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Paper 8
Entered: December 8, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

ALLERGAN, INC.,
Patent Owner.

Case IPR2016-01127
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
37 C.F.R. § 42.108

I. INTRODUCTION

Mylan Pharmaceuticals Inc. ("Petitioner") filed a Petition to institute an *inter partes* review of claims 1–36 (Paper 3; "Pet.") of US 8,685,930 B2 (Ex. 1001, "the '930 patent"). Allergan, Inc. ("Patent Owner") filed a Patent Owner Preliminary response. Paper 7 ("Prelim. Resp.").

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 above-mentioned Petition and Preliminary Responses, we conclude that Petitioner has established that there is 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 indicate that the following judicial matters 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. Texas); *Allergan, Inc., v. Innopharma, Inc. and Pfizer, Inc.*, No. 2:15-cv-1504 (E.D. Texas); and *Allergan, Inc. v. Famy Care, Ltd.*, No. 2:16-cv-0401 (E.D. Texas). Pet. 11; Paper 6, 2.

Moreover, Petitioner has sought *inter partes* review for related patents in the following proceedings: Case IPR2016-01128 (U.S. Patent No. 8,629,111 B2), Case IPR2016-01129 (U.S. Patent No. 8,642,556 B2), Case IPR2016-01130 (U.S. Patent No. 8,633,162 B2), Case IPR2016-01131 (U.S. Patent No. 8,648,048 B2), and Case IPR2016-01132 (U.S. Patent No.

9,248,191 B2).

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:

> 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.

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