

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CELLTRION, INC.
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Patent No. 11,253,572

Inter Partes Review No. IPR2024-00260

PATENT OWNER'S MANDATORY NOTICES

Patent Owner, Regeneron Pharmaceuticals, Inc., hereby files mandatory notices pursuant to 37 C.F.R. § 42.8(a)(2).

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

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

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

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.). The '572 patent is also currently being challenged in *Samsung Bioepis Co., Ltd. v. Regeneron Pharmaceuticals, Inc.*, Case No. IPR2023-00884 (P.T.A.B), and *Biocon Biologics Inc. v. Regeneron Pharmaceuticals, Inc.*, Case No. IPR2024-00298.

Related U.S. Patent No. 10,888,601 is being challenged in *Mylan Pharmaceuticals Inc. v. Regeneron Pharmaceuticals, Inc.*, Case No. IPR2022-01226 (P.T.A.B.), in *Celltrion, Inc. v. Regeneron Pharmaceuticals, Inc.*, Case No. IPR2023-00533 (P.T.A.B.) and *Samsung Bioepis Co., Ltd. v. Regeneron Pharmaceuticals, Inc.*, Case No. IPR2023-00566 (P.T.A.B.), which have been joined with IPR2022-01226. U.S. Patent No. 10,888,601 is also being challenged

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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.).

Related U.S. Patent No. 10,130,681 is being challenged in *Mylan Pharmaceuticals Inc. v. Regeneron Pharmaceuticals, Inc.*, Case No. IPR2022-01225 (P.T.A.B.) and in *Celltrion, Inc. v. Regeneron Pharmaceuticals, Inc.*, Case No. IPR2023-00532 (P.T.A.B.), which has been joined with IPR2022-01225. U.S. Patent No. 10,130,681 is also being challenged in *Samsung Bioepis Co., Ltd. v. Regeneron Pharmaceuticals, Inc.*, Case No. 2023-00442 (P.T.A.B.).

Related 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.

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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-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 Biopis, Co., Ltd.*, No. 1:23-cv-00094-TSK (N.D. W.Va.); and *Regeneron Pharmaceuticals, Inc. v. Formycon AG*, No. 1:23-cv-00097-TSK (N.D. W.Va.).

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 abundance of caution, Patent Owner further identifies *Apotex Inc. v. Regeneron Pharmaceuticals, Inc.*, Case No. IPR2023-00099 (P.T.A.B.) (proceeding terminated), regarding U.S. Patent No. 10,857,205, which was related to U.S. Patent No. 11,253,572 and 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))

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A Power of Attorney is being filed concurrently with these Mandatory Notices.

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

Please direct all correspondence regarding this proceeding to the counsel at the addresses listed above. Patent Owner also consents to electronic service by email to Regeneron-MoFo-IPR@mofo.com.

The Patent Trial and Appeal Board is hereby authorized to charge any fees associated with this proceeding to Deposit Account **03-1952**.

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