UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2023-00884

U.S. Patent No. 11,253,572

PETITIONER'S AMENDED MANDATORY NOTICES

Pursuant to 37 C.F.R. § 42.8, Petitioner Samsung Bioepis Co., Ltd. ("Petitioner") respectfully submits the following mandatory notices to notify the Board of the addition of Zachariah Summers, Sarah M. Cork, and Elliot Choi from Quinn Emanuel LLP as back-up counsel. A current listing of counsel is provided below. Patent Owner also provides an update to the Related Matters.

A. Real Party-In-Interest (37 C.F.R. § 42.8(b)(1))

The real party-in-interest for Petitioner is Samsung Bioepis Co., Ltd.

B. Related Matters (37 C.F.R. § 42.8(b)(2)) (Amended)

Apotex filed an IPR Petition on September 9, 2022 asserting five grounds for invalidating the non-DME claims of U.S. Patent No. 11,253,572 ("'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 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. 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"). Petitioner filed a petition against the '681 patent on January 6, 2023 (IPR2023-00442) asserting different grounds of invalidity than in the Mylan '681 IPR. A decision on Petitioner's petition is pending. 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). Petitioner 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 Petitioner's IPR petition and granted its motion for joinder on March 22, 2023 in IPR2023-00566. *Id.*, Paper 10.

Petitioner 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. A decision on Petitioner's petition is pending.

Biocon Biologics Inc. filed a petition requesting IPR of the '601 patent on November 20, 2023 and filed a motion for joinder with the IPR2023-0079. *See*, Biocon v. Regeneron Pharmaceuticals, Inc., IPR2024-00566, Papers 2-3.

Biocon Biologics Inc. filed a petition requesting IPR of the '572 patent on December 18, 2023 and filed a motion for joinder with the above-captioned IPR. *See*, Biocon v. Regeneron Pharmaceuticals, Inc., IPR2024-00298, Papers 1-2.

Celltrion, Inc. filed a petition requesting IPR of the '572 patent on December 14, 2023 and filed a motion for joinder with the above-captioned IPR. *See*, Celltrion Inc. v. Regeneron Pharmaceuticals, Inc., IPR2024-00260, Papers 1-3.

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. Samsung Bioepis, Inc., No. 1:23-cv-00094 (N.D. W.Va.); Regeneron Pharmaceuticals, Inc. v. Samsung Bioepis, Inc., No. 1:23-cv-00106 (N.D. W.Va.); Regeneron Pharmaceuticals, Inc. v. Formycon, No. 1:23-cv-00097 (N.D. W.Va.); Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc., No. 1:22-cv-00061 (N.D. W.Va.); and Regeneron Pharmaceuticals, Inc. v. Celltrion, Inc., No. 1:23-CV-0089 (N.D. W.Va).

C. Lead and Backup Counsel (37 C.F.R. § 42.8(b)(3)-(4)) (Amended)

Petitioner hereby identifies its lead and backup counsel as follows:

Lead Counsel	Backup Counsel
Raymond N. Nimrod (Reg. No. 31,987) QUINN EMANUEL URQUHART & SULLIVAN, LLP 51 Madison Ave., 22nd Floor New York, NY 10010 General Tel: (212) 849-7000 Direct Tel: (212) 849-7322	Matthew A. Traupman (Reg. No. 50,832) Elliot Choi (*pro hac vice* to be applied for) QUINN EMANUEL URQUHART & SULLIVAN, LLP 51 Madison Ave., 22nd Floor New York, NY 10010

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