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 IPR2023-00739[1]

U.S. Patent No. 10,888,601

PETITIONER'S AMENDED MANDATORY NOTICES

[1] IPR2024-00201 has been joined with IPR2023-00739.

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 Richard Erwine 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)

Mylan filed a petition requesting IPR of U.S. Patent No. 10,888,601 ("'601 patent") on July 1, 2022, but that IPR does not involve any of the Challenged Claims here, which are directed to a specific indication (DR/DME) and different dosing regimen. *See* IPR2022-01226 ("Mylan IPR"). The Mylan IPR was instituted on January 11, 2023. Ex.1053, '601 ID. Petitioner filed a "copycat" IPR petition on February 10, 2023 copying Mylan's petition and seeking to join Mylan's IPR in a silent understudy role, rather than mount a redundant challenge in this petition to the non-DR/DME claims. *See*, Samsung Bioepis Co., Ltd. v. Regeneron Pharmaceuticals, Inc., IPR2023-00566, Papers 2-3. The Patent Trial and Appeal Board ("Board") instituted Petitioner's IPR petition and granted its motion for joinder on March 22, 2023 in IPR2023-00566. *Id.*, Paper 10.

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

The ’601 patent is in the same family as U.S. Patent Nos. 9,254,338 (“’338 patent”) and 9,669,069 (“’069 patent”). In May 2021, Mylan Pharmaceuticals Inc. filed petitions requesting for inter partes review of those two 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.1025, ’338 IPR, Paper 94 (“’338 FWD”); ’069 IPR, Paper 89.

The ’601 patent is also in the same family as U.S. Patent No. 10,130,681 (“’681 patent”). 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.1054, Mylan ’681 IPR Institution Decision (“’681 ID”). Petitioner filed a petition against the ’681 patent on January 6, 2023 asserting different grounds of invalidity than in the Mylan ’681 IPR. *See* IPR2023-00442.

The ’601 patent is also in the same family as U.S. Patent No. 11,253,572 (“’572 patent”).

Petitioner filed a petition requesting of the ’572 patent on April 27, 2023. *See* Samsung Bioepis Co., Ltd. v. Regeneron Pharmaceuticals, Inc., IPR2023-00884.

Celltrion, Inc. filed a petition requesting IPR of the ’572 patent on December 14, 2023 and filed a motion for joinder with IPR2023-00884. *See*, Celltrion Inc. v. Regeneron Pharmaceuticals, Inc., IPR2024-00260, Papers 1-3.

Biocon Biologics Inc. filed a petition requesting IPR of the ’572 patent on December 18, 2023 and filed a motion for joinder with IPR2023-00884. *See*, Biocon v. Regeneron Pharmaceuticals, Inc., IPR2024-00298, Papers 1-2.

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.); Regeneron Pharmaceuticals, Inc. v. Celltrion, Inc., No. 1:23-CV-0089 (N.D. W.Va.), and Regeneron Pharmaceuticals, Inc. v. Amgen, Inc., No. 2-24-00264 (C.D. Cal.). Out of abundance of caution, Patent Owner further identifies Chengdu Kanghong Biotechnology Co. Ltd. v. Regeneron Pharmaceuticals, Inc., Case No. PGR2021-00035 (P.T.A.B.) (proceeding terminated) regarding U.S. Patent No. 10,828,345, which is also related to the ’681 patent. Related U.S. Patent No. 10,857,205 was

challenged in Mylan Pharmaceuticals Inc. v. Regeneron Pharmaceuticals, Inc., Case No. IPR2023-00099 (P.T.A.B.).

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
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Pursuant to 37 C.F.R. § 42.10(b), a Power of Attorney has been filed herewith.

D. Service Information (37 C.F.R. § 42.8(b)(4))

Please send all correspondence to the lead and backup counsel at the addresses shown above. Petitioner consents to service by e-mail at qe-samsungbioepis@quinnemanuel.com.

DATED: March 26, 2024

Respectfully submitted,

By /Raymond N. Nimrod/

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Attorneys for Petitioner Samsung Bioepis

CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing Petitioner's Amended Mandatory Notice to 37 C.F.R. § 42.10(b) was served on March 26, 2024, to the following Counsel for Petitioner via email to Regeneron-MoFo-IPR@mofo.com and Counsel for Biocon Biologics, Inc. at MYL_REG_IPR@rmmslegal.com.

DATED: March 26, 2024

Respectfully submitted,

By /Raymond N. Nimrod/

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