

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIOCON BIOLOGICS INC.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

IPR2024-00298
Patent 11,253,572 B2

Petitioner's Amended Mandatory Notices

Biocon Biologics Inc. (“Petitioner”) submits the following amended mandatory notices to identify additional related matters and to update back-up counsel information.

A. REAL PARTIES-IN-INTEREST (37 C.F.R. § 42.8(b)(1)).

Petitioner Biocon Biologics Inc., Biocon Limited, Biocon Biologics Limited, Biocon Biologics UK Limited, and Biosimilar Collaborations Ireland Limited are real parties-in-interest (“RPIs”) to the current Petition. Biocon Biologics Limited is a subsidiary of Biocon Limited, a publicly traded company. Biocon Biologics UK Limited is a wholly owned subsidiary of Biocon Biologics Limited, and Biosimilar Collaborations Ireland Limited and Biocon Biologics Inc. are wholly owned subsidiaries of Biocon Biologics UK Limited.

Further RPIs include Mylan Pharmaceuticals Inc. (“Mylan”) and Johnson & Johnson. Viatris Inc. and Mylan Inc. are parent companies of Mylan Pharmaceuticals Inc. Accordingly, Viatris Inc., Mylan Inc., and Mylan Pharmaceuticals Inc. are identified as RPIs to the current Petition. Momenta Pharmaceuticals, Inc. and Janssen Research & Development LLC are wholly-owned subsidiaries of Johnson & Johnson, a publicly held company. Momenta Pharmaceuticals, Inc., Janssen Research & Development LLC, and Johnson & Johnson are also RPIs to the current Petition.

No other parties exercised or could have exercised control over this Petition;

no other parties funded, directed, and controlled this Petition. *See* Trial Practice Guide, 15-16 (November 2019).

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

Petitioner identifies *Samsung Bioepis Co., Ltd. v. Regeneron Pharms., Inc.*, IPR2023-00884 (P.T.A.B.), *Mylan Pharms. Inc. v. Regeneron Pharms., Inc.*, No. IPR2022-01225 (P.T.A.B.), *Mylan Pharms. Inc. v. Regeneron Pharms., Inc.*, No. IPR2022-01226 (P.T.A.B.), *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, Nos. 2024-1567 and 2024-1564 (consolidated) (Fed. Cir.), and *In Re: Aflibercept Patent Litig.*, 1-24-md-03103-TSK (N.D.W. Va.). Petitioner also identifies *Mylan Pharms. Inc. v. Regeneron Pharms., Inc.*, No. IPR2021-00880 (P.T.A.B.), *Mylan Pharms. Inc. v. Regeneron Pharms., Inc.*, No. IPR2021-00881 (P.T.A.B.), *Mylan Pharms. Inc. v. Regeneron Pharms., Inc.*, No. IPR2023-00099 (P.T.A.B.), *Biocon Biologics Inc. v. Regeneron Pharms., Inc.*, No. IPR2024-00201 (P.T.A.B.), *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, No. 2023-1395 (Fed. Cir.), *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, No. 2023-1396 (Fed. Cir.), *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, 1:22-cv-00061-TSK (N.D.W. Va.); *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, Nos. 2024-1402 and 2024-1405 (consolidated) (Fed. Cir.);¹ *Regeneron Pharms., Inc. v. Celltrion, Inc.*, 1:23-cv-00089-TSK

¹ These consolidated appeals of the district court trial decision in *Regeneron*

(N.D.W. Va.); *Regeneron Pharms., Inc. v. Samsung Bioepis, Co. Ltd.*, 1:23-cv-00094-TSK (N.D.W. Va.); *Regeneron Pharms., Inc. v. Formycon AG*, 1:23-cv-00097-TSK (N.D.W. Va.); *Regeneron Pharms., Inc. v. Samsung Bioepis, Co. Ltd.*, 1:23-cv-00106-TSK (N.D.W. Va.); *Regeneron Pharms., Inc. v. Amgen Inc.*, 2:24-cv-00264-JAK-E (C.D. Cal.); and *Regeneron Pharms., Inc. v. Amgen Inc.*, 1:24-cv-00039-TSK. To the best of Petitioner’s knowledge, the following are additional judicial or administrative matters that would affect, or be affected by, a decision in this proceeding: *Celltrion, Inc. v. Regeneron Pharms., Inc.*, No. IPR2024-00260 (P.T.A.B.), *Apotex Inc. v. Regeneron Pharmaceuticals, Inc.*, No. IPR2022-01524 (P.T.A.B.), *Samsung Bioepis Co., Ltd. v. Regeneron Pharms., Inc.*, IPR2023-00442 (P.T.A.B.), *Samsung Bioepis Co. Ltd. v. Regeneron Pharms., Inc.*, No. IPR2023-00739 (P.T.A.B.), *United States v. Regeneron Pharms., Inc.*, No. 1:20-cv-11217-FDS (D. Mass.), and *Horizon Healthcare Servs., Inc. v. Regeneron Pharms., Inc.*, No. 1:22-cv-10493-FDS (D. Mass.).

U.S. Patent Nos. 9,254,338 B2; 9,669,069 B2; 10,857,205 B2; 10,828,345 B2; 10,130,681 B2; 10,888,601 B2; 11,559,564 B2; 11,707,506 B2; and 11,730,794 B2;

Pharms., Inc. v. Mylan Pharms. Inc., 1:22-cv-00061-TSK (N.D.W. Va.) have been dismissed given that the Court’s trial decision “resolved fewer than all claims at issue.” (See IPR2023-00884, Paper 55).

and U.S. Patent Application Nos. 17/072,417; 17/112,063; and 18/496,472 each claim the benefit of the '572 patent's purported priority date.

C. LEAD AND BACK-UP COUNSEL AND SERVICE INFORMATION (37 C.F.R. § 42.8(b)(3)-(4)).

Petitioner identifies its lead and backup counsel below.

Lead	Back-Up
<p>Paul J. Molino (Reg. No. 45,350) paul@rmmslegal.com</p> <p><u>Postal and Hand Delivery Address</u> Rakoczy Molino Mazzochi Siwik LLP 6 West Hubbard Street Chicago, IL 60654 Telephone: (312) 222-6300 Facsimile: (312) 843-6260</p> <p><i>Petitioner consents to email service at:</i> MYL_REG_IPR@rmmslegal.com</p>	<p>William A. Rakoczy (<i>pro hac vice</i> to be filed) wrakoczy@rmmslegal.com</p> <p>Deanne M. Mazzochi (Reg. No. 50,158) dmazzochi@rmmslegal.com</p> <p>Heinz J. Salmen (<i>pro hac vice</i> to be filed) hsalmen@rmmslegal.com</p> <p>Eric R. Hunt (<i>pro hac vice</i> to be filed) ehunt@rmmslegal.com</p> <p>Neil B. McLaughlin (Reg. No. 70,810) nmclaughlin@rmmslegal.com</p> <p>Lauren M. Lesko (<i>pro hac vice</i> to be filed) llesko@rmmslegal.com</p> <p>L. Scott Beall (Reg. No. 52,601) sbeall@rmmslegal.com</p> <p>Thomas H. Ehrich (Reg. No. 67,122) tehrich@rmmslegal.com</p>

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