Trials@uspto.gov
Tel: 571-272-7822

Paper 12
Entered: July 12, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FAMY CARE LIMITED,
Petitioner,

v.

ALLERGAN, INC.,
Patent Owner.

Case IPR2017-00571
Patent 8,685,930 B2

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

SNEDDEN, *Administrative Patent Judge*.

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

I. INTRODUCTION

Famy Care Limited ("Petitioner") filed a Petition to institute an *inter partes* review of claims 1–36 (Paper 4; "Pet.") of US 8,685,930 B2 (Ex. 1001, "the '930 patent"). Allergan, Inc. ("Allergan" or "Patent Owner") did not file a Preliminary Response to the Petition.

Petitioner also filed a Motion for Joinder pursuant to 35 U.S.C. § 315(c), seeking to join this proceeding with *Mylan Pharmaceuticals, Inc. v. Allergan, Inc.*, IPR2016-01127 ("Mylan IPR"). Paper 5. Patent Owner opposes Petitioner's joinder motion. Paper 10. 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 consideration of the Petition, we determine that Petitioner has established a reasonable likelihood that it will prevail with respect to at least one of the challenged claims. We institute an *inter partes* review as to claims 1–36 of the '930 patent.

A. Related Proceedings

The parties identify petitions for *inter partes* review previously filed by other petitioners that challenge the claims of the '930 patent and related patents. Pet. 4–5; Paper 9, 2–3. Certain petitions were terminated before decisions on institution were entered. Pet. 5; Paper 9, 2. 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,

IPR2017-00568, 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, IPR2017-00567, IPR2017-00596, IPR2017-00578); U.S. Patent No. 8,642,556 (IPR2016-01129, IPR2017-00570, IPR2017-00598, IPR2017-00579); U.S. Patent No. 8,648,048 (IPR2016-01131, IPR2017-00566, IPR2017-00600, IPR2017-00585); and U.S. Patent No. 9,248,191 (IPR2016-01132, IPR2017-00569, IPR2017-00601, IPR2017-00586). Paper 9, 2–3.

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 9, 2.

B. The ’930 patent (Ex. 1001)

The ’930 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, 2:54–3:60. According to the specification, the prior art recognized the use of emulsions containing CsA and CsA derivatives to treat ophthalmic conditions. *Id.* at 1:17–64. 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 cyclosporin A.” *Id.* at 1:65–67. 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 1:67–2:5.

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 2:34–37. 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 effectiveness of the composition. *Id.* at 2:41–47. Furthermore, using reduced amounts of cyclosporin component mitigates against undesirable side effects or potential drug interactions. *Id.* at 2:47–50.

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 13:45–60. 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 13:63–67. The patent indicates that "[t]his is surprising for a number of reasons." *Id.* at 14:1. 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 14:1–4. 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 14:4–9. 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 14:31–35.

C. Illustrative Claims

Petitioner challenges claims 1–36 of the '930 patent. Independent claims 1, 13, and 25 are illustrative of the challenged claims and are reproduced below with some changes to paragraphing:

> 1. A topical ophthalmic emulsion for treating an eye of a human having keratoconjunctivitis sicca,
>
> wherein the 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 topical ophthalmic emulsion is therapeutically effective in treating keratoconjunctivitis sicca.
>
> 13. A topical ophthalmic emulsion for treating an eye of a human having dry eye,
>
> wherein the 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 topical ophthalmic emulsion is therapeutically effective in treating dry eye.
>
> 25. A topical ophthalmic emulsion for increasing tear production in an eye of a human having keratoconjunctivitis sicca,
>
> wherein the 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 topical ophthalmic emulsion is therapeutically effective in increasing tear production in the eye of the human having keratoconjunctivitis sicca.

Ex. 1001, 14:41–48, 15:14–21, 16:4–13.

Claims 2–12 depend from claim 1, either directly or indirectly. Claims 14–24 depend from claim 13, either directly or indirectly. Claims 26–36 depend from claim 25, either directly or indirectly.

D. The Asserted Grounds

Petitioner challenges claims 1–36 of the '930 patent on the following grounds. Pet. 6.

Ground	Reference[s]	Basis	Claims challenged
1	Ding '979[1]	§ 102	1–36
2	Ding '979 and Sall[2]	§ 103	1–36

[1] Ding et al., U.S. Patent No. 5,474,979, issued December 12, 1995 (Ex. 1006, "Ding '979").

[2] Kenneth 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 631–639 (2000) (Ex. 1007, "Sall").

Ground	Reference[s]	Basis	Claims challenged
3	Ding '979, Sall, and Acheampong[3]	§ 103	11, 23, and 35

Petitioner also relies on the Declarations of Peter Kador, Ph.D. (Ex. 1002) and Michael Lemp, M.D. (Ex. 1003).

II. ANALYSIS

A. Motion for Joinder

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).

---

[3] Andrew 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*, *in* LACRIMAL GLAND, TEAR FILM, AND DRY EYE SYNDROMES 2, BASIC SCIENCE AND CLINICAL RELEVANCE, 1001–1004 (1998) (Ex. 1008, "Acheampong").

Although Famy Care's Petition is similar to Mylan's Petition in terms of the art relied on for each patentability challenge, it is not a "me-too" petition and differs significantly in its presentation of arguments. For example, Famy Care relies upon the declarations of Dr. Peter Kador (Ex. 1002) and Dr. Michael A. Lemp (Ex. 1003) to support its Petition, whereas Mylan relies upon the declaration of Mansoor Amiji, Ph.D. Famy Care also presents extensive additional arguments and evidence regarding secondary considerations. Pet. 46–67.

Allergan asserts that there are "significant differences between Famy Care's petition and Mylan's petition." Paper 10, 2. 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.

Paper 10, 2.

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 11, 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 2–3. 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 3–4. 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.* at 4. 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 IPR2016-01127 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 grounds 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 IPR2016-01127. 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. 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. Claim Interpretation

We interpret claims using the "broadest reasonable construction in light of the specification of the patent in which [they] appear[]." 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs. LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under the broadest reasonable construction standard, claim terms are generally given their "ordinary and customary meaning," as would be understood by one of ordinary skill in the art at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007) (quoting *Phillips v. AWH Corp*, 415 F.3d 1303, 1312 (Fed. Cir. 2006)). "Absent claim language carrying a narrow meaning, the PTO should only limit the claim based on the specification . . . when [it] expressly disclaim[s] the broader definition." *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004) (citation omitted). "Although an inventor is indeed free to define the specific terms used to describe his or her invention, this must be done with reasonable clarity, deliberateness, and precision." *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

1. "therapeutically effective"

Claims 1–36 recite a composition for "therapeutically effective in treating keratoconjunctivitis sicca" or "therapeutically effective in increasing tear production in the eye of the human having keratoconjunctivitis sicca." Petitioner asserts that the plain meaning of the word "therapeutic" includes palliative as well as curative treatments. Thus, Petitioner contends that "an emulsion effective to increase tear production or reduce symptoms is therapeutically effective in treating dry eye disease/KCS." Pet. 14–17 (citing Ex. 1002 ¶¶ 75; Ex. 1003 ¶¶ 85–89).

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)).

C. Principles of Law

An *inter partes* review may be instituted only if "the information presented in the [Petition and Preliminary Response, if filed,] shows that

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). To prevail in its challenges to the patentability of the claims, a petitioner must establish facts supporting its challenges by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

We analyze the proposed grounds of unpatentability in accordance with the following stated principles.

1. Law of Anticipation

The Court of Appeals for the Federal Circuit summarized the analytical framework for determining whether prior art anticipates a claim as follows:

> If the claimed invention was "described in a printed publication" either before the date of invention, 35 U.S.C. § 102(a), or more than one year before the U.S. patent application was filed, 35 U.S.C. § 102(b), then that prior art anticipates the patent. Although § 102 refers to "the invention" generally, the anticipation inquiry proceeds on a claim-by-claim basis. *See Hakim v. Cannon Avent Group, PLC*, 479 F.3d 1313, 1319 (Fed. Cir. 2007). To anticipate a claim, a single prior art reference must expressly or inherently disclose each claim limitation. *Celeritas Techs., Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998). But disclosure of each element is not quite enough—this court has long held that "[a]nticipation requires the presence in a single prior art disclosure of all elements of a claimed invention *arranged as in the claim*." *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983) (citing *Soundscriber Corp. v. United States*, 175 Ct. Cl. 644, 360 F.2d 954, 960 (1966) (emphasis added)).

Finisar Corp. v. DirecTV Grp., Inc., 523 F.3d 1323, 1334–35 (Fed. Cir. 2008). We must analyze prior art references as a skilled artisan would. *See Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1576

(Fed. Cir. 1991) (To anticipate, "[t]here must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.").

When a patent claims a range, that range is anticipated by a prior art reference if the reference discloses a point within the broader range. *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 782 (Fed. Cir. 1985). If the prior art discloses its own range, rather than a specific point, then the prior art is anticipatory insofar as it describes the claimed range with sufficient specificity. *See ClearValue, Inc. v. Pearl River Polymers, Inc.*, 668 F.3d 1340, 1345 (Fed. Cir. 2012); *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999 (Fed. Cir. 2006).

2. Law of Obviousness

A patent may not be obtained 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 obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. 35 U.S.C. § 103(a). The legal question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

In *KSR International Co. v. Teleflex Inc.*, the Supreme Court stated that an invention may be found obvious if trying a course of conduct would have been obvious to a person having ordinary skill:

> 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. 398, 421 (2007). "*KSR* affirmed the logical inverse of this statement by stating that § 103 bars patentability unless 'the improvement is more than the predictable use of prior art elements according to their established functions.'" *In re Kubin*, 561 F.3d 1351, 1359–1360 (Fed. Cir. 2009) (citing *KSR*, 550 U.S. at 417).

The factual inquiries for an obviousness determination also include secondary considerations based on evaluation and crediting of objective evidence of nonobviousness. *Graham v. John Deere Co*., 383 U.S. at 17–18. Notwithstanding what the teachings of the prior art would have suggested to one with ordinary skill in the art at the time of the invention, the totality of the evidence submitted, including objective evidence of nonobviousness, may lead to a conclusion that the claimed invention would not have been obvious to one with ordinary skill in the art. *In re Piasecki*, 745 F.2d 1468, 1471–72 (Fed. Cir. 1984).

Such a conclusion, however, requires the finding of a nexus to establish that the evidence relied upon traces its basis to something novel in the claim and not to something in the prior art. *Institut Pasteur & Universite Pierre et Marie Curie v. Focarino*, 738 F.3d 1337, 1347 (Fed. Cir. 2013). Generally, objective evidence of nonobviousness must be shown to have a nexus. *In re GPAC Inc*., 57 F.3d 1573, 1580 (Fed. Cir. 1995) (nexus

generally); *In re Kao*, 639 F.3d 1057, 1069 (Fed. Cir. 2011) (unexpected results); *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996) (commercial success); *Rambus Inc. v. Rea*, 731 F.3d 1248, 1256 (Fed. Cir. 2013) (long-felt need).

Objective evidence of nonobviousness also must be reasonably commensurate in scope with the claim. *Kao*, 639 F.3d at 1068. This does not mean that the proffered evidence must reach every embodiment within the scope of the claim, so long as there is an "adequate basis to support the conclusion that other embodiments falling within the claim will behave in the same manner." *Id.*

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, cover, 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

Ex. 1006, 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) (*id.* at 4:1–5), glycerine, sodium hydroxide, and purified water at a pH range of 7.2–7.6. *Id.* at 4:32–43. 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 discloses that "[b]oth the CsA emulsions and vehicle were sterile, nonpreserved castor oil in water emulsions whose precise formulation is proprietary." *Id.* at 632.

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 6.

E. Asserted Grounds of Unpatentability

1. Anticipation of Claim 1–36 Over Ding '979

Petitioner contends that claims 1–36 of the '930 patent are anticipated by Ding '979. Pet. 18–34. 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 and provides a detailed claim chart explaining how each claim limitation is disclosed in Ding '979. *Id.*

We recognize 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. 26 (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." (quoting *In re Petering*, 49 CCPA 993, 301 F.2d 676, 681 (1962))). 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 1–36 as anticipated by Ding '979

2. Obviousness of Claims 1–36 over the Combination of Ding '979 and Sall

Petitioner contends that claims 1–36 are rendered obvious by the combined teachings of Ding '979 and Sall. Pet. 34–44. The 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. *Id.* at 38–42.

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, Sall "provides a strong rationale to deliver the 0.05% CsA and 1.25% castor oil emulsion to increase tear production and treat dry eye/KCS." Pet. 36.

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. 36; 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 it will prevail in showing that claims 1–36 are obvious over the teachings of Ding '979 and Sall.

3. Obviousness of Claims 11, 23, and 35 Based on Ding '979, Sall, and Acheampong

Petitioner asserts that claims 11, 23, and 35 are unpatentable as obvious over Ding '979, Sall, and Acheampong. Pet. 44–46. We incorporate here our findings and discussion above regarding the teachings of Ding '979 and Sall.

Claims 11, 23, and 35 depend directly from claims 1, 13, and 25 and further recite as follows: "wherein, when the topical ophthalmic emulsion is

administered to an eye of a human in an effective amount in treating [dry eye], 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 "at peak and trough levels." Pet. 45 (citing Ex. 1008, Table 1). Petitioner further asserts that "Acheampong and Sall together give the ordinarily-skilled artisan a reasonable expectation that administering a 0.05% CsA/1.25% castor oil emulsion yields 'substantially no detectable concentration of cyclosporin A' in the blood." *Id.* (citing Ex. 1002 ¶¶ 251–52; Ex. 1003, ¶¶ 152–54).

Based on the arguments presented and evidence of record, we determine that Petitioner has demonstrated a reasonable likelihood that claims 11, 23, and 35 are obvious over the teachings of Ding '979, Sall, and Acheampong.

III. CONCLUSION

We conclude that Petitioner has established a reasonable likelihood of prevailing on its assertions that claims 1–36 of the '930 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 response and upon completion of the current record.

IV. ORDER

For the reasons given, it is

ORDERED that the Petition is granted with regard to the following asserted grounds:

A. Claims 1–36 of the ’930 patent under 35 U.S.C. § 102 as anticipated by Ding ’979;

B. Claims 1–36 of the ’930 patent under 35 U.S.C. § 103(a) as obvious over the combination of Ding ’979 and Sall; and

C. Claims 11, 23, and 35 of the ’930 patent under 35 U.S.C. § 103(a) as obvious over the combination of Ding ’979, Sall, 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 IPR2016-01127 is *denied*.

PETITIONER:

Deanne M. Mazzochi
John D. Polivick
Patrick Abbott
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
dmazzochi@rmmslegal.com
jpolivick@rmmslegal.com
pabbott@rmmslegal.com

PATENT OWNER:

Dorothy P. Whelan
Michael Kane
FISH & RICHARDSON P.C.
whelan@fr.com
kane@fr.com