

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:

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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 cyclosporin 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

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