

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,

Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,

Patent Owner.

IPR2022-01225
Patent 10,130,681 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, 3–11, 13, 14, 16–24, and 26 of US Patent 10,130,681 B2 (Ex. 1001, the “’681 patent”). Patent Owner Regeneron Pharmaceuticals, Inc. (“Patent Owner”) timely filed a Preliminary Response. Paper 14 (“Prelim. Resp.”). With our authorization (*see* Paper 16 at 1), Petitioner filed a Reply to the Preliminary Response (Paper 16 (“Reply”)), and Patent Owner filed a Sur-Reply. Paper 18 (“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 ’681 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 8 at 1. Patent Owner identifies Regeneron Pharmaceuticals, Inc. as the real party-in-interest. Paper 5 at 1.

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B. Related Matters

Petitioner and Patent Owner identify *Mylan Pharms. Inc. v. Regeneron Pharms., Inc.*, IPR2021-00880, IPR2021-00881, IPR2022-01226 (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 6 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 would affect, or be affected by, a decision in this proceeding: *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 6 at 1–2.

Petitioner also identifies additional patents and patent applications that claim priority to the '681 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 6 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). Both the '681 patent and US 9,254,338 B2 (the “'338 patent”) in IPR2021-00881 share a common Specification. *See generally*, Ex. 1001, IPR2021-00881, Ex. 1001. 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, 3–11, 13, 14, 16–24, and 26 of the '681 patent are unpatentable, based upon the following grounds:

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1	1, 3–11, 13, 14, 16–24, 26	102 ¹	Dixon ²
1	1, 3–11, 13, 14, 16–24, 26	102	Adis ³
3	1, 3–11, 13, 14, 16–24, 26	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. 2007.

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, 3–11, 13, 14, 16–24, 26	103	Dixon alone or in view of Papadopoulos ⁵ and/or Wiegand ⁶
5	1, 3–11, 13, 14, 16–24, 26	103	Dixon in combination with Rosenfeld-2006 ⁷ , and if necessary, Papadopoulos patent and/or Wiegand
6	1, 3–11, 13, 14, 16–24, 26	103	Dixon in combination with Heimann-2007, and if necessary, Papadopoulos and/or Wiegand

Petitioner also relies upon the Declarations of Dr. Thomas A. Albini (the “Albini Declaration,” Ex. 1002) and Dr. Mary Gerritsen (the “Gerritsen Declaration,” Ex. 1003). Patent Owner relies upon the Declaration of Dr. Diana V. Do (the “Do Declaration,” Ex. 2001).

⁵ Papadopoulos et al. (US 7,374,758 B2, May 20, 2008) (“Papadopoulos”) Ex. 1010.

⁶ Wiegand et al. (US 7,531,173 B2, May 12, 2009) (“Wiegand”) Ex. 1007.

⁷ 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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