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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

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Medicis Pharmaceutical Corporation,)

No. CV 10-1780-PHX-JAT

10

Plaintiff,)

ORDER

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vs.)

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Acella Pharmaceuticals Incorporated,)

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Defendant.)

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After holding a *Markman* hearing on February 23, 2011, the Court enters the following claim construction Order.

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I. Background

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Plaintiff Medicis Pharmaceutical Corporation (“Medicis”) owns, through assignment, United States Letters Patent No. 7,776,355 (the “Patent”). The Patent claims a topical drug delivery system comprised of a pad, a container, and a liquid composition that includes dermatologically active ingredients. Medicis uses the Patent’s drug delivery system in Medicis products, including its Triaz® Foaming Cloths. Triaz® Foaming Cloths deliver benzoyl peroxide to the skin to treat acne. Triaz® Foaming Cloths are available in three different strengths: 3%, 6%, and 9%.

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Defendant Acella Pharmaceuticals Inc. (“Acella”) sells benzoyl peroxide foaming cloths in three different strengths: 3%, 6%, and 9%. Medicis believes the Acella foaming cloths directly infringe the Patent. Medicis therefore filed this suit for patent infringement

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1 on August 19, 2010.

2 The parties have asked the Court to construe four of the Patent’s claim terms.¹
3 Pursuant to *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996), the Court
4 must construe the claims as a matter of law. The parties have filed briefs supporting their
5 proposed constructions of the claim terms. Having considered the arguments and evidence
6 presented in the parties’ briefs, exhibits, and at the *Markman* hearing, the Court construes the
7 disputed terms as follows.

8 II. Legal Standard

9 Section 112 of the Patent Act provides that a patent specification “shall contain a
10 written description of the invention, and of the manner and process of making and using it
11 in such full, clear, concise, and exact terms as to enable any person skilled in the art to which
12 it pertains . . . to make and use the same . . .” 35 U.S.C. §112. The section further provides
13 that a specification “shall conclude with one or more claims particularly pointing out and
14 distinctly claiming the subject matter which the applicant regards as his invention.” *Id.*

15 “It is a ‘bedrock principle’ of patent law that ‘the claims of a patent define the
16 invention to which the patentee is entitled the right to exclude.’” *Phillips v. AWH Corp.*, 415
17 F.3d 1303, 1312 (Fed. Cir. 2005) (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration*
18 *Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). Claim construction, which is the
19 determination of the meaning of the terms in a patent, is a question of law exclusively within
20 the province of the Court. *Markman*, 517 U.S. at 372. Thus,

21 The determination of infringement is a two-step process. First,
22 the court construes the claims to correctly determine the scope
23 of the claims. Second, it compares the properly construed
24 claims to the accused device. Claim construction is a matter of
law However, a determination of infringement, both literal
and under the doctrine of equivalents, is a question of fact.

25 ¹The Court ordered the parties to jointly submit a stipulated chart that lists all the
26 claim terms the parties wanted the Court to construe. (Doc. 132). The Court bases this Order
27 on the stipulated chart (Doc. 133) submitted by the parties in compliance with the Order at
28 Docket entry 132.

1 *Dow Chem. Co. v. Sumitomo Chem. Co.*, 257 F.3d 1364, 1372 (Fed. Cir. 2001) (internal
2 citations omitted).

3 To interpret claims, the Court first considers the claims themselves. *Vitronics Corp.*
4 *v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). The Court should “look to the
5 words of the claims themselves” giving them “their ordinary and customary meaning,” unless
6 clearly stated otherwise. *Id.* The “ordinary and customary” meaning of a claim term is “the
7 meaning that the term would have to a person of ordinary skill in the art in question at the
8 time of the invention . . .” *Phillips*, 415 F.3d at 1313; *see also Texas Digital Sys., Inc. v.*
9 *Telegenix, Inc.*, 308 F.3d 1193, 1202 (Fed. Cir. 2002) (“The terms used in the claims bear
10 a ‘heavy presumption’ that they mean what they say and have the ordinary meaning that
11 would be attributed to those words by persons skilled in the relevant art.”).

12 In some cases, the ordinary meaning of claim language as understood by someone
13 skilled in the art may be readily apparent even to lay judges. *Phillips*, 415 F.3d at 1314. In
14 such cases, claim construction involves little more than applying the widely accepted
15 meaning of commonly understood words. *Id.* General purpose dictionaries may prove
16 helpful in such circumstances. *Id.*

17 After the claims themselves, the Court looks to the patent specification. *Vitronics*, 90
18 F.3d at 1582. The specification is highly relevant to the claim construction analysis and
19 usually is dispositive. *Id.* The specification is the single best guide to the meaning of a
20 disputed term. *Id.* The importance of the specification in construing claims derives from its
21 statutory role. *Phillips*, 415 F.3d at 1316. The relevance of the written description is
22 enforced by the statutory requirement that the specification describe the claimed invention
23 “in full, clear, concise, and exact terms.” *Id.* (quoting 35 U.S.C. §112). Courts therefore may
24 rely heavily on the written description of the claims in the specification for guidance when
25 conducting claim construction. *Id.* at 1317.

26 The specification may give a special definition to a claim term that differs from the
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1 meaning it otherwise would have. *Id.* at 1316. In such cases, the inventor’s special
2 definition, or lexicography, governs. *Id.* In other cases, the specification intentionally may
3 disclaim or limit the scope of the claim. *Id.* In those cases too, the inventor’s decision to
4 expressly limit the scope of the claim is dispositive. *Id.*

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6 When reviewing the specification, however, courts must avoid reading limitations
7 from the specification into the claims. *Id.* 1323. Distinguishing between using the
8 specification to interpret the meaning of a claim and importing limitations from the
9 specification into the claim can be difficult in practice. *Id.*

10 However, the line between construing terms and importing
11 limitations can be discerned with reasonable certainty and
12 predictability if the court’s focus remains on understanding how
13 a person of ordinary skill in the art would understand the claim
14 terms. For instance, although the specification often describes
15 very specific embodiments of the invention, we have repeatedly
16 warned against confining the claims to those embodiments.

17 *Id.* (internal citations omitted). To avoid importing limitations, the Court must consider the
18 purposes of the specification, which are to teach and enable those of skill in the art to make
19 and use the invention and to provide the best way for doing so. *Id.*

20 In addition to the claims themselves and the specification, courts should consider the
21 patent’s prosecution history, if in evidence. *Phillips*, 415 F.3d at 1317. The prosecution
22 history consists of the record of the proceedings before the Patent and Trademark Office (the
23 “PTO”) and includes the prior art cited during the examination of the patent. *Id.* The
24 prosecution history, which is part of the “intrinsic evidence,” provides evidence of how the
25 PTO and the inventor understood the patent.² *Id.* The prosecution history often informs the

26 ²Like the specification, the inventor created the prosecution history in an attempt to
27 explain and also to obtain the patent. *Phillips*, 415 F.3d at 1317. But because the history
28 represents ongoing negotiations between the PTO and the applicant, rather than the final
product of the negotiations, the prosecution history often lacks the clarity of the specification
and therefore is less useful for claim construction purposes. *Id.*

1 meaning of the claim language by demonstrating how the inventor understood the invention
2 and whether the inventor limited the invention in the course of the prosecution, thereby
3 making the claim scope narrower than it otherwise would be. *Id.*

4 Although the intrinsic evidence – the Patent and the prosecution history – is the most
5 important for claim construction, the Court also may rely on extrinsic evidence if necessary.
6 Extrinsic evidence is all evidence external to the patent and prosecution history, such as
7 expert and inventor testimony, dictionaries,³ and learned treatises. *Id.* Although it may prove
8 useful, extrinsic evidence is less significant than the intrinsic record for determining the
9 meaning of claim language. *Id.* In most situations, analysis of the patent and its prosecution
10 history will resolve any ambiguity in a disputed claim term. *Vitronics*, 90 F.3d at 1583.

11 Extrinsic evidence in the form of expert testimony can help a court’s construction in
12 a variety of ways. *Phillips*, 415 F.3d at 1318. Expert testimony may provide background on
13 the technology involved, explain how the invention works, ensure that the court’s
14 understanding of the patent’s technical aspects is consistent with that of a person in the art,
15 or “establish that a particular term in the patent or the prior art has a particular meaning in
16 the pertinent field.” *Id.* But conclusory, unsupported assertions by experts as to the proper
17 construction of a claim term do not aid the Court. *Id.* And the Court discounts any expert
18 testimony “that is clearly at odds with the claim construction mandated by the claims
19 themselves, the written description, and the prosecution history, in other words, with the
20 written record of the patent.” *Id.* (internal quotations omitted).

21 Although the Court must endeavor to construct the claims as precisely as possible, “a
22 sound claim construction need not always purge every shred of ambiguity.” *Acumed LLC*

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25 ³“Because dictionaries, and especially technical dictionaries, endeavor to collect the
26 accepted meanings of terms used in various fields of science and technology, those resources
27 have been properly recognized as among the tools that can assist the court in determining the
28 meaning of particular terminology to those of skill in the art of the invention.” *Phillips*, 415
F.3d at 1318.

1 v. *Stryker Corp.*, 483 F.3d 800, 806 (Fed. Cir. 2007). Some line-drawing problems may be
2 left to the trier of fact. *Id.*

3 **III. The Patent**

4 The Patent issued on August 17, 2010. (US Patent No. 7,776,355, Ex. A to Plaintiff's
5 Opening Claim Construction Brief, Doc. 55-1). The Patent's field of invention is listed as
6 drug delivery systems; particularly systems comprised of pads, sealed containers, and liquid
7 compositions. The Summary of the Invention section of the Patent provides in part:

8 The present invention overcomes many of the problems
9 experienced in the art. In this invention, the dermatologically
10 active ingredients are insoluble drugs suitable for human or
11 animal use, and the composition is a liquid comprising one or
12 more dermatologically active ingredients. The composition is
13 retained by the pad preferentially over the container.
14 Dermatologically active ingredients, e.g. without limitation,
15 BPO, and insoluble antifungals, do not preferentially migrate or
16 absorb from the composition (e.g. without limitation, emulsion)
17 onto or into the pad, and therefore does not result in an uneven
18 concentration of the dermatologically active ingredient in the
19 composition versus the pad. Further, the pad is packaged in a
20 container and one or more pads may be packaged in each
21 container.

22 * * *

23 In accordance with the present invention, insoluble
24 dermatologically active ingredients are mixed in an emulsion
25 composition, e.g. without limitation, an oil-in-water emulsion or
26 a water-in-oil emulsion, preferably an oil-in-water emulsion.
27 This composition is suited to causing the dermatologically
28 active ingredient to be substantially uniformly distributed
throughout the composition upon routine mixing during
formulation, and remain so during the product's shelf life. . . .
Further, the viscosity of the composition is carefully adjusted to
be low enough that the composition will permeate the matrix of
the pad's fibers and be held on the pad by capillary action.
However, the viscosity must not be so low that the composition
is so thin that it drains off the pad prematurely. On the other
hand, if the viscosity is too high, not only will the composition
fail to be taken into the pad's fibers' matrix, it will tend to be
released from the surface of the pad to the walls of the container,
and remain there, unavailable for application to the patient's
skin.

Use of the present invention by wiping the pad across
skin results in a transfer to the skin of the dermatologically
active ingredient, meaning that the skin is substantially

1 uniformly medicated. During this wiping, an adequate
2 therapeutic dose of the dermatologically active ingredient is
3 delivered to the skin. One advantage of this invention may be
a reduced irritation to the skin as compared to similar
compositions applied without the pad.

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5 (Doc. 55-1, Column "Col." 2-3).

6 The Patent issued with four independent claims – claims 1, 2, 8, and 9 – and twenty
7 dependent claims. A dependent claim is written by specifically referencing another claim.
8 35 U.S.C. §112. A dependent claim does not recite the elements of the referenced
9 independent claim, but is construed to incorporate all of the limitations of that claim. *Id.* A
10 dependent claim also specifies a further limitation of the subject matter claimed. *Id.*
11 Independent claims are presumed to have broader scope than their dependents. *Acumed*, 483
12 F.3d at 806. In fact, the presence of a particular limitation in a dependent claim raises a
13 presumption that the limitation is not found in the independent claim. *Id.*⁴

14 All of the disputed terms are in the independent claims. The independent claims read:

15 What is claimed is:

16 1. A drug delivery system comprising
17 a pad;
a container; and
18 a liquid composition, wherein the composition comprises:
19 (1) an effective amount of one or more insoluble
dermatologically active ingredients, and (2) an emulsion vehicle
20 for the dermatologically active ingredients, wherein the
composition has a viscosity which is low enough for the
21 composition to substantially uniformly absorb onto the pad via
capillary action, and high enough to be substantially retained on
the pad, not the container, and
22 wherein the active ingredient comprises benzoyl peroxide
particles of less than 50 microns.

23 2. A drug delivery system comprising
24 a pad;

25 ⁴“That presumption is especially strong when the limitation in dispute is the only
26 meaningful difference between an independent and dependent claim, and one party is urging
27 that the limitation in the dependent claim should be read into the independent claim.”
Acumed, 483 F.3d at 806.

1 a container; and
2 a liquid composition, wherein the composition comprises:
3 (1) an effective amount of one or more insoluble
4 dermatologically active ingredients, and (2) an emulsion vehicle
5 for the dermatologically active ingredients, wherein the
6 composition has a viscosity which is low enough for the
7 composition to substantially uniformly absorb onto the pad via
8 capillary action, and high enough to be substantially retained on
9 the pad, not the container, and wherein the active ingredient
10 comprises particles of about 10 to about 150 microns.

11 ***

12
13 8. A drug delivery system comprising
14 a pad;
15 a container; and
16 a liquid composition, wherein the composition comprises:
17 (1) an effective amount of one or more insoluble
18 dermatologically active ingredients, and (2) an emulsion vehicle
19 for the dermatologically active ingredients, wherein the
20 composition has a viscosity which is low enough for the
21 composition to substantially uniformly absorb onto the pad via
22 capillary action, and high enough to be substantially retained on
23 the pad, not the container, and wherein the active ingredient
24 comprises particles of up to about 300 microns.

25 9. A drug delivery system comprising
26 a pad;
27 a container; and
28 a liquid composition, wherein the composition comprises:
(1) an effective amount of one or more insoluble
dermatologically active ingredients, and (2) an emulsion vehicle
for the dermatologically active ingredients, wherein the
composition has a viscosity which is low enough for the
composition to substantially uniformly absorb onto the pad via
capillary action, and high enough to be substantially retained on
the pad, not the container, and wherein the active ingredient
comprises particles of less than 50 microns.

(Doc. 55-1, Col. 7- Col. 8).

IV. Claim Construction

The following chart summarizes the Court's construction of the disputed claim terms.
The analysis supporting the constructions follows.

Disputed Claim Term	Construction
Pad	Includes, but is not limited to, pads, pledgets, towels, towelettes, cloths, and sponges that may be of woven or nonwoven material, may be of synthetic or natural material, and may comprise more than one layer.
Container	Packaging that contains one or more pads, does not leak the composition, and does not degrade excessively over time once it is sealed.
Effective Amount	Adequate therapeutic dose.
Viscosity which is low enough for the composition to substantially uniformly absorb onto the pad via capillary action, and high enough to be substantially retained on the pad, not the container.	Viscosity which is low enough for the composition to substantially uniformly absorb onto the pad via capillary action, and high enough to be substantially retained on the pad, not the container, but less than 10,000 centipoise.

A. Pad

Plaintiff offers the following definition of pad: “A pad is a component of the drug delivery system that is woven or nonwoven and includes, but is not limited to pads, pledgets, towels, towelettes, cloths, and sponges.” (Doc. 133, p.2). Defendant suggests the following construction: “Pads, pledgets, towels, towelettes, cloths and sponges; the pads may be woven or non-woven material, may be made of synthetic or natural material and may comprise more than one layer. There is no limitation on the material used to form the pad or its characteristics (such as porosity or absorption) that affect interaction with the composition.” (Id.)

1 The Court adopts neither construction, but draws its own slightly different
2 construction from the claims themselves and the specification. The claims provide that the
3 pad is the material that is used in the drug delivery system to absorb and then deliver the
4 drugs to the skin. The specification elaborates on the type of material. The specification
5 provides that “pads include but are not limited to pads, pledgets, towels, towelettes, cloths,
6 and sponges; the pads may be woven or nonwoven material;” that the pad “may be made of
7 synthetic or natural material;” and that “materials for the pad may comprise more than one
8 layer.” (Doc. 55-1, Col. 2; 51-53 & Col. 4; 46-47 & 52).

9 The Court has chosen a construction that tracks the specification more closely than
10 either proposed construction, and the specification is the single best guide to the meaning of
11 a disputed term. *Vitronics*, 90 F.3d at 1582. The Court’s definition does not contain the
12 extraneous verbiage suggested by Defendant that is not found in the specification, and
13 contains more description from the specification than suggested by Plaintiff. The Court finds
14 the ordinary and customary meaning of the term “pad” as used in the Patent and understood
15 by a person of ordinary skill in the art, *see Phillips*, 415 F.3d at 1313, means “Includes, but
16 is not limited to, pads, pledgets, towels, towelettes, cloths, and sponges that may be of woven
17 or nonwoven material, may be of synthetic or natural material, and may comprise more than
18 one layer.”

19 **B. Container**

20 Plaintiff asks the Court to construe container as “a structure that contains one more
21 pads, does not leak the composition, nor does it degrade excessively over time once it is
22 sealed.” (Doc. 155, p.3). Defendant argues the Court should construe container as “Any
23 material that packages the pad with the composition and does not degrade or leak the
24 composition for a sufficient period of time, such as shelf life of the invention. There is no
25 limitation on the material used to form the container or its characteristics that affect
26 interaction with the composition.” (Id.).

27 The Court essentially has adopted Plaintiff’s proposed definition with only slight
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1 wording changes. Plaintiff and the Court derive this meaning from the specification.
2 Regarding the container, the specification reads: “Packaging for the pad has an additional set
3 of considerations. A container may contain one or more pads, does not leak the composition
4 nor does it degrade excessively over time once it is sealed.” (Doc. 55-1, Col. 4; 61-64).
5 Defendant also quotes from the specification, but adds language not found in the
6 specification or the claims.

7 The Court does not need to look beyond the specification for the construction of
8 “container” and finds no need to augment the claim term with language not found in the
9 specification. The Court therefore finds that the ordinary and customary meaning of the term
10 “container” as used in the Patent and understood by person of ordinary skill in the art means:
11 “Packaging that contains one or more pads, does not leak the composition, and does not
12 degrade excessively over time once it is sealed.”

13 **C. Effective Amount**

14 Plaintiff proposes the following construction of the term “effective amount”: “An
15 effective amount of a dermatologically active ingredient means an adequate therapeutic dose
16 will be delivered to the skin by wiping the pad onto the skin.” (Doc. 133, p.3). Defendant’s
17 proffered definition builds on Plaintiff’s and adds a limitation: “An adequate therapeutic dose
18 delivered to the skin by wiping the pad onto the skin meaning the skin is uniformly
19 medicated; provided, the dermatologically active ingredients are particles of a size within the
20 range recited by the patent claim.” (Id.).

21 The specification provides that an “effective amount of the dermatologically active
22 ingredient means an adequate therapeutic dose will be delivered to the skin by wiping the pad
23 onto the skin.” (Doc. 55-1, Col. 3; 30-32). The Court reads that phrase as if it had a comma
24 and the word “which” before the word “will,” i.e. “effective amount of the dermatologically
25 active ingredient means an adequate therapeutic dose, *which* will be delivered to the skin by
26 wiping the pad onto the skin.” In other words, the Court finds that the specification’s
27 definition of “effective amount” – therapeutic dose – is found in the first clause and that the
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1 second part of the sentence describes the method of delivery for the effective amount.

2 The Court finds that this interpretation of the specification comports with the ordinary
3 meaning of the claim term as understood by someone in the art, which is apparent even to
4 a lay judge. *Phillips*, 415 F.3d at 1314. When a term’s meaning is apparent even to a lay
5 judge, claim construction involves little more than applying the widely accepted meaning of
6 commonly understood words. *Id.* General purpose dictionaries may prove helpful in such
7 circumstances. *Id.*

8 Random House defines “effective” as “adequate to accomplish a purpose; producing
9 the intended or expected result” and “amount” as “quantity; measure.” *Dictionary.com*
10 *Unabridged*. Random House, Inc. 16 Feb. 2011. <[Dictionary.com](http://dictionary.reference.com/browse/effective)
11 <http://dictionary.reference.com/browse/effective>>. So, the “effective amount” is the quantity
12 of dermatologically active ingredients that is adequate to produce the intended result. The
13 word “therapeutic” in the construction indicates that the intended result is curative and
14 medicinal.

15 Both Plaintiff and Defendant have suggested constructions that include phrases about
16 the method for delivering the adequate dose to the skin. Defendant goes even further and
17 includes a requirement that the dermatologically active ingredients’ particle sizes be within
18 a certain range. But the quantity of drugs needed to treat the skin is separate from the
19 Patent’s innovative delivery system for uniformly delivering that quantity. Nor does the
20 Court find that the specification dictates the inclusion of the method of delivery in the
21 definition of “effective amount” if read how the Court has explained. Further, nothing in the
22 intrinsic evidence argues for including a particle size limitation for the dermatologically
23 active ingredients in the definition of effective amount.

24 When construing “effective amount,” the Court need only apply the widely accepted
25 meaning of commonly understood words. “Amount” is a quantitative term, which is
26 modified in the Patent by “effective.” The Court finds that the ordinary and customary
27 meaning of the term “effective amount” within the meaning of the Patent is an “adequate
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1 therapeutic dose.”

2 **D. Viscosity That is Low Enough to Allow the Composition . . .**

3 **1. Indefiniteness**

4 Defendant argues that the Court cannot construe the viscosity phrase because it fails
5 for indefiniteness. Defendant argues in the alternative that the Court construe the phrase with
6 a viscosity range of 500 to less than 10,000 centipoise.⁵ The Court will address the
7 indefiniteness argument first.

8 The definiteness requirement of the Patent Act requires a specification to conclude
9 with claims that particularly point out and distinctly claim the subject matter that the inventor
10 regards as her invention. *Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1320 (Fed. Cir.
11 2003). Deciding whether a claim term is indefinite requires analysis of whether a person
12 skilled in the art would understand the bounds of the claim when read in light of the patent.
13 *Id.* at 1320-21 (internal citations omitted). The Act’s definiteness requirement ensures that
14 the patent’s claims delineate the scope of the invention with language that adequately notifies
15 the public of the patentee’s right to exclude. *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1346
16 (Fed. Cir. 2007). “If the claims read in light of the specification reasonably apprise those
17 skilled in the art of the scope of the invention, §112 demands no more.” *Omega*, 334 F.3d
18 at 1321.

19 Claims are considered indefinite if they are not “amenable to construction or are
20 insolubly ambiguous.” *Young*, 492 F.3d at 1346 (internal citations omitted). A claim is
21 insolubly ambiguous only if a person of ordinary skill in the art could not determine the
22 bounds of the claims. *Halliburton Energy Serv., Inc. v. M-I LLC*, 514 F.3d 1244, 1249 (Fed.
23 Cir. 2008). Claim terms are not indefinite merely because they present difficulties in claim
24 construction. *Id.* “[I]f the meaning of the claim is discernible, even though the task may be
25 formidable and the conclusion may be one over which reasonable persons will disagree, we

26
27 ⁵Centipoise is a unit of viscosity equal to one hundredth of a poise.

1 have held the claim sufficiently clear to avoid invalidity on indefiniteness grounds.” *Id.*
2 (internal citations omitted).

3 When determining definiteness, the general principles of claim construction apply.
4 *Young*, 492 F.3d at 1346. The Court first and primarily considers the intrinsic evidence. *Id.*
5 But the Court also may rely on extrinsic evidence, such as expert testimony. *Phillips*, 415
6 F.3d at 1317.

7 The Court begins its analysis with the presumption that the Patent is valid as drafted.
8 *Young*, 492 F.3d at 1345. An accused infringer has the burden of demonstrating invalidity
9 by clear and convincing evidence. *Id.* Proof of indefiniteness requires such exacting
10 evidence because claim construction often poses a difficult task over which experts and
11 judges may disagree. *Halliburton*, 514 F.3d at 1249. Defendant can meet this burden by
12 showing by “clear and convincing evidence that a skilled artisan could not discern the
13 boundaries of the claim based on the claim language, the specification, and the prosecution
14 history, as well as her knowledge of the relevant art area.” *Id.* at 1249-50.

15 The Patent specification emphasizes the importance of the viscosity range to the
16 invention’s ability to deliver an adequate and uniform amount of dermatological drugs to the
17 skin:

18 Further, the viscosity of the composition is carefully adjusted to
19 be low enough that the composition will permeate the matrix of
20 the pad’s fibers and will be held on the pad by capillary action.
21 However, the viscosity must not be so low that the composition
22 is so thin that it drains off the pad prematurely. On the other
23 hand, if the viscosity is too high, not only will the composition
24 fail to be taken into the pad’s fibers’ matrix, it will tend to be
25 released from the surface of the pad to the walls of the container,
26 and remain there, unavailable for application to the patient’s
27 skin.

28 (Doc. 55-1, Col. 3; 5-16). The prosecution history distinguishes the invention from prior art
in part based on the Patent’s preferable level of viscosity for retention and uniform
application of the dermatologically ingredients. (*See, e.g.*, June 5, 2006 Request for
Reconsideration, Doc. 85-15, p.17)(“[T]he art of record, especially the ‘237 Patent, teaches

1 away from a low viscosity by teaching the use of thickeners to achieve a high viscosity . . .
2 In contrast to the high viscosities of the ‘237 Patent, the viscosities of the present invention
3 are significantly lower and the specific values are necessary for the present invention to
4 work.”).

5 The specification teaches that the viscosity of the liquid composition must be within
6 a range that is both low enough to allow uniform permeation of the pad and high enough for
7 the composition to stay on the pad and not the container. The independent claims discuss the
8 parameters for the viscosity range in functional, rather than quantitative, terms, which
9 nonetheless are ascertainable by visual inspection of the pad and the container. (Fed. Cir.
10 2003). The Court therefore finds that a person skilled in the art of topical drug delivery
11 systems, *Omega*, 334 F.3d at 1320-21, would understand the functional boundaries for the
12 viscosities as described in the independent claims.

13 The testimony and declarations of Mr. Bogardus, a person highly skilled in the art of
14 topical drug delivery systems, support the Court’s finding. Mr. Bogardus testified that one
15 skilled in the art would understand readily the Patent’s functional description of viscosity.
16 He explained that viscosity can be described functionally and that functional viscosity can
17 be ascertained by observation of the functional behavior of the liquid. And he testified that
18 the ability to observe how viscosity functions in a product is within the skill set of people
19 working in the field of dermatological formulations.

20 Defendant offers only the Declarations of Edith Mathiowitz to support its
21 indefiniteness claim. In her Declaration in support of Acella’s claim construction brief, Dr.
22 Mathiowitz states that the claims’ viscosity term “does not provide any substantial
23 information that would allow a person of ordinary skill to formulate the delivery system.”
24 (December 17, 2010 Declaration of Dr. Edith Mathiowitz, Doc. 81-2, ¶8). Dr. Mathiowitz
25 suggests that the composition’s viscosity description requires the specification of parameters
26 not recited in the Patent, such as particle size distribution and particle volume fraction. (Id.
27 ¶9).

1 Dr. Mathiowitz's conclusory assertions do not provide much aid to the Court.
2 *Phillips*, 415 F.3d at 1318. They certainly do not rise to the level of the clear and convincing
3 evidence required to demonstrate the invalidity of the Patent. *Young*, 492 F.3d at 1345. The
4 Court therefore finds that the viscosity term is sufficiently definite and will proceed to
5 construct the term.⁶

6 2. Construction

7 Plaintiff proposes the following claim construction for the viscosity term: "Viscosity
8 is low enough to achieve the function of becoming absorbed onto the pad, and high enough
9 to achieve the function of being substantially retained on the pad, not the container." (Doc.
10 133, p.4). As an alternative to finding the term indefinite, Defendant suggests the following
11 definition: "The composition has a viscosity in the range of 500 to less than 10,000 cps and
12 is low enough that the composition will permeate the matrix of the pad's fibers and be held
13 on the pad by capillary action."

14 Defendant argues, pursuant to the doctrine of prosecution history estoppel, that
15 Plaintiff has limited the scope of its claims to liquid compositions with viscosities less than
16 10,000 centipoise ("cps"). Plaintiff counters that the doctrine of prosecution history estoppel
17 does not apply to a claim of literal infringement and that the doctrine of claim differentiation
18 prohibits the insertion of limitations from dependent claims into the independent claim.

19 Plaintiff correctly argues that the presence of a limitation, such as the centipoise
20 limitations here, in a dependent claim raises a *presumption* that the limitation is not present
21 in the independent claim. *Am. Med. Sys., Inc. v. Biolitec, Inc.*, 618 F.3d 1354, 1360 (Fed.
22 Cir. 2010)(citing *Phillips*, 415 F.3d at 1315)(emphasis added). But presumptions can be
23 overcome. Further, the Court's construction of the viscosity phrase does not import
24 limitations from the dependent claims. Rather, it narrows the term based on Plaintiff's

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26 ⁶The Court notes that the PTO issued the Patent after initially rejecting the claims
27 based in part on indefiniteness. (*See, e.g.*, September 28, 2005 Amendment and Request for
28 Reconsideration, Doc. 85-14, pp.6-8).

1 specific disavowals.

2 Plaintiff also correctly notes that the doctrine of prosecution history estoppel does not
3 apply if literal infringement may exist, as Plaintiff alleges here. *Fromson v. Advance Offset*
4 *Plate, Inc.*, 720 F.2d 1565, 1571 (Fed. Cir. 1983). Instead, prosecution disclaimer, which is
5 similar to prosecution history estoppel, applies in literal infringement cases. *Omega*, 334
6 F.3d at 1326 n.1. Plaintiff argues that prosecution disclaimer also does not apply because the
7 patent applicants did not clearly disavow the scope of their claims.

8 The Court begins with a heavy presumption that claim terms carry their full ordinary
9 and customary meaning, unless the patentee expressly relinquishes claim scope during
10 prosecution. *Omega*, 334 F.3d at 1323. Pursuant to the doctrine of prosecution disclaimer,
11 “a patentee may limit the meaning of a claim term by making a clear and unmistakable
12 disavowal of scope during prosecution.” *Purdue Pharma L.P. v. Endo Pharmaceuticals Inc.*,
13 438 F.3d 1123, 1136 (Fed. Cir. 2006). Disavowal may occur, for instance, when the patentee
14 “explicitly characterizes an aspect of his invention in a specific manner to overcome prior
15 art.” *Id.* The doctrine of prosecution disclaimer precludes patentees from recapturing
16 meanings through claim interpretation that they disclaimed during prosecution. *Omega*, 334
17 F.3d at 1323.

18 To limit the scope of a claim, alleged disavowing statements must be both clear and
19 unmistakable. *Id.* 1325-26. The patentee must have taken a position before the PTO that
20 would lead a competitor to believe that the applicant had disavowed coverage of the relevant
21 subject matter. *Id.* at 1325 (citing *Schwing GmbH v. Putzmeister Aktiengesellschaft*, 305 F.3d
22 1318, 1324-25 (Fed. Cir. 2002)). But if a patentee “has unequivocally disavowed a certain
23 meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the
24 ordinary meaning of the claim congruent with the scope of the surrender.” *Id.* at 1324.

25 After reviewing the prosecution history, the Court finds that the applicants took a
26 position before the PTO that would lead competitors to believe that they had disavowed
27 coverage of liquid compositions with viscosities of 10,000 cps or greater. *See Omega*, 334
28

1 F.3d at 1325. In arguing against the PTO Examiner’s rejection of claims 4, 5, and 8-12 as
2 obvious in light of U.S. Patent No. 5,562,642, the applicants asserted, in relevant part:

3 The Examiner has rejected claims 4, 5, and 8-12 under 35
4 U.S.C. §103 on the basis of a single reference: the ‘642 Patent.
5 In advancing this rejection, the Examiner again concedes that
6 the ‘642 Patent does not teach the particle size and viscosity
7 limitations of these claims. Indeed, the ‘642 Patent makes no
8 mention of the viscosity of the liquid that is applied to the pad
9 or cloth. . . .

7 At page 6 of the Office Action the Examiner states that
8 “the composition disclosed by US ‘642 . . . comprises the same
9 elements disclosed by applicants that are retained in [the] pad of
10 non-woven material inside [a] container made of metal and
11 plastic.” This statement is true only in that the reference
12 discloses a liquid that has insoluble particles on a pad in a
13 container. The ‘642 Patent does not mention viscosity or
14 particle size at all, much less the specific ranges called for by
15 claims 4, 5, and 8-12. . . .

12 The Examiner supplies the missing viscosity claim
13 element by asserting that “it is expected” that the viscosity
14 would be the same. This assertion is flatly contradicted by the
15 art of record. The ‘642 Patent does not mention the viscosity of
16 the liquid that is delivered. The only reference of record in this
17 application that mentions the viscosity of a liquid delivered by
18 a pad is the ‘237 Patent, which describes viscosities of from
19 10,000 to 300,000 centipoise, *which is in excess of the range
20 called for by the claimed invention.* Applicant has pointed this
21 out, but the Examiner has responded that “one cannot show
22 nonobviousness by attacking references individually where the
23 rejections are based on a combination of references.” In this, the
24 Examiner states a proposition that, while true, is irrelevant to
25 this application. In the entire body of prior art of record there is
26 only one disclosure of the viscosity of the liquid on the pad, and
27 in that disclosure the viscosity is well outside the claimed range,
28 e.g., “most preferably from about 50,000 to 150,000 centipoise.”
In pointing this out, the Applicant is not attacking the references
individually. The Applicant is pointing out that the only
viscosity disclosures in the entire body of art fails to disclose or
suggest the viscosity claim limitation, and that the art of record
suggest that one should use liquids that do not meet the viscosity
limitation of the pending claims.

24 (Doc. 85-15, pp.12-13)(emphasis added).

25 In response to the Examiner’s rejection of Claim 19 pursuant to 35 U.S.C. §103(a) as
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1 being unpatentable over prior art,⁷ the applicants again emphasized the importance of the
2 lower viscosity of the claimed invention. The applicants argued:

3 Additionally, as discussed above, the art of record, especially
4 the '237 Patent, teaches away from a low viscosity by teaching
5 the use of thickeners to achieve high viscosity. For the example,
6 the '237 Patent states that, “[p]referred emulsions have a high
7 viscosity, of from about 10,000 to about 300,000 centipoise,
8 more preferably from about 20,000 to about 200,000 centipoise,
9 most preferably from about 50,000 to about 150,000 centipoise.”
10 Column 13, lines 25-28. In contrast to the high viscosities of the
11 '237 Patent, the viscosities of the present invention are
12 significantly lower and the *specific values are necessary for the*
13 *present invention to work. . . .* Therefore, the '237 Patent teaches
14 away from a composition having a low enough viscosity for the
15 composition to substantially uniformly absorb onto the pad via
16 capillary action and high enough to be substantially retained on
17 the pad not the container.

18 (Doc. 85-15, p.17)(emphasis added).

19 Before the PTO, the Patent applicants specifically characterized their invention's
20 liquid composition's viscosity as being below the range of 10,000 to 300,000 centipoise to
21 differentiate the invention from prior art. Moreover, they emphasized that the specified
22 lower viscosities were necessary in order for the claimed invention to work. *See Purdue*
23 *Pharma*, 438 F.3d at 1136 (holding patentee did not disclaim all non-four-fold dosage ranges
24 during prosecution where patentee did not present the four-fold dosage range as a necessary
25 feature of the claimed formulations). The Court therefore holds that the Patent applicants
26 clearly and unmistakably disavowed liquid compositions with viscosities of 10,000 cps and
27 greater in order to overcome prior art. *See Purdue Pharma*, 438 F.3d at 1136. Consequently,
28 prosecution disclaimer applies and limits the scope of the Patent's claims to liquid
29 compositions having viscosities of less than 10,000 cps.

30 The Court finds that it does not need to construe the viscosity phrase in the

31 ⁷At the time of the June 5, 2006 Request for Reconsideration, Claim 19 read in
32 pertinent part, “wherein the composition has a viscosity which is low enough for the
33 composition to be substantially uniformly absorb [sic] onto the pad via capillary action, and
34 high enough to be substantially retained on the pad, not the container.” (Doc. 85-15, p.4).

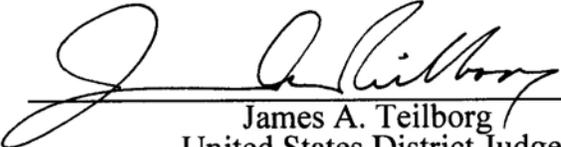
1 independent claims because the phrase is plain on its face and would be understood by a
2 person skilled in the art of topical drug delivery systems. The Court, however, adds the
3 limitation regarding viscosity centipoise in order to narrow the ordinary meaning of the
4 phrase to be congruent with the scope of the applicants' clear disavowal. The Court therefore
5 holds that the meaning of the term "viscosity which is low enough for the composition to
6 substantially uniformly absorb onto the pad via capillary action, and high enough to be
7 substantially retained on the pad, not the container" within the Patent is "Viscosity which is
8 low enough for the composition to substantially uniformly absorb onto the pad via capillary
9 action, and high enough to be substantially retained on the pad, not the container, but less
10 than 10,000 centipoise."

11 **V. Conclusion**

12 For the foregoing reasons, the Court construes the four disputed claim terms as set
13 forth in the table above.

14 **IT IS SO ORDERED.**

15 DATED this 2nd day of March, 2011.

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19 _____
20 James A. Teilborg
21 United States District Judge
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