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Paper 94
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.

IPR2021-00881[1]
Patent 9,254,338 B2

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

FRANKLIN, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
Denying in part and Dismissing in part Petitioners' Motion to Exclude
Denying in part and Dismissing in part Denying Patent Owner's Motion to Exclude
35 U.S.C. § 318(a)

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[1] IPR2022-00258 and IPR2022-00298 have been joined with this proceeding. *See* Papers 35 and 36.

I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review of claims 1, 3–11, 13, 14, 16–24 and 26 ("the challenged claims") of U.S. Patent No. 9,254,338 B2 (Ex. 1001, "the '338 patent"). We have jurisdiction under 35 U.S.C. § 6, and enter this Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons set forth below, we determine that Petitioners have shown by a preponderance of the evidence that the challenged claims are unpatentable. *See* 35 U.S.C. § 316(e).

Additionally, we deny in part and dismiss in part the Motions to Exclude Evidence.

A. Procedural History

The original petitioner in this case was Mylan Pharmaceuticals, Inc. ("Petitioner Mylan"). Petitioner Mylan filed a Petition requesting an *inter partes* review of the challenged claims under 35 U.S.C. § 311. Paper 1 ("Petition" or "Pet."). Petitioner Mylan supported the Petition with the Declarations of Thomas Albini M.D. (Ex. 1002), and Mary Gerritsen Ph.D. (Ex. 1003). Regeneron Pharmaceuticals, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 10 ("Prelim. Resp."). Patent Owner supported the Preliminary Response with the Declarations of Diana V. Do, M.D. (Ex. 2001). With our authorization, Paper 13, Petitioner Mylan filed a Reply to the Preliminary Response, and Patent Owner filed a Sur-reply to address further issues involving 35 U.S.C. § 325(d). Paper 16 ("Reply"); Paper 19 ("Sur-reply").

On November 10, 2021, pursuant to 35 U.S.C. § 314, we instituted trial to determine whether any challenged claim of the '338 patent is unpatentable based on the six grounds raised in the Petition:

Claims Challenged	32 U.S.C. §	Reference(s)
1, 3–11, 13, 14, 16–24, 26	102	Dixon[2]
1, 3–11, 13, 14, 16–24, 26	102	Adis[3]
1, 3–11, 13, 14, 16–24, 26	102	Regeneron 2008[4]
1, 3–11, 13, 14, 16–24, 26	102	NCT-795[5]
1, 3–11, 13, 14, 16–24, 26	102	NCT-377[6]
1, 3–11, 13, 14, 16–24, 26	103	Dixon, Papadopoulos,[7] Dix[8]

Paper 21 ("Institution Decision" or "Inst. Dec.").

On February 9, 2022, we instituted an *inter partes* review in IPR2022-00258 and granted the motion for joinder with IPR2021-00881, adding Celltrion, Inc. as a petitioner in the instant proceeding. Paper 35. On the

[2] James A. Dixon et al., "VEGF Trap-Eye for the treatment of neovascular age-related macular degeneration," 18(10) *Expert Opin. Investig. Drugs* 1573–1580 (2009) (Ex. 1006, "Dixon")).
[3] Adis Data Information BV, "Aflibercept," 9(4) *Drugs R&D* 261–269 (2008) (Ex. 1007, "Adis").
[4] Press Release, Regeneron, "Bayer and Regeneron Dose First Patient in Second Phase 3 Study for VEGF Trap-Eye in Wet Age-Related Macular Degeneration" (May 8, 2008) (Ex. 1013, "Regeneron 2008").
[5] Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW1), NCT00509795, ClinicalTrials.gov (Apr. 28, 2009), https://clinicaltrials.gov/ct2/show/NCT00509795 (Ex. 1014, "NCT-795").
[6] VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW2), NCT00637377, ClinicalTrials.gov (Mar. 17, 2008), https://clinicaltrials.gov/ct2/show/NCT00637377 (Ex. 1015, "NCT-377").
[7] Papadopoulos et al., US 7,374,758 B2, issued May 20, 2008, (Ex. 1010, "Papadopoulos").
[8] Patent Application Publication No. 2006/0217311 A1 by Dix et al., published Sep. 28, 2006 (Ex. 1033, "Dix").

same date, we also instituted an *inter partes* in IPR2022-00298 and likewise granted the motion for joinder with IPR2021-00881, adding Apotex, Inc. as a petitioner in the instant proceeding. Paper 36. Accordingly, we refer to Mylan Pharmaceuticals, Inc., Celltrion, Inc. and Apotex, Inc., collectively, as "Petitioners."

Patent Owner filed a Corrected Patent Owner Response to the Petition. Paper 41 (redacted, public version), Paper 40 (sealed version), (collectively, "PO Resp.").[9] Patent Owner supported the Patent Owner Response with the declarations of Diana V. Do, M.D. (Ex. 2001; Ex. 2051); Lucian V. Del Priore, M.D., Ph.D. (Ex. 2048 (sealed version); Ex. 2048 (redacted, public version)); Alexander M. Klibanov, Ph.D. (Ex. 2049); David M. Brown, M.D. (Ex. 2050); Richard Manning, Ph.D. (Ex. 2052 (sealed version); Ex. 2052 (public, redacted version)).

Petitioners filed a Reply to the Patent Owner Response. Papers 61 (sealed version), 62 (redacted, public version) (collectively, "Pet. Reply"). Petitioners supported the Reply with Supplemental Declarations from Dr. Albini (Ex. 1114) and Dr. Gerritsen (Ex. 1115), along with a Declaration from Dr. Hofmann (Ex. 1137) (sealed version), (Ex. 1137) (redacted, public version). Patent Owner filed a Sur-reply to Petitioners' Reply. Paper 73 ("PO Sur-reply").

Patent Owner and Petitioners each filed a Motion to Exclude Evidence. Papers 83 ("PO Mot."), 81 ("Pet. Mot."). Each party filed an Opposition to the corresponding motion. Papers 85 ("PO Opp."), 84 ("Pet.

[9] In this Decision, we refer only to the public versions of papers and exhibits and not to confidential material.

Opp.”). Each party also filed a Reply to the corresponding Opposition. Papers 86 (“PO Mot. Reply”), 87 (“Pet. Mot. Reply”).

On August 10, 2022, the parties presented arguments at an oral hearing. Paper 78 (Order Granting Requests for Oral Hearing). The hearing transcript has been entered in the record. Paper 93 (“Tr.”).

B. Real Parties-in-Interest

Petitioner Mylan identifies itself, Viatris Inc., Mylan Inc., Momenta Pharmaceuticals, Inc., Janssen Research & Development LLC, and Johnson & Johnson as real parties-in-interest. Pet. 3, Paper 18 (Petitioner Mylan’s Amended Mandatory Notices). Petitioner Celltrion, Inc. identifies itself, Celltrion Healthcare Co. Ltd., and Celltrion Healthcare U.S.A., Inc. as real parties-in-interest. *See* IPR2022-00258, 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* IPR2022-00298, Paper 1, 3. Patent Owner identifies itself as the real party-in-interest. Paper 5, 2.

C. Related Proceedings

Petitioners and Patent Owner identify *Mylan Pharms. Inc. v. Regeneron Pharms., Inc.*, IPR2021-00880 (PTAB May 5, 2021) (“the -880 IPR”) as a related matter. Pet. 3; Paper 5, 2. The -880 IPR challenges claims 1 and 8–12 of U.S. Patent No. 9,669,069 B2 (“the ’069 patent”). The parties further identify *Chengdu Kanghong Biotechnol. Co. v. Regeneron Pharms., Inc*., PGR2021-00035 (petition dismissed and proceeding terminated, Paper 8 (PTAB June 25, 2021)) challenging the claims of U.S. Patent No. 10,828,345 B2 (“the ’345 patent”), which is related to the ’338 patent and the ’069 patent. Pet. 4; Paper 5, 2.

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