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Paper No. 12
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FAMY CARE LIMITED,
Petitioner,

v.

ALLERGAN, INC.,
Patent Owner.

Case IPR2017-00570
Patent 8,642,556 B2

Before SHERIDAN K. SNEDDEN, TINA E. HULSE, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

PAULRAJ, *Administrative Patent Judge*.

DECISION

Institution of *Inter Partes* Review and Denial of Motion for Joinder
35 U.S.C. § 315(c); 37 C.F.R. § 42.108

I. INTRODUCTION

Famy Care Limited ("Famy Care" or "Petitioner") filed a Petition, seeking an *inter partes* review of claims 1–20 of U.S. Patent No. 8,642,556 B2 ("the '556 patent," Ex. 1001). Paper 4 ("Pet"). Allergan, Inc. ("Allergan" or "Patent Owner") did not file a Preliminary Response to the Petition.

Along with the Petition, Petitioner filed a Motion for Joinder to join this proceeding with *Mylan Pharmaceuticals Inc. v. Allergan, Inc.*, IPR2016-01129. Paper 5 ("Mot"). Patent Owner filed an Opposition to the Motion for Joinder. Paper 9.

For the reasons stated below, we deny Petitioner's motion for joinder.

As for the Petition, we have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Upon considering the Petition, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of claims 1–20. Accordingly, we institute an *inter partes* review of those claims.

A. Related Proceedings

The parties identify petitions for *inter partes* review previously filed by other petitioners that challenge the claims of the '556 patent and related patents. Pet. 4–5; Paper 8, 2–3. Certain petitions were terminated before decisions on institution were entered. *Id.* Other petitions have been granted and *inter partes* review has been instituted for the following U.S. Patents:

U.S. Patent No. 8,633,162 (IPR2016-01130, IPR2017-00599, IPR2017-00583); U.S. Patent No. 8,685,930 (IPR2016-01127, IPR2017-00594, IPR2017-00576); U.S. Patent No. 8,629,111 (IPR2016-01128, IPR2017-00596, IPR2017-00578); U.S. Patent No. 8,642,556 (IPR2016-01129, IPR2017-00598, IPR2017-00579); U.S. Patent No. 8,648,048 (IPR2016-01131, IPR2017-00600, IPR2017-00585); and U.S. Patent No. 9,248,191 (IPR2016-01132, IPR2017-00601, IPR2017-00586). Paper 8, 3.

The parties also identify several district court cases that may affect or be affected by a decision in this proceeding: *Allergan, Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 2:15-cv-01455 (E.D. Tex.); *Allergan, Inc., v. Innopharma, Inc.*, No. 2:15-cv-1504 (E.D. Tex.); *Allergan, Inc. v. Famy Care, Ltd.*, No. 2:16-cv-0401 (E.D. Tex.); and *Allergan, Inc. v. DEVA Holding AS*, No. 2:16-cv-1447 (E.D. Tex.). Pet. 5; Paper 8, 2.

Petitioner has also sought *inter partes* review for related patents in the following proceedings: IPR2017-00566 (U.S. Patent No. 8,648,048 B2), IPR2017-00567 (U.S. Patent No. 8,629,111 B2), IPR2017-00568 (U.S. Patent No. 8,633,162 B2), IPR2017-00569 (U.S. Patent No. 9,248,191 B2), and IPR2017-00571 (U.S. Patent No. 8,685,930 B2).

B. The '556 Patent (Ex. 1001)

The '556 patent generally relates to methods of providing therapeutic effects using cyclosporin components, and more specifically to a formulation containing, *inter alia*, cyclosporin-A ("CsA") and castor oil emulsions for treating dry eye syndrome (i.e., keratoconjunctivitis sicca). Ex. 1001, 1:18–20, 1:58–65, 2:63–64. According to the specification, the prior art recognized the use of emulsions containing CsA and CsA

derivatives to treat ophthalmic conditions. *Id.* at 1:26–65. The specification notes, however, that "[o]ver time, it has been apparent that cyclosporin A emulsions for ophthalmic use preferably have less than 0.2% by weight of cylcosporin A." *Id.* at 1:66–2:1. Moreover, if reduced amounts of CsA are used, reduced amounts of castor oil are needed because one of the functions of castor oil is to solubilize cyclosporin A. *Id.* at 1:66–2:6.

Accordingly, the specification states that "[i]t has been found that the relatively increased amounts of hydrophobic component together with relatively reduced, yet therapeutically effective, amounts of cyclosporin component provide substantial and advantageous benefits." *Id.* at 2:35–38. The relatively high concentration of hydrophobic component provides for a more rapid breaking down of the emulsion in the eye, which reduces vision distortion and/or facilitates the therapeutic efficacy of the composition. *Id.* at 2:42–48. Furthermore, using reduced amounts of cyclosporin component mitigates against undesirable side effects or potential drug interactions. *Id.* at 2:48–51.

The patent identifies two particular compositions that were selected for further testing, as shown below:

	Composition I wt %	Composition II wt %
Cyclosporin A	0.1	0.05
Castor Oil	1.25	1.25
Polysorbate 80	1.00	1.00
Premulen ®	0.05	0.05
Glycerine	2.20	2.20
Sodium hydroxide	qs	qs
Purified Water	qs	qs
pH	7.2-7.6	7.2-7.6
Weight Ratio of Cyclosporin A to Castor Oil	0.08	0.04

Id. at 15:1–13. Based on the results of a Phase III clinical study, the specification concludes that "Composition II . . . provides overall efficacy in treating dry eye disease substantially equal to that of Composition I." *Id.* at 15:18–22. The patent indicates that "[t]his is surprising for a number of reasons." *Id.* at 15:23. According to the specification, a reduced concentration of CsA in Composition II would have been expected to result in reduced overall efficacy in treating dry eye disease. *Id.* at 15:24–26. Moreover, although the large amount of castor oil relative to the amount of CsA in Composition II might have been expected to cause increased eye irritation, it was found to be substantially non-irritating in use. *Id.* at 15:26–32. Accordingly, the specification states that physicians can prescribe Composition II "to more patients and/or with fewer restrictions and/or with reduced risk of the occurrence of adverse events, e.g., side effects, drug interactions and the like, relative to providing Composition I." *Id.* at 15:54–58.

C. Illustrative Claims

Petitioner challenges claims 1–20 of the '556 patent. Independent claim 1 is illustrative, and is reproduced below:

> 1. A first topical ophthalmic emulsion for treating an eye of a human, wherein the first topical ophthalmic emulsion comprises cyclosporin A in an amount of about 0.05% by weight, polysorbate 80, acrylate/C10-30 alkyl acrylate cross-polymer, water, and castor oil in an amount of about 1.25% by weight; and
>
> wherein the first topical ophthalmic emulsion is therapeutically effective in treating dry eye disease; and
>
> wherein the first topical ophthalmic emulsion provides overall efficacy substantially equal to a second topical ophthalmic emulsion comprising cyclosporin A in an amount of

about 0.1% by weight and castor oil in an amount of about 1.25% by weight.

Independent claims 13, 14, and 15 also recite a topical ophthalmic emulsion comprising CsA in an amount of about 0.05% by weight and castor oil in an amount of 1.25% by weight, and further specify particular amounts for other components.

D. Asserted Grounds of Unpatentability

Petitioner challenges the patentability of the claims of the ’556 patent on the following grounds:

References	**Basis**	**Claim(s) challenged**
Ding ’979[1]	§ 102	1–20
Ding ’979 and Sall[2]	§ 103(a)	1–20
Ding ’979, Sall, and Glonek[3]	§ 103(a)	14 and 19
Ding ’979, Sall, and Acheampong[4]	§ 103(a)	11, 18, and 20
Ding ’979, Sall, Glonek, and Acheampong	§ 103(a)	19

[1] Ding et al., US 5,474,979, issued Dec. 12, 1995 (Ex. 1006).
[2] Sall et al., *Two Multicenter, Randomized Studies of the Efficacy and Safety of Cyclosporine Ophthalmic Emulsion in Moderate to Severe Dry Eye Disease*, 107 OPHTHALMOLOGY 631–39 (2000) (Ex. 1007).
[3] Glonek et al., US 5,578,586, issued Nov. 26, 1996 (Ex. 1009).
[4] Acheampong et al., *Cyclosporine Distribution into the Conjunctiva, Cornea, Lacrimal Gland, and Systemic Blood Following Topical Dosing of Cyclosporine to Rabbit, Dog, and Human Eyes*, LACRIMAL GLAND, TEAR FILM, AND DRY EYE SYNDROMES 2: BASIC SCIENCE AND CLINICAL RELEVANCE 1001–04 (David A. Sullivan et al. eds., 1998) (Ex. 1008).

Petitioner further relies upon the declarations of Dr. Peter Kador (Ex. 1002) and Dr. Michael A. Lemp (Ex. 1003).

II. ANALYSIS

A. Motion for Joinder

Famy Care requests joinder with IPR2016-01129, which was instituted as to claims 1–20 of the '556 patent based on a petition filed by Mylan Pharmaceuticals Inc. ("Mylan").

Based on authority delegated to us by the Director, we have discretion to join an *inter partes* review to a previously instituted *inter partes* review. 35 U.S.C. § 315(c). Section 315(c) provides, in relevant part, that "[i]f the Director institutes an inter partes review, the Director, in his or her discretion, may join as a party to that inter partes review any person who properly files a petition under section 311." *Id.* When determining whether to grant a motion for joinder we consider factors such as timing and impact of joinder on the trial schedule, cost, discovery, and potential simplification of briefing. *Kyocera Corp. v. SoftView, LLC*, Case IPR2013-00004, slip op. at 4 (PTAB Apr. 24, 2013) (Paper 15).

Although Famy Care's Petition is similar to Mylan's Petition in terms of the patentability challenges presented, it differs in its presentation of arguments. For example, Famy Care relies upon the declarations of Dr. Kador (Ex. 1002) and Dr. Lemp (Ex. 1003) to support its Petition, whereas Mylan relies upon the declaration of Mansoor Amiji, Ph.D. Famy Care also presents additional arguments and evidence regarding secondary considerations that were not presented with Mylan's Petition. Pet. 58–78.

Allergan asserts that there are "significant differences between Famy Care's petition and Mylan's petition." Paper 9, 1. Nevertheless, Allergan indicated that it will not oppose joinder if Famy Care agrees to participate in the joined proceedings under the following conditions:

> 1. Famy Care agrees to rely solely on Mylan's expert;
>
> 2. Famy Care agrees to consolidated briefing subject to the word count limits for a single party except for motions that involve only Famy Care;
>
> 3. Famy Care agrees that cross-examination of Patent Owner's witnesses will occur within the timeframe that the rules allot for one party; and
>
> 4. Famy Care agrees that Mylan will conduct the oral argument.

Id.

In its Reply in support of the Motion for Joinder, Famy Care indicates that it only agrees to one of Allergan's conditions—to conduct the cross-examination of Patent Owner's witnesses within the timeframe allotted for one party. Paper 10, 1. Famy Care, however, states that it cannot agree to forgo reliance on its expert declarants because its experts "include a distinguished clinician who can provide the Board a valuable perspective on the secondary considerations arguments Allergan leans heavily on." *Id.* at 2. Famy Care also asserts that it cannot agree to limit its briefing in the joined proceeding on the basis that it "believes additional briefing, including on its secondary considerations arguments, will give [Famy Care] a fair chance to present its own arguments and aid the Board in considering the instituted grounds." *Id.* at 4. Famy Care only agrees to "consolidate its briefing with

Mylan if permitted separate briefing of up to seven pages (including but not limited to arguments on which Mylan lacks standing, or [Famy Care] and Mylan disagree)." *Id.* Finally, with respect to oral arguments, Famy Care agrees to have Mylan argue first, but asserts a right to "present its own arguments (if necessary) only on issues where the Petitioners disagree, or where Mylan has no standing to address, all within the allotted time for one party." *Id.* at 3.

Under the circumstances, we determine that joinder of Famy Care to IPR2016-01129 is not appropriate. Famy Care argues that if an *inter partes* review is instituted based on its Petition, "but joinder is denied, Allergan would be compelled to go through duplicative discovery to defend against two IPR petitions, and the Board would be required to consider similar arguments on the same ground twice." *Id.* at 4. As noted above, however, Famy Care does not concede to simply taking a "silent understudy" role with respect to Mylan, and instead seeks the opportunity to present additional arguments, briefing, and evidence, including two additional expert declarations, beyond what is being considered based on Mylan's Petition in IPR2016-01129. Moreover, to the extent that a denial of joinder would result in duplicative proceedings for Allergan, we note that Allergan has opposed joinder in this instance. Accordingly, we determine that joinder under these conditions would not "secure the just, speedy, and inexpensive resolution" of the proceeding. *See* 37 C.F.R. § 42.1(b). Thus, Famy Care's Motion for Joinder is denied.

Having determined that joinder is not appropriate, we now consider Famy Care's Petition on the merits.

B. Person of Ordinary Skill in the Art

Petitioner asserts that as of September 15, 2003, a person of ordinary skill in the art would likely have had "some combination of: (a) knowledge regarding designing and preparing products intended for ocular administration; and/or (b) the ability to understand results and findings presented or published by others in the field." Pet. 10 (citing Ex. 1002 ¶ 54). Petitioner further contends that this person typically would have an advanced degree, such as a medical degree, or a Ph.D. in organic chemistry, pharmaceutical chemistry, medicinal chemistry, pharmaceutics, physical pharmacy, or a related field, or less education but considerable professional experience in these fields. *Id.*

On this record, we adopt Petitioner's definition of the level of ordinary skill in the art. We further note that the prior art itself demonstrates the level of skill in the art at the time of the invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required "where the prior art itself reflects an appropriate level and a need for testimony is not shown") (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp*., 755 F.2d 158, 163 (Fed. Cir. 1985)).

C. Claim Construction

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016) (affirming applicability of broadest reasonable construction standard to *inter partes*

review proceedings). Under that standard, and absent any special definitions, we generally give claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

1. "effective"/"therapeutically effective"

Independent claims 1 and 13 state that the emulsion is "therapeutically effective in treating dry eye disease." Claim 11 recites administering "an effective amount in treating dry eye disease." Petitioner asserts that the plain meaning of the word "therapeutic" includes palliative as well as curative treatments, and, in the context of the '556 patent, an emulsion effective to increase tear production or reduce symptoms is an example of one therapeutically effective in treating dry eye. Pet. 17–18 (citing Ex. 1002 ¶¶ 63–66; Ex. 1003 ¶¶ 76–78).

At this stage of the proceeding, we are persuaded that Petitioner's arguments and evidence support the broadest reasonable interpretation in light of the specification, and find that "effective," "therapeutically effective," and similar terms encompass both palliative and curative treatments of dry eye disease/KCS.

2. Remaining Claim Terms

Petitioner proposes constructions for a number of additional claim terms. At this stage of the proceeding, we determine it is unnecessary to expressly construe any other claim terms for purposes of this Decision. *See*

Wellman, Inc. v. Eastman Chem. Co., 642 F.3d 1355, 1361 (Fed. Cir. 2011) ("[C]laim terms need only be construed 'to the extent necessary to resolve the controversy.'") (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

D. Content of the Prior Art

Petitioner relies upon the following prior art in its challenges.

1. Ding '979 (Ex. 1006)

Ding '979, assigned to Patent Owner, relates to ophthalmic emulsions including cyclosporin, castor oil, and polysorbate 80 that have a high comfort level and low irritation potential. Ex. 1006, Abstract, 1:4–9. Ding '979 explains that cyclosporins have "known immunosuppressant activity" and have been found "effective in treating immune medicated keratoconjunctivitis sicca (KCS or dry eye disease) in a patient suffering therefrom." *Id.* at 1:10–16. Although the solubility of cyclosporins in water is extremely low, cyclosporins have some solubility in oily preparations containing higher fatty acid glycerides such as castor oil. *Id.* at 1:40–41, 2:39–42. Ding '979 notes, however, that formulations with a high concentration of oils have several drawbacks, including exacerbation of the symptoms of dry eyes and low thermodynamic activity of cyclosporin, which leads to poorer drug bioavailability. *Id.* at 2:42–57. Accordingly, Ding '979 "is directed to an emulsion system which utilizes higher fatty acid glycerides but in combination with polysorbate 80 which results in an emulsion with a high comfort level and low irritation potential suitable for delivery of medications to sensitive areas such as ocular tissues." *Id.* at 2:65–3:3.

Ding '979 discloses that the preferable weight ratio of CsA to castor oil is below 0.16, and more preferably between 0.12 and 0.02. *Id.* at 3:15–20. Specifically, Ding '979 discloses several compositions as Example 1, shown below:

Example 1

	A	B	C	D	E
Cyclosporin A	0.40%	0.20%	0.20%	0.10%	0.05%
Castor oil	5.00%	5.00%	2.50%	1.25%	0.625%
Polysorbate 80	1.00%	1.00%	1.00%	1.00%	1.00%
Pemulen ®	0.05%	0.05%	0.05%	0.05%	0.05%
Glycerine	2.20%	2.20%	2.20%	2.20%	2.20%
NaOH	qs	qs	qs	qs	qs
Purified water	qs	qs	qs	qs	qs
pH	7.2–7.6	7.2–7.6	7.2–7.6	7.2–7.6	7.2–7.6

Id. at 4:32–43. Example 1 identifies compositions A through E, which contain varying amounts of CsA, castor oil, polysorbate 80, Pemulen®(an acrylate/C10-30 alkyl acrylate cross-polymer), glycerine, sodium hydroxide, and purified water at a pH range of 7.2–7.6. *Id.* According to Ding '979, the formulations of Example 1 was "made for treatment of keratoconjunctivitis sicca (dry eye) syndrome)." *Id.* at 5:10–12.

2. Sall (Ex. 1007)

Sall describes the results of two identical clinical trials—supported by a grant from Patent Owner—in which patients were treated twice daily with either CsA 0.05% or 0.1% ophthalmic emulsions or vehicle for six months. Ex. 1007, Abstract, 631. The study sought to compare the efficacy and safety of CsA 0.05% and 0.1% to vehicle in patients with moderate to severe dry eye disease. *Id.* Sall found that topical treatment with either CsA 0.05% or 0.1% resulted in significantly greater improvements than vehicle

treatment in two objective signs of dry eye disease. *Id.* at 637. Sall also found that treatment with CsA 0.05% resulted in significantly greater improvements in several subjective parameters. *Id.* Sall also found that trough blood concentrations of CsA were undetectable in all samples of CsA 0.05%, whereas CsA was quantifiable in only six samples for six different patients in the CsA 0.1% group. *Id.*

Sall notes that the only treatments available for dry eye disease are palliative in nature. *Id.* at 638. In light of the results of the study, Sall states that it "represents the first therapeutic treatment specifically for dry eye disease and a significant breakthrough in the management of this common and frustrating condition." *Id.*

3. Acheampong (Ex. 1008)

Acheampong describes a study by Patent Owner as part of its evaluation of the clinical efficacy of 0.05%–0.4% cyclosporin emulsion for the treatment of immuno-inflammatory eye diseases such as dry eye syndrome. Ex. 1008, 1001. Acheampong describes the results of its research to determine the ocular tissue distribution of cyclosporin in rabbits and dogs, and to compare tissue concentrations in rabbits, dogs, and humans after topical administration. *Id.*

In the study of humans, the subjects with dry eye disease received an eyedrop of vehicle or 0.05%, 0.1%, 0.2%, or 0.4% cyclosporin emulsions twice daily for 12 weeks. *Id.* at 1002. Blood samples were collected from all subjects at morning troughs after 1, 4, and 12 weeks of dosing, and from certain subjects at 1, 2, and 4 hours after the last dose at week 12. *Id.* Acheampong found that the human blood cyclosporin A concentrations were less than 0.2 ng/ml for each emulsion, which is lower than the 20-100 ng/ml

blood trough concentration used for monitoring the safety of patients receiving systemic cyclosporin therapy. *Id.* at 1004.

4. Glonek (Ex. 1009)

Glonek relates to a dry eye treatment process and a composition "capable of augmenting and maintaining a stable tear film over the ocular surface and/or delivering a medicant to said surface without causing substantial blurring of vision." Ex. 1009, 1:25–29. Glonek teaches that "an emulsion over the surface of the eye is expected to cause blurring" and "[t]he duration of blur is dependent upon the time required for the emulsion to differentiate and form separate layers replicating a tear film. . . . [I]t is preferred that the emulsion be stable for long term storage, but rapidly differentiate in the eye." *Id.* at 6:37–50. Glonek studied the effect of surfactant concentration in different emulsion formulations, and concluded that "[t]he lower concentrations resulted in poor to fair tear film formation up to about 0.05% surfactant content," whereas the "[b]est results were obtained within a range of from 0.05 to 0.15% surfactant. Additional surfactant provided little improvement and blurring occurred at the higher concentrations." *Id.* at 20:25–31.

E. Anticipation of Claims 1–20 by Ding '979

Petitioner contends that claims 1–20 of the '556 patent are anticipated by Ding '979. Pet. 28–40. In support of its assertion that Ding '979 teaches each element of the challenged claims, Petitioner sets forth the teachings of Ding '979 discussed above. Petitioner also provides a claim chart including citations to Ding '979. *Id.* at 21–27.

We recognize that that Ding '979 does not disclose the specific composition of the challenged claims having 0.05% by weight CsA, 1.25%

by weight castor oil, polysorbate 80, and an acrylate/C10-30 alkyl acrylate polymer. However, Ding '979 discloses five specific compositions having the following CsA/castor oil ratios: 0.40%/5.00% (Sample A), 0.20%/5.00% (Sample B), 0.20%/2.50% (Sample C), 0.10%/1.25% (Sample D), and 0.05%/0.625% (Sample E). Ex. 1006, 4:30–45. With respect to the CsA and castor oil elements, Petitioner points out that Example 1E of Ding '979 specifically uses 0.05% CsA, and that Example 1D specifically uses 1.25% castor oil. Pet. 30 (citing Ex. 1006, 4:33–43). Additionally, Ding '979 discloses that the weight ratio of CsA to castor oil is below 0.16 and preferably between 0.12 and 0.02. Ex. 1006, 3:15–20. A composition containing 0.05% cyclosporin/1.25% castor oil yields a weight ratio of cyclosporin to castor oil of 0.04, which falls within the range disclosed in Ding '979.

The primary issue presented is whether one skilled in the art would "at once envisage" the claimed composition based on the ratio range and examples disclosed in Ding '979. *See Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015) ("[A] reference can anticipate a claim even if it 'd[oes] not expressly spell out' all the limitations arranged or combined as in the claim, if a person of skill in the art, reading the reference, would 'at once envisage' the claimed arrangement or combination."). Here, based on the current record, Petitioner has demonstrated a reasonable likelihood of showing that the skilled artisan would have at once envisaged a combination that includes about 0.05% CsA and about 1.25% castor oil based on Ding '979. Furthermore, on the present record, there is insufficient evidence demonstrating the criticality of the

claimed amounts or any difference in the claimed emulsion where CsA and castor oil are present across the range disclosed in the prior art. *See ClearValue, Inc. v. Pearl River Polymers, Inc.*, 668 F.3d 1340, 1345 (Fed. Cir. 2012) (explaining the importance of establishing the criticality of a claimed range to the claimed invention in order to avoid anticipation by a prior art reference disclosing a broader range); *see also Ineos USA LLC v. Berry Plastics Corp.*, 783 F.3d 865, 870 (Fed. Cir. 2015) (finding that patentee failed to establish that certain properties would differ if range from prior art patent was substituted for range of limitation); *OSRAM Sylvania, Inc. v. Am. Induction Techs., Inc.*, 701 F.3d 698, 705–06 (Fed. Cir. 2012) (emphasizing that "how one of ordinary skill in the art would understand the relative size of a genus or species in a particular technology is of critical importance").

Accordingly, on the current record, we determine that there is a reasonable likelihood that Petitioner would prevail in demonstrating the unpatentability of claims 1–20 as anticipated by Ding '979.

F. Obviousness of Claims 1–20 Based on Ding '979 and Sall

Petitioner contends that claims 1–20 are rendered obvious by the combined teachings of Ding '979 and Sall. Pet. 40–54. The primary issue before us is whether it would have been obvious to use the particular concentrations of 0.05% CsA and 1.25% castor oil recited in the challenged claims.

As noted above, Ding '979 specifically identifies examples that include 0.05% CsA and 1.25% castor oil, albeit not as part of the same composition. Ex. 1006, 4:32–43. Petitioner contends, however, that the

skilled artisan would have looked to Sall's teachings regarding 0.05% and 0.10% CsA emulsions in formulating a topical emulsion for dry eye treatment. Pet. 41. (citing Ex. 1007, 1; Ex. 1002 ¶218, Ex. 1003 ¶ 126–129).

Upon consideration of the arguments set forth in the Petition, we conclude that Petitioner has shown a reasonable likelihood that a skilled artisan would have found it obvious to make the castor oil concentration in the emulsion to reach the claimed amount of 1.25% by balancing the need to minimize any undesirable effects associated with castor oil used at an excessive concentration with the desire to take advantage of the "substantial palliative benefits" of castor oil for the treatment of dry eye. Pet. 42; Ex. 1007, 1. *See In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003) ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Boesch*, 617 F.2d 272, 276 (CCPA 1980) ("[D]iscovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." (citations omitted)).

Thus, based on the arguments presented and evidence of record, we determine that Petitioner has demonstrated a reasonable likelihood that claims 1–20 are obvious over the teachings of Ding '979 and Sall.

G. Obviousness of Claims 14 and 19 Based on Ding '979, Sall, and Glonek

Petitioner asserts that claims 14 and 19 are unpatentable as obvious over Ding '979, Sall, and Glonek. Pet. 54–55.

Claim 14 recites a topical ophthalmic emulsion with the same ingredients as claim 1, and further recites that the emulsion "breaks down

more quickly in the eye of a human . . . thereby reducing vision distortion" as compared to a second emulsion with only half as much castor oil. Claim 19 depends from claim 14, and recites that "when the first topical ophthalmic emulsion is administered to an eye of a human, the blood of the human has substantially no detectable concentration of cyclosporin A."

Petitioner asserts "Glonek discloses oil-in-water emulsions for the treatment of dry eye which are formulated so 'blurred vision is reduced or eliminated and the residence time of tear film on the eye is prolonged.'" Pet. 54 (citing Ex. 1009, 3:3–7). Petitioner also relies upon Glonek's teaching that "[t]he duration of the blurring is dependent upon the time required for the emulsion to differentiate and form separate layers," and that "it is preferred that the emulsion be stable for long term storage, but rapidly differentiate in the eye." *Id.* at 55 (citing Ex. 1009, 6:37–40, 6:48–50). Based on these teachings of Glonek, Petitioner contends that a skilled artisan "would reasonably expect a 1.25% castor oil emulsion to break down into its differentiated eye layers faster than a 0.625% castor oil emulsion because of the increased instability from the higher oil concentration, and that the faster differentiation would result in a reduction of blurring." *Id.* (citing Ex. 1002 ¶ 271; Ex. 1003 ¶¶ 167–169).

Based on the arguments presented and evidence of record, we determine that Petitioner has demonstrated a reasonable likelihood that claims 14 and 19 are obvious over the teachings of Ding '979, Sall, and Glonek.

H. Obviousness of Claims 11 and 18–20 Based on Ding '979, Sall, and Acheampong

Petitioner asserts that claims 11 and 18–20 are unpatentable as obvious over Ding '979, Sall, and Acheampong. Pet. 55–57.

Claims 11, 18, and 20 depend from independent claims 1, 13, and 15 respectively and further recite that "when the first topical ophthalmic emulsion is administered to an eye of a human, the blood of the human has substantially no detectable concentration of cyclosporin A." Petitioner asserts that Acheampong teaches that an emulsion with 0.05% CsA resulted in no detectable CsA in the blood, even at the maximum time point. Pet. 56 (citing Ex. 1008, 6 (Table 1); Ex. 1002 ¶¶ 274–77; Ex. 1003 ¶¶ 172–78). Petitioner asserts that Acheampong, together with Sall's teaching, would provide a skilled artisan with a reasonable expectation of success that when the 0.05% CsA-in-castor oil emulsion is administered to the eye there is "substantially no detectable concentration of cyclosporin A" in the blood. *Id.* at 57.

Based on the arguments presented and evidence of record, we determine that Petitioner has demonstrated a reasonable likelihood that claims 11, 18, and 20 are obvious over the teachings of Ding '979, Sall, and Acheampong.

I. Obviousness of Claim 19 Based on Ding '979, Sall, Glonek, and Acheampong

Petitioner asserts that claim 19 is unpatentable as obvious over Ding '979, Sall, Glonek, and Acheampong. Pet. 57. Petitioner contends that "[t]he obviousness of the blood level limitation of claim 19 is further demonstrated by Acheampong for the reasons explained in Ground 4." *Id.* (citing Ex. 1002 ¶ 278; Ex. 1003 ¶¶ 179–82).

Based on the arguments presented and evidence of record, we determine that Petitioner has demonstrated a reasonable likelihood that claim 19 is obvious over the teachings of Ding '979, Sall, Glonek, and Acheampong.

III. CONCLUSION

We conclude that Petitioner has established a reasonable likelihood of prevailing on its assertions that claims 1–20 of the '556 patent are unpatentable as anticipated and/or obvious.

At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claim or the construction of any claim term. Thus, our view with regard to any conclusion reached in the foregoing could change upon consideration of Patent Owner's merits response and upon completion of the current record.

IV. ORDER

Accordingly, it is

ORDERED that trial is instituted in IPR2017-00570 on the following grounds:

A. Claims 1–20 under 35 U.S.C. § 102(b) as anticipated by Ding '979,

B. Claims 1–20 under 35 U.S.C. § 103(a) as obvious over Ding '979 and Sall,

C. Claims 14 and 19 under 35 U.S.C. § 103(a) as obvious over Ding '979, Sall, and Glonek,

D. Claims 11, 18, and 20 under 35 U.S.C. § 103(a) as obvious over Ding '979, Sall, and Acheampong,

E. Claim 19 under 35 U.S.C. § 103(a) as obvious over Ding '979, Sall, Glonek, and Acheampong;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial commencing on the entry date of this decision; and

FURTHER ORDERED that Famy Care's Motion for Joinder with IPR2016-01129 is *denied*.

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