

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIOCON BIOLOGICS INC.
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.
Patent Owner.

Patent No. 10,888,601

Inter Partes Review No. IPR2024-00201

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:

The '601 patent 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; and in *Samsung Bioepis Co., Ltd. v. Regeneron Pharmaceuticals, Inc.*, Case No. IPR2023-00739 (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.); in *Celltrion, Inc. v. Regeneron Pharmaceuticals, Inc.*, Case No. IPR2023-00532 (P.T.A.B.), which has been joined with IPR2022-01225; and in

IPR2024-00201

Samsung Bioepis Co., Ltd. v. Regeneron Pharmaceuticals, Inc., Case No.

IPR2023-00442 (P.T.A.B.).

Related U.S. Patent No. 11,253,572 was challenged in *Apotex Inc. v. Regeneron Pharmaceuticals, Inc.*, Case No. IPR2022-01524 (P.T.A.B.), and is also being challenged in *Samsung Bioepis Co., Ltd. v. Regeneron Pharmaceuticals, Inc.*, Case No. IPR2023-00884 (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.

The '601 Patent and related patents were asserted in each of *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 Bioepis,*

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 U.S. Patent No. 10,828,345, which is also related to U.S. Patent No. 10,888,601.

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 U.S. Patent No. 10,857,205, which was related to U.S. Patent No. 10,888,601 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. 10,888,601.

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

Lead Counsel	Backup Counsel
Adam R. Brausa Reg. No. 60,287 MORRISON & FOERSTER LLP 425 Market Street San Francisco, California 94105 Tel: (415) 268-6053 Fax: (415) 268-7522 ABrausa@mofo.com	Rebecca Weires Reg. No. 77,895 MORRISON & FOERSTER LLP 425 Market Street San Francisco, California 94105 Tel: (415) 268-6028 Fax: (415) 268-7522 RWeires@mofo.com

Backup Counsel	Backup Counsel
Kira A. Davis (<i>pro hac vice</i> to be filed) MORRISON & FOERSTER LLP 707 Wilshire Blvd., Suite 6000 Los Angeles, California 90017 Tel: (213) 892-5654 Fax: (213) 892-5454 KiraDavis@mofo.com	Daralyn J. Durie (<i>pro hac vice</i> to be filed) MORRISON & FOERSTER LLP 425 Market Street San Francisco, California 94105 Tel: (415) 268-6055 Fax: (415) 268-7522 DDurie@mofo.com

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** referencing docket no. **28410-00000.06.**

Dated: December 11, 2023

By: /Adam R. Brausa/
Adam R. Brausa, Reg. No. 60,287
MORRISON & FOERSTER LLP
425 Market Street
San Francisco, California 94105
Tel: (415) 268-6053
ABrausa@mofo.com

Counsel for Patent Owner

Certificate of Service (37 C.F.R. § 42.6(e)(4))

I hereby certify that the attached PATENT OWNER'S MANDATORY NOTICES and POWER OF ATTORNEY were served as of the below date via email on the Petitioner (by agreement) at the following correspondence address:

Paul J. Molino (Reg. No. 45,350)
William A. Rakoczy (*pro hac vice* pending)
Deanne M. Mazzochi (Reg. No. 50,158)
Heinz J. Salmen (*pro hac vice* pending)
Jeff A. Marx (Reg. No. 56,977)
Eric R. Hunt (*pro hac vice* pending)
Neil B. McLaughlin (Reg. No. 70,810)
Lauren M. Lesko (admitted *pro hac vice*)
L. Scott Beall (Reg. No. 52,601)
Thomas H. Ehrich (Reg. No. 67,122)
Steven J. Birkos (Reg. No. 65,300)
Rakoczy Molino Mazzochi Siwik LLP
6 West Hubbard Street
Chicago, IL 60654
Tel: (312) 222-6300
Tel: (312) 527-2157
Fax: (312) 843-6260
Email: MYL_REG_IPR@rmmslegal.com

Dated: December 11, 2023

/Adam R. Brausa/
Adam R. Brausa, Reg. No. 60,287