

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 IPR2023-00442

U.S. Patent No. 10,130,681

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)

U.S. Patent No. 10,130,681 (“’681 patent”) is in the same family as U.S. Patent No. 9,254,338 (“’338 patent”) and U.S. Patent No. 9,669,069 (“’069 patent”). In May 2021, Mylan Pharmaceuticals Inc. (“Mylan”) filed petitions requesting for inter partes review of those two patents. See ’338 IPR and IPR2021-00880 (“’069 IPR”). The Board instituted petitions for the ’338 and ’069 patents and found all challenged claims unpatentable in Final Written Decisions issued on November 9, 2022. See Ex. 1004, ’338 FWD; Ex. 1046, ’069 IPR, Paper 89 (Nov. 9, 2022) (“’069 FWD”).

Mylan filed a petition requesting IPR of the ’681 patent on July 1, 2022 (IPR2022-01225) (“Mylan ’681 IPR”). The Board granted institution of the IPR in this proceeding on January 11, 2023.

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The '681 patent is in the same family as U.S. Patent Nos. 11,253,572 ("572 patent") and 10,888,601 ("601 patent").

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.

Biocon Biologics Inc. filed a petition requesting IPR of the '601 patent on November 20, 2023 and filed a motion for joinder with the IPR2023-00739. *See, Biocon v. Regeneron Pharmaceuticals, Inc.*, IPR2024-00566, Papers 2-3.

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,*

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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). 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. IPR202300099 (P.T.A.B.). A Decision Denying Institution of Inter Partes Review was issued on March 1, 2023.

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:

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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.

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DATED: January 4, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing PETITIONER'S AMENDED MANDATORY NOTICES was served on January 4, 2024, to the following Counsel for Petitioner via email to RegeneronEyleaIPRs@arnoldporter.com and the following addresses:

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