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Paper 12
Entered: July 12, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FAMY CARE LIMITED,
Petitioner,

v.

ALLERGAN, INC.,
Patent Owner.

Case IPR2017-00566
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 and Denying 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 to institute an *inter partes* review of claims 1–23 (Paper 3; "Petition" or "Pet.") of US 8,648,048 B2 (Ex. 1001; "the '048 patent"). Allergan, Inc. ("Allergan" or "Patent Owner") did not file a Preliminary Response to the Petition.

Petitioner also filed a Motion for Joinder pursuant to 35 U.S.C. § 315(c), seeking to join this proceeding with *Mylan Pharmaceuticals, Inc. v. Allergan, Inc.*, IPR2016-01131 ("Mylan IPR"). Paper 5. Patent Owner opposes Petitioner joinder motion. 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 consideration of the Petition, we determine that Petitioner has established 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 identify petitions for *inter partes* review previously filed by other petitioners that challenge the claims of the '048 patent and related patents. Pet. 4–5; Paper 8, 2–3. Certain petitions were terminated before decisions on institution were entered. Pet. 5; Paper 6, 2. Other petitions have been granted and *inter partes* review has been instituted for the following U.S. Patents: U.S. Patent No. 8,633,162 (IPR2016-01130,

IPR2017-00568, IPR2017-00599, IPR2017-00583); U.S. Patent No. 8,685,930 (IPR2016-01127, IPR2017-00571, IPR2017-00594, IPR2017-00576); U.S. Patent No. 8,629,111 (IPR2016-01128, IPR2017-00567, IPR2017-00596, IPR2017-00578); U.S. Patent No. 8,642,556 (IPR2016-01129 IPR2017-00570, 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, IPR2017-00569, IPR2017-00601, IPR2017-00586). Paper 6, 2–3.

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 1:66–2:2. 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. The Asserted Grounds

Petitioner challenges claims 1–23 of the '048 patent on the following grounds. Pet. 6–7.

Ground	Reference[s]	Basis	Claims challenged
1	Ding '979 [1]	§ 103	1– 23
2	Ding '979 and Sall[2]	§ 103	1– 23
3	Ding '979, Sall, and Acheampong[3]	§ 103	11 and 21
4	Ding '979, Sall, and Glonek[4]	§ 103	15

Petitioner also relies on the Declarations of Peter Kador, Ph.D. (Ex. 1002) and Michael Lemp, M.D. (Ex. 1003).

D. Illustrative Claims

Independent claims 1, 18, and 22 are illustrative of the challenged claims, and are reproduced below:

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[1] Ding et al., U.S. Patent No. 5,474,979, issued December 12, 1995 (Ex. 1006, "Ding '979").

[2] Kenneth 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 631–639 (2000) (Ex. 1007, "Sall").

[3] Andrew 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, in* LACRIMAL GLAND, TEAR FILM, AND DRY EYE SYNDROMES 2, BASIC SCIENCE AND CLINICAL RELEVANCE, 1001–1004 (1998) (Ex. 1008, "Acheampong").

[4] Glonek et al., U.S. Patent No. 5,578,586, issued Nov. 26, 1996. Ex. 1009 ("Glonek").

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