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Paper No. 8
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

ALLERGAN, INC.,
Patent Owner.

Case IPR2016-01130
Patent 8,633,162 B2

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

HULSE, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Mylan Pharmaceuticals Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–24 of U.S. Patent No. 8,633,162 B2 (Ex. 1001, "the '162 patent"). Paper 3 ("Pet."). Allergan, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. 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 considering the Petition and Preliminary Response, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of claims 1–24. Accordingly, we institute an *inter partes* review of those claims.

A. Related Proceedings

The parties identify several petitions for *inter partes* review previously filed by Apotex Corp. and Apotex Inc. and challenging claims of the '162 patent and related patents. Pet. 11; Paper 6, 2 (referring to IPR2015-01278, IPR2015-01282, IPR2015-01286, and IPR2015-01283). All of the petitions were terminated before institution decisions were entered. Pet. 11; Paper 6, 2. 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.); and *Allergan, Inc. v. Famy Care, Ltd.*, No. 2:16-cv-0401 (E.D. Tex.). Pet. 12; Paper 6, 2.

Petitioner has also sought *inter partes* review for related patents in the following proceedings: Case IPR2016-01127 (U.S. Patent No. 8,685,930 B2), Cases IPR2016-01128 and IPR2016-01232 (U.S. Patent No. 8,629,111 B2), Case IPR2016-01129 (U.S. Patent No. 8,642,556 B2), Case IPR2016-01131 (U.S. Patent No. 8,648,048 B2), and IPR2016-01132 (U.S. Patent No. 9,248,191 B2).

B. The '162 Patent

The '162 patent generally relates to 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 cylcosporin 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, 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 14:20–30. 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.

C. Illustrative Claim

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;

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