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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

Medicis Pharmaceutical Corporation, Plaintiff, vs. Acella Pharmaceuticals Incorporated, Defendant.	No. CV 10-1780-PHX-JAT **ORDER**

Currently pending before the Court is Defendant Acella Pharmaceuticals Inc.'s Motion for Summary Judgment (Doc. 250). The Court now rules on the Motion.

I. Background

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%.

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

19, 2010.

A. The Patent

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

> The present invention overcomes many of the problems experienced in the art. In this invention, the dermatologically active ingredients are insoluble drugs suitable for human or animal use, and the composition is a liquid comprising one or more dermatologically active ingredients. The composition is retained by the pad preferentially over the container. Dermatologically active ingredients, e.g. without limitation, BPO, and insoluble antifungals, do not preferentially migrate or absorb from the composition (e.g. without limitation, emulsion) onto or into the pad, and therefore does not result in an uneven concentration of the dermatologically active ingredient in the composition versus the pad. Further, the pad is packaged in a container and one or more pads may be packaged in each container.
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> In accordance with the present invention, insoluble dermatologically active ingredients are mixed in an emulsion composition, e.g. without limitation, an oil-in-water emulsion or a water-in-oil emulsion, preferably an oil-in-water emulsion. This composition is suited to causing the dermatologically 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.
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> 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 uniformly medicated. During this wiping, an adequate therapeutic dose of the dermatologically active ingredient is

> delivered to the skin. One advantage of this invention may be a reduced irritation to the skin as comparted to similar compositions applied without the pad.
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(Doc. 55-1, Column "Col." 2-3).

The Patent issued with four independent claims – claims 1, 2, 8, and 9 – and twenty dependent claims. The independent claims read:

> What is claimed is:
>
> 1. A drug delivery system comprising
> a pad;
> a container; and
> 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 benzoyl peroxide particles of less than 50 microns.
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> 2. A drug delivery system comprising
> a pad;
> a container; and
> 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 about 10 to about 150 microns.
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> 8. A drug delivery system comprising
> a pad;
> a container; and
> 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 up to about 300 microns.

9. A drug delivery system comprising
a pad;
a container; and
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.

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

The dependent claims read:

3. The system of claim 1 wherein the composition has a viscosity of about 500 to about 9000 cps measured on a Brookfield viscometer LVT model at about 27° C. for 60 seconds and a spindle set for 30 rpm.

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5. The system of claim 1 wherein the composition has a viscosity of about 500 to about 10,000 cps measured on a Brookfield viscometer RVT model with spindle #4 at 20 rpm 30 for 60 seconds at 25° C.+-1° C.

6. The system of claim 1 wherein the composition has a viscosity of about 1900 to about 7,000 cps measured on a Brookfield viscometer RVT model with spindle #4 at 20 rpm for 60 seconds at 25° C.+-1° C.

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10. The system of claim 2 wherein the composition has a viscosity of about 500 to about 9000 cps measured on a Brookfield viscometer LVT model at about 27° C. for 60 seconds and a spindle set for 30 rpm.

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12. The system of claim 2 wherein the composition has a viscosity of about 500 to about 10,000 cps measured on a Brookfield viscometer RVT model with spindle #4 at 20 rpm for 60 seconds at 25° C.+-1° C.

> 13. The system of claim 2 wherein the composition has a viscosity of about 1900 to about 7,000 cps measured on a Brookfield viscometer RVT model with spindle #4 at 20 rpm for 60 seconds at 25° C.+-1° C.
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> 15. The system of claim 8 wherein the composition has a viscosity of about 500 to about 9000 cps measured on a Brookfield viscometer LVT model at about 27° C. for 60 seconds and a spindle set for 30 rpm.
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> 17. The system of claim 8 wherein the composition has a viscosity of about 500 to about 10,000 cps measured on a Brookfield viscometer RVT model with spindle #4 at 20 rpm for 60 seconds at 25° C.+-1° C.
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> 18. The system of claim 8 wherein the composition has a viscosity of about 1900 to about 7,000 cps measured on a Brookfield viscometer RVT model with spindle #4 at 20 rpm for 60 seconds at 25° C.+-1° C.
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> 20. The system of claim 9 wherein the composition has a viscosity of about 500 to about 9000 cps measured on a Brookfield viscometer LVT model at about 27° C. for 60 seconds and a spindle set for 30 rpm.
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> 22. The system of claim 9 wherein the composition has a viscosity of about 500 to about 10,000 cps measured on a Brookfield viscometer RVT model with spindle #4 at 20 rpm for 60 seconds at 25° C.+-1° C.
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> 23. The system of claim 9 wherein the composition has a viscosity of about 1900 to about 7,000 cps measured on a Brookfield viscometer RVT model with spindle #4 at 20 rpm for 60 seconds at 25° C.+-1° C.

(*Id.*, Col. 8- Col. 10).

B. Claim Construction

The Court held a *Markman* hearing on February 23, 2011. (Doc. 140.) After reviewing the briefing and the evidence presented at the hearing, the Court construed the four disputed claim terms, all of which appear in the independent claims, as 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.

II. LEGAL STANDARD

Summary judgment is appropriate when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(a). To defeat a motion for summary judgment, the non-movant must show that genuine factual issues exist "that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (U.S. 1986).

When ruling on a motion for summary judgment, the Court draws all reasonable inferences in favor of the party opposing the motion. *Finish Eng'g Co. v. Zerpa Indus.*, 806

F.2d 1041, 1043 (Fed. Cir. 1986). The Court must resolve all doubt regarding the existence of a genuine issue of material fact in favor of the non-movant. *Chore-Time Equip. v. Cumberland Corp.*, 713 F.2d 774, 778 (Fed. Cir. 1983).

If a party moves for summary judgment on the issue obviousness, and the ultimate legal conclusion of obviousness is disputed, but not the underlying facts, then there is no issue of fact for trial. *Tokai Corp. v. Easton Enter.*, 632 F.3d 1358, 1369 (Fed. Cir. 2011). This is true even if some facts favor obviousness, but some favor non-obviousness. *Id*.

III. ANALYSIS AND CONCLUSION

Acella has moved for summary judgment on two issues: obviousness and lost profits. Because the Court finds the Patent invalid for obviousness, it need not reach the issue of lost profits.

Acella asserts that the Patent is invalid for obviousness based on prior art. Acella argues that all of the elements of the Patent were known in the prior art and that it would have been obvious to combine the elements from the prior art as the Patent inventors did.

An issued patent is presumed valid. *Microsoft Corp. v. i4i Ltd. P'ship*, _ _ U.S. _ _, 131 S.Ct. 2238, 2245 (2011)(citing 35 U.S.C. §282). The party asserting invalidity bears the burden of proving invalidity by clear and convincing evidence. *Id*. at 2246. The burden does not change just because the factfinder is reviewing evidence that was not before the Patent and Trademark Office (the "PTO") at the time the PTO issued the patent. *Id*. at 2251. But if the PTO did not have all material facts before it, then its considered judgment may lose significant force. *Id.* And the burden of proving invalidity by clear and convincing evidence may be easier to sustain. *Id.*[1]

A patent is obvious "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been

[1]The PTO did not have some of the prior art relied on by Acella in its Motion during prosecution of the Patent.

obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. §103(a). Obviousness is an issue of law based on underlying findings of fact. *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1237 (Fed. Cir. 2010).

The underlying factual inquiries are: 1) the scope and content of the prior art; 2) the differences between the prior art and the claims at issue; 3) the level of ordinary skill in the pertinent art; and 4) secondary considerations of non-obviousness. *Perfect Web Tech. v. Infousa*, 587 F.3d 1324, 1327 (Fed. Cir. 2009)(citing *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966)). If the content of the prior art, the scope of the patent claim, and the level of ordinary skill in the art are not in material dispute, and the obviousness of the claim is apparent in light of those factors, then summary judgment is appropriate. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 427 (2007).

A. Scope and Content of the Prior Art

Acella offers several patents in the prior art that, taken together,[2] contain all the elements of the Patent. Medicis concedes that all the elements of the Patent were independently known in the prior art.

1. Smith Patent

U.S. Patent 5,562,642 ("Smith") discloses a pad applicator system for the delivery of benzoyl peroxide ("BPO") for treatment of acne. (Doc. 163-26, col.12 lns. 24-28 "A preferred peroxide-containing composition for use on one of the pads of the present applicator system comprises an effective anti-acne amount . . . of an organic peroxide, preferably benzoyl peroxide . . .") The Smith drug delivery system includes a pad, container, and a liquid composition containing an effective amount of BPO. The BPO composition disclosed by Smith includes an emulsion vehicle.

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[2]The Court should consider prior art references as a whole to determine their teachings. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 448-49 (Fed. Cir. 2009).

Smith explains that the BPO composition is "absorbed by and retained by" the pad. (*Id*., col.11 ln. 32.) In the section of the patent describing the Polyhydric Alcohol Emollient, Smith also explains that the applicator pads, after absorbing an emulsion, were not unduly wet or sticky to the touch and applied a homogenous nonsticky film of the emulsion to the skin. (*Id*., col. 20, lns. 29-32.) Smith does not quantify the viscosity of his BPO composition.

2. Preuilh Patent

U.S. Patent 6,106,848 ("Preuilh") describes a topically applicable oil-in-water emulsion with at least one glycol and one biologically active ingredient for the treatment of acne. Preuilh's list of exemplary active agents for the composition includes anti-acne agents such as "retinoic acid, benzoyl peroxide or adapalene . . ." (Doc. 163-21, col. 3 lns. 39-40.) Preuilh therefore discloses a liquid composition in an emulsion containing an effective amount of BPO.

In the Background of the Invention section, Preuilh differentiates the invention from the prior art, "To facilitate the application of topical compositions . . ., it would be desirable to provide novel formulations of the [oil-in-water] emulsion type, whose viscosity would be intermediate between the hair lotions which are too fluid . . . and the [oil-in-water] creams which are too viscous and which have a fatty and sticky characteristic . . ." (*Id*., col. 1 lns. 43-49.) The viscosity of Preuilh's composition ranges from 3,000 to 10,000 centipoise ("cps") as "measured with a Brookfield apparatus model LVDV II+paddle No. 4, at a speed of 30 revolutions/min for 30 seconds and at a temperature of 25ºC.$\pm$3ºC." (*Id*., col. 1 ln.64-col.2 ln.3.)

Acella notes that other prior art discloses ranges of viscosity overlapping the ranges recited in the Patent. U.S. Patent No. 6,387,383 ("Dow") discloses a liquid composition with an effective amount of dermatologically active ingredient and an emulsion vehicle wherein the viscosity of the composition is less than 15,000 cps and preferably between 300 and 10,000 cps. (Doc. 163-22, col. 4 lns. 8-20.) U.S. Patent No. 5,650,146 ("Shaw") discloses

a topical emulsion with a preferred viscosity between 1,000 and 10,000 cps. (Doc. 163-23, col. 2 ln.64-col.3 ln.6.) French Patent No. FR2703907 ("Jacques") discloses an emulsion with a viscosity of 1,000 to 14,000 cps as measured at 20 rpm at 25ºC on a Brookfield RVT viscometer. (Doc. 240-7 Ex. D at p.6.) Jacques teaches that viscosity in this range improves the hydration of the superficial layers of the epidermis. (*Id.* at p.7.)

3. Tarasov Patent

U.S. Patent No. 4,401,835 ("Tarasov") discloses a method for preparing BPO particles of less than 10 microns for use in the treatment of acne. (Doc. 163-12, Abstract, "A method for the preparation of benzoyl peroxide in crystalline form, which crystals may range in size below 10 microns . . .") Tarasov explains that the BPO particles are reduced in size for two reasons: 1) to create as smooth a texture as possible to gain greater consumer satisfaction (*Id.*, col. 1 lns. 15-18) and 2) to increase the effective surface area and thereby maximize the BPO's medicinal efficacy (*Id.*, col. 1 lns. 34-39). Tarasov describes the desire reflected in the prior art to have BPO particles below 25 microns in pharmaceutical compositions. (*Id.*, col. 1 lns. 21-23.)

4. Gruber Patent

U.S. Patent No. 4,593,046 ("Gruber") discloses a composition containing BPO for use in the treatment of acne. Gruber teaches a composition with BPO particles of less than 100 microns that reduces skin irritation. (Doc. 163-9, col. 4 lns. 55-63 & col. 8 lns. 19-21.) Gruber explains that BPO particles of less than 50 microns are preferred because they cannot be felt and recognized as particles by the average user. (*Id.*, col. 4 lns. 21-24.)

Medicis claims that Acella does not make any attempt to define the overall scope or content of the art to which the Patent pertains. But Medicis does not argue that the above-recited prior art is not analogous. *See Wyers*, 616 F.3d at 1237 (listing the two criteria for determining whether prior art is analogous: "(1) whether the art is from the same field of endeavor, regardless of the problem addressed, and (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular

problem with which the inventor is involved.").[3] Nor does Medicis contest Acella's description of the content and scope of the prior art. The Court therefore finds that there is no material issue of fact as to the scope and content of the prior art cited by Acella.

B. Differences Between the Prior Art and the Claims at Issue

Medicis argues that there is a genuine dispute as to the differences between the prior art and the Patent because Acella's Motion does not address the functional properties of the prior art compositions. But Medicis does not explain how this creates an issue of fact Medicis does not point to a disagreement between the parties regarding the differences between the claims in suit and the prior art. Medicis has not contradicted Acella's description of the differences between the prior art and the Patent.

The parties seem to agree regarding the content of the prior art and the content of the Patent, even if Medicis emphasizes the importance of the functional properties of the Patent. Their disagreement centers on whether it would have been obvious to a person of ordinary skill in the pertinent art to combine the elements from the prior art in a way that would result in the Patent. The Court therefore finds that Medicis has not demonstrated that there is a genuine dispute as to the differences between the prior art and the Patent.

C. Level of Ordinary Skill in the Pertinent Art

Medicis argues that a genuine dispute exists regarding the appropriate level of skill in the art to which the Patent pertains. Acella suggests that the appropriate level of skill in the pertinent art is a person with a bachelor's degree in chemical engineering, chemistry, polymer science, or pharmaceutical science, at least two years experience in the field of formulation of drug delivery systems, and an understanding of capillary action. Whereas Medicis contends that a person of ordinary skill must have the bachelor's degree and experience in the formulation of topical dermatologic drug delivery systems.

Although the parties disagree regarding the appropriate level of experience for a

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[3]The Court construes the scope of analogous art broadly. *Wyers*, 616 F.3d at 1238.

person of ordinary skill in the art – Medicis would require more specialized experience in the formulation of topical dermatologic drug delivery systems, rather than experience with general drug delivery systems, this does not create an issue of material fact precluding summary judgment. Medicis argues for a higher requisite level of skill than Acella. But a less sophisticated level of skill generally favors a determination of nonobviousness and therefore the patentee, while a higher level of skill favors a determination of obviousness. *Innovention Toys, LLC v. MGA Entertainment, Inc.*, 637 F.3d 1314, 1323 (Fed. Cir. 2011).

For the purposes of this Motion, it would not help Medicis for the Court to adopt the standard Medicis urges. Because if the Court finds that the Patent's claims would have been obvious to a less specialized and sophisticated person in the art, then the Court could not arrive at a different conclusion by adopting the viewpoint of one with greater experience. *Tokai Corp.*, 632 F.3d at 1369 ("Since the district court found that the asserted claims would have been obvious to a less sophisticated artisan, then under the facts of this case the court could not have arrived at a different conclusion by adopting the viewpoint of one with greater skill and experience. Accordingly, the parties' disagreement at the district court as to the appropriate level of skill in the art did not create a genuine issue of material fact precluding summary judgment.").

Moreover, the Court finds that the subject matter of the Patent and the prior art in this case are easily understandable and the Court therefore does not need to make a factual determination regarding the appropriate level of skill in the art. *Chore-Time Equip.*, 713 F.2d at 779 ("Similarly, there is no genuine issue respecting the level of skill in the art. Chore-Time has not shown error in Judge Wilson's determination that because the subject matter of the patent and the prior art were in this case so easily understandable, a factual determination of the level of skill in the art was unnecessary."); *see also Innovention Toys*, 637 F.3d at 1323 ("For example, no reversal is necessary where a district court makes a determination that an invention would have been obvious to one having the lowest level of skill, i.e., a layperson, because what is obvious to a layperson is necessarily obvious to one

with a higher level of skill in the field of the invention.").

Because adopting Acella's standard for a person of skill would actually help Medicis and because the Court finds that the subject matter of the Patent and prior art are easily understandable, the Court holds that there is not a genuine issue regarding the requisite level of skill of a person in the art that precludes granting summary judgment.

D. Apparent Obviousness

If, as here, the content of the prior art, the scope of the patent claim, and the level of ordinary skill in the art are not in material dispute, then summary judgment is appropriate if the obviousness of the patent is apparent. *KSR*, 550 U.S. at 427. Because Medicis concedes that all of the elements of the Patent were independently known in the prior art, much of the obviousness determination in this case depends on whether it would have been obvious to combine the elements from the prior art in the way claimed by the Patent.

A patent comprised of several elements is not obvious just because each of its elements was independently known in the prior art. *Id*. at 418. "Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id*.

In *KSR*, the Supreme Court rejected the Federal Circuit's teaching, suggestion, or motivation test in favor of a more flexible approach to determining motivation to combine. *Id*. at 415. The Federal Circuit previously had held that the reason, suggestion, or motivation to combine could be found explicitly or implicitly: "1) in the prior art references themselves; 2) in the knowledge of those of ordinary skill in the art that certain references, or disclosures in those references, are of special interest or importance in the filed; or 3) from the nature of the problem to be solved . . ." *Perfect Web*, 587 F.3d at 1329 (internal citations omitted).

KSR's more flexible approach expanded the possible sources for motivation to combine to include market forces, design incentives, the interrelated teachings of multiple

patents, any need or problem known in the field of endeavor at the time of the invention addressed by the patent, and the background knowledge, creativity, and common sense of the person of ordinary skill. *Perfect Web*, 587 F.3d at 1329 (citing *KSR*, 550 U.S. at 418-20). In *KSR*, the Supreme Court eschewed rigid rules that denied factfinders recourse to common sense and logic. 550 U.S. at 421; *Wyers*, 616 F.3d at 1240 ("Thus, in appropriate cases, the ultimate inference as to the existence of a motivation to combine references may boil down to a question of 'common sense' appropriate for resolution on summary judgment . . ."). And the Supreme Court clarified that expert testimony regarding motivation to combine may be unnecessary and, even if offered, may not create a genuine issue of material fact.[4] *Wyers*, 616 F.3d at 1239 (citing *KSR*, 550 U.S. at 427).

Relevant to the obviousness determination in this case, the asserted independent claims[5] of the Patent generally require: a pad, a container, and a liquid composition. The liquid composition contains (1) an effective amount of one or more insoluble dermatologically active ingredients and (2) an emulsion vehicle, and has a viscosity that 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. Claim 1 requires that the active ingredient comprise BPO particles of less than 50 microns. Claims 2,8, and 9 do not require BPO as the active ingredient and recite different particles sizes for the active ingredient.

The Smith patent's drug delivery system includes a pad, container, and a liquid composition containing an effective amount of BPO. The BPO composition disclosed by Smith also includes an emulsion vehicle. So, the Smith patent teaches every element of the Patent but the numerical viscosity for the liquid composition and the particle size for the

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[4]*KSR* and more recent Federal Circuit cases establish that motivation to combine can be decided on summary judgment in appropriate cases. *Wyers*, 616 F.3d at 1239.

[5]The dependent claims each recite a numeric viscosity range of the liquid composition as measured on either a Brookfield LVT viscometer or Brookfield RVT viscometer.

dermatologically active ingredient or BPO.

Although Smith does not specifically quantify the viscosity of the liquid composition, he does explain that the BPO composition is "absorbed by and retained by" the pad, like the Patent here. Smith also explains that his applicator pads, after absorbing the emulsion, were not unduly wet or sticky to the touch and applied a homogenous nonsticky film of the emulsion to the skin.

Preuilh discloses a topically applicable liquid composition with an oil-in-water emulsion and BPO. Preuilh teaches that an intermediate viscosity avoids the problem in the prior art of compositions being either too fluid or too viscous and sticky. She specifically claims a liquid composition with viscosity from 3,000 to 10,000 cps as measured with a Brookfield apparatus model LVDV II+paddle No. 4. But Preuilh does not disclose a pad and a container or a specific size for the BPO particles.

Tarasov teaches that a particle size of less than 10 microns will create a smoother texture and increase the medicinal efficacy of the BPO and notes an existing industry preference for a particle size of less than 25 microns. Gruber teaches a particle size of less than 100 microns to reduce skin irritation and prefers less than 50 microns because users will not feel the particles. So, Tarasov and Gruber teach the smaller particles size incorporated in the Patent, but do not disclose the pad applicator system for an emulsion vehicle with an intermediate viscosity.

Market forces, design incentives, the interrelated teachings of multiple patents, any need or problem known in the field, and the background knowledge, creativity, and common sense of the person of ordinary skill can provide motivation to combine elements from prior art. *Perfect Web*, 587 F.3d at 1329. The Patent itself cites a "long-standing" demand for a "way to topically deliver particle suspension of dermatologically active ingredients by way of a pad." (Doc. 55-1, col. 2 lns. 31-33.) And Mr. Bogardus, Medicis's expert, has testified that there was such a long-standing demand in the market.

Market incentives therefore would have motivated a person of ordinary skill to

combine the BPO pad applicator system of Smith with the intermediate viscosity of Preuilh, which addresses the too fluid versus too thick issue, to solve the stated absorption and migration problems in the field. And because the prior art established that consumers prefer smaller-sized BPO particles, market forces would have motivated a person of ordinary skill to decrease the micron size of the drug particles delivered by the pad applicator system.

In *KSR*, the Supreme Court stated:

> When there is a design need or market pressure to solve a problem and there are a finite number of identified predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103.

550 U.S. at 421.

Logic would motivate a person of ordinary skill to try combining the claimed viscosity range of Preuilh, which purports to solve the problem of a liquid composition's emulsion containing BPO being either too thin or too viscous, with the Smith pad applicator system to resolve the problems in the prior art. And common sense would motivate a person to minimize the particle size of the BPO in the combination of Smith's pad applicator system with Preuilh's viscosity because the prior art, i.e., Gruber and Tarasov, teaches that smaller micron size increases consumer satisfaction and medicinal efficacy. The Court therefore finds that it would have been obvious to combine the prior art in the manner claimed in the Patent.

Mr. Bogardus has testified that it would not have been obvious to a person of ordinary skill to combine the Smith, Preuilh, Gruber and/or Tarasov patents in the manner claimed by the Patent. He testified that even though he and his competitors worked on the problem of developing a BPO pad in the 1980s, they did not think to combine separate elements from the prior art as eventually combined in the Patent. But expert testimony regarding a lack of motivation to combine does not necessarily create a genuine issue of material fact. *Wyers*,

616 F.3d at 1239. Because the Court does not need expert testimony to understand the technology at issue or the apparent motivation to combine, Mr. Bogardus's testimony regarding a lack of obviousness to combine does not preclude summary judgment.

Because it would have been obvious to combine the elements from the prior art in the manner claimed and because each element from the prior art – BPO pad applicator system, intermediate viscosity, and small particle size – performed no more than predictably when combined in the Patent, *see Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 282 (1976)(holding that a combination is obvious if a patent "simply arranges old elements with each performing the same function it had been known to perform" and yields predictable results), the Court finds that Acella has established a prima facie case of obviousness.[6] The Court's finding of prima facie obviousness applies to both the independent and dependent claims of the Patent.

The viscosity range disclosed by Preuilh (3,000 to 10,000 cps) inherently meets the functional viscosity limitations of the independent claims and overlaps the numerical viscosity ranges recited in each of the asserted dependent claims. And the particle sizes recited in Gruber and Tarasov overlap the particle size ranges of the Patent's independent claims. The ranges in the independent and dependent claims are therefore obvious. *See Tyco Healthcare Group LP v. Mut. Pharm. Co.*, 642 F.3d 1370, 1372-73 (Fed. Cir. 2011)("Ordinarily, where there is a range disclosed in the prior art, and the claimed invention falls within that range, there is a presumption of obviousness); *In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003)("We therefore conclude that a prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a prima facie case of obviousness.").

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[6]Both parties rely on the PTO's recent nonfinal action in the *ex parte* reexamination of the Patent. The PTO rejected twelve of the sixteen patent claims asserted in this case as obvious and affirmed four. But this Court is not bound by the PTO's actions and must make its own determination of obviousness. *Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1322 (Fed. Cir. 2005).

E. Secondary Considerations of Nonobviousness

Although the Court has found a prima facie case of obviousness, the analysis does not end there. Secondary evidence of nonobviousness may overcome the prima facie case, and the Court must always consider any objective evidence of nonobviousness. *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA Inc.*, 617 F.3d 1296, 1305 (Fed. Cir. 2010). Some examples of secondary evidence of nonobviousness are: commercial success; long felt but unsolved needs, and the failure of others to solve the problem solved by the claims at issue. *Graham*, 383 U.S. at 17-18.

Medicis notes at the beginning of its Response that factual disputes as to secondary considerations of non-obviousness may preclude summary judgment (Doc. 260 p.3), but does not later argue why factual disputes regarding secondary considerations would prevent summary judgment here. Medicis does not offer any specific arguments regarding objective indicia of nonobviousness.

But in the section of its Response dedicated to motivation to combine, Medicis does mention that in the 1980s Mr. Bogardus worked to formulate a BPO pad drug delivery system without success. In his Declaration submitted with the Response, Mr. Bogardus states that for many years workers in the field of topical dermatologic drug delivery systems tried to find a way to deliver insoluble particulate active ingredients, such as BPO, to the skin using a pad or cloth. (Doc. 261-1 ¶20.) He testifies that he and his co-coworkers at Richardson-Vicks were among the workers in the field who attempted and failed to develop such a product.[7] (*Id*.) Mr. Bogardus further testifies that the makers of Stridex also failed to make pads or cloths that delivered insoluble active ingredients. (*Id*.)

Viewing the facts in the light most favorable to Medicis, Mr. Bogardus's Declaration

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[7]Acella notes that Mr. Bogardus did not have the benefit of the prior art cited in its Motion. But Mr. Bogardus claims that all of the separate elements of the Patent were known in the prior art at the time he worked at Richardson-Vicks, even if the prior art cited had not yet issued. (Doc. 261-1 ¶28.)

establishes that there was a long felt need for the Patent's pad applicator system for insoluble particulate active ingredients. His Declaration further demonstrates that others, including himself, had failed to solve the problem solved by the Patent.

Additionally, evidence of the commercial success of Medicis's Triaz® Foaming Cloths exists in the record. But Medicis must demonstrate a nexus between the evidence of commercial success and the patented invention. *Wyers*, 616 F.3d at 1246. Medicis does not attempt to prove that nexus in its Response. Establishing a nexus might pose a problem for Medicis because its Triaz® Foaming Cloths do not fall within the claims in suit as construed by the Court.

Although Medicis has introduced evidence of objective indicia of nonobviousness such as a long felt need in the field and a failure of others to meet the need prior to the Patent, the Court finds that these secondary considerations do not overcome the strong prima facie case of obviousness. *Perfect Web*, 587 F.3d at 1333 ("Moreover, as we have often held, evidence of secondary considerations does not always overcome a strong prima facie showing of obviousness."); *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1372 (Fed. Cir. 2007)("Although secondary considerations must be taken into account, they do not necessarily control the obviousness conclusion. Here, the record establishes such a strong case of obviousness that Pfizer's alleged unexpectedly superior results are ultimately insufficient.")(internal citations omitted).

Because the secondary considerations of nonobviousness do not overcome the strong prima facie case of obviousness, the Court finds that Acella has met its burden of demonstrating the Patent is invalid as obvious. The Court therefore will grant the Motion for Summary Judgment. As Medicis's only claim in this case is for patent infringement and the Patent is invalid, the action is terminated.

Accordingly,

IT IS ORDERED granting Defendant Acella's Motion for Summary Judgment (Doc. 250). The Court holds that all the asserted claims of the Patent are invalid as obvious. The

Clerk therefore will enter judgment for Defendant Acella.

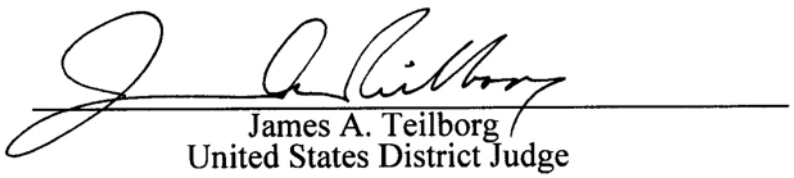
IT IS FURTHER ORDERED Granting judgment to Defendant/Counter-Plaintiff Acella on its Counter-Claim for Declaratory Relief (Doc. 178) because the Court has found the Patent invalid.

IT IS FURTHER ORDERED vacating the Final Pretrial Conference set for January 17, 2012 and the trial set for January 24, 2012.

IT IS FURTHER ORDERED denying as moot Medicis's Motion for Leave to Supplement Brief of Medicis in Opposition to Acella's Motion for Summary Judgment (Doc. 271) because the proposed supplement relates only to the lost profits argument, which the Court did not reach.

IT IS FURTHER ORDERED denying as moot Medicis's Motion to Seal (Doc. 274).

DATED this 3rd day of November, 2011.



James A. Teilborg
United States District Judge