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Paper 154
Entered: September 27, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
TEVA PHARMACEUTICALS USA, INC., and AKORN INC.
Petitioners,

v.

SAINT REGIS MOHAWK TRIBE and ALLERGAN, INC.,
Patent Owners.

Case IPR2016-01129
Patent 8,642,556 B2[1]

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

SNEDDEN, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

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[1] Cases IPR2017-00579 and IPR2017-00598 have been joined with IPR2016-01129.

ORDERS

Dismissing Petitioner's Motion to Exclude (Paper 50)
37 C.F.R. § 42.64(c)

Dismissing Patent Owner's Motion to Exclude (Paper 43)
37 C.F.R. § 42.64(c)

I. INTRODUCTION

This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. Mylan Pharmaceuticals Inc., Teva Pharmaceuticals USA, Inc., and Akorn Inc. (collectively, "Petitioner") bears the burden of proving unpatentability of the challenged claims, and that burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must prove unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

For the reasons that follow, we determine that Petitioner has shown, by a preponderance of the evidence, that claims 1–20 of U.S. Patent No. 8,642,556 B2 (Ex. 1001, "the '556 patent") are unpatentable.

A. Procedural History

Petitioner filed a Petition to institute an *inter partes* review of claims 1–20 of the '556 patent. Paper 3 ("Pet."). Allergan, Inc. ("Patent Owner") filed a Patent Owner Preliminary Response. Paper 7. Upon consideration of the Petition and Preliminary Response, we instituted an *inter partes* review of claims 1–20 of the '556 patent on each ground of unpatentability set forth in the Petition, which are as follows:

Ground	Reference[s]	Basis	Claims Challenged
1	Ding '979[2]	§ 102(b)	1–20
2	Ding '979 and Sall[3]	§ 103(a)	1–20
3	Ding '979, Sall, and Glonek[4]	§ 103(a)	14 and 19
4	Ding '979, Sall, and Acheampong[5]	§ 103(a)	11, 18, and 20
5	Ding '979, Sall, Glonek, and Acheampong	§ 103(a)	19

Paper 8 ("Decision on Institution" or "Dec.").

Subsequently, Patent Owner filed a Patent Owner Response (Paper 16; "PO Resp."), Petitioner filed a Reply (Paper 34; "Reply"), and Patent Owner filed a Sur-Reply (Paper 42; "Sur-Reply").[6]

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[2] Ding et al., US 5,474,979, issued December 12, 1995 (Ex. 1006, "Ding '979").

[3] 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").

[4] Glonek et al., US 5,578,586, issued Nov. 26, 1996 (Ex. 1009, "Glonek").

[5] 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) (Ex. 1008, "Acheampong").

[6] On September 8, 2017, the Saint Regis Mohawk Tribe (the "Tribe") entered an appearance as the purported Patent Owner. Paper 63. We denied the Tribe's Motion to Terminate on sovereign immunity grounds and Allergan's Motion to Withdraw. Paper 127; Paper 129.

Teva Pharmaceuticals USA, Inc. ("Teva") and Akorn, Inc. ("Akorn") each filed Petitions requesting an *inter partes* review of claims 1–20 of the '556 patent in cases IPR2017-00579 and IPR2017-00598, respectfully. IPR2017-00579, Paper 4; IPR2017-00598, Paper 2. Teva and Akorn each filed a motion to join their respective cases with this case. IPR2017-00579, Paper 3; IPR2017-00598, Paper 3. We granted Teva and Akorn's Petition and each of their motions for joinder. IPR2017-00579, Paper 9; IPR2017-00598, Paper 9.

Per the parties' request, an oral hearing was not held for this proceeding. Paper 147.

B. Related Proceedings

In addition to this proceeding challenging the '556 patent, Petitioner has sought *inter partes* review of all claims of U.S. Patent No. 8,685,930 B2 ("the '930 patent") in IPR2016-00127; U.S. Patent No. 8,629,111 B2 ("the '111 patent") in IPR2016-01128; U.S. Patent No. 8,633,162 B2 ("the '162 patent") in IPR2016-01130; U.S. Patent No. 8,648,048 B2 ("the '048 patent") in IPR2016-01131; and U.S. Patent No. 9,248,191 B2 ("the '191 patent") in IPR2016-01132 (collectively, "the Challenged Patents").

Four of the six Challenged Patents—the '111, '048, '930, and '191 patents—were also at issue in *Allergan, Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 2:15-cv-01455 (E.D. Tex.) ("*Allergan v. Teva*"). The dispute in *Allergan v. Teva* was a "Hatch-Waxman Act case relate[d] to a condition known as 'dry eye' and a pharmaceutical product known as 'Restasis' that is intended to address that condition." Ex. 1164, 1. "Restasis is an emulsion consisting of various components, including the active ingredient

cyclosporin A, an immunosuppressant, which is dissolved in castor oil, a fatty acid glyceride." *Id.* The product Restasis is protected by the Challenged Patents and each of the Challenged Patents is listed in the FDA's Orange Book as patents that claim Restasis, "with respect to which a claim of patent infringement could reasonably be asserted."[7] *Id.* at 1, 27–29 (citing 21 U.S.C. § 355(b)(1), (c)(2)).

In *Allergan v. Teva*, the district court found thirteen representative claims from those four Challenged Patents invalid as obvious. Ex. 1164. The court explained that its obviousness analysis served to invalidate all claims of those four patents. *Id.* at 32–108. The Federal Circuit affirmed the district court's decision by Rule 36 judgment. *Allergan, Inc. v. Teva Pharms. USA, Inc.*, 742 F. App'x 511 (Mem.) (Fed. Cir. Nov. 13, 2018) (Ex. 1172). Patent Owner's petition for a writ of certiorari was denied. *Allergan, Inc. v. Teva Pharms. USA, Inc.*, 139 S. Ct. 2674 (Mem.) (2019).

During the district court litigation, Patent Owner agreed to treat the thirteen litigated claims as representative of all claims of the Challenged Patents and states that "judgment as to those thirteen claims can be properly applied to all claims of those four patents." PO Supp. Br. 9. With the Federal Circuit's affirmance and the Supreme Court's denial of review, the district court's judgment invalidating all claims of the '111, '048, '930, '191 and patents is now final.

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[7] The district court refers to the Challenged Patents as the "Restasis patents." Ex. 1164, 23–24.

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