and filed counterclaims for declaratory judgments of non-infringement and invalidity of the '383 patent. (D.I. 77) The parties have been engaging in discovery, which is set to close August 17, 2012. (D.I. 24 at 2) On September 8, 2011, this case was referred to me to hear and resolve all pretrial matters, up to and including the resolution of case-dispositive motions. (D.I. 22)

The parties filed simultaneous opening claim construction briefs on March 27, 2012, and simultaneous responsive briefs on April 20, 2012. (D.I. 57, 59, 87, 89) The Court held a *Markman* hearing on May 8, 2012. (D.I. 104, hereinafter "Tr.")

II. STANDARD OF REVIEW

The proper construction of claim terms is a question of law for the Court. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). The Court should generally give claim terms their "'ordinary and customary meaning[,]'" which is "the meaning that the term[s] would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (citations omitted). However, when determining the ordinary meaning of claim terms, the Court should not extract and isolate those terms from the context of the patent, but rather should endeavor to reflect their "meaning . . . to the ordinary artisan after reading the entire patent." *Id.* at 1321; *accord Markman*, 52 F.3d at 978 (noting that a patent is a "fully integrated written instrument").

To that end, the Court should look first and foremost to the language of the claims, because "[i]t is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips*, 415 F.3d at 1312 (internal quotation marks and citations omitted). For example, the context in which a term is used in a claim may be "highly instructive." *Id.* at 1314. In addition, "[o]ther claims of the patent, both asserted and unasserted, can be valuable" in discerning the meaning of particular claim term. *Id.* This is "[b]ecause claim terms are normally used consistently throughout the patent, [and so] the usage of a term in one claim can often illuminate the meaning of the same term in other claims." *Id.* Moreover, "differences among claims can also be a useful guide," as when "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314–15.

In addition to the words of the claims, the Court should look to the remainder of the patent specification. This written description "may reveal a special definition . . . that differs from the meaning [that a given term] would otherwise possess." *Id.* at 1316. In that case, "the inventor's lexicography governs." *Id.* Even if the specification does not contain a special definition of the term-at-issue, it "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." *Id.* at 1315 (internal citations and quotation marks omitted). That said, however, the specification "is not a substitute for, nor can it be used to rewrite, the chosen claim language." *SuperGuide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). In addition to the specification, a court should also consider the patent's prosecution history, if it is in evidence, because it "can often inform the meaning of the claim language by demonstrating how the inventor understood

the invention." *Phillips*, 415 F.3d at 1317 (citations omitted).

Extrinsic evidence, "including expert and inventor testimony, dictionaries, and learned treatises," can also "shed useful light on the relevant art." *Id.* (internal quotation marks and citations omitted). Dictionaries (especially technical dictionaries) may be useful in this process because they typically provide "the accepted meanings of terms used in various fields of science and technology." *Id.* at 1318. However, the Federal Circuit has cautioned that "heavy reliance on [a] dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term to the artisan into the meaning of the term in the abstract, out of its particular context, which is the specification." *Id.* at 1321. In addition to dictionary definitions, expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Id.* at 1318. Nonetheless, courts must not lose sight of the fact that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* Overall, while extrinsic evidence may be useful, it is "less significant than the intrinsic record in determining the legally operative meaning of claim language." *Id.* at 1317 (internal quotation marks and citations omitted); *accord Markman*, 52 F.3d at 981.

In utilizing these resources during the claim construction process, courts should keep in mind that "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998).

III. DISCUSSION

A. Agreed Terms

The parties presented five terms from the '383 patent for construction in their Joint Claim Construction Chart, filed on February 23, 2012: (1) "aqueous gel composition"; (2) "lightly cross-linked polyacrylic acid polymer"; (3) "base to adjust pH"; (4) "a container that accurately administers a portion of the composition" and "a container from which drops are accurately administered" (collectively, "the container terms"); and (5) "for a period of time sufficient to improve the skin disorder." (D.I. 51, ex. A at 1–22) At that time, the parties disputed the first four listed terms, and agreed on the construction for the fifth term. (*See id.*) Since then, the parties further narrowed their disputes, and now agree on how the Court should deal with three of the five original terms-at-issue.

First, the parties agree that the phrase "aqueous gel composition" requires no construction. (D.I. 59 at 7 n.3; D.I. 57 at 1 n.1) Given that no dispute in this case appears to turn on the construction of this term, the Court therefore will not construe this term or further consider its meaning at this juncture.

Second, the parties agree that the phrase "for a period of time sufficient to improve the skin disorder" should mean "over a course of treatment of sufficient duration to improve the skin disorder." (D.I. 59 at 17) This proposed construction accurately reflects the claim context and teachings of the specification, which distinguish between the actual time that the therapeutic gel is physically in contact with the skin, and the span of time during which treatment proceeds. (*See, e.g.*, '383 patent, col. 2:38–43; 8:36–64; 10:59–11:43 (describing the improvement in skin conditions over a twelve-week period of time)) Only the latter concept properly reflects the

meaning of the claim term-at-issue. Because the parties agree on a definition that is consistent with the intrinsic record, the Court will adopt the agreed construction. *See, e.g.*, *Cooper Notification, Inc. v. Twitter, Inc.*, Civil Action No. 09-865-LPS, 2012 WL 528137, at *3 (D. Del. Feb. 17, 2012) (construing the term "first message" consistent with a proposal agreed to by both sides at the *Markman* hearing).

Third, the parties have also now reached agreement on the phrase "base to adjust pH." Although Defendant initially disputed Plaintiffs' construction, Defendant later embraced this proposal, asserting that "the Court [should] adopt Plaintiffs' proposed construction of 'a basic compound that can be used to adjust pH.'" (D.I. 87 at 1) Consistent with Plaintiffs' proposal, the specification repeatedly describes the role of the base as being present in quantities sufficient to adjust the pH to the desired range. (*See, e.g.*, '383 patent, col. 5:49–59 (noting that a pH-adjusting agent may be added "as needed at a level to adjust the pH to the desired range"); col. 7:22–30 (describing the addition of a "pH adjusting agent to adjust the pH to the desired range")) Because the parties agree on a definition for this term that is consistent with the intrinsic record, the Court will adopt the agreed construction.

B. Disputed Terms

1. "lightly cross-linked polyacrylic acid polymer"

The first of the remaining terms-at-issue is the phrase "lightly cross-linked polyacrylic acid polymer," which appears in every independent claim in the '383 patent. Its use in claim 1, reproduced below, is representative:

> 1. A topical aqueous gel composition having a pH of about 3 to about 9 and a viscosity of less than about 15,000 cP for treating a skin disorder in a human subject, which composition consists

essentially of

(a) a therapeutically-effective amount of at least one compound useful for treating such disorder,

(b) a hydrophilic pharmaceutically-acceptable, *lightly cross-linked polyacrylic acid polymer* compatible with the compound,

(c) a pharmaceutically-acceptable base to adjust pH,

(d) optionally a water miscible solvent,

(e) optionally a preservative, and

(f) water.

('383 patent, col. 19:42–55 (emphasis added)) Defendant originally proposed that this term be construed to mean "a cross-linked polyacrylic acid polymer with a viscosity of less than 15,000 cP." (D.I. 57 at 6) In response to criticism by Plaintiffs in their opening brief, Defendant modified its proposal to be: "a cross-linked polyacrylic acid polymer with a viscosity of less than 15,000 cP *where the polymer is in a 0.5% solution at pH 7.5 and the viscosity is measured with a Brookfield viscometer at 20 rpm.*" (D.I. 87 at 3 (emphasis added)) Plaintiffs argue that this term "does not need to be construed, and should be understood to have its plain and ordinary meaning to a person of ordinary skill in the art." (D.I. 59 at 8) Plaintiffs do not explain what a person of ordinary skill in the art would understand this "plain and ordinary meaning" to be.

a. Whether the Claim Term-at-Issue Must Be Construed

Given Plaintiffs' position, the Court must first resolve whether this phrase needs to be construed. A district court is not obligated to construe "*every* limitation present in a patent's asserted claims." *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., Ltd.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008) (emphasis in original). However, a "determination that a claim term 'needs no

construction' or has the 'plain and ordinary meaning' may be inadequate when a term has more than one 'ordinary' meaning or when reliance on a term's 'ordinary' meaning does not resolve the parties' dispute." *Id.* at 1361. As such, a court must discern whether there is a "fundamental dispute" between the parties regarding the scope or meaning of a claim term; if there is such a dispute, it is "the court's duty to resolve it" by construing the term. *Id.* at 1362; *accord Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, C.A. No. 08-309-LPS, 2012 WL 938926, at *6 (D. Del. Mar. 13, 2012).

Defendant argues that the phrase "lightly cross-linked polyacrylic acid polymer" is precisely the sort of claim limitation that must be construed by the Court, because Plaintiffs' claim of infringement turns on the scope of this limitation, and declining to construe the phrase now will only delay the inevitable, given that some explicit definition must ultimately be assigned to this limitation. (D.I. 87 at 4–5; *see also* D.I. 57 at 8–10) Plaintiffs criticize Defendant's discussion of the parties' infringement dispute, characterizing it as "an improper distraction from the task at hand, namely, construing the claim terms." (D.I. 89 at 3)

Apart from the impact of this claim term on any future infringement analysis, it is clear that there is a "fundamental dispute" between the parties as to this term: whether the claimed polymeric material should be defined in terms of its viscosity (as Defendant has suggested) and, if so, what the contours of that definition should be. Plaintiffs vehemently and repeatedly criticize the inclusion of an explicit viscosity limitation in the construction of this phrase, suggesting that the parties' dispute in this regard is truly fundamental. (D.I. 59 at 10–11; D.I. 89 at 5–6; *see also* Tr. at 72 (Plaintiffs' counsel acknowledging that there is a "huge dispute" between the parties as to whether a "lightly cross-linked polyacrylic acid polymer should be

narrow[ed] with a viscosity limitation"))

In addition, simply invoking an unspoken, undefined, "plain and ordinary" meaning of this phrase is inadequate to resolve the parties' fundamental dispute. This point is perhaps best illustrated by a declaration submitted by Plaintiffs from Joel L. Zatz, Ph.D., a professor of Pharmaceutics at Rutgers University. (D.I. 91) Professor Zatz states that "[t]he phrase 'a lightly cross-linked polyacrylic acid polymer' would be immediately recognizable to a person having ordinary skill in the art and needs no further explication." (*Id.* at ¶ 15) While a person of extraordinary experience, like Professor Zatz, might be able to easily recognize what constitutes a "lightly cross-linked polyacrylic acid polymer" in an abstract sense, that does not reveal what the patentee meant by this phrase in the particular context of the '383 patent.

More tellingly, Professor Zatz's statement merely begs the question—what *is* the plain and ordinary meaning of this term? In his declaration, Professor Zatz does not say. At the *Markman* hearing, the Court asked this question of Plaintiffs' counsel repeatedly, but counsel could not give content to the "plain and ordinary meaning" of the term. Instead, Plaintiffs' counsel simply stated that, at some point later in the case, experts will answer that question.[4] If, as Professor Zatz contends, it is possible to "immediately recognize" what constitutes the claimed polymer, then it should not be difficult for Plaintiffs to articulate the meaning of the term now, at the claim construction stage. The fact that neither Professor Zatz nor Plaintiffs have even

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[4] (*See* Tr. at 68–69 (Plaintiffs' counsel stating only that "people of ordinary skill in the art would understand" what the term means); *id.* at 79–80 (Plaintiffs' counsel stating that "experts know exactly what [the meaning of the term] is"); *id.* at 94 (Plaintiffs' counsel noting that the definition of the term is "a matter of expert testimony"); *id.* at 95 (Plaintiffs' counsel stating that "[w]hen we hear the experts discuss whether or not the product at issue is lightly cross-linked, we will hear whether [a polymer falls into a particular] category" of cross-linking))

attempted to do so strongly suggests that the scope of this claim term is not nearly as straightforward as Plaintiffs contend.

As the foregoing discussion indicates, the Court finds that the parties fundamentally dispute the scope of the claimed phrase, and that simply referring to its unspecified "plain and ordinary meaning" cannot resolve that dispute.[5] As such, the Court must construe this phrase.

b. Defining the Claim Term-at-Issue

In construing this phrase, the Court looks first and foremost to the claim language itself. The "lightly cross-linked polyacrylic acid polymer" is one of several components that make up "[a] topical aqueous gel composition having a pH of about 3 to about 9 and a viscosity of less than about 15,000 cP for treating a skin disorder." ('383 patent, col. 19:42–44) Although the independent claims of the '383 patent do not require a particular quantity of the "polymer," certain dependent claims require that the polymer comprise between roughly 0.1% and 0.5% of the weight of the overall gel composition. (*See, e.g.*, *id.*, claims 6, 7, 10, 26, 27, 42, 43, 46) Additionally, while several of the dependent claims also specifically require certain active ingredients (such as clindamycin phosphate), solvents (such as propylene glycol), and preservatives (such as methylparaben), none of the claims ever require the use of a particular polymer; this element of the overall gel composition is always referred to generically as a "lightly cross-linked polyacrylic acid polymer" or simply the "polymer." (*Cf. id.*, claims 1 & 7)

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[5] In reaching this conclusion, the Court notes that there are a number of terms in claim 1, such as "water," that may be sufficiently defined with just a gesture to a well-understood and universally known "plain and ordinary meaning." But that is not the case with a phrase like "lightly cross-linked polyacrylic acid polymer," which not only is a technical term specific to the relevant field of the patent, but also includes a qualifying term ("lightly"). *Cf. Power Integrations*, 2012 WL 938926, at *6 (noting that where claim term relates to "complex technology," construction is warranted to assist the jury in understanding the term).

The remainder of the specification provides considerable insight into what is meant by the "polymer" phrase. The specification first refers broadly to a "polymeric material" that is included in the gel composition "in an amount sufficient to bring the viscosity of the composition to a level of not more than about 15,000 cP, preferably between about 100 and about 12,000, and more preferably between about 300 and about 10,000." (*Id.*, col. 4:8–13) These viscosity measurements are "determined at room temperature . . . using a Brookfield viscometer model DV-I+." (*Id.*, col. 4:13–14) The specification also draws a direct link between these viscosity levels and the overall import of the invention, noting that "[b]y keeping the viscosity below about 15,000 cP, the advantages of more appealing cosmetic characteristics and ease of accurate application through improved flow and pourability are achieved." (*Id.*, col. 4:17–20)

The discussion in the specification next turns to a "particularly useful" type of "polymeric material," which includes "lightly cross-linked polyacrylic acid polymers." (*Id.*, col. 4:21–23) These polymers, which are "generically referred to as carbomers," have chemical cross-links or "interconnect[ions]" between the constituent linear acrylic acid chains.[6] (*Id.*, col. 4:25, 4:65–66; col. 5:5–9) Five different "lightly cross-linked polyacrylic polymers . . . for use in the present invention" are discussed in the '383 patent; all of them are identified as being sold in powder form by B.F. Goodrich under the tradename "CARBOPOL®": CARBOPOL 910, 941, 971, 981, and ETD 2050. (*Id.*, col. 4:21–24; 4:27–29) Of these five, two "lightly cross-linked polyacrylic acid polymers"—CARBOPOL 941 and 981—are highlighted as "particularly valuable for the present invention because the viscosity of a gel based on [either carbomer] is low relative to [its]

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[6] The basic repeating unit in a polyacrylic acid polymer is acrylic acid, which has the chemical formula $C_3H_4O_2$. *See* http://toxipedia.org/display/toxipedia/Polyacrylic+Acid (last visited June 11, 2012).

concentration." (*Id.*, col. 4:30–32) This particular "value" derives directly from the "low level of cross-linking within the polymer structure in a neutralized aqueous system." (*Id.*, col. 4:33–35)

The '383 patent does not merely cite examples of "lightly cross-linked polyacrylic polymers." It also identifies three different *highly* cross-linked polyacrylic polymers—namely, CARBOPOL 940, 974P, and 980. (*Id.*, col. 4:35–38, 4:43–45) In contrast to the low level of cross-linking found in carbomers such as CARBOPOL 941 and 981, the specification explains that these highly cross-linked polymers "produce gels with higher viscosities" as compared to gels made with "comparable concentrations" of lightly cross-linked polymers. (*Id.*, col. 4:38–39) In particular, as measured using a Brookfield viscometer, a 0.5% aqueous solution of CARBOPOL 941 or 981 has a viscosity in the range of 4,000–11,000 cP, while the 0.5% aqueous solution of CARBOPOL 940 or 980 can have a viscosity up to 10 times greater, falling in the range of 40,000–60,000 cP.[7] (*Id.*, col. 4:40–45)

The fact that aqueous solutions of "lightly cross-linked polyacrylic acid polymers" have a "lower-level viscosity feature" has important consequences for the composition described in the '383 patent. First, "[a] gel made from one of these lightly cross-linked polymers provides better skin feel and lubricity than a gel of comparable viscosity made from a highly cross-linked polymer." (*Id.*, col. 4:49–52; *see also id.*, col. 7:4–7 (noting that a prior art gel composition "is not as well accepted as the less viscous material of the invention made with a more lightly cross-linked polymer")) Second, the resulting low-viscosity gel "can be administered very accurately

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[7] These data are taken from the B.F. Goodrich Product Guide, Bulletin 2, which is incorporated by reference in the '383 patent. (*See* '383 patent, col. 4:44–45) It is therefore part of the intrinsic record. *Systems Division, Inc. v. Teknek LLC*, 59 F. App'x 333, 340 (Fed. Cir. 2003). Defendant provided a copy of this document to the Court. (*See* D.I. 57, ex. 3)

by a dropper or drip-type dispenser as compared to other . . . thicker gels." (*Id.*, col. 4:52–55)

With this extensive intrinsic discussion of a "lightly cross-linked polyacrylic acid polymer" in mind, the Court now turns to the parties' arguments regarding this phrase.[8] With one exception outlined below, the Court finds that Defendant's proposed construction properly reflects the intrinsic and extrinsic record, and therefore should be adopted. In reaching this conclusion, the Court has considered each of Plaintiffs' objections to Defendant's construction in light of the record evidence.

Plaintiffs first argue that Defendant's initial proposal (defining the term-at-issue as "a cross-linked polyacrylic acid polymer with a viscosity of less than 15,000 cP") was "scientifically unsupported," because viscosity is a property that can only be measured in fluids. Because the polymers in question are powders (not fluids), Plaintiffs asserted that it would be nonsensical to define the "lightly cross-linked polyacrylic acid *polymers*" in terms of their *viscosity*. (D.I. 59 at 10 (emphasis added)) However, in response to this critique, Defendant modified its proposal to read: "a cross-linked polyacrylic acid polymer with a viscosity of less than 15,000 cP where the polymer is in a 0.5% solution at pH 7.5 and the viscosity is measured with a Brookfield viscometer at 20 rpm." This new proposal clarifies that the viscosity measurement is with respect to an aqueous, 0.5% solution of the polymer, rendering Plaintiffs' initial objection moot. (D.I. 87 at 3–4) Plaintiffs have not come forward with any evidence demonstrating that Defendant's modified proposal is scientifically unsound.

Plaintiffs next criticize Defendant's proposed construction as being "[u]ntethered to the

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[8] Typically a court weighs different proposed constructions from the parties. The Court here lacks the benefit of competing proposals, because Plaintiffs have not attempted to define this phrase, other than to invoke its undefined "plain and ordinary meaning."

[e]vidence." (D.I. 59 at 10) Specifically, Plaintiffs contend that "[e]very mention [of viscosity] in the specification in the patent concerns the gel composition *as a whole*, not the polymer component." (*Id.* (emphasis in original); *see also* D.I. 89 at 5 ("Rather, every instance [where viscosity is mentioned in the specification] unambiguously refers to the viscosity of the aqueous gel composition as a whole."))

As the foregoing discussion of the specification indicates, Plaintiffs' characterization is incorrect. While the specification often refers to the viscosity of the overall gel composition, it also repeatedly refers to the individual viscosities of cross-linked polymers (when in an aqueous solution) and draws an inextricable connection between the viscosities of the polymers-in-solution and the inventive aspects of the overall gel composition.[9] As previously noted, five "lightly cross-linked polymers" are identified in the specification as being suitable for the "present invention," with viscosity measurements explicitly provided for two of them, and similar measurements provided for the remaining "lightly cross-linked polymers" through the incorporated B.F. Goodrich Product Guide. ('383 patent, col. 4:27–29) Those viscosity ranges, which the patent describes as being measured in a 0.5% aqueous solution at pH 7.5 by a Brookfield viscometer at 20 rpm, are as follows:

CARBOPOL 910:	3,000–7,000 cP
CARBOPOL 941:	4,000–11,000 cP
CARBOPOL 971:	4,000–11,000 cP
CARBOPOL 981:	4,000–10,000 cP

[9] (*See, e.g.*, '383 patent, col. 4:40–45 ("A 0.5% solution of either CARBOPOL 941 or 981 at pH 7.5 has a viscosity measurement of from 4,000 to 11,000 cP (Brookfield viscometer at 20 rpm) compared to a viscosity measurement of from 40,000 to 60,000 cP for a comparable 0.5% solution of either CARBOPOL 940 or 980."); *id.*, col. 4:46-49 ("This lower level viscosity feature of the lightly cross-linked polyacrylic acid polymers . . . offers two advantages to the composition of the present invention . . . ."))

CARBOPOL ETD 2050: 3,000–15,000 cP

('383 patent, col. 4:40–41; D.I. 57, ex. 3 at MED_ACT 000033118) There are also three highly cross-linked polymers identified in the same manner; the viscosity ranges for two are explicitly identified, and the third is incorporated by reference from the same Product Guide:

CARBOPOL 940: 40,000–60,000 cP
CARBOPOL 974P: 29,400–39,400 cP
CARBOPOL 980: 40,000–60,000 cP

('383 patent, col. 4:43–45; D.I. 57, ex. 3 at MED_ACT 000033118) As these data indicate, all of the identified "lightly cross-linked polyacrylic acid polymers" have a viscosity (at pH 7.5 in a 0.5% solution) of 15,000 cP or less,[10] and all of the identified highly cross-linked polyacrylic acid polymers have a viscosity of 29,400 cP or greater under the same conditions. Contrary to Plaintiffs' argument, Defendant's proposed construction for this term is thus directly tethered to the intrinsic evidence.

Plaintiffs also argue that while the claim language "references the viscosity of the claimed composition . . . the [limitation directed to] the polymer ingredient does not mention viscosity." (D.I. 89 at 6) While that is certainly true, it does not alone resolve whether it would be appropriate to define the "lightly cross-linked polyacrylic acid polymer" as having a viscosity of below about 15,000 cP (like the overall gel composition). The Court must look to other intrinsic evidence to resolve this issue.

After examining the specification, the Court finds that it is entirely appropriate to define

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[10] The measurement for CARBOPOL 910 is for a 1.0% solution, not a 0.5% solution. (D.I. 57, ex. 3 at MED_ACT 000033118) The viscosity measurement for a lower-concentration aqueous solution of CARBOPOL 910 would decrease relative to the stated value of 3,000–7,000 cP, such that it would, like the other four carbomers listed, have a viscosity of less than 15,000 cP in a 0.5% solution.

"lightly cross-linked" polyacrylic acid polymers by reference to their viscosity.[11] Among the six potential ingredients of the claimed gel composition, there can be no question that the polymer is the key to determining the composition's overall viscosity, and that the polymer is also the key to the overall cosmetic features of the claimed gel. (*See* '383 patent, col. 2:59–60 (identifying the "polymeric material" as the element of the composition that "*provides* a gel material that has a very low viscosity") (emphasis added); *id.*, col. 4:30-36 (noting that the "viscosity of a gel based on CARBOPOL 941 or 981 is low relative to its concentration" because of "the low level of cross-linking within the polymer structure in a neutralized aqueous system"))

Moreover, the specification draws particular attention to the low viscosity feature *of the polymer itself* (and its resulting impact on the viscosity of the overall resulting gel composition), noting that this "feature . . . of the present invention . . . [results in a gel composition that] provides better skin feel and lubricity than a *gel of comparable viscosity* made from a highly cross-linked polymer." ('383 patent, col. 4:46–52 (emphasis added)) In other words, it is not enough for the overall gel composition to have a low viscosity; the *polymeric material* used to make that gel must also have a low viscosity—as it does when the polyacrylic acid polymers in question are "lightly cross-linked." This is necessary because while it is possible to produce a gel composition with an overall viscosity of less than 15,000 cP through the use of a low concentration of a highly cross-linked polymer, such a composition would not offer the

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[11] At the *Markman* hearing, the Court repeatedly asked Plaintiffs' counsel whether Plaintiffs believe that such polymers should be defined by reference to some characteristic other than viscosity, or in some other way. (Tr. at 76, 79) Other than by speculating that such a definition could include reference to "the length of the [chemical] chain" making up such a polymer, or "the number of repetitive units" of a polymer, Plaintiffs' counsel did not provide an answer to these questions. (*Id.* at 78) Instead, as previously noted, Plaintiffs' position is that the precise definition of the term must wait for definition by experts later in the case. (*Id.* at 80)

advantages that are described in the '383 patent as being part of the "present invention." (*Id.*) When a patent repeatedly emphasizes a particular inventive element in this way, the Court's construction should reflect that context. *See, e.g.*, *Honeywell Int'l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1318 (Fed. Cir. 2006) (affirming a district court's construction of the term "fuel injection system component" as limited only to a fuel filter because the patent referred to the filter as "this invention" or "the present invention"); *accord Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1353–54 (Fed. Cir. 2010).

Plaintiffs' next objection to Defendant's proposed construction is that it would "read[] the word 'lightly' out of the claim entirely." (D.I. 59 at 11) To the contrary, the '383 patent makes clear that the level of cross-linking in a polyacrylic acid polymer determines its viscosity, so that by describing a polymer as "lightly cross-linked," the patent is also inherently describing it as having lower viscosity than a polymer with more cross-links in the same concentration in an aqueous solution. (*See* '383 patent, col. 4:34–36) This is also consistent with the ordinary connotation that is given to a lightly cross-linked polymer. *See, e.g.*, Raymond C. Rowe, et al, Handbook of Pharmaceutical Excipients, at 110 (6th ed. 2009) (noting that "[l]ightly crosslinked carbomers" are understood to have "lower viscosity," while "[h]ighly crosslinked carbomers" have "higher viscosity"). Rather than reading the term "lightly" out of the claim language, Defendant's proposal goes to the heart of what "lightly" means, according to the '383 patent.

Lastly, at times in their briefing and at the *Markman* hearing, Plaintiffs make the general objection that to define "lightly cross-linked polyacrylic acid polymers" by reference to the polymers' viscosity would be to improperly "import a viscosity limitation" from the specification into the meaning of that term. (D.I. 59 at 10; *see also* Tr. at 73–76) This type of argument—that

the proposed definition improperly imports a limitation from the specification—would have greater force, for example, if the Defendant was seeking to limit the definition of this term simply to refer to the five particular lightly cross-linked polymers that are set out in the specification (CARBOPOL 910, 941, 971, 981, and ETD 2050). ('383 patent, col. 4:21–24; 4:27–29) But here the question is not whether the definition of such a polymer should be limited to those preferred embodiments, but instead whether the polymers should be defined by reference to their viscosity (or in some other way). And on that question, as noted above, the patent repeatedly indicates that an upper limit on viscosity is the only appropriate way to ascribe meaning to the claim limitation at issue.

Although the Court finds that Defendant's proposal for this term is generally consistent with the intrinsic and extrinsic record, one aspect of that proposal is at odds with the specification—Defendant's proposal that the polymer's viscosity be "less than 15,000 cP[.]" Of the five examples of "lightly cross-linked" polymers in the specification, the highest viscosity range (that of CARBOPOL ETD 2050) includes a top level of 15,000 cP—meaning that Defendant's construction would exclude at least one of the preferred embodiments. Claim constructions that exclude preferred embodiments are generally disfavored. *Primos Inc. v. Hunter's Specialties Inc.*, 451 F.3d 841, 848 (Fed. Cir. 2006). Also weighing against a rigid upper limit on the viscosity of a polymer-in-solution is the claim language itself, which provides that the overall gel composition must have a "viscosity of less than *about* 15,000 cP." ('383 patent, col. 19:43 (emphasis added)) Given that the overall gel viscosity need not conform to a rigid numerical limit, it would be odd to impose such a requirement on a constituent polymer. *See, e.g., Ecolab, Inc. v. Envirochem, Inc.*, 264 F.3d 1358, 1367 (Fed. Cir. 2001) (noting that "the

term 'about,' . . . is a descriptive term commonly used in patent claims to 'avoid a strict numerical boundary to the specified parameter'") (internal citations omitted).[12]

For the foregoing reasons, the Court construes the term "lightly cross-linked polyacrylic acid polymer" to mean "a cross-linked polymer of acrylic acid with a viscosity of less than about 15,000 cP, where the polymer is in a 0.5% solution at pH 7.5, as measured by a Brookfield viscometer at 20 rpm."

2. The Container Terms

The only other terms in dispute are the container terms, which appear in dependent claims 16 and 52, as shown below:

> 16. The composition of claim **1** in combination with *a container that accurately administers a portion of the composition* for topical administration to a patient.
>
> 52. The method of claim **37**, which method further comprises placing the composition in *a container from which drops are accurately administered* for topical administration to a patient.

('383 patent, col. 20:51–53, col. 23:13–16 (emphasis added)) Defendant contends that these phrases are indefinite under 35 U.S.C. § 112. (D.I. 57 at 13) Plaintiffs counter that these phrases are not indefinite, and proposes that the Court construe them both to mean "a container that enables a user to administer a quantity of the compound in an amount that is intended by the user." (D.I. 59 at 15)

Section 112 of the Patent Act requires that every patent must "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant

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[12] Indeed, the '383 patent itself echoes this fact, noting that "ranges are generally introduced with the term 'about' to indicate a certain flexibility in the range, i.e. ± 10%." ('383 patent, col. 3:60–63)

regards as his invention." 35 U.S.C. § 112, ¶ 2. This language gives rise to what is generally known as the "definiteness" requirement; if a patent fails to satisfy this requirement, then it is invalid as indefinite. *See, e.g.*, *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1371 (Fed. Cir. 2008). A claim cannot be found indefinite unless it "is insolubly ambiguous, and no narrowing construction can properly be adopted." *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1319 (Fed. Cir. 2008) (internal citations and quotation marks omitted). "Indefiniteness is a matter of claim construction, and the same principles that generally govern claim construction are applicable to determining whether allegedly indefinite claim language is subject to construction." *Id.* Thus, "[i]f the meaning of [a] claim [limitation] is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, [then] the claim [is] sufficiently clear to avoid invalidity on indefiniteness grounds." *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001) (citations omitted).

"[B]ecause claim construction frequently poses difficult questions over which reasonable minds may disagree, proof of indefiniteness must meet an exacting standard." *Haemonetics Corp. v. Baxter Healthcare Corp.*, 607 F.3d 776, 783 (Fed. Cir. 2010) (internal citations and quotation marks omitted). As such, the burden is on the party asserting indefiniteness to "demonstrate by clear and convincing evidence that one of ordinary skill in the relevant art could not discern the boundaries of the claim based on the claim language, the specification, the prosecution history, and the knowledge in the relevant art." *Id.*

The question for the Court is therefore whether, at this stage, Defendant has proven by clear and convincing evidence that the container terms are insolubly ambiguous and therefore not

amenable to construction.[13] Answering this question requires the Court to analyze two subsidiary issues: (1) whether the Court can discern the meaning of the limitation in the container terms that describes a quantity of the gel composition (a "portion" in the case of claim 16 and a "drop" in the case of claim 52); and (2) whether the Court can discern the meaning of the limitation in the container terms that refers to the capability of the claimed container to "administer" that gel quantity "accurately." (*See, e.g.*, Tr. at 58 (identifying these two issues as central to the parties' dispute over whether the meaning of the container terms can be determined))

The Court begins its analysis of the first of these issues with the claim language itself. As an initial matter, although both parties have addressed the container terms in a unitary fashion, there is a clear difference between them. Claim 16 refers broadly to administration of "a portion of the composition," while claim 52 more specifically refers to administration of a *particular* portion of the composition—namely, a "drop[]." This context strongly suggests that while only containers that can dispense "drops" would fall within the scope of claim 52, claim 16 encompasses any container that could accurately administer a "portion" of the claimed composition, whether or not that portion could fairly be considered a "drop." The Court's reading is confirmed by the ordinary, identifiable meaning of the terms "drop" and "portion." While a "drop" typically refers to a small quantity that is "more or less spherical," the term "portion" simply refers to "a part of any whole."[14] There is no indication that the specification has used

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[13] A Court may consider the question of indefiniteness during claim construction. *UCB, Inc. v. KV Pharm. Co.*, Civil Action No. 08-223-JJF, 2009 WL 2524519, at *9 n.4 (D. Del. Aug. 18, 2009).

[14] *Cf.* http://dictionary.reference.com/browse/portion (last visited June 11, 2012); http://dictionary.reference.com/browse/drop (last visited June 11, 2012).

either term in a manner that deviates from these commonly understood meanings. (*See, e.g.*, '383 patent, Abstract; *see also id.*, col. 8:55–63)

The specification also offers insight into the meaning of the second key limitation in the container terms—namely, how the claimed container enables accurate administration of the gel. A container that "accurately administers," as that phrase is used in the '383 patent, is one that can dispense the claimed gel in a manner consistent with the prescribed dosage. The link between the claimed container and the prescribed treatment instructions is exemplified by the section of the '383 patent specification that is devoted to discussing the claimed container. (*See* '383 patent, col. 8:65–9:50 (describing the "Article of Manufacture"); *see also* Tr. at 20 (identifying this portion of the '383 patent specification as that which is "devoted to" describing the claimed container)) This article of manufacture includes the gel composition "in a suitable container . . . in combination with labeling instructions." (*Id.*, col. 8:65–9:2) Reflecting these multiple components, one half of that section describes the physical characteristics of exemplary containers, ('383 patent, col. 9:1–24), and the other half describes the instructions that accompany that container (*id.*, col. 9:25–50).

As for the physical characteristics of the container, the most preferred embodiment is a dropper bottle. (*See id.*, col. 9:1–2 (noting that the invention could be placed "in a suitable container, preferably in a dropper bottle"); *see also id.*, Abstract (noting that "the low viscosity composition has an advantage of being administered more accurately when combined with a container that administers the composition as drops"); *id.*, col. 2:59–62 (describing the topical gel delivery system of the invention as "providing a pourable composition that flows through a dropper tip easily"); *id.*, col. 4:52–55 (noting that the claimed, low-viscosity gel "can be

administered very accurately by a dropper or drip-type dispenser")) Table D describes a particular dropper bottle example, which has an extended orifice tip that measures 15 mm. (*Id.*, col. 9:12–24)

However, the "article of manufacture" encompasses more than just dropper bottles. "Other means of administration are an eyedropper, or tube with a suitable small orifice size, such as an extended tip tube," or a "clear plastic squeeze bottle" that has a "reduced orifice tip" as compared to "an ointment tube." ('383 patent, col. 9:4–6; *id.*, col. 7:7–11) The '383 patent criticizes ointment tubes with larger dispensing orifices, because more "accurate dosage control"—i.e., administration that is more consistent with prescribed doses—is achieved by "using a reduced orifice tip." (*Id.*, col. 7:7–12)

Aside from these physical characteristics, the '383 patent highlights the treatment instructions that must accompany the container, describing one particular example of those treatment instructions as "labeling instructions." These labeling instructions "can come in the form of a pamphlet, [or as] a label applied to or associated with the packaging" for the claimed gel. (*Id.*, col. 9:25–27) Tracking the language of the claims, these "labeling instructions provide for administering a composition of the invention to an affected area . . . in an amount and for a period of time sufficient to improve the skin disorder." (*Id.*, col. 9:28–31) These instructions "are an important aspect of the invention," and "provide the necessary dosage, administration and usage." (*Id.*, col. 9:28–45) "Thus, the combination of the composition with the dropper bottle with appropriate treatment instructions is important for the *proper usage of the drug* once it gets on the market." (*Id.*, col. 9:46–48 (emphasis added)) As this section makes clear, the baseline for determining proper and accurate administration of the claimed composition is the prescribed

course of treatment, which will be communicated to the user in the form of treatment instructions.

Although neither the patent claims nor the specification are a model of clarity when describing the claimed containers, the Court concludes that Defendant has failed to meet its heavy burden of demonstrating that the container terms are not amenable to construction. As discussed above, the specification provides a number of examples of containers (with dropper bottles being the preferred embodiment) that are within the scope of the invention described in claims 16 and 52. All of those examples, be they tubes, bottles, or droppers, have a sufficiently small orifice to dispense the gel in quantities that are in accordance with the prescribed doses. In other words, an orifice that is of reduced size as compared to prior art ointment tubes is not merely a preferred embodiment; it is what allows the user to take advantage of the low viscosity of the composition (whether the gel is dispensed as a "portion," as in claim 16, or as a "drop," as in claim 52). Moreover, that physical characteristic of the containers must be designed to dispense the gel quantity in accordance with the prescribed treatment instructions, in order for the "administration" of gel to be "accurate."[15]

Although the Court thus agrees with Plaintiffs that the container terms are amenable to construction, Plaintiffs' proposal fails to properly reflect the context of the '383 patent in three respects. First, Plaintiffs' proposed construction does not account for the difference in claim

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[15] The Court notes that the use of the term "accurate" in the patent, which the Court has linked to the baseline of the prescribed dosage, is consistent with the ordinary meaning of this term. *See, e.g.*, http://www.merriam-webster.com/dictionary/accurate (defining accurate to mean "conforming . . . to a standard") (last visited June 11, 2012); http://dictionary.reference.com /browse/accurate (defining accurate to mean "consistent with a standard, rule, or model") (last visited June 11, 2012).

language between claims 16 and 52, and instead collapses the distinct concepts of "drops" and "portions" into the single concept of "quantity." Claim 52 is directed to a container that is capable of dispensing the gel composition as drops, while claim 16 is more broadly directed to containers that accurately dispense a generic "portion" of the gel. Plaintiffs' proposed construction improperly reads out the reference to "drops" in claim 52. *See, e.g., Callicrate v. Wadsworth Mfg., Inc.*, 427 F.3d 1361 (Fed. Cir. 2005) (holding that a district court erred in "read[ing] out" a limitation that required a claimed loop to be "preformed"). Having determined that both claims are amenable to construction, the Court therefore construes them separately to account for the difference in claim scope.

Second, Plaintiffs' proposal refers to administering a quantity of the "compound," not to a quantity of the composition. As used in the claims, a "compound" refers to the active pharmaceutical ingredient, not the overall gel composition. (*See,* '383 patent, col. 19:46–47; *see also* Tr. 34 (Plaintiffs' counsel noting that their definition should have referred to the "composition," not to the "compound")) The Court's construction below reflects this change.

Third, Plaintiffs' proposal introduces the amorphous concept of the user's intent. The Court finds no discussion in the specification that invokes the intent of the user to set the boundaries as to the meaning of the terms-at-issue—either as to the amount of composition dispensed from the container or as to what it means to "accurately" administer an amount of the composition.[16]

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[16] At the *Markman* hearing, Plaintiffs' counsel also suggested an alternative construction, wherein the "accuracy" limitation in the container terms would refer to "the function of the container to be able to replicate or repeat that precise quantity time and time again." (Tr. 29) However, as is the case with Plaintiffs' invocation of a "user's intent," the Court does not find any portion of the patent specification that introduces or applies the concept of

Plaintiff also asserted at the *Markman* hearing that using "treatment instructions" as the point of reference for determining accuracy would violate the doctrine of claim differentiation. (Tr. at 25–26) This doctrine "stems from 'the common sense notion that different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope.'" *Seachange Int'l, Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1368 (Fed. Cir. 2005) (citations omitted). As a consequence, ordinarily "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." *Phillips*, 415 F.3d at 1315. In this case, Plaintiffs argue that because dependent claims 17 and 53 (which depend, respectively, from claims 16 and 52) refer to a composition "in combination with labeling instructions," it is presumptively improper to include a limitation directed to instructions in the Court's construction for claims 16 and 52.

As an initial matter, the Court is not convinced that the presumption of claim differentiation applies. The Court has not suggested that the container terms should be construed to refer to "*labeling* instructions," but rather has determined that the "accuracy" limitation in those terms must be gauged with respect to the broader concept of *treatment* instructions. The '383 patent uses the term labeling instructions exclusively to refer to written materials, such as a "pamphlet" or a "label applied to" the container. ('383 patent, col. 9:25–27) In contrast, the broader term "treatment instructions" in the Court's construction would encompass more than just written materials, and could include, for instance, oral instructions from a physician. (*See id.*, col. 9:46–50) As such, if claims 16 and 52 were construed to incorporate the concept of treatment instructions, claims 17 and 53 would nonetheless be of different and narrower scope

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reproducibility to the container.

(because they reference only one subset of a broader universe of possible treatment instructions).

More importantly, even if the presumption of claim differentiation did apply, the Court finds that the clear teachings of the specification discussed above rebut that presumption, because treatment instructions are the only means by which to evaluate the accuracy of gel administration that are described in the '383 patent. *See, e.g.*, *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296, 1305 (Fed. Cir. 2011) ("[A]ny presumption created by the doctrine of claim differentiation will be overcome by a contrary construction dictated by the written description or prosecution history . . . .") (internal quotation marks and citations omitted); *accord Simplification LLC v. Block Fin. Corp.*, 593 F. Supp. 2d 700, 711 (D. Del. 2009) (finding that the claim differentiation presumption was "trump[ed]" by the "prosecution history and specification").

For the foregoing reasons, the Court construes the "container" term in claim 16 to mean "a container that has a sufficiently small orifice tip to dispense quantities of the low-viscosity gel composition in accordance with treatment instructions," and construes the "container" term in claim 52 to mean "a container that has a sufficiently small orifice tip to dispense generally spherical quantities of the low-viscosity gel composition in accordance with treatment instructions."

While the Court has concluded that the container terms are amenable to construction, that does not resolve the question of whether those terms may ultimately be found invalid (for indefiniteness or on some other grounds). During briefing, Defendant's principal objection to Plaintiffs' construction was that "[i]t is difficult to imagine a container which would not . . . infringe under Plaintiffs' proposed construction." (D.I. 57 at 15; *see also* D.I. 87 at 9 ("That Plaintiffs' proposed construction is broad enough to cover innumerable prior art containers

demonstrates the indefiniteness of the claim phrase.") As an initial matter, the Court notes that its construction above is narrower and more precise than that offered by Plaintiffs, so Defendant's objection may no longer apply. However, although the Court was able to reduce the meaning of claims 16 and 52 to words, Defendant still may argue at summary judgment or at trial that "a person of ordinary skill in the art cannot translate [that] definition into meaningfully precise claim scope." *Bristol-Myers Squibb Co. v. Mylan Pharms. Inc.*, Civil Action No. 09-651-LPS, 2012 WL 1753670, at *6–7 (D. Del. May 16, 2012) (internal quotation marks and citations omitted). In other words, Defendant may argue not only that claims 16 and 52 read onto the prior art, but also that a person of ordinary skill in the art would not understand, based on the Court's construction, where the prior art ends, and the scope of those claims begins. At this stage, however, Defendant has put forward no such evidence (let alone clear and convincing evidence), that would lead the Court to conclude that claims 16 and 52, although able to be construed, are of such indeterminate scope. (*See, e.g.*, Tr. at 46 (noting that expert testimony, which has not thus far been offered, would "bolster" a claim of indefiniteness))

Moreover, Defendant's objection appears, at least in part, to inappropriately collapse the indefiniteness inquiry into broader questions of whether the claim is anticipated or rendered obvious. *See, e.g.*, *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1252 (Fed. Cir. 2008) (noting that if a claim is of undue breadth, that does not necessarily render it invalid for indefiniteness, but rather should shift "the focus . . . [to] other validity challenges (e.g., anticipation)"). At the *Markman* hearing, Defendant's counsel asserted that if the Court's construction for these terms is broad, then that will have an effect "when it comes time to dispute the obviousness or the anticipation of these claims." (Tr. at 47–48) But the issues of anticipation

and obviousness are not properly before the Court at this stage, and the Court here makes no conclusion as to the ultimate validity of the claims, except for its determination that Defendant has, at this stage, failed to show by clear and convincing evidence that claims 16 and 52 are indefinite.

IV. CONCLUSION

For the foregoing reasons, I recommend that the Court adopt the following constructions:

1. "for a period of time sufficient to improve the skin disorder" means "over a course of treatment of sufficient duration to improve the skin disorder"

2. "base to adjust pH" means "a basic compound that can be used to adjust pH"

3. "lightly cross-linked polyacrylic acid polymer" means "a cross-linked polymer of acrylic acid with a viscosity of less than about 15,000 cP, where the polymer is in a 0.5% solution at pH 7.5, as measured by a Brookfield viscometer at 20 rpm"

4. The "container" recited in claim 16 means "a container that has a sufficiently small orifice tip to dispense quantities of the low-viscosity gel composition in accordance with treatment instructions"

5. The "container" recited in claim 52 means "a container that has a sufficiently small orifice tip to dispense generally spherical quantities of the low-viscosity gel composition in accordance with treatment instructions."

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The failure of a party to object to legal conclusions may result in the

loss of the right to de novo review in the district court. *See Henderson v. Carlson*, 812 F.2d 874, 878–79 (3d Cir. 1987); *Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006).

The parties are directed to the Court's Standing Order In Non-Pro Se Matters For Objections Filed Under Fed. R. Civ. P. 72, dated November 16, 2009, a copy of which is available on the Court's website (http://www.ded.uscourts.gov).

Dated: June 12, 2012

Christopher J. Burke
United States Magistrate Judge