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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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SAMSUNG BIOEPIS CO., LTD.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner

_____

Case IPR2023-00442
U.S. Patent No. 10,130,681

PATENT OWNER'S AMENDED MANDATORY NOTICES

Pursuant to 37 C.F.R. § 42.8, Patent Owner Regeneron Pharmaceuticals, Inc. ("Patent Owner") respectfully submits the following mandatory notices to identify additional related matters.

I. 37 C.F.R. § 42.8(b)(1): NOTICE OF REAL PARTY-IN-INTEREST

U.S. Patent No. 10,130,681 ("the '681 Patent") is currently assigned to Regeneron Pharmaceuticals, Inc.

II. 37 C.F.R. § 42.8(b)(2): RELATED MATTERS (AMENDED)

The '681 Patent and related U.S. Patent No. 10,888,601 ("the '601 Patent") are being challenged in *Mylan Pharmaceuticals Inc. v. Regeneron Pharmaceuticals, Inc.*, Case No. IPR2022-01225 (P.T.A.B.) and in *Mylan Pharmaceuticals Inc. v. Regeneron Pharmaceuticals, Inc.*, Case No. IPR2022-01226 (P.T.A.B.), respectively. IPR2022-01225 was joined with IPR203-00532. IPR2022-01226 was joined with IPR2023-00533 and IPR2023-00566. Final Written Decisions were issued on January 9, 2024 in both IPR2022-01225 and IPR2022-01226.

The '601 Patent is also being challenged by Petitioner in *Samsung Bioepis Co., Ltd. v. Regeneron Pharmaceuticals, Inc.*, Case No. IPR2023-00739 (P.T.A.B.). The Board granted institution of the IPR in this proceeding on October 20, 2023. IPR2023-00739 was joined with IPR2024-00201.

Related U.S. Patent No. 11,253,572 ("the '572 Patent") was challenged in *Apotex Inc. v. Regeneron Pharmaceuticals, Inc.*, Case No. IPR2022-01524

(P.T.A.B.). A Decision Denying Institution of *Inter Partes* Review in IPR2022-01524 was issued on March 10, 2023. The '572 Patent is also being challenged by Petitioner in *Samsung Bioepis Co., Ltd. v. Regeneron Pharmaceuticals, Inc.*, Case No. IPR2023-00884 (P.T.A.B.). The Board granted institution of the IPR in this proceeding on November 17, 2023. IPR2023-00884 was joined with IPR2024-00260 and IPR2024-00298.

Related patents U.S. Patent Nos. 9,669,069 and 9,254,338 were challenged in *Mylan Pharmaceuticals Inc. v. Regeneron Pharmaceuticals, Inc.*, Case No. IPR2021-00880 (P.T.A.B.) and in *Mylan Pharmaceuticals Inc. v. Regeneron Pharmaceuticals, Inc.*, Case No. IPR2021-00881 (P.T.A.B.), respectively. IPR2021-00880 was joined with IPR2022-00257 and IPR2022-00301. IPR2021-00881 was joined with IPR2022-00258 and IPR2022-00298. Patent Owner has appealed the Board's decisions in those cases to the Federal Circuit, in *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.*, No. 2023-1395 (Fed. Cir.) and *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.*, No. 2023-1396 (Fed. Cir.), respectively.

Patent Owner identifies that a judgment was entered in *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.*, No. 1:22-cv-00061-TSK (N.D. W.Va.) on December 27, 2023, which may affect a decision in this proceeding.

The following judicial matters will affect, or be affected by, a decision in this proceeding: *Regeneron Pharmaceuticals, Inc. v. Celltrion, Inc.*, No. 1:23-CV-00089-TSK (N.D. W.Va), *Regeneron Pharmaceuticals, Inc. v. Samsung Bioepis, Co., Ltd.*, No. 1:23-cv-00094-TSK (N.D. W.Va.), *Regeneron Pharmaceuticals, Inc. v. Formycon AG*, 1:23-cv-00097-TSK (N.D. W.Va), *Regeneron Pharmaceuticals, Inc. v. Samsung Bioepis, Co., Ltd.*, No. 1:23-cv-00106-TSK (N.D. W.Va.), and *Regeneron Pharmaceuticals, Inc. v. Amgen, Inc.*, 2:24-cv-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.). A Decision Denying Institution of *Inter Partes* Review was issued on March 1, 2023.

III. 37 C.F.R. § 42.8(b)(3): LEAD AND BACK-UP COUNSEL

Patent Owner identifies the following lead and back-up counsel:

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IV. 37 C.F.R. § 42.8(b)(4): SERVICE INFORMATION

Patent Owner may be served at the addresses found in Part III. Patent Owner consents to electronic service at:

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Dated: February 14, 2024 Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing PATENT OWNER'S AMENDED MANDATORY NOTICES was served on February 14, 2024, to the following Counsel for Petitioner via e-mail at qe-samsungbioepis@quinnemanuel.com and:

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