IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GALDERMA LABORATORIES L.P., GALDERMA S.A. and NESTLÉ SKIN HEALTH S.A.,

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant.

No. 17-cv-1783-RGA

MEMORANDUM OPINION

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August 21, 2019

ANDREWS, U.S. DISTRICT JUDGE:

On April 21, 2017, Galderma Laboratories L.P., Galderma S.A., and Nestlé Skin Health S.A. (collectively, "Galderma") brought this action against Teva Pharmaceuticals USA, Inc. for infringement of several patents under 35 U.S.C. § 271(d)(2)(A). (D.I. 1). I held a bench trial from June 10 to 12, 2019. (D.I. 253-56).[1] By trial the parties had narrowed the case to three patents—U.S. Patent Nos. 9,089,587 ("the '587 patent"), 9,233,117 ("the '117 patent"), and 9,233,118 ("the '118 patent") (collectively, "the asserted patents").[2]

Presently before the Court are the issues of validity and infringement of the asserted patents. Galderma asserts infringement of claim 12 of the '587 patent, claims 2, 3, and 6 of the '117 patent, and claims 6, 7, 10, and 11 of the '118 patent. (D.I. 241). The parties stipulated to infringement of claim 6 of the '118 patent, assuming the claim is valid and enforceable. (D.I. 230, Ex. B). Teva argues, however, that each of the asserted claims are invalid for lack of written description, anticipation, and obviousness. (D.I. 240). I have considered the parties' post-trial briefing. (D.I. 240, 241, 244, 245, 248, 249).

For the following reasons, I find each of the asserted claims invalid for anticipation.

I. BACKGROUND

The asserted patents are directed to methods of treating papulopustular rosacea. I have construed "papulopustular rosacea" as a "chronic inflammatory disorder characterized by facial papules, pustules, persistent erythema, and the presence of inflammatory infiltrates that accompany flares." (D.I. 126 at 2). I also adopted the parties' agreed-upon construction of "inflammatory lesions of [papulopustular] rosacea" as "papules and/or pustules." (*Id.* at 3).

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[1] I cite to the trial transcript as "Tr."

[2] The parties stipulated to the resolution and/or dismissal of all other claims and counterclaims, which related to U.S. Patent Nos. 8,362,069 ("the '069 patent"), 8,815,816 ("the '816 patent"), and 9,782,425 ("the '425 patent"). (D.I. 69; D.I. 70 at 20; D.I. 129; D.I. 219 at 3 n.1; D.I. 230).

Galderma owns NDA No. 206255 for Soolantra (ivermectin) Cream 1% for the treatment of inflammatory lesions of rosacea. (D.I. 228 ¶¶ 5-6). Ivermectin is an anti-parasitic drug derivative that has been approved for human use since 1996. PX-1 at 1:50-54. All the asserted patents are listed in the Orange Book for Soolantra. (D.I. 228 ¶ 7). Teva filed ANDA No. 210019 on December 30, 2016 seeking FDA approval for the commercial manufacture, use, and sale of a generic 1% ivermectin cream ("Teva's ANDA product"). (*Id.* ¶¶ 17, 20). Teva's ANDA label states that the product is "indicated for the treatment of inflammatory lesions of rosacea." (*Id.* ¶ 25). Teva sent its Paragraph IV certification to Galderma on March 10, 2017 stating that the asserted patents are "invalid, unenforceable, and/or will not be infringed" by its ANDA product. (*Id.* ¶ 20). Galderma then filed this action alleging infringement by Teva's ANDA submission. (D.I. 1); 35 U.S.C. § 271(d)(2)(A).

II. ASSERTED CLAIMS

All of the asserted claims require (1) topically administering, (2) once daily, (3) to a skin area affected by the inflammatory lesions of rosacea, (4) a pharmaceutical composition comprising 1% by weight ivermectin and a pharmaceutically acceptable carrier. *E.g.*, PX-3 at 24:20-23. In addition, some claims require certain efficacies based on reduction in lesion count, improvement in Investigator's Global Assessment (IGA) score,[3] delayed time to first relapse,[4] and/or comparison to a second pharmaceutical composition comprising 0.75% by weight metronidazole.[5]

Galderma asserts dependent claim 12 of the '587 patent. The relevant claims provide:

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[3] The IGA measures disease severity on a scale from 0 (clear) to 4 (severe). PX-1 at 11:39-42.

[4] I adopted the parties agreed-upon construction for "relapse-free time/time to first relapse" as "the time elapsed between initial successful treatment to an IGA of rosacea of 0 or 1 to the first reoccurrence of the IGA to 2 or more in a subject." (D.I. 126 at 2).

[5] The asserted patents describe metronidazole as a "conventional anti-rosacea medication." *E.g.*, PX-1 at 2:7-8.

8. A method of treating papulopustular rosacea or inflammatory lesions of rosacea in a subject in need thereof, comprising topically administering, once daily, to a skin area affected by the papulopustular rosacea or the inflammatory lesions of rosacea a pharmaceutical composition comprising about 0.1% to about 1% by weight ivermectin and a pharmaceutically acceptable carrier to thereby obtain a significant reduction in inflammatory lesion count in the subject, and a significant improvement in at least one selected from the group consisting of a higher investigator's global assessment success rate and a delayed time to first relapse in the subject in comparison to that achieved by topically administering to the subject, twice daily, a second pharmaceutical composition comprising 0.75% by weight metronidazole.

11. The method of claim 8, wherein the pharmaceutical composition comprises about 0.5% to about 1% by weight ivermectin.

12. The method of claim 11, wherein the pharmaceutical composition comprises about 1% by weight ivermectin.

PX-1 at 24:19-44.

Galderma asserts dependent claims 2, 3, and 6 of the '117 patent. The relevant claims provide:

1. A method of treating inflammatory lesions of rosacea in a subject in need thereof, comprising topically administering, once daily, to a skin area affected by the inflammatory lesions of rosacea a pharmaceutical composition comprising 1% by weight ivermectin and a pharmaceutically acceptable carrier, wherein as early as 2 weeks after the initial administration of the pharmaceutical composition, a significant reduction in inflammatory lesion count is observed.

2. The method of claim 1, wherein the treatment results in more reduction in inflammatory lesion count in the subject in comparison to that achieved by topically administering to the subject, twice daily, a second pharmaceutical composition comprising 0.75% by weight metronidazole.

3. The method of claim 1, wherein the treatment results in longer relapse-free time of the inflammatory lesions of rosacea in the subject in comparison to that achieved by twice daily topically administering to the subject a second pharmaceutical composition comprising 0.75% by weight metronidazole.

5. The method of claim 1, wherein the subject has moderate to severe papulopustular rosacea before the treatment.

6. The method of claim 5, wherein the subject has 15 or more of the inflammatory lesions before the treatment.

PX-2 at 28:43-67.

Galderma asserts independent claim 6 and dependent claims 7, 10, and 11 of the '118 patent. The parties have stipulated to infringement of claim 6. (D.I. 230, Ex. B). The relevant claims provide:

> 6. A method of treating inflammatory lesions of papulopustular rosacea in a subject in need thereof, comprising topically administering, once daily, to a skin area affected by the inflammatory lesions of papulopustular rosacea a pharmaceutical composition comprising about 1% by weight ivermectin and a pharmaceutically acceptable carrier to thereby obtain a significant reduction in inflammatory lesion count in the subject.
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> 7. The method of claim 6, wherein as early as 2 weeks after the initial administration of the pharmaceutical composition, the significant reduction in inflammatory lesion count is observed.
>
> 8. The method of claim 6, wherein the pharmaceutical composition is administered once daily to the skin area.
>
> 10. The method of claim 8, wherein the once daily topical administration to the subject the pharmaceutical composition results in more reduction in inflammatory lesion count in the subject in comparison to that achieved by topically administering to the subject, twice daily, a second pharmaceutical composition comprising 0.75% by weight metronidazole.
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> 11. The method of claim 8, wherein the once daily topical administration to the subject the pharmaceutical composition results in longer relapse-free time of the inflammatory lesions in the subject in comparison to that achieved by topically administering to the subject, twice daily, a second pharmaceutical composition comprising 0.75% by weight metronidazole.

PX-3 at 24:18-63.

III. LEGAL STANDARD

"To show that a patent claim is invalid as anticipated, the accused infringer must show by clear and convincing evidence that a single prior art reference discloses each and every element of a claimed invention." *Silicon Graphics, Inc. v. ATI Techs., Inc.*, 607 F.3d 784, 796 (Fed. Cir. 2010). "[E]very element of the claimed invention [must be described], either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue

experimentation." *Callaway Golf Co. v. Acushnet Co.*, 576 F.3d 1331, 1346 (Fed. Cir. 2009) (quoting *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000)). As with infringement, the court construes the claims and compares them against the prior art. *See Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1337-39 (Fed. Cir. 2010).

IV. ANALYSIS

Teva argues that the asserted claims are invalid as anticipated by either the McDaniel patent (DX-16) or the Manetta patent (DX-8). (D.I. 240 at 10-20). For the following reasons, I find each asserted claim anticipated by McDaniel. Therefore, I do not address Teva's arguments regarding Manetta.[6]

A. Findings of Fact

1. Nestlé is the owner of the asserted patents. (D.I. 228 ¶ 43).

2. Galderma S.A. is an exclusive licensee of the asserted patents and has granted Galderma Laboratories, L.P. exclusive rights under the asserted patents. (*Id.* ¶ 44).

3. A person of ordinary skill in the art is a dermatologist with five or more years of experience, with either an understanding of clinical trial design and execution, and formulation of topical pharmaceutical compositions, or who works in collaboration with a biostatistician and formulator. (D.I. 240 at 5; D.I. 245 at 3).

4. Claims 2 and 6 of the '117 patent and claims 6, 7, and 10 of the '118 patent each have a priority date of July 8, 2013. (D.I. 228 ¶ 45).

5. Claim 12 of the '587 patent, claim 3 of the '117 patent, and claim 11 of the '118 patent each have a priority date of March 13, 2014. (*Id.* ¶ 47).

6. McDaniel is prior art to each of the asserted claims under 35 U.S.C. § 102(a)(1). (*Id.* ¶¶ 95-96).

7. Manetta enables McDaniel in 2012 as to the formulation. (D.I. 219 at 12).

[6] Teva also argues that the asserted claims are invalid for lack of written description and obviousness. (D.I. 240 at 9-10, 20-30). Because I find the claims invalid as anticipated, I do not reach Teva's alternative invalidity theories.

8. The Manetta formulation is the formulation for Soolantra. (D.I. 228 ¶ 93); Tr. at 17:9-13, 313:1-3.

9. McDaniel explicitly discloses a treatment method comprising (1) topically administering, (2) once daily, (3) to a skin area affected by the inflammatory lesions of papulopustular rosacea, (4) a pharmaceutical composition comprising about 1% by weight ivermectin and a pharmaceutically acceptable carrier.

10. McDaniel inherently discloses the treatment results of its treatment method as enabled by the Manetta formulation.

11. McDaniel anticipates claim 12 of the '587 patent, claims 2, 3, and 6 of the '117 patent, and claims 6, 7, 10, and 11 of the '118 patent.

B. Conclusions of Law

1. McDaniel Anticipates the Claimed Treatment Method

All of the asserted claims recite the same treatment method. The claims also include various efficacy limitations relating to the results of the treatment method, which I address separately. *See infra* Section IV.B.2. The claimed treatment method comprises: "[1] topically administering, [2] once daily, [3] to a skin area affected by the inflammatory lesions of papulopustular rosacea[7] [4] a pharmaceutical composition comprising about 1% by weight ivermectin and a pharmaceutically acceptable carrier." *E.g.*, PX-3 at 24:20-23.

McDaniel claims an invention relating to "a method for treatment of rosacea (acne rosacea) in humans employing orally-administered or topically-applied ivermectin." DX-16 at 1:5-7. McDaniel defines "[r]osacea, originally termed acne rosacea," as having clinical signs including "papules" and "pustules." *Id.* at 1:13-17. Under my construction, papules and/or pustules are inflammatory lesions of papulopustular rosacea. (D.I. 126 at 3). Although

[7] Claim 12 of the '587 patent requires administering "to a skin area affected by the papulopustular rosacea or the inflammatory lesions of rosacea." PX-1 at 24:19-44. Claims 2, 3, and 6 of the '117 patent require administering "to a skin area affected by the inflammatory lesions of rosacea." PX-2 at 28:43-67. Claims 6, 7, 10, and 11 of the '118 patent require administering "to a skin area affected by the inflammatory lesions of papulopustular rosacea." PX-3 at 24:18-31, 24:51-64. Under my construction, "inflammatory lesions of rosacea" and "inflammatory lesions of papulopustular rosacea" have the same meaning. (D.I. 126 at 3).

McDaniel describes its preferred embodiment as using oral ivermectin, it also explicitly discloses an embodiment using topical ivermectin:

> [I]vermectin is formulated into a cosmetically-accept[a]ble topical lotion, cream, or gel and applied to skin affected by rosacea. Because of the well-known barrier effect the skin presents to the penetration of topical medications, such a route of treatment with ivermectin would be anticipated to require once- or twice-daily applications for as long as four weeks to achieve sufficient follicle penetration and effective miticidal activity.[8] A topical formulation that could achieve this effect would contain about 1-5% ivermectin.

DX-16 at 2:66-3:8.

McDaniel discloses every element of the claimed treatment method. The topical use embodiment, in view of the rest of the specification, discloses a method of treatment comprising:

> (1) "topically administering" ("a method for treatment of rosacea (acne rosacea) in humans employing . . . topically-applied ivermectin," *id.* at 1:5-7; "ivermectin is . . . applied to skin," *id.* at 2:66-3:1),
>
> (2) "once daily" ("such a route of treatment with ivermectin would be anticipated to require once- or twice-daily applications," *id.* at 3:1-5),
>
> (3) "to a skin area affected by the inflammatory lesions of papulopustular rosacea" ("applied to skin affected by rosacea," *id.* at 2:66-3:1; "rosacea" having clinical signs including "papules" and "pustules," *id.* at 1:13-17),
>
> (4) "a pharmaceutical composition comprising about 1% by weight ivermectin and a pharmaceutically acceptable carrier" ("ivermectin is formulated into a cosmetically-accept[a]ble topical lotion, cream, or gel," *id.* at 2:66-3:1; "[a] topical formulation . . . would contain about 1-5% ivermectin," *id.* at 3:7-8).

The fact that McDaniel also discloses alternatives to the claimed method (*e.g.*, twice-daily applications) does not change the anticipation analysis. *See Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1376 (Fed. Cir. 2005) (rejecting the argument that one of a list of ingredients cannot anticipate "because it appears without special emphasis in a longer list"); *Hewlett-Packard Co. v. Mustek Sys., Inc.*, 340 F.3d 1314, 1324 n.6 (Fed. Cir. 2003) ("The anticipation

[8] McDaniel's invention is based on the theory that rosacea is linked to the presence of *Demodex folliculorum* mites in the skin. DX-16 at 1:5-12.

analysis asks solely whether the prior art reference discloses and enables the claimed invention, and not how the prior art characterizes that disclosure or whether alternatives are also disclosed.").

Galderma argues that McDaniel fails to disclose (1) the use of topical ivermectin for the purpose of treating inflammatory lesions of papulopustular rosacea and (2) the use of 1% ivermectin once daily.

First, Galderma argues that McDaniel fails to disclose the use of ivermectin to treat inflammatory lesions because it discloses a method that "elicit[s] . . . lesion formation" and co-administers ivermectin with "conventional anti-rosacea medications." (D.I. 245 at 3-4). Galderma relies on the following passage in McDaniel:

> After ivermectin carries out its miticidal activity on skin *Demodex folliculorum* organisms, inflammatory responses to them begin to diminish but remnants of dead mites still elicit some flushing and lesion formation until the cleanup processes of the body remove them, a process requiring six to eight weeks. During this initial phase of ivermectin administration, conventional anti-rosacea medications such as oral tetracycline and topical metronidazole can be employed to suppress early flareups and to give early clinical response. No such medications are needed to treat manifestations of rosacea after six to eight weeks have elapsed.

DX-16 at 2:51-62.[9]

The cited passage is inapposite. McDaniel describes a potential delay in benefits from the ivermectin treatment due to the remnants of dead mites. Any increase in lesion formation is temporary. Regardless, lesion formation is a measure of efficacy and is irrelevant to whether McDaniel discloses the steps of the treatment method. As for the co-administration of "conventional" medications, McDaniel merely suggests that other drugs can be "employed" with ivermectin in the early stages of treatment. This is not a requirement of co-administration in the

[9] McDaniel provides this explanation in the context of oral ivermectin. It is not clear whether the same issues apply to the use of topical ivermectin. *See* DX-16 at 2:35-3:13.

early stages. Therefore, McDaniel does not limit its disclosure to methods involving co-administration in the early stages of treatment.[10]

Second, Galderma argues that McDaniel's disclosure of "about 1-5% ivermectin" is not "sufficiently specific" to anticipate the asserted claims and is not connected to the once-daily dosing frequency. (D.I. 245 at 4-5). Galderma cites to, without explanation, *Atofina v. Great Lakes Chemical Corp.*, 441 F.3d 991 (Fed. Cir. 2006) and *Impax Laboratories, Inc. v. Lannett Holdings, Inc.*, 246 F. Supp. 3d 1024 (D. Del. 2017), *aff'd on other grounds*, 893 F.3d 1372, 1377 (Fed. Cir. 2018) (anticipation argument not argued on appeal).

The Federal Circuit discussed *Atofina* at length in *ClearValue, Inc. v. Pearl River Polymers, Inc.*, 668 F.3d 1340 (Fed. Cir. 2012). The asserted patent in *Atofina* claimed a method of synthesizing a composition at a narrow temperature range of 330-450 °C, and more preferably 350-400 °C. The patentees described the temperature range as "critical" during prosecution. The prior art, however, taught a broad temperature range of 100-500 °C. *Id.* at 1344-45. The *ClearValue* court explained:

> [T]he prior art's teaching of a broad genus (i.e., broad temperature range) does not disclose every species within that genus. In *Atofina*, the evidence showed that one of ordinary skill would have expected the synthesis process to operate differently outside the claimed temperature range, which the patentee described as "critical" to enable the process to operate effectively. Based on this "considerable difference" between the prior art's broad disclosure and the "critical" temperature range claimed in the patent, we held that "no reasonable fact finder could conclude that the prior art describes the claimed range with sufficient specificity to anticipate this limitation of the claim."

Id. at 1345.

In contrast, the *ClearValue* court found a prior art genus of 150 ppm or less anticipated the claim limitation of 50 ppm. *Id.* at 1345-46. The court noted, "unlike *Atofina* where there

[10] McDaniel is even clearer in its disclosure of the use of ivermectin alone after six to eight weeks have elapsed. DX-16 at 2:60-62.

was a broad genus and evidence that different portions of the broad range would work differently," in *ClearValue* there was "no allegation of criticality or any evidence demonstrating any difference across the range." *Id.* at 1345. Therefore, there was no "considerable difference between the claimed range and the range in the prior art." *Id.*

I relied on *Atofina* as one of two alternative bases to find no anticipation in *Impax*. The claims in *Impax* required certain pHs, all of which were acidic. 246 F. Supp. 3d at 1035. The prior art disclosed broad pH ranges of 4 to 9 and 5 to 8, which included both acidic and alkaline pHs. *Id.* I found that the broad pH ranges were not "sufficiently specific" to anticipate the pH limitations. *Id.* As in *Atofina*, my alternative ruling was based on there being too great a difference between the prior art's broad disclosure and the narrow acidic range required by the claims. *See id.*

Both *Atofina* and *Impax* are distinguishable. Although McDaniel discloses a genus of 1-5% ivermectin, there is no evidence that 1-5% is a particularly broad range for the purposes of the claimed treatment method. Rather, as in *ClearValue*, Galderma has made no allegation of criticality or provided any evidence demonstrating any difference across the range. *See* 668 F.3d at 1345. There is thus no "considerable difference" between the 1% ivermectin limitation and the 1-5% ivermectin range in McDaniel. Therefore, I find McDaniel's disclosed range sufficiently specific to anticipate the 1% ivermectin limitation.

McDaniel also ties the use of 1% ivermectin to a once-daily dosage. The topical ivermectin embodiment discloses both the required percentage of ivermectin and the frequency of application. McDaniel explains that to have "sufficient follicle penetration and effective miticidal activity," the topical ivermectin "would be anticipated to require once- or twice-daily applications," and a "topical formulation that could achieve [that] effect would contain about 1-

5% ivermectin." DX-16 at 3:1-8. In contrast, in *Impax*, I found the prior art did not disclose "all of the elements as arranged in the claim" because it "gave no reason to connect" the disclosure of the pH element with the disclosure of the drug element. 246 F. Supp. 3d at 1035. McDaniel provides a clear reason to connect the disclosure of 1% ivermectin with once-daily applications as it explicitly teaches the use of both elements together.

Therefore, McDaniel anticipates the claimed treatment method.

2. McDaniel Anticipates the Claimed Efficacies

Aside from the treatment method, the only remaining limitations are those relating to efficacy. Therefore, McDaniel anticipates the asserted claims if the efficacy limitations are inherent to the treatment method. "Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates." *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999). "Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art." *Id.* "In general, a limitation or the entire invention is inherent and in the public domain if it is the natural result flowing from the explicit disclosure of the prior art." *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1379 (Fed. Cir. 2003) (internal quotation marks omitted).

The asserted claims recite particular efficacies that result from the claimed treatment method. Those claimed efficacies are:

> (1) "a significant reduction in inflammatory lesion count in the subject" ('587 patent, claim 12; '118 patent, claims 6, 7, 10, 11);
>
> (2) "a significant improvement in at least one selected from the group consisting of a higher investigator's global assessment success rate and a delayed time to first relapse in the subject in comparison to that achieved by topically administering to the subject, twice daily, a second pharmaceutical composition comprising 0.75% by weight metronidazole" ('587 patent, claim 12);

(3) "as early as 2 weeks after the initial administration of the pharmaceutical composition, a significant reduction in inflammatory lesion count" ('117 patent, claims 2, 3, 6; '118 patent, claims 7, 10, 11);

(4) "as early as 2 weeks after the initial administration of the pharmaceutical composition, a significant reduction in inflammatory lesion count," "wherein the subject has moderate to severe papulopustular rosacea before the treatment," and "wherein the subject has 15 or more of the inflammatory lesions before the treatment" ('117 patent, claim 6);

(5) "more reduction in inflammatory lesion count in the subject in comparison to that achieved by topically administering to the subject, twice daily, a second pharmaceutical composition comprising 0.75% by weight metronidazole" ('117 patent, claim 2; '118 patent, claim 10); and

(6) "longer relapse-free time of the inflammatory lesions of rosacea in the subject in comparison to that achieved by twice daily topically administering to the subject a second pharmaceutical composition comprising 0.75% by weight metronidazole" ('117 patent, claim 3; '118 patent, claim 11).

The Federal Circuit addressed an analogous situation in *Perricone*. There, the asserted claims recited "particular skin benefits together with methods of achieving those benefits (i.e., topically applying a particular compound)." *Perricone*, 432 F.3d at 1378. The court found that the prior art anticipated so long as it disclosed the claimed method. *Id.* at 1378-80. For several of the asserted claims, the claimed method only required topical application of the recited composition. *Id.* The court found those claims inherently anticipated because the prior art disclosed the same composition and taught its topical application. *Id.* at 1380. The court held, "Using the same composition claimed by [plaintiff] in the same manner claimed by [plaintiff] naturally results in the same claimed skin benefits." *Id; see also Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1377 (Fed. Cir. 2001) ("Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent.").

In contrast, the court found the claims that required topical application "to skin sunburn" not anticipated. *Perricone*, 432 F.3d at 1378-79. The issue was not "whether [the prior art's]

lotion *if applied* to skin sunburn would inherently treat that damage, but whether [the prior art] disclose[d] the application of its composition to skin sunburn." *Id.* at 1378. The court found that disclosing topical application to skin generally was insufficient to anticipate the sunburn limitation because "there is an important distinction between topical application to skin for the purpose of avoiding sunburn, and the much narrower topical application to skin sunburn." *Id.* at 1379. The former is a method of prevention while the latter is a method of treatment. *Id.* (providing the analogy, "the disclosure that a sunburn can be prevented by wearing a hat clearly does not anticipate a claim to the discovery that one can treat an existing sunburn by putting on a hat.").

Relying on the sunburn analysis in *Perricone*, Galderma argues that McDaniel's treatment of rosacea generally is insufficient for anticipation because it will not necessarily result in treatment of inflammatory lesions of papulopustular rosacea. (D.I. 245 at 7).[11] *Perricone* does not support Galderma's argument. As the court explained, the issue is not whether McDaniel's formulation *if applied* would inherently treat inflammatory lesions of papulopustular rosacea, but whether McDaniel discloses the application of the formulation to inflammatory lesions of papulopustular rosacea. *See id.* at 1378. I find that it does. *See supra* Section IV.B.1. Further, both McDaniel and the asserted claims state that the composition is applied to skin "affected by" rosacea. DX-16 at 2:66-3:1; PX-1 at 24:21-23; PX-2 at 28:44-46; PX-3 at 24:20-21. Therefore, unlike in *Perricone* where the prior art disclosed a method for preventing sunburn and the asserted claims recited a method for treating sunburn, both McDaniel and the asserted claims are directed to a method for treating rosacea. *See* 432 F.3d at 1379; *see also Ben Venue*,

[11] Galderma also argues that McDaniel's treatment is not directed at reducing inflammatory lesions of rosacea. (D.I. 245 at 6). Galderma's only explanation is a cite to its earlier argument, which relied on McDaniel's discussion of the temporary increase in lesion formation during the time required to clear dead mites. (*Id.*). I already rejected Galderma's arguments related to that portion of McDaniel. *See supra* Section IV.B.1.

246 F.3d at 1377 (finding the asserted claims did "no more than claim a result (efficacy) of three-hour paclitaxel infusions in cancer patients," which was no different from the purpose—treating cancer—disclosed in the prior art).

The only remaining issue is whether McDaniel also discloses using the same ivermectin formulation as in the asserted claims. The parties have stipulated, "Manetta enables McDaniel in 2012 as to the formulation." (D.I. 219 at 12); *see also Ben Venue*, 246 F.3d at 1379 ("Enablement of an anticipatory reference may be demonstrated by a later reference."). Thus, as of 2012, before the critical dates of the asserted claims, a person of ordinary skill in the art would have been able to practice McDaniel's disclosed treatment method with Manetta's formulation without undue experimentation. *See In re Morsa*, 803 F.3d 1374, 1377 (Fed. Cir. 2015) ("Enablement of prior art requires that the reference teach a skilled artisan—at the time of filing—to make or carry out what it discloses in relation to the claimed invention without undue experimentation.") The Manetta formulation is the formulation for Galderma's product, Soolantra. (D.I. 228 ¶ 93); Tr. at 17:9-13; 313:1-3.

Galderma argues that Teva has failed to meet its burden on anticipation because it must show that all 1% ivermectin formulations disclosed in McDaniel would necessarily achieve the claimed efficacies. (D.I. 245 at 7-9). Galderma cites no authority. To the contrary, it is well established that "[f]or a prior-art reference to be enabling, it need not enable the claim in its entirety, but instead the reference need only enable a single embodiment of the claim." *In re Morsa*, 803 F.3d at 1377. It is undisputed that the topical application of Soolantra, once daily, to skin affected by inflammatory lesions of rosacea, is an embodiment of the asserted claims. (D.I. 241 at 3-5 ("Galderma's Clinical Studies Establish That the Use of Soolantra® Will Meet Every Element of the Asserted Claims")). Therefore, McDaniel need only enable its treatment method

with respect to Soolantra. As Soolantra is the Manetta formulation, the parties have stipulated to such enablement. (D.I. 219 at 12).

The asserted claims consist of the same steps described in McDaniel and are directed to the same use—treating inflammatory lesions of papulopustular rosacea. "Using the same composition claimed by [Galderma] in the same manner claimed by [Galderma] naturally results in the same claimed skin benefits." *See Perricone*, 432 F.3d at 1380. Therefore, the claimed efficacies are nothing more than "the natural result flowing from the explicit disclosure" of the claimed treatment method. *See Schering*, 339 F.3d at 1379. As such, those efficacies are inherent to and anticipated by McDaniel's disclosure of the claimed treatment method.

V. CONCLUSION

For the foregoing reasons, I find each of the asserted claims invalid for anticipation by McDaniel. I therefore do not need to reach Teva's alternative invalidity arguments. As invalidity is an affirmative defense to infringement, I find none of the asserted claims infringed.

The parties shall submit a final judgment consistent with this memorandum opinion **within one week**.