Trials@uspto.gov
571-272-7822

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 IPR2016-01128
Patent 8,629,111 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
37 C.F.R. § 42.108

I. INTRODUCTION

Mylan Pharmaceuticals, Inc. ("Petitioner") filed a Petition (Paper 3, "Pet."), requesting institution of an *inter partes* review of claims 1–27 of U.S. Patent No. 8,629,111 B2 (Ex. 1001, "the '111 patent"). Allergan, Inc. ("Patent Owner") timely filed a 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." Upon consideration of the Petition and the Preliminary Response, and for the reasons explained below, we determine that Petitioner has shown that there is a reasonable likelihood that it would prevail with respect to at least one of the challenged claims. We thus institute an *inter partes* review of claims 1–27 of the '111 patent.

A. Related Proceedings

An IPR petition for the '111 patent was previously filed by Apotex Corp. and Apotex Inc. as IPR2015-01282, as were petitions for related U.S. Patent Nos. 8,648,048 (IPR2015-01284), 8,633,162 (IPR2015-01278), 8,642,556 (IPR2015-01286), and 8,685,930 (IPR2015-01283), but all were terminated prior to institution decisions. Pet. 11. Additionally, concurrent IPR petitions for related patents were filed by Petitioner in IPR2016-1127, IPR2016-01129, IPR2016-01130, IPR2016-01131, and IPR2016-01132. *Id.* Furthermore, Petition and Patent Owner identify the following related litigation matters: *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. 2:15-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.

B. The '111 Patent (Ex. 1001)

The '111 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 cylcosporin 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 14:20–30. 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 14:49–52. 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 15:5–8.

C. Illustrative Claims

Petitioner challenges claims 1–27 of the '111 patent. Independent claim 1 is illustrative, and is reproduced below:

> 1. A topical ophthalmic emulsion for treating an eye of a human comprising 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;
>
> wherein cyclosporin A is the only peptide present in the topical ophthalmic emulsion.

Independent claims 13 and 18 also recite a topical ophthalmic emulsion comprising CsA in an amount of about 0.05% by weight and castor oil in an amount of 1.25% by weight, and further specify particular amounts for the other components.

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of the claims of the '111 patent on the following grounds:

References	Basis	Claims challenged
Ding '979[1]	§ 102(b)	1–27
Ding '979 and Sall[2]	§ 103(a)	1–27
Ding '979, Sall, and Acheampong[3]	§ 103(a)	11 and 16

[1] Ding et al., US 5,474,979, issued Dec. 12, 1995 (Ex. 1003).
[2] Sall et al., *Two Multicenter, Randomized Studies of the Efficacy and Safety of Cyclosporine Ophthalmic Emulsion in Moderate to Severe Dry Eye Disease*, 107 OPHTHALMOLOGY 631–39 (2000).
[3] 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).

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