

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

ALLERGAN, INC.,
Patent Owner.

Case IPR2016-01131
Patent 8,648,048 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 1–23 (Paper 3; “Pet.”) of US 8,648,048 B2 (Ex. 1001; “the ’048 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 1–23 of the ’048 patent.

A. *Related Proceedings*

The parties indicate that the following judicial matter may affect or be affected by a decision in this proceeding: *Allergan, Inc. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 2:15-cv-01455 (E.D. Texas), *Allergan, Inc., v. Innopharma, Inc. and Pfizer, Inc.*, No. 2:15cv1504 (E.D. Texas), and *Allergan, Inc. v. Famy Care, Ltd.*, No. 2:16-cv-0401 (D. Texas). Pet. 12; Paper 6, 2.

Moreover, Petitioner has sought inter partes review for related patents in the following proceedings: Case IPR2016-01127 (U.S. Patent No. 8,685,930 B2), 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), and Case IPR2016-01132 (U.S. Patent No. 9,248,191 B2).

B. The '048 patent (Ex. 1001)

The '048 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, 2:55–3:11. 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 2:1–2:6.

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 effectiveness 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 14:15–30. 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 14:35–40. The patent indicates that “[t]his is surprising for a number of reasons.” *Id.* at 14:41. 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 14:41–44. 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 14:44–49. 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 15:4–8.

C. Illustrative Claims

Petitioner challenges claims 1–23 of the ’048 patent. Independent claims 1, 18, and 22 are illustrative of the challenged claims, and are reproduced below:

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.

18. A method of treating keratoconjunctivitis sicca, 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;

a tonicity component or a demulcent component in an amount of about 2.2% by weight;

a buffer; and

water;

wherein the emulsion is effective in treating keratoconjunctivitis sicca and wherein the topical ophthalmic emulsion has a pH in the range of about 7.2 to about 7.6.

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.

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