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Paper 89
Date: November 9, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., CELLTRION, INC., and APOTEX, INC.,
Petitioners,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

IPR2021-00880[1]
Patent 9,669,069 B2

Before ERICA A. FRANKLIN, JOHN G. NEW, and SUSAN L.C. MITCHELL, *Administrative Patent Judges.*

NEW, *Administrative Patent Judge*

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
Denying Petitioner's Motion to Exclude Evidence
Denying in part and Dismissing in Part Patent Owner's Motion to Exclude Evidence
35 U.S.C. § 318(a), 37 C.F.R. § 42.64(c)

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[1] IPR2022-00257 and IPR2022-00301 have been joined with this proceeding. *See* Papers 35 and 36.

I. INTRODUCTION

We have jurisdiction to hear this *inter partes* review under 35 U.S.C. § 6, and this Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons set forth below, we determine that Mylan Pharmaceuticals Inc., Celltrion, Inc. and Apotex, Inc. (collectively "Petitioner") have established by a preponderance of the evidence that claims 1 and 8–12 of Patent Owner Regeneron Pharmaceuticals, Inc.'s ("Patent Owner") U.S. Patent No. 9,669,069 B2 (Ex. 1001, "'069 patent") are unpatentable. We additionally deny Petitioner's pending Motion to Exclude Evidence and deny in part and dismiss in part Patent Owner's pending Motion to Exclude Evidence.

A. Procedural History

On May 5, 2021, Mylan Pharmaceuticals, Inc., the original Petitioner, filed a Petition (Paper 1, "Petition") seeking *inter partes* review of claims 1 and 8–12 of the '069 patent. Patent Owner timely filed a Preliminary Response. (Paper 10). We authorized additional briefing (Papers 16 and 19) and pursuant to 35 U.S.C. § 314, on November 10, 2021, we instituted *inter partes* review of all of the challenged claims of the '069 patent (Paper 21, "Institution Decision" or "Dec.").

After institution of trial, Patent Owner filed a corrected Response (Paper 39, "PO Resp."), to which Petitioner filed a Reply[2] (Paper 57, "Pet. Reply"), and Patent Owner, in turn, filed a Sur-Reply (Paper 68, "Sur-Reply").

On February 9, 2022, we instituted an *inter partes* review in IPR2022-00257 and granted the motion for joinder with IPR2021-00880, adding Celltrion, Inc. as a petitioner in the instant proceeding. Paper 35. On the same date, we also instituted an *inter partes* in IPR2022-00301 and likewise granted the motion for joinder with IPR2021-00880, adding Apotex, Inc. as a petitioner in the instant proceeding. Paper 36. We refer to Mylan Pharmaceuticals, Inc., Celltrion, Inc. and Apotex, Inc., collectively, as "Petitioner."

Oral argument was held on August 10, 2022. A transcript of the oral argument is included in the record. (Paper 88, "Hearing Trans.").

B. Related Proceedings

Petitioner and Patent Owner identify *Mylan Pharms. Inc. v. Regeneron Pharms., Inc.*, IPR2021-00881 (PTAB May 5, 2021) (the "-881 IPR") as a related matter. Pet. 4; Paper 5, 2. The -881 IPR challenges

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[2] Petitioner filed a Reply containing confidential information (Paper 56), together with a redacted Reply (Paper 57). Although we have reviewed both briefs, in this Decision we quote or cite only to information presented in the redacted brief.

claims of U.S. Patent No. 9,254,338 B2 ("the '338 patent"). The parties further identify *Chengdu Kanghong Biotechnol. Co. v. Regeneron Pharms., Inc.*, PGR2021-00035 (PTAB Jan. 7, 2021) challenging the claims of U.S. Patent No. 10,828,345 B2 ("the '345 patent"), which is related to the '069 patent and the '338 patent. Pet. 5. This latter proceeding has been terminated. *See Chengdu*, PGR2021-00035, Paper 8.

Petitioner also identifies additional patents and patent applications that claim priority to the '069 patent, namely: U.S. Patent Nos. 10,130,681 B2, 10,857,205 B2, 10,828,345 B2, and 10,888,601 B2, and U.S. Application Serial Nos. 17/072,417, 17/112,063, and 17/112,404. Pet. 5.

C. Real Parties-in-Interest

Petitioner states that Viatris Inc. and Mylan Inc. are parent companies of Petitioner Mylan Pharmaceuticals Inc. Paper 87, 1. Accordingly, Petitioner identifies Viatris Inc., Mylan Inc., and Mylan Pharmaceuticals Inc. as real parties-in-interest to the current Petition. *Id.* Petitioner also states that Momenta Pharmaceuticals, Inc. and Janssen Research & Development LLC are wholly-owned subsidiaries of Johnson & Johnson, a publicly held company. *Id.* Consequently, Petitioner also identifies Momenta Pharmaceuticals, Inc., Janssen Research & Development LLC, and Johnson & Johnson as real parties-in-interest to the current Petition. *Id.*

Petitioner Celltrion, Inc. identifies itself, Celltrion Healthcare Co. Ltd., and Celltrion Healthcare U.S.A., Inc. as real parties-in-interest. *See* IPR2022-00257, Paper 2, 3. Petitioner Apotex, Inc. identifies itself, Apotex

Corp., Apotex Pharmaceutical Holdings Inc., and Aposherm Delaware Holdings Corp. as real parties-in-interest. *See* IPR2022-00301, Paper 1, 3.

Patent Owner identifies Regeneron Pharmaceuticals, Inc. as the real party-in-interest. Paper 5, 2.

D. The Instituted Grounds of Unpatentability

Petitioner contends that claims 1 and 8–12 of the '069 patent are unpatentable, based upon the following grounds, all of which have been instituted in this proceeding:

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
I	1, 9–12	102	Dixon[3]
II	1, 9–12	102	Heier 2009[4]
III	1, 9–12	102	Regeneron I[5]
IV	1, 8–12	102 and/or 103	Dixon

[3] J.A. Dixon et al., *VEGF Trap-Eye for the Treatment of Neovascular Age-Related Macular Degeneration*, 18(10) EXPERT OPIN. INVESTIG. DRUGS 1573–80 (2009) ("Dixon") Ex. 1006.

[4] J.S. Heier, *Intravitreal VEGF Trap for AMD: An Update*, October 2009 RETINA TODAY 44–45 (2009) ("Heier 2009") Ex. 1020.

[5] Press Release, *Bayer and Regeneron Extend Development Program for VEGF Trap-Eye to Include Central Retinal Vein Occlusion*, April 30, 2009 ("Regeneron I") Ex. 1028.

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