Trials@uspto.gov
571-272-7822

Paper 22
Date: January 11, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,

Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,

Patent Owner.

IPR2022-01226
Patent 10,888,601 B2

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

NEW, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Petitioner Mylan Pharmaceuticals Inc. ("Petitioner") has filed a Petition (Paper 2, "Pet.") seeking *inter partes* review of claims 1–9, 34–39, 41–43, and 45 of US Patent 10,888,601 B2 (Ex. 1001, the "'601 patent"). Patent Owner Regeneron Pharmaceuticals, Inc. ("Patent Owner") timely filed a Preliminary Response. Paper 13 ("Prelim. Resp."). With our authorization (*see* Paper 16 at 1), Petitioner filed a Reply to the Preliminary Response (Paper 17 ("Reply")), and Patent Owner filed a Sur-Reply. Paper 19 ("Sur-Reply").

Under 35 U.S.C. § 314, the Board "may not authorize an *inter partes* review to be instituted unless … the information presented in the petition … and any response … shows that 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, Preliminary Response, Reply, Sur-Reply, and the evidence of record, we determine that the evidence presented demonstrates a reasonable likelihood that Petitioner would prevail in establishing the unpatentability of at least one challenged claim of the '601 patent.

II. BACKGROUND

A. Real Parties-in-Interest

Petitioner identifies Viatris Inc., Mylan Inc., Mylan Pharmaceuticals Inc., Momenta Pharmaceuticals, Inc., Janssen Research & Development LLC, and Johnson & Johnson as the real parties-in-interest. Paper 11 at 1. Patent Owner identifies Regeneron Pharmaceuticals, Inc. as the real party-in-interest. Paper 5 at 1.

B. Related Matters

Petitioner and Patent Owner identify *Mylan Pharms. Inc. v. Regeneron Pharms., Inc.*, IPR2021-00880, IPR2021-00881, IPR2022-01225 (PTAB), and *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, 1:22-cv-00061-TSK (N.D.W. Va.) as related matters. Paper 5 at 1; Paper 11 at 1. Patent Owner also identifies *Chengdu Kanghong Biotechnology Co. v. Regeneron Pharms., Inc.*, PGR2021-00035 (PTAB) (proceeding terminated). Paper 5 at 2–3. Petitioner further identifies the following as judicial or administrative matters that could affect, or be affected by, a decision in this *inter partes* review: *Apotex Inc. v. Regeneron Pharmaceuticals, Inc.*, No. IPR2022-01524 (PTAB), *United States v. Regeneron Pharms., Inc.*, No. 1:20-cv-11217-FDS (D. Mass.), and *Horizon Healthcare Servs., Inc. v. Regeneron Pharms., Inc.*, No. 1:22-cv-10493-FDS (D. Mass.). Paper 11 at 1–2.

Petitioner also identifies additional patents and patent applications that claim priority to the '601 patent, namely: US 9,254,338 B2; US 9,669,069 B2; US 10,857,205 B2; US 10,828,345 B2; US 10,888,601 B2; and US 11,253,572 B2; and US Appl. Ser. Nos. 17/072,417; 17/112,063; 17/112,404; 17/350,958; and 17/740,744. Paper 11 at 2.

Of particular relevance to our decision in this proceeding is the Final Written Decision entered in IPR2021-00881 on November 9, 2022. *See* IPR 2021-00881, Paper 94 (the "-00881 Decision" Ex. 3001). In the -00881 Decision, the panel found that the challenged claims were unpatentable on at

least one of the same grounds asserted against the challenged claims in the present Petition. *See generally* Ex. 3001.

C. The Asserted Grounds of Unpatentability

Petitioner contends that claims 1–9, 34–39, 41–43, and 45 of the '601 patent are unpatentable, based upon the following grounds:

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1	1–9, 34–39, 41–43, 45	102[1]	Dixon[2]
1	1–9, 34–39, 41–43, 45	102	Adis[3]
3	1–9, 34–39, 41–43, 45	102	Regeneron 2008[4]

[1] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112–29, 125 Stat. 284 (2011), amended 35 U.S.C. §§ 102 and 103, effective March 16, 2013. Because the application from which the '601 patent issued has an effective filing date after that date, the AIA versions of §§ 102 and 103 apply.

[2] 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.

[3] Adis R&D Profile, *Aflibercept: AVE 0005, AVE 005, AVE0005, VEGF Trap – Regeneron, VEGF Trap (R1R2), VEGF Trap-Eye*, 9(4) DRUGS R D 261–269 (2008) ("Adis") Ex. 1007.

[4] Press Release, *Regeneron and Bayer HealthCare Announce Encouraging 32-Week Follow-Up Results from a Phase 2 Study of VEGF Trap-Eye in Age-Related Macular Degeneration*, April 28, 2008 ("Regeneron 2008") Ex. 1012.

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
4	1–9, 34–39, 41–43, 45	102	NCT-795[5]
5	1, 3–11, 13, 14, 16–24, 26	103	Dixon alone or in view of Papadopoulos[6] and/or Wiegand[7]
6	1, 3–11, 13, 14, 16–24, 26	103	Dixon in combination with Rosenfeld-2006[8], and if necessary, Papadopoulos patent and/or Wiegand
7	1, 3–11, 13, 14, 16–24, 26	103	Dixon in combination with Heimann-2007, and if necessary, Papadopoulos and/or Wiegand

[5] ClinicalTrials.gov (archive), *Vascular Endothelial Growth Factor (VEGF)Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW1)*, *available at*: https://clinicaltrials.gov/ct2/history/NCT00509795?A=8&B=9&C=merged#StudyPageTop (last visited December 21, 2022) Ex. 1014.

[6] Papadopoulos et al. (US 7,374,758 B2, May 20, 2008) ("Papadopoulos") Ex. 1010.

[7] Wiegand et al. (US 7,531,173 B2, May 12, 2009) ("Wiegand") Ex. 1008.

[8] P.J. Rosenfeld et al., *Ranibizumab for Neovascular Age-Related Macular Degeneration*, 355 (14) N. ENGL. J. MED. 1419–31; Suppl. App'x 1–17 (2006) ("Rosenfeld") Ex. 1058.

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