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Paper 9
Date: October 20, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO. LTD,
Petitioner,
v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

IPR2023-00739
Patent 10,888,601 B2

Before JOHN G. NEW, ROBERT A. POLLOCK, and RYAN H. FLAX, *Administrative Patent Judges*.

NEW, *Administrative Patent Judge*.

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

I. INTRODUCTION

Petitioner Samsung Bioepis Co. Ltd. ("Petitioner") has filed a Petition (Paper 1, "Pet.") seeking *inter partes* review of claims 10–12, 17–19, 21, 25–28, and 33[1] of U.S. Patent 10,888,601 B2 (Ex. 1001, the "'601 patent"). Patent Owner Regeneron Pharmaceuticals, Inc. ("Patent Owner") timely filed a Preliminary Response. Paper 6 ("Prelim. Resp."). With our authorization (*see* Ex. 3001), Petitioner filed a Reply to the Preliminary Response (Paper 7 ("Reply")), and Patent Owner filed a Sur-Reply. Paper 8 ("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. We therefore institute *inter partes* review of the challenged claims.

[1] Petitioner originally challenged claims 10–33, 46, and 47 of the '601 patent. Pet. 1. Patent Owner states that claims 13–14, 22, and 29–30 were disclaimed on July 11, 2022, before the Petition was filed. Prelim. Resp. 1, n.1 (citing Ex. 2001). Patent Owner also states that, subsequent to the filing of the Petition, claims 15, 16, 20, 23, 24, 31, 32, 46 and 47 were also disclaimed. *Id.* (citing Ex. 2002). Consequently, only claims 10–12, 17–19, 21, 25–28, and 33 of the '601 patent remain challenged by Petitioner.

II. BACKGROUND

A. Real Parties-in-Interest

Petitioner identifies Samsung Bioepis Co. Ltd. as the real party-in-interest. Pet. 6. Patent Owner identifies Regeneron Pharmaceuticals, Inc. as the real party-in-interest. Paper 5 at 2.

B. Related Matters

Petitioner and Patent Owner identify *Mylan Pharms. Inc. v. Regeneron Pharms., Inc.*, IPR2022-01226, as challenging different claims of the '601 patent. Pet. 6–7, Paper 4, 1. Petitioner confirms that, in *Samsung Bioepis Co., Ltd. v. Regeneron Pharms., Inc.*, IPR2023-00566, it filed a "copycat" petition, seeking joinder in IPR2022-01226, and proposing to join Mylan's *inter partes* review as a "silent understudy." *Id.* at 7 (citing IPR2023-00566, Papers 2, 3). Joinder of IPR2022-01226 and IPR2023-00566 was granted on March 22, 2023 in IPR2023-00566. *Id.* (citing IPR2023-00566, Paper 10).

The parties also identify *Mylan Pharms. Inc. v. Regeneron Pharms., Inc.*, IPR2021-00880 and *Mylan Pharms. Inc. v. Regeneron Pharms., Inc.*, IPR2021-00881, challenging claims of US 9,254,338 and US 9,669,069, respectively, both of which are in the same family as the '601 patent. Pet. 7, Paper 4, 2. Final Written Decisions were entered in both IPR2021-00880 and -00881 on November 9, 2022, finding all challenged claims of both patents unpatentable. *Id.* Patent Owner has since appealed those decisions to the U.S. Court of Appeals for the Federal Circuit as *Regeneron Pharms, Inc. v. Mylan Pharms. Inc.*, No. 2023-1395 (Fed. Cir.) and *Regeneron*

Pharms., Inc. v. Mylan Pharms. Inc., No. 2023-1396 (Fed. Cir.), respectively. *Id.*

Furthermore, in *Mylan Pharms. Inc. v. Regeneron Pharms., Inc.*, IPR2022-01225, Mylan challenged the patentability of claims 1, 3–11, 13, 14, 16–24, and 26 of US 10,130,681. Pet. 7. Petitioner has separately challenged the patentability of the same claims of that patent in in *Samsung Bioepis Co., Ltd. v. Regeneron Pharms., Inc.*, IPR2023-00442, institution of which was granted on July 19, 2023. *See* IPR2023-00442, Paper 10. Celltrion, Inc. has similarly sought, and been granted, joinder with both IPR2022-001225 and -01226, and has also assumed a "silent understudy" posture in those cases. *See* IPR2023-00532, Papers 3, 7; IPR2023-00533, Papers 3, 7.

The parties further identify *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, 1:22-cv-00061-TSK (N.D. W. Va.) as a related matter. *See, e.g.*, Pet. 8. Petitioner also identifies as a related matter *United States v. Regeneron Pharms., Inc.*, No. 1:20-cv-11217-FDS (D. Mass.). *Id.* Patent Owner also identifies *Chengdu Kanghong Biotechnol. Co. v. Regeneron Pharms., Inc.*, PGR2021-00035 (PTAB) (proceeding terminated). Paper 4, 2.

C. The Asserted Grounds of Unpatentability

Petitioner contends that claims 10–12, 17–19, 21, 25–28, and 33 of the '601 patent are unpatentable, based upon the following grounds:

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
2[2]	10–12, 18, 19, 21, 26–28	103[3]	2009 Press Release[4], Shams[5]
3	10–12, 18, 19, 21, 26–28	103	2009 Press Release, Elman[6]
6	17, 25, 33	103	2009 Press Release, Elman, CATT[7], PIER[8]

[2] Grounds 1, 4, and 5 of the Petition challenged claims that have been disclaimed by Patent Owner. *See* n.1, *supra*; Pet. 11. We therefore do not address those Grounds in this Decision.

[3] 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.

[4] Press Release, Regeneron, Enrollment Completed in Regeneron and Bayer HealthCare Phase 3 Studies of VEGF Trap-Eye in Neovascular Age-Related Macular Degeneration (Wet AMD) (September 14, 2009) (the "2009 Press Release") Ex. 1009.

[5] Shams (WO 2006/047325 Al, May 4, 2006) ("Shams") Ex. 1010.

[6] M.J. Elman et al., *Randomized Trial Evaluating Ranibizumab Plus Prompt or Deferred Laser or Triamcinolone Plus Prompt Laser for Diabetic Macular Edema*, 117(6) OPHTHALMOLOGY 1064–1077.e35 (2010) ("Elman") Ex. 1006.

[7] CATT Patient Eligibility Criteria, *retrieved from*: https://web.archive.org/web/20100713035617/http:/www.med.upenn.edu/cpob/studies/documents/CATTEligibilityCriteria_000.pdf ("CATT") Ex. 1018.

[8] C.D. Regillo et al., *Randomized, Double-Masked, Sham-Controlled Trial of Ranibizumab for Neovascular Age-related Macular Degeneration: PIER Study Year 1*, 145(2) AM. J. OPHTHALMOL. 239–48 (2008) ("PIER") Ex. 1004.

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