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Paper 30
Date: January 30, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CELLTRION, INC.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

IPR2024-00260
Patent 11,253,572 B2

Before SUSAN L. C. MITCHELL, ROBERT A. POLLOCK, and RYAN H. FLAX, *Administrative Patent Judges*.

FLAX, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
Granting Motion for Joinder
35 U.S.C. § 314; 35 U.S.C. § 315(c); 37 C.F.R. § 42.122

I. INTRODUCTION

Regeneron Pharmaceuticals, Inc. ("Patent Owner" or "Regeneron") is the owner of U.S. Patent 11,253,572 B2 ("the '572 patent"). Paper 5, 1. On December 14, 2023, Celltrion, Inc. ("Petitioner" or "Celltrion") filed a Petition for *inter partes* review challenging the patentability of claims 1–30 (all claims) of the '572 patent. Paper 1 ("Pet."). The same day, Petitioner filed a Motion for Joinder, seeking that this proceeding be joined with pending *inter partes* review IPR2023-00884 ("IPR'884"). Paper 3 ("Motion" or "Mot."). On January 26, 2024, a conference call was held between the Panel, Celltrion, Biocon Biologics Inc. ("Biocon," the petitioner in related IPR2024-00298), Samsung Bioepis Co., Ltd. ("Samsung," the petitioner in related IPR'884), and Regeneron. *See* Paper 7. At this conference call, Regeneron indicated that it did not oppose Celltrion's Motion and waived its right to file a preliminary response in this proceeding. *Id.*

Under 37 C.F.R. § 42.4(a), we have authority to determine whether to institute trial in an *inter partes* review. We may institute an *inter partes* review if the information presented in the petition filed under 35 U.S.C. § 311, and any preliminary response filed under § 313, shows that there is a reasonable likelihood that Petitioner would prevail with respect to at least one of the claims challenged in the petition. 35 U.S.C. § 314.

As discussed below, we conclude Petitioner demonstrates a reasonable likelihood it would prevail in showing that at least one challenged claim of the '572 patent is unpatentable under the presented grounds. Therefore, we grant institution of *inter partes* review. Further, we grant Petitioner's unopposed Motion to join this proceeding with IPR'884.

A. REAL PARTIES-IN-INTEREST

Petitioner states, "[t]he real part[ies]-in-interest for Petitioner [are] Celltrion Inc., Celltrion Healthcare Co. Ltd. [a]nd Celltrion Healthcare U.S.A., Inc." Pet. 16. Patent Owner identifies itself, Regeneron, as the real party-in-interest. Paper 3, 1.

B. RELATED MATTERS

Regarding related matters, Petitioner states:

> Apotex filed an IPR Petition on September 9, 2022 asserting five grounds for invalidating the non-DME claims of the '572 patent, all of which recite "results limitations." Ex.1008 ("Apotex Petition"). Grounds 1-4 of Apotex's petition were based on anticipation: (1) anticipation of claims 1-5, 8-11, 14, and 26-30 based on Dixon; (2) anticipation of claims 1-5, 8-11, 14, and 26-30 based on a May 8, 2008 Regeneron Press Release; (3) anticipation of claims 1-5, 8-11, 14, and 26-30 based on NCT-795 (i.e., VIEW 1 ClinicalTrials.gov entry); and (4) anticipation of claims 1-5, 8-11, 14, and 26-30 based on NCT-377 (i.e., VIEW 2 ClinicalTrials.gov entry). Ex.1008, 12.
>
> With respect to the "results limitations" in these claims, Apotex argued that they (1) were not entitled to patentable weight (*id*., 17-20); or (2) were inherently anticipated by practice of the claimed method (*id*., 35-68). Notably, Apotex did not rely on obviousness to address the visual acuity limitations in any of the claims.
>
> Apotex only asserted obviousness for claims 6, 7, 12, and 13 in its Ground 5. For those claims, Apotex relied on any of the above anticipatory references in view of Hecht. Ex.1008, 12. Apotex's obviousness argument in Ground 5 was solely directed to the "isotonic solution" limitation in dependent claims 6 and 12 and the "nonionic surfactant" limitation in dependent claims 7 and 13—not the "results limitations." Ex.1008, 68-71.
>
> In its Institution Decision, the Board determined that the "results limitations" were entitled to patentable weight.

Ex.1004 ("Apotex '572 ID"), 14-18. The Board then went on to determine that the prior art did not inherently disclose the "results limitations" for at least two reasons: (1) less than all of the patients in the VIEW 1/2 trials achieved the claimed visual acuity limitations; and (2) the patient population reported in the prior art as achieving the recited gains was not the same as that described in the '572 patent. *Id*, 30-36. It therefore denied institution. *Id.*

The '572 patent is in the same family as U.S. Patent Nos. 9,254,338 ("'338 patent"), 9,669,069 ("'069 patent"), 10,130,681 ("'681 patent"), and 10,888,601 ("'601 patent"). Ex.1001.

In May 2021, Mylan Pharmaceuticals Inc. filed petitions requesting *inter partes* review of the '338 and '069 patents. *See* IPR2021-00881 ("'338 IPR") and IPR2021-00880 ("'069 IPR"). The Board instituted review for the '338 and '069 patents, and Celltrion filed joinder petitions to both of those proceedings—IPR2022-00258 and IPR2022-00257, respectively. The Board found all challenged claims of those patents unpatentable in Final Written Decisions issued on November 9, 2022. *See* Ex.1011, '338 IPR, Paper 94 ("'338 FWD"); '069 IPR, Paper 89. Regeneron appealed the Board's Final Written Decisions to the Court of Appeals for the Federal Circuit—Consolidated Appeal Nos. 2023-1395 and -001396.

Mylan filed a petition requesting IPR of the '681 patent on July 1, 2022 (IPR2022-01225) ("Mylan '681 IPR"). The Mylan '681 IPR was instituted on January 11, 2023. Ex.1012 ("'681 ID"). Celltrion filed a "copycat" petition and a motion for joinder on February 10, 2023. *See, Celltrion, Inc. v. Regeneron Pharmaceuticals, Inc.*, IPR2023-00532, Papers 2-3. The petition was granted on March 22, 2023. *See id.* Paper 7. Samsung Bioepis filed a petition against the '681 patent on January 6, 2023 (IPR2023-00442) asserting different grounds of invalidity than in the Mylan '681 IPR. The Board instituted review on July 19. 2023.

Mylan filed a petition requesting IPR of the non-DME claims of the '601 patent on July 1, 2022. *See* IPR2022-01226

("Mylan '601 IPR"). The Mylan 601 IPR was instituted on January 11, 2023. Ex.1013 ('601 ID). Celltrion filed a "copycat" petition and a motion for joinder on February 10, 2023. *See, Celltrion, Inc. v. Regeneron Pharmaceuticals, Inc.*, IPR2023-00533, Papers 2-3. The petition was granted on March 22, 2023. *See id.* Paper 7. Samsung Bioepis filed a "copycat" IPR petition on February 10, 2023. *See, Samsung Bioepis Co., Ltd. v. Regeneron Pharmaceuticals, Inc.*, IPR2023-00566, Papers 2-3. The Board instituted Samsung Bioepis' IPR petition and granted its motion for joinder on March 22, 2023 in IPR2023-00566. *Id.*, Paper 10.

Samsung Bioepis filed a petition requesting IPR of the DME claims of the '601 patent on March 26, 2023. *See Samsung Bioepis Co., Ltd. v. Regeneron Pharmaceuticals, Inc.*, IPR2023-00739. Institution was granted on October 20, 2023.

In the interest of completeness, Petitioner notes that it filed IPR2023-00462, challenging claims 1-18 of US Patent No. 10,464,992, which claims formulations of VEGF antagonists, i.e., formulations of aflibercept. Review was instituted on July 20, 2023. Samsung Bioepis filed a "copycat" IPR petition on August 18, 2023. *See, Samsung Bioepis Co., Ltd. v. Regeneron Pharmaceuticals, Inc.,* IPR2023-01312, Papers 1-2. The Board instituted Samsung Bioepis' IPR petition and granted its motion for joinder on December 11, 2023 in IPR2023-01312. *Id.*, Paper 30.

To the best of Petitioner's knowledge, the following are judicial or administrative matters that potentially would affect, or be affected by, a decision in this proceeding: *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.*, NDWV-1-22-cv-00061 ("Mylan Litigation"), *United States v. Regeneron Pharms., Inc.*, No. 1:20-cv-11217-FDS (D. Mass.).

Pet. 16–20.

Regarding related matters, Patent Owner states:

U.S. Patent No. 11,253,572 was previously challenged in *Apotex Inc. v. Regeneron Pharmaceuticals, Inc.*, Case No. IPR2022-01524 (P.T.A.B.). The '572 patent is also currently

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