

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

Before SUSAN L. C. MITCHELL, ROBERT A. POLLOCK, and
RYAN H. FLAX, *Administrative Patent Judges*.

FLAX, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
Granting Motion for Joinder
35 U.S.C. § 314; 35 U.S.C. § 315(c); 37 C.F.R. § 42.122

I. INTRODUCTION

Regeneron Pharmaceuticals, Inc. (“Patent Owner” or “Regeneron”) is the owner of U.S. Patent 11,253,572 B2 (“the ’572 patent”). Paper 5, 1. On December 18, 2023, Biocon Biologics Inc. (“Petitioner” or “Biocon”) filed a Petition for *inter partes* review challenging the patentability of claims 1–30 (all claims) of the ’572 patent. Paper 1 (“Pet.”). The same day, Petitioner filed a Motion for Joinder, seeking that this proceeding be joined with pending *inter partes* review IPR2023-00884 (“IPR’884”). Paper 2 (“Motion” or “Mot.”). On January 26, 2024, a conference call was held between the Panel, Biocon, Celltrion, Inc. (“Celltrion,” the petitioner in related IPR2024-00260),¹ Samsung Bioepis Co., Ltd. (“Samsung,” the petitioner in related IPR’884), and Regeneron. *See* Paper 8. At this conference call, Regeneron indicated that it did not oppose Celltrion’s Motion and waived its right to file a preliminary response in this proceeding. *Id.*

Under 37 C.F.R. § 42.4(a), we have authority to determine whether to institute trial in an *inter partes* review. We may institute an *inter partes* review if the information presented in the petition filed under 35 U.S.C. § 311, and any preliminary response filed under § 313, shows that there is a reasonable likelihood that Petitioner would prevail with respect to at least one of the claims challenged in the petition. 35 U.S.C. § 314.

As discussed below, we conclude Petitioner demonstrates a reasonable likelihood it would prevail in showing that at least one challenged claim of the ’572 patent is unpatentable under the presented

¹ IPR2024-00260 has been joined with IPR2023-00884.

grounds. Therefore, we grant institution of *inter partes* review. Further, we grant Petitioner's unopposed Motion to join this proceeding with IPR'884.

A. REAL PARTIES-IN-INTEREST

Petitioner states, 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. Viatri Inc. and Mylan Inc. are parent companies of Mylan Pharmaceuticals Inc. Accordingly, Viatri 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).

Paper 7, 1–2. Patent Owner identifies itself, Regeneron, as the real party-in-interest. Paper 5, 1.

B. RELATED MATTERS

Regarding related matters, Petitioner states:

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.), and *Mylan Pharms. Inc. v. Regeneron Pharms.*,

Inc., No. IPR2022-01226 (P.T.A.B.). 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. Celltrion, Inc.*, 1:23-cv-00089-TSK (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.); and *Regeneron Pharms., Inc. v. Amgen Inc.*, 2:24-cv-00264-JAK-E (C.D. Cal.). 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; 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.

Paper 7, 2–3. Regarding related matters, Patent Owner states:

U.S. Patent No. 11,253,572 was previously challenged in *Apotex Inc. v. Regeneron Pharmaceuticals, Inc.*, Case No.

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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 *Celltrion, Inc. v. Regeneron Pharmaceuticals, Inc.*, Case No. IPR2024-00260.

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 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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