

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
TEVA PHARMACEUTICALS USA, INC., and AKORN INC.,
Petitioners,

v.

SAINT REGIS MOHAWK TRIBE and ALLERGAN, INC.,
Patent Owners.

Case IPR2016-01130
Patent 8,633,162 B2¹

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

SNEDDEN, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

¹ Cases IPR2017-00583 and IPR2017-00599 have been joined with IPR2016-01130.

ORDERS

Dismissing Petitioner's Motion to Exclude (Paper 50)
37 C.F.R. § 42.64(c)

Dismissing Patent Owner's Motion to Exclude (Paper 43)
37 C.F.R. § 42.64(c)

I. INTRODUCTION

This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. Mylan Pharmaceuticals Inc., Teva Pharmaceuticals USA, Inc., and Akorn Inc. (collectively, "Petitioner") bears the burden of proving unpatentability of the challenged claims, and that burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must prove unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

For the reasons that follow, we determine that Petitioner has shown, by a preponderance of the evidence, that claims 1–24 of U.S. Patent No. 8,633,162 B2 (Ex. 1001, "the '162 patent") are unpatentable.

A. Procedural History

Petitioner filed a Petition to institute an *inter partes* review of claims 1–24 of the '162 patent. Paper 3 ("Pet."). Allergan, Inc. ("Patent Owner") filed a Patent Owner Preliminary Response. Paper 7. Upon consideration of the Petition and Preliminary Response, we instituted an *inter partes* review of claims 1–24 of the '162 patent on each ground of unpatentability set forth in the Petition, which are as follows:

Ground	Reference[s]	Basis	Claims Challenged
1	Ding '979 ² and Sall ³	§ 103(a)	1–10, 12–14, 16–20, and 22–24
2	Ding '979, Sall, and Acheampong ⁴	§ 103(a)	11 and 21
3	Ding '979, Sall, and Glonek ⁵	§ 103(a)	15

Paper 8 (“Decision on Institution” or “Dec.”).

Subsequently, Patent Owner filed a Patent Owner Response (Paper 16; “PO Resp.”), Petitioner filed a Reply (Paper 34; “Reply”), and Patent Owner filed a Sur-Reply (Paper 42; “Sur-Reply”).⁶

Teva Pharmaceuticals USA, Inc. (“Teva”) and Akorn, Inc. (“Akorn”) each filed Petitions requesting an *inter partes* review of claims 1–24 of the

² Ding et al., US 5,474,979, issued December 12, 1995 (Ex. 1006, “Ding ’979”).

³ 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 OPTHALMOLOGY 631–639 (2000) (Ex. 1007, “Sall”).

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, “Acheampong”).

⁵ Glonek et al., US 5,578,586, issued Nov. 26, 1996 (Ex. 1009, “Glonek”).

⁶ On September 8, 2017, the Saint Regis Mohawk Tribe (the “Tribe”) entered an appearance as the purported Patent Owner. Paper 63. We denied the Tribe’s Motion to Terminate on sovereign immunity grounds and Allergan’s Motion to Withdraw. Paper 127; Paper 129.

'162 patent in cases IPR2017-00583 and IPR2017-00599, respectfully. IPR2017-00583, Paper 4; IPR2017-00599, Paper 2. Teva and Akorn each filed a motion to join their respective cases with this case. IPR2017-00583, Paper 3; IPR2017-00599, Paper 3. We granted Teva and Akorn's Petitions and each of their motions for joinder. IPR2017-00583, Paper 9; IPR2017-00599, Paper 9.

Per the parties' request, an oral hearing was not held for this proceeding. Paper 150.

B. Related Proceedings

In addition to this proceeding challenging the '162 patent, Petitioner has sought *inter partes* review of all claims of U.S. Patent No. 8,685,930 B2 ("the '930 patent") in IPR2016-00127; U.S. Patent No. 8,629,111 B2 ("the '111 patent") in IPR2016-01128; U.S. Patent No. 8,642,556 B2 ("the '556 patent") in IPR2016-01129; U.S. Patent No. 8,648,048 B2 ("the '048 patent") in IPR2016-01131; and U.S. Patent No. 9,248,191 B2 ("the '191 patent") in IPR2016-01132 (collectively, "the Challenged Patents").

Four of the six Challenged Patents—the '111, '048, '930, and '191 patents—were also at issue in *Allergan, Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 2:15-cv-01455 (E.D. Tex.) ("*Allergan v. Teva*"). The dispute in *Allergan v. Teva* was a "Hatch-Waxman Act case relate[d] to a condition known as 'dry eye' and a pharmaceutical product known as 'Restasis' that is intended to address that condition." Ex. 1164, 1. "Restasis is an emulsion consisting of various components, including the active ingredient cyclosporin A, an immunosuppressant, which is dissolved in castor oil, a fatty acid glyceride." *Id.* The product Restasis is protected by the

Challenged Patents and each of the Challenged Patents is listed in the FDA's Orange Book as patents that claim Restasis, "with respect to which a claim of patent infringement could reasonably be asserted."⁷ *Id.* at 1, 27–29 (citing 21 U.S.C. § 355(b)(1), (c)(2)).

In *Allergan v. Teva*, the district court found thirteen representative claims from those four Challenged Patents invalid as obvious. Ex. 1164. The court explained that its obviousness analysis served to invalidate all claims of those four patents. *Id.* at 32–108. The Federal Circuit affirmed the district court's decision by Rule 36 judgment. *Allergan, Inc. v. Teva Pharms. USA, Inc.*, 742 F. App'x 511 (Mem.) (Fed. Cir. Nov. 13, 2018) (Ex. 1172). Patent Owner's petition for a writ of certiorari was denied. *Allergan, Inc. v. Teva Pharms. USA, Inc.*, 139 S. Ct. 2674 (Mem.) (2019).

During the district court litigation, Patent Owner agreed to treat the thirteen litigated claims as representative of all claims of the Challenged Patents and states that "judgment as to those thirteen claims can be properly applied to all claims of those four patents." PO Supp. Br. 9. With the Federal Circuit's affirmance and the Supreme Court's denial of review, the district court's judgment invalidating all claims of the '111, '048, '930, '191 patents is now final.

In light of the parallel proceeding and the finding of obviousness of the representative claims, we authorized supplemental briefing on the impact of the Federal Circuit's Rule 36 affirmance on the patentability issues in

⁷ The district court refers to the Challenged Patents as the "Restasis patents." Ex. 1164, 23–24.

these proceedings. Paper 139, 3. Pursuant to our order, Petitioner filed their Supplemental Briefing (“Pet. Supp. Br.,” Paper 140) and Patent Owner filed its response (“PO Supp. Br.,” Paper 142).

C. The ’162 Patent (Ex. 1001)

In *Allergan v. Teva*, the district court found that the specifications of the six Challenged Patents are identical with only minor variations. Ex. 1164, 23. Accordingly, we find the ’162 specification to be representative of the six Challenged Patents.

The ’162 patent discloses methods of providing therapeutic effects using cyclosporin components, and more specifically to a formulation containing 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 become apparent that cyclosporin A emulsions for ophthalmic use preferably have less than 0.2% by weight of cyclosporin A.” *Id.* at 1:66–2:1. Moreover, if reduced amounts of cyclosporin are used, reduced amounts of castor oil are needed because one of the functions of castor oil is to solubilize CsA. *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 2:36–39. 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 2:43–49. Furthermore, using reduced amounts of cyclosporin component mitigates against undesirable side effects or potential drug interactions. *Id.* at 2:49–52.

The patent identifies two particular compositions that were selected for further testing, Composition I and Composition II. The table below provides a list of the components in the two compositions.

	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 14:20–30. Based on the results of a Phase 3 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 14:44–48. The patent indicates that “[t]his is surprising for a number of reasons.” *Id.* at 14:49. 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 14:49–52. 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 14:52–57. 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 15:12–15.

D. Illustrative Claims

Petitioner challenges claims 1–24 of the ’162 patent, of which claims 1, 18, and 23 are independent claims. Claim 23 is illustrative, and is reproduced below:

23. A method of treating dry eye disease, the method comprising the step of topically administering to an eye of a human in need thereof an emulsion at a frequency of twice a day, the emulsion comprising:

- cyclosporin A in an amount of about 0.05% by weight;
- castor oil in an amount of about 1.25% by weight;
- polysorbate 80 in an amount of about 1.0% by weight;
- acrylate/C10-30 alkyl acrylate cross-polymer in an amount of about 0.05% by weight;
- glycerine in an amount of about 2.2% by weight;
- sodium hydroxide; and
- water;

wherein the emulsion is effective in treating dry eye disease.

E. Summary of Asserted Prior Art

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 code (73), 1:4–9.

Ding '979 explains that cyclosporins have “known immunosuppressant activity” and have been found “effective in treating immune mediated 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 cyclosporin 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:

<u>Example 1</u>					
	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 is a table identifying compositions A through E and their corresponding amounts of cyclosporin A, 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 were “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 cyclosporin A 0.05% or 0.1% ophthalmic emulsions or vehicle for six months. Ex. 1007, Abstract. The study sought to compare the efficacy and safety of cyclosporin A 0.05% and 0.1% to vehicle in patients with moderate to severe dry eye disease. *Id.* Sall found that topical treatment with either cyclosporin A 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 cyclosporin A 0.05% resulted in significantly greater improvements in several subjective parameters. *Id.*

Sall also found that trough blood concentrations of cyclosporin A were undetectable in all samples of cyclosporin A 0.05%, whereas cyclosporin A was quantifiable in only six samples for six different patients in the cyclosporin 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, 3. 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 4. 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.

4. *Glonek (Ex. 1009)*

Glonek relates to a composition for augmenting and maintaining a stable tear film over the ocular surface and delivering a medicine to the eye without causing substantial blurring of vision. Ex. 1009, 1:21–29. Glonek explains that an emulsion over the surface of the eye is expected to cause blurring, which is likely to occur until the emulsion differentiates. *Id.* at 6:37–42. If the emulsion is too stable, excess emulsion will be discharged from the eye. *Id.* at 6:42–44. Thus, Glonek states that it is preferred that an emulsion be stable for long term storage, but rapidly differentiate in the eye. *Id.* at 6:48–50.

II. DISCUSSION

A. *Collateral Estoppel*

1. *Legal Principles*

Collateral estoppel, also known as issue preclusion, precludes a party from relitigating an issue “when an issue of fact or law is actually litigated and determined by a valid and final judgment, and the determination is essential to the judgment,” in which case “the determination is conclusive in a subsequent action between the parties, whether on the same or a different claim.” Restatement (Second) of Judgments § 27 (1982). The Supreme Court

has long recognized that “the determination of a question directly involved in one action is conclusive as to that question in a second suit.” The idea is straightforward: Once a court has

decided an issue, it is ‘forever settled as between the parties,’ thereby “protect[ing]” against “the expense and vexation attending multiple lawsuits, conserv[ing] judicial resources, and foster[ing] reliance on judicial action by minimizing the possibility of inconsistent verdicts.” In short, “a losing litigant deserves no rematch after a defeat fairly suffered.”

B & B Hardware, Inc. v. Hargis Indus., Inc., 135 S. Ct. 1293, 1302–03 (2015) (internal citations omitted). The Federal Circuit has articulated the following test for determining the proper application of collateral estoppel:

- (1) a prior action presents [the] identical issue;
- (2) the prior action actually litigated and adjudged that issue;
- (3) the judgment in that prior action necessarily required determination of the identical issue; and
- (4) the prior action featured full representation of the estopped party.⁸

VirnetX Inc. v. Apple, Inc., 909 F.3d 1375, 1377 (Fed. Cir. 2018) (quoting *Stephen Slesinger, Inc. v. Disney Enters., Inc.*, 702 F.3d 640, 644 (Fed. Cir. 2012)).

The Federal Circuit has applied collateral estoppel in the context of *inter partes* reviews. *Maxlinear, Inc. v. CF CRESPE LLC*, 880 F.3d 1373, 1376 (Fed. Cir. 2018) (“It is well established that collateral estoppel . . . applies in the administrative context.”). Moreover, application of collateral

⁸ The fourth factor of the collateral estoppel test has sometimes been referred to as “(4) the party defending against preclusion had a full and fair opportunity to litigate the issues.” *Levi Strauss & Co. v. Abercrombie & Fitch Trading Co.*, 719 F.3d 1367, 1371 (Fed. Cir. 2013). We consider the analysis to be the same regardless of how that factor is articulated.

estoppel in *inter partes* reviews “is not limited ‘to patent claims that are identical. Rather, it is the identity of the *issues* that were litigated that determines whether collateral estoppel should apply.’” *Nestle USA, Inc. v. Steuben Foods, Inc.*, 884 F.3d 1350, 1352 (Fed. Cir. 2018) (quoting *Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013) (emphasis in original)). The collateral-estoppel effect of an administrative decision of unpatentability generally requires the invalidation of related claims that present identical issues of patentability. *Maxlinear, Inc.*, 880 F.3d at 1377. “If the differences between the unadjudicated patent claims and adjudicated patent claims do not materially alter the question of invalidity, collateral estoppel applies.” *Id.*; see also *Soverain Software LLC v. Victoria’s Secret Direct Brand Mgmt., LLC*, 778 F.3d 1311, 1315 (Fed. Cir. 2015); *Bourns, Inc. v. United States*, 537 F.2d 486, 493 (Ct. Cl. 1976) (per curiam).

2. *The identical issue was presented in Allergan v. Teva—that is, the court considered whether the subject matter of the Challenged Patents would have been obvious*

A primary issue before the court in *Allergan v. Teva* was the obviousness of the subject matter of the claims in the Challenged Patents. The Challenged Patents contain a total of 157 claims, including both product and method claims. Ex. 1164, 23. The court found:

A limitation that is common to all of the claims (with slight variations in wording) is the formulation for Restasis, which is an emulsion “comprising cyclosporin A in an amount of about 0.05% by weight; castor oil in an amount of about 1.25% by weight; polysorbate 80 in an amount of about 1.0% by weight; acrylate/C10-30 alkyl acrylate cross-polymer in an amount of

about 0.05% by weight; glycerine in an amount of about 2.2% by weight; sodium hydroxide; and water.”

Id. The Challenged Patents also include claims directed to methods of using Restasis, such as in methods for treating dry eye and increasing tear production. *Id.* at 31.

The parties explain that, in *Allergan v. Teva*, Patent Owner originally asserted all of the Challenged Patents, but during the course of that litigation and prior to trial, Patent Owner agreed to use thirteen claims from four of the six Challenged Patents as representative claims for the purposes of streamlining the case. Pet. Supp. Br. 1–2; PO Supp. Br. 4; Ex. 2118; Ex. 1164 at 29–30 (“Allergan selected 13 claims from four of the Restasis patents to be litigated at trial.”). Those Representative Claims are: claims 26 and 27 of the ’111 patent; claims 1, 11, 13, 14, and 23 of the ’048 patent; claim 35 of the ’930 patent; and claims 13, 16, 22, 26, and 27 of the ’191 patent. Pet. Supp. Br. 1–2; PO Supp. Br. 4; Ex. 1164, 30.

The claims of the ’048 patent are most similar to claims of the ’162 patent. Representative Claims 1, 11, 13, 14, and 23 of the ’048 patent (as well as independent claim 22 from which claim 23 depends) are set forth below:

1. A method of increasing tear production in the eye of a human, the method comprising topically administering to the eye of a human in need thereof an emulsion at a frequency of twice a day, wherein the 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 effective in increasing tear production.

11. The method of claim 1, wherein the emulsion is administered to an eye of a human in an effective amount in increasing tear production, the blood of the human has substantially no detectable concentration of cyclosporin A.

13. The method of claim 1, wherein the emulsion is as substantially therapeutically effective as a second emulsion administered to a human in need thereof at a frequency of twice a day, the second emulsion comprising cyclosporin A in an amount of 0.1% by weight and castor oil in an amount of 0.5% by weight.

14. The method of claim 1, wherein the emulsion achieves at least as much therapeutic effectiveness as a second emulsion administered to a human in need thereof at a frequency of twice a day, the second emulsion comprising cyclosporin A in an amount of 0.1% by weight and castor oil in an amount of 1.25% by weight.

22. A method comprising:
administering an emulsion topically to the eye of a human having keratoconjunctivitis sicca at a frequency of twice a day, wherein the emulsion comprises:

cyclosporin A in an amount of about 0.05% by weight;
castor oil in an amount of about 1.25% by weight;
polysorbate 80 in an amount of about 1.0% by weight;
acrylate/C10-30 alkyl acrylate cross-polymer in an amount of about 0.05% by weight;
glycerine in an amount of about 2.2% by weight;
sodium hydroxide; and
water; and

wherein the emulsion is effective in increasing tear production in the human having keratoconjunctivitis sicca.

23. The method of claim 22, wherein the emulsion has a pH in the range of about 7.2 to about 7.6.

Ex. 1164, 31–32.

The '162 patent is one of the two Challenged Patents that is not represented by the Representative Claims. As in the '048 patent, however,

the claims of the '162 patent are similarly directed to methods of using the Restasis emulsion formulation.⁹ We begin with a comparison between claim 1 of the '162 patent and claims 1 and 22 of the '048 patent. Claims 1 and 22 of the '048 patent were held to be invalid as obvious by the district court. Exs. 1164, 1165. It is readily apparent from a side-by-side comparison of claim 1 of the '162 and claims 1 and 22 of the '048 patent that there is substantial identity between the claims. The following chart provided by Petitioner is a claim chart comparing the text of claim 1 of the '162 to the text of claims 1 and 22 of the '048 patent.

⁹ We adopt the district court's findings that each of the claims of the Challenged Patents, which includes the 24 claims of the '162 patents, covers Restasis. Ex. 1164, 23.

'048 Patent	'048 Patent	'162 Patent
1. A method of increasing tear production in the eye of a human, the method comprising topically administering to the eye of the human in need thereof an emulsion at a frequency of twice a day, wherein the 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 effective in increasing tear production.	22. A method comprising: administering an emulsion topically to the eye of a human having keratoconjunctivitis sicca at a frequency of twice a day, wherein the emulsion comprises: cyclosporin A in an amount of about 0.05% by weight; castor oil in an amount of about 1.25% by weight; polysorbate 80 in an amount of about 1.0% by weight; acrylate/C10-30 alkyl acrylate cross-polymer in an amount of about 0.05% by weight; [...]and water; and wherein the emulsion is effective in increasing tear production in the human having keratoconjunctivitis sicca. 23. The method of claim 22, wherein the emulsion has a pH in the range of about 7.2 to about 7.6.	1. A method of treating dry eye disease, the method comprising topically administering to the eye of a human in need thereof an emulsion at a frequency of twice a day, wherein the 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 effective in treating dry eye disease

Pet. Supp. Br. 8.

As shown in the table above, independent claim 1 of the '048 patent and independent claim 1 of the '162 patent both recite a “method comprising topically administering to the eye of [the/a] human in need thereof an emulsion at a frequency of twice a day, wherein the emulsion comprises” a) “cyclosporine A in an amount of about 0.05% by weight;” b) “polysorbate 80;” c) “acrylate/C10-30 alkyl acrylate cross-polymer;” d) “water;” and e) “castor oil in an amount of about 1.25% by weight.” The only difference between the claims is that claim 1 of the '048 patent recites a “method of increasing tear production . . . wherein the topical ophthalmic emulsion is effective in increasing tear production,” while claim 1 of the '162 patent recites a “method of treating dry eye disease . . . wherein the topical ophthalmic emulsion is effective in treating dry eye disease.” Dependent claims 2–17 of the '162 patent are otherwise identical to dependent claims 2–17 of the '048 patent.

Claims 18–22 of the '162 patent are identical to claims 18–21 of the '048 patent with one exception: claim 18 of the '162 patent recites a “method of reducing side effects in a human being treated for dry eye syndrome” while claim 18 of the '048 patent recites “method of treating keratoconjunctivitis sicca.”¹⁰

Claims 23–24 of the '162 patent are identical to claims 22–23 of the '048 patent with one exception: the '162 patent recites a “method of treating

¹⁰ The extra claim in the '162 patent, claim 22, requires the claimed emulsion to be “effective in treating dry eye disease,” which is similar to the recitation in claim 1.

dry eye disease” while the ’048 patent recites a method of “administering an emulsion topically to the eye of a human having keratoconjunctivitis sicca.”

Accordingly, in view of the above, we determine that the differences between the claims of the ’162 and ’048 patents are minor and relate only to the terms of the condition being treated by the emulsion—namely dry eye, symptoms of dry eye (insufficient tear production), or particular conditions of dry eye such as keratoconjunctivitis sicca. Indeed, each of those variations of dry eye-related symptoms and conditions were at issue in *Allergan v. Teva*, and thoroughly considered by the district court. Ex. 1164, 34–108. In this regard, we note that the district court found that “keratoconjunctivitis sicca” (or KCS) refers to “[t]he condition in which dry eye is associated with inflammation and involves a deficiency in aqueous tear production.” *Id.* at 3. As there is nothing of record to suggest otherwise, we adopt the same finding for purposes of our analysis. The parties have treated the claims in a similar manner and made the same arguments regardless of the particular condition recited in the claims. *See* Pet. 22–32 (applying same prior art teachings and arguments for independent claims 1, 18, and 23 of the ’162 patent); PO Resp. 18–40 (making the same unexpected results arguments as to all independent claims). Patent Owner has not persuasively identified any meaningful difference between the subject matter claimed in the ’162 patent and the subject matter claimed in the ’048 patent that would have affected the patentability analysis. *See generally* PO Supp. Br. Similar to the claims compared in *Ohio Willow Wood*, the claims of the ’162 and ’048 patents “use slightly different language to describe substantially the same invention.” 735 F.3d at 1342.

Moreover, the district court considered the obviousness of the subject matter claimed by the Representative Claims in view of Ding '979,¹¹ Sall, and Acheampong, which are the same references asserted in this case. Ex. 1164, 34–108. The district court also considered the obviousness of the claimed composition and methods in view of Patent Owner's assertion that the Restasis formulation covered by the claims exhibited unexpected results compared to the prior art, which is the same argument Patent Owner has asserted in this case. *Compare* Ex. 1167, 34–108, with PO Resp. 21–35. Accordingly, we find that the district court in the prior case, *Allergan v. Teva*, considered the identical issue before us in this case, i.e., the obviousness of the subject matter in light of Ding '979, Sall, and Acheampong as well as Patent Owner's arguments of unexpected results.

Having considered the question of obviousness at issue in the district court proceeding, we find that the unpatentability analysis in this case would not be materially different in order to account for the difference between the scope of the claims in the '162 and '048 patents. Accordingly, we determine that the differences between the claims of the '162 patent and the claims of the Challenged Patents, the '048 patent in particular, do not materially alter the question of patentability presented before us in this proceeding.

¹¹ Ding '979 is referred to as Ding I by the district court.

3. Obviousness of the claimed subject matter was actually litigated and adjudged

In the district court proceedings, the Patent Owner explicitly confirmed that the thirteen chosen claims were “representative claims of all of the claims in the various patents [Challenged Patents], including the unasserted claims.” Pet. Supp. Br., 2 (emphasis omitted) (citing Ex. 1173, 7:25–8:2 (Pretrial Hearing Transcript)). The court also made clear that the purpose of the representative claims was to streamline the case while also “mak[ing] sure that this matter is dispositive of the entire dispute between the parties.” Ex. 1173, 7:5–7. Specifically, the court explained the objective as follows:

Okay, on representative claims, as I say, you’ve been – it’s been very helpful. I just want to make sure again that we’re all on the same page here. The objective is to make sure that this matter is dispositive of the entire dispute between the parties. Now, I understand that there’s a difference between the one -- the 271(e)(2) infringement claim and potentially down the road if it comes to that potential (a) claims and (b) claims. But for purposes of the Hatch-Waxman Act proceeding before us, these claims, these representative claims, we are all agreed, I take it, will be the dispositive -- will dispose of all the disputes between the parties. I don’t want to find us, ourselves, after this saying, oh, well, but we still have the following invalidity arguments, we still have the following infringement arguments, we still have the following claims. Now, am I -- do I correctly understand that the parties agree that the 13 representative claims will dispose of the dispute in this case?

Id. at 7:3–19. The parties subsequently agreed that any remedy entered as to the Representative Claims would apply equally to the unasserted claims. *Id.* at 8:2–4, 9:3–5. Specific to the ’162 and ’556 patents, Patent Owner gave a

covenant not to sue with regard to those patents and, as such, the '162 and '556 patents were dropped from the case. PO Supp. Br. 5.

After a bench trial, the district court issued a decision determining the Representative Claims to be invalid as obvious. Ex. 1164, 108–132; Ex. 1165. The Federal Circuit affirmed that decision by Rule 36 judgment on November 13, 2018. Ex. 1172. In rendering its decision, the district court considered the obviousness of the subject matter claimed by the Representative Claims in view of Ding '979, Sall, and Acheampong. Ex. 1164, 34–108. As noted by the district court:

The obviousness dispute in this case centers on Allergan's assertion that the Restasis formulation exhibited unexpected results compared to the prior art. Allergan recognizes that the [Ding '979] patent discloses ranges of amounts of cyclosporin (0.05% to 0.40%) and castor oil (0.625% to 5.0%) that cover Restasis. Allergan argues, however, that the particular combination in Restasis of 0.05% cyclosporin and 1.25% castor oil is a critical value that produces unexpected results far better than would be expected for the range of values disclosed in [Ding '979]. For that reason, Allergan contends that the critical value of 0.05% cyclosporin with 1.25% castor oil is patentable, even though it falls within the ranges disclosed and claimed in Ding I.

Ex. 1164, 35. The district court, however, rejected Patent Owner's argument that Restasis surprisingly outperformed the known formulations disclosed by Ding '979. Ex. 1164, 41–99. In particular, the court was not persuaded that the Phase 2 and Phase 3 studies show surprising efficacy for the Restasis formulation as compared to Examples 1D and 1E in Ding '979. *Id.* at 41. The court also explained how its analysis applied not only to the

Representative Claims, but also to the subject matter of each of the asserted claims. *Id.* at 106–108.

Accordingly, in view of the above, we find that obviousness of the subject matter of the Representative Claims of the '048 patent, which is substantially similar to the obviousness arguments presented in this case for the '162 patent, was actually litigated and adjudged in the district court proceeding.

4. *The judgment in Allergan v. Teva invalidating the Representative Claims necessarily required determination of obviousness of the claimed subject matter*

The court in *Allergan v. Teva* entered a final judgment that declared the Representative Claims of the Challenged Patents invalid on the ground of obviousness. Ex. 1165. Indeed, the obviousness ground was the only basis for the district court's conclusion of invalidity. Accordingly, we find that the judgment in *Allergan v. Teva* invalidating the Representative Claims, and in particular the Representative Claims of the '048 patent, necessarily required determination of obviousness of the subject matter claimed in the '162 patent.

5. *Allergan v. Teva featured full representation of Patent Owner*

Having considered the parties' positions and evidence of record, summarized above, we also determine that Patent Owner received a full and fair opportunity to litigate the obviousness issues in *Allergan v. Teva* and, indeed, the court provided a detailed analysis on the obviousness issue, which accounts for the bulk of the court's decision. See Ex. 1164, 32–108.

Patent Owner asserts that the district court urged Allergan to reduce the number of total claims it would assert at trial for purposes of streamlining the case. PO Supp. Br., 4, 14. To the extent that Patent Owner is arguing that *Allergan v. Teva* did not feature full representation of the Patent Owner, or that it otherwise did not have a full and fair opportunity to litigate the obviousness issue due to the streamlining of the case that resulted in a complete analysis of only the Representative Claims, we are not persuaded. Patent Owner does not explain how complying with the district court's desire to streamline the case equates to depriving the Patent Owner of a full and fair opportunity to litigate the question of obviousness at the district court. As discussed above, the parties agreed that the Representative Claims would be representative "of all of the claims in the various [Challenged Patents], including the unasserted claims." Ex. 1173, 7:25–8:2 (emphasis removed). The court also made clear that the purpose of the Representative Claims was to streamline the case while also "mak[ing] sure that this matter is dispositive of the entire dispute between the parties." *Id.* at 7:5–7.

Furthermore, even if we agree with Patent Owner that the '162 patent was dropped from *Allergan v. Teva* due to the fact that Patent Owner had granted Petitioner a covenant not to sue on the '162 patent, collateral estoppel does not require that the same patent be at issue in the prior action. Collateral estoppel applies, "[i]f the differences between the unadjudicated patent claims and adjudicated patent claims do not materially alter the question of [patentability]." See *Ohio Willow Wood*, 735 F.3d at 1342); see also *Papst Licensing GMBH & Co. KG v. Samsung Elecs. Am., Inc.*, 924 F.3d 1243, 1252 (Fed. Cir. 2019) (applying collateral estoppel where the

claim “recites a materially identical ‘without requiring’ limitation”). As discussed above, we determine that the differences between the ’162 patent and the ’048 patent do not materially alter the question of patentability.

In view of the above, we determine that Patent Owner had a full and fair opportunity to litigate the limitations of each claim of the ’162 patent in *Allergan v. Teva*. Accordingly, we find that collateral estoppel applies to each claim of the ’162 patent.

B. Conclusion

For all of the foregoing reasons, we find that the obviousness of the subject matter of claims 1–24 of the ’048 patent was actually litigated and was necessary to the final judgment of invalidity in *Allergan v. Teva*, and that the unpatentability analysis in this case would not be materially different in order to account for any differences between the scope of the claims in the ’162 and ’048 patents. Additionally, we find that Patent Owner was fully represented and had a full and fair opportunity to litigate the same obviousness issue. Accordingly, we determine, on the basis of collateral estoppel, that Petitioner has demonstrated by a preponderance of the evidence that claims 1–24 of the ’162 patent are unpatentable.

III. MOTIONS TO EXCLUDE

A. Petitioner’s Motion to Exclude

Petitioner filed a motion to exclude evidence. Paper 50. Patent Owner opposed (Paper 51) and Petitioner submitted a reply in support of its motion (Paper 58). Petitioner moves to exclude a) Exhibit 2008; b) portions of the Declarations of Dr. Sheppard (Ex. 2024) and Dr. Loftsson (Ex. 2025);

c) Exhibit 2038; d) portions of Exhibit 2028; and e) Exhibit 2077–2079. Paper 50, 1. Because we do not rely on any of the exhibits or portions of exhibits sought to be excluded by Petitioner to reach the final decision, we dismiss Petitioner’s motion to exclude as moot.

B. Patent Owner’s Motion to Exclude

Patent Owner filed a motion to exclude evidence. Paper 43. Patent Owner opposed (Paper 52) and Patent Owner submitted a reply in support of its motion (Paper 57). Patent Owner moves to exclude the testimony of Dr. Calman (Ex. 1039) and Dr. Bloch (Ex. 1040), under F.R.E. 402, 403, and 702. Paper 43, 1. Because we do not rely on either Exhibit 1039 or Exhibit 1040 to reach the final decision, we dismiss Patent Owner’s motion to exclude as moot.

IV. ORDER

Accordingly, it is:

ORDERED that claims 1–24 of the ’162 patent have been shown to be unpatentable;

FURTHER ORDERED that Petitioner’s motion to exclude (Paper 50) is dismissed as moot;

FURTHER ORDERED that Patent Owner’s motion to exclude (Paper 43) is dismissed as moot; and

FURTHER ORDERED that, because this is a final written decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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