

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD., CELLTRION INC,
and BIOCON BIOLOGICS INC.

Petitioners,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Patent No. 11,253,572

Inter Partes Review No. IPR2023-00884¹

PATENT OWNER'S UPDATED MANDATORY NOTICES

¹ IPR2024-00260 and IPR2024-00298 are joined with IPR2023-00884.

Patent Owner, Regeneron Pharmaceuticals, Inc., hereby files mandatory notices pursuant to 37 C.F.R. § 42.8(a)(3).

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

The real party-in-interest is Regeneron Pharmaceuticals, Inc.

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

In accordance with the Office Patent Trial Practice Guide (77 Fed. Reg. 48756, at 48759-60 (Aug. 14, 2012)), Patent Owner identifies the following related matters:

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.).

Related U.S. Patent No. 10,888,601 was challenged in *Mylan Pharmaceuticals Inc. v. Regeneron Pharmaceuticals, Inc.*, Case No. IPR2022-01226 (P.T.A.B.), which was joined with IPR2023-00533 and IPR2023-00566. Patent Owner has appealed the Board's decision in IPR2022-01226 to the Federal Circuit in *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.*, No. 24-1567 (Fed. Cir.). U.S. Patent No. 10,888,601 is also being challenged in *Samsung Bioepis Co., Ltd. v. Regeneron Pharmaceuticals, Inc.*, Case No. IPR2023-00739 (P.T.A.B.) and in *Biocon Biologics Inc. v. Regeneron Pharmaceuticals, Inc.*, Case No. IPR2024-00201 (P.T.A.B.), which has been joined with IPR2023-00739.

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Related U.S. Patent No. 10,130,681 was challenged in *Mylan Pharmaceuticals Inc. v. Regeneron Pharmaceuticals, Inc.*, Case No. IPR2022-01225 (P.T.A.B.), which was joined with IPR2023-00532. Patent Owner has appealed the Board's decision in IPR2022-01225 to the Federal Circuit in *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.*, No. 24-1564 (Fed. Cir.). U.S. Patent No. 10,130,681 is also being challenged in *Samsung Bioepis Co., Ltd. v. Regeneron Pharmaceuticals, Inc.*, Case No. IPR2023-00442 (P.T.A.B.).

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. IPR2021-000880 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.

U.S. Patent No. 11,253,572 and related patents have been asserted in *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.*, No. 1:22-cv-

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00061-TSK (N.D. W.Va.); *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*, No. 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. v. Regeneron Pharms., Inc.*, Case No. PGR2021-00035 (P.T.A.B.) (proceeding terminated) regarding related U.S. Patent No. 10,828,345.

Out of an abundance of caution, Patent Owner further identifies *Apotex Inc. v. Regeneron Pharmaceuticals, Inc.*, Case No. IPR2023-00099 (P.T.A.B.) (proceeding terminated), regarding related U.S. Patent No. 10,857,205, which Regeneron disclaimed.

Patent Owner does not concede that the identified matters would affect, or be affected by, a decision in the present *Inter Partes* Review of U.S. Patent No. 11,253,572.

C. Lead and Back-Up Counsel (37 C.F.R. § 42.8(b)(3)) – UPDATED

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