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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. 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).

Paper 7, 1–2. Patent Owner identifies itself, Regeneron, as the real party-ininterest. 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.). Petitioneralso 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.

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. 2023-1395 (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-00061-TSK (N.D. W.Va.); *Regeneron Pharmaceuticals, Inc. v. Celltrion, Inc.*, No. 1:23cv-00089-TSK (N.D. W.Va.); *Regeneron Pharmaceuticals, Inc. v. Samsung Biopeis, 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.

Paper 5, 1–3.

C. The '572 Patent

The '572 patent is summarized in our Institution Decision ("DI") in IPR '884 (*see* Paper 13, 4–9, of that proceeding). Therefore, for efficiency's sake, we will not restate our summary of the challenged patent and its challenged claims, but refer to our decision in IPR '884, which is incorporated by reference.²

² The parties are not authorized to incorporate arguments or briefing by reference in any papers.

D. Asserted Grounds for Unpatentability

Petitioner, identically to Samsung in IPR'884 (*see* Paper 2, the petition in that proceeding) asserts the following grounds for the unpatentability of claims 1–30 of the '572 patent:

Ground	Claims Challenged	35 U.S.C. § ³	Reference(s)/Basis
1	15,24	102(a)	2009 PR ⁴ <i>or</i> Dec. 2010 PR, ⁵ individually
2	1–5, 8–11, 16, 17, 20, 21	102(a)	Dec. 2010 PR
3	26–30	102(a)	Nov. 2010 PR ⁶
4	1-5, 8-11, 26-30	103(a)	Dixon, ⁷ 2006 PR ⁸

³ The priority date to be accorded the '572 patent is contested (*see* Pet. 16–17); however, as discussed in our Institution Decision in IPR'884 (DI 9 n.1, 30–34), we agree with Patent Owner that all claims should be accorded at least a January 21, 2011, priority date, which is before the AIA revisions to 35 U.S.C. §§ 102 and 103 took effect on March 16, 2013. 35 U.S.C. § 100 (note). Therefore, pre-AIA § 102 and § 103 apply.

⁴ Regeneron, Enrollment Completed in Regeneron and Bayer HealthCare Phase 3 Studies of VEGF Trap-Eye in Neovascular Age-Related Macular Degeneration (Wet AMD) (Sept. 14, 2009) (Ex. 1005, "2009 PR").

⁵ Regeneron, Regeneron and Bayer Report Positive Results for VEGF Trap-Eye in Phase 3 Study in Central Retinal Vein Occlusion (CRVO) and in Phase 2 Study in Diabetic Macular Edema (DME) (Dec. 20, 2010) (Ex. 1006, "Dec. 2010 PR").

⁶ Regeneron, Bayer and Regeneron Report Positive Top-Line Results of Two Phase 3 Studies with VEGF Trap-Eye in Wet Age-related Macular Degeneration (Nov. 22, 2010) (Ex. 1007, "Nov. 2010 PR").

⁷ James A. Dixon et al., *VEGF Trap-Eye for the treatment of neovascular age-related macular degeneration*, 18(10) EXPERT OPIN. INVESTIG. DRUGS 1573–80 (2009) (Ex. 1009, "Dixon").

⁸ Regeneron Pharm., Regeneron Reports Positive Phase 1 Data for the VEGF Trap in Age-Related Macular Degeneration, Preliminary results show improvements in vision and retinal swelling, VEGF Trap was well tolerated

Ground	Claims Challenged	35 U.S.C. § ³	Reference(s)/Basis
5	16, 17, 20, 21	103(a)	2009 PR, 2007 ARVO, ⁹
			Dixon, 2010 ARVO ¹⁰
6	6, 7, 12, 13	103(a)	Dixon, Hecht, ¹¹ 2006
			PR, Dec. 2010 PR
7	18, 19, 22, 23	103(a)	Dec. 2010 PR, Hecht,
			2009 PR, 2007 ARVO,
			Dixon, 2010 ARVO
8	14	103(a)	Dixon, Dec. 2010 PR,
			CATT, ¹² PIER,
9	25	103(a)	2009 PR, Shams, ¹³
			Elman 2010 ¹⁴
10	1-5, 8-11, 26-30	102(a)	Dixon
11	1-5, 8-11, 26-30	102(a)	2009 PR

at all dose levels, Company also announces initiation of phase 2 trial (May 1, 2006) (Ex. 1027, "2006 PR").

⁹ D.V. Do et al., ARVO Annual Meeting Abstract, *Results of a Phase I Study of Intravitreal VEGF Trap in Subjects with Diabetic Macular Edema: The CLEAR-IT DME Study*, 48 Investigative Ophthalmology & Visual Sci. 1430 (May 2007) (Ex. 1030, "2007 ARVO").

¹⁰ J.C. Major, Jr. & D.M. Brown, ARVO Annual Meeting Abstract, *DA VINCI: DME and VEGF Trap-Eye: Investigation of Clinical Impact: Phase 2 Study in Patients with Diabetic Macular Edema (DME)*, 51 Investigative Ophthalmology & Visual Sci. 6426 (April 2010) (Ex. 1010, "2010 ARVO").

¹¹ Gerald Hecht, PhD, *Ophthalmic Preparations*, in II REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY, 19th ed., Ch. 89, 1563–76 (Alfonso R. Gennaro ed., 1995) (Ex. 1016, "Hecht").

¹² CATT and PIER refer to clinical trials concerning ranibizumab and bevacizumab, and are described in the Petition as encompassing Exhibits 1020–1026.

¹³ WO 2006/047325 A1 (published May 4, 2006) (Ex. 1017, "Shams").

¹⁴ Michael J. Elman et al., Randomized Trial Evaluating Ranibizumab Plus Prompt or Deferred Laser or Triamcinolone Plus Prompt Laser for Diabetic Macular Edema, 117(6) OPHTHALMOLOGY 1064–77 (June 2010) (Ex. 1018, "Elman 2010"). See Pet. 14–16. We instituted trial in IPR'884 on all of the above-listed grounds. See generally IPR'884 DI.

In support of these grounds for unpatentability Petitioner submits, *inter alia*, the Declaration of Edward Chaum, MD. Ex. 1002. Petitioner certifies in its Motion that this is "the same expert declaration" as filed by Samsung in IPR'884. Mot. 3.

II. INSTITUTION OF TRIAL

A. INSTITUTION IS WARRANTED

The Petition here is substantively identical to Samsung's Petition in IPR'884, challenging the same patent and claims, based on the same grounds of unpatentability, and relying upon the same evidence (including the same prior art combinations and supported by the same expert declaration). *See generally* Pet.; *see also* Mot. 5 (Petitioner certifies that the Petition here and that of the Samsung IPR'884 are "Substantively Identical"). Petitioner seeks institution over the same claims and under the same grounds for which the Board instituted in IPR'884, stating that "[t]he instant petition for IPR filed by Biocon challenges the same patent claims, contains the same grounds of unpatentability, and is the same in all substantive aspects as the Samsung IPR['884], aside from minor non-substantive edits to accommodate word count." Mot. 5.

We explained in our Institution Decision in IPR'884 why we conclude that Samsung demonstrated a reasonable likelihood of prevailing at trial in showing that the challenged claims are unpatentable. *See generally* IPR'884 DI. The present Petition advances identical arguments, challenging the same claims over the same combinations of prior art. We consequently adopt the same reasoning here as in our IPR'884 Institution Decision, and conclude

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that Petitioner is likely to prevail in demonstrating the unpatentability of the same challenged claims. *Id.* We incorporate our previous analysis regarding the asserted grounds of unpatentability and conclude that Petitioner demonstrates a reasonable likelihood of prevailing at trial with respect to at least one claim of the '572 patent challenged in the Petition for the same reasons as in IPR'884. *See id.*

Therefore, we determine that the Petition warrants institution of *inter partes* review on all claims and all grounds asserted in the Petition. 37 C.F.R. § 42.108(a) ("When instituting . . . review, the Board will authorize the review to proceed on all of the challenged claims and on all grounds of unpatentability asserted for each claim."); *see also SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018).

III. JOINDER WITH IPR2023-00884

A. LEGAL STANDARD FOR JOINDER

The Patent Act, 35 U.S.C. § 315(c), governs joinder of *inter partes* review proceedings and states:

(c) JOINDER. — If the Director institutes an interpartes review, the Director, in his or her discretion, may join as a party to that inter partes review any person who properly files a petition under section 311 that the Director, after receiving a preliminary response under section 313 or the expiration of the time for filing such a response, determines warrants the institution of an inter partes review under section 314.

Joinder may be authorized when warranted, but the decision to grant joinder is discretionary. *See* 35 U.S.C. § 315(c); 37 C.F.R. § 42.122. We determine whether to grant joinder on a case-by-case basis, taking into account the particular facts of each case, substantive and procedural issues, and other considerations. When exercising that discretion, we are mindful

that patent trial regulations, including the rules for joinder, must be construed to secure the just, speedy, and inexpensive resolution of every proceeding. *See* 35 U.S.C. § 316(b); 37 C.F.R. § 42.1(b).

As the moving party, Petitioner bears the burden of proving that it is entitled to the requested relief. 37 C.F.R. § 42.20(c). A motion for joinder should: (1) set forth the reasons joinder is appropriate; (2) identify any new grounds of unpatentability asserted in the petition; and (3) explain what impact (if any) joinder would have on the trial schedule for the existing review. *See Kyocera Corp. v. Softview, LLC,* IPR2013-00004, Paper 15 at 4 (PTAB Apr. 24, 2013); *see also,* USPTO, *America Invents Act (AIA) Frequently Asked Questions,*" *available at:* uspto.gov/patents/laws/americainvents-act-aia/america-invents-act-aia-frequently-asked#type-inter-partesreview_3244 (last visited February 2, 2022).

B. JOINDER IS WARRANTED

Petitioner filed its Petition and Motion for Joinder on December 18, 2023, which was within one month of our IPR'884 DI (entered Nov. 17, 2023), thus, the Motion is timely (December 17, 2023, a Sunday, was a non-business day). 37 C.F.R. § 42.122(b).

Petitioner certifies and we agree that the Petition is substantively identical to that of IPR'884, where we found Samsung had met its burden to show a reasonable likelihood it would prevail at trial in establishing at least one challenged claim unpatentable under the asserted grounds. Mot. 5–6, 8; *see generally* IPR'884 DI. Petitioner also certifies and we agree that it relies on the same evidence here as in IPR'884. Mot. 5–6. Patent Owner waives its right to file a preliminary response in this proceeding, for the sake of efficiency. *See* Paper 8, 2.

Petitioner also certifies that it will take on a "limited understudy role" with respect to Samsung in IPR'884 if the proceedings are joined; thus, there will be no impact to the schedule of that instituted trial. Mot. 5–6 n.2, 7–9. Moreover, Petitioner asserts that, structured in this way, the joined proceeding will simplify briefing and discovery (i.e., they will be singular, rather than occurring in two proceedings). *Id.* at 7.

Petitioner asserts that Patent Owner will not be prejudiced by joinder. *Id.* at 9–10. As noted above, Patent Owner does not oppose the motion and, so, does not expressly disagree. *See* Paper 8.

Here, institution is warranted, and joining this proceeding with IPR'884 will provide a more just, speedy, and inexpensive resolution of the proceeding(s). We conclude the circumstances warrant the joinder of this proceeding with IPR'884.

IV. CONCLUSION

Having reviewed the Petition, as well as Petitioner's representations in its Motion for Joinder, which Patent Owner does not oppose, we determine that, under the circumstances, it is appropriate to institute *inter partes* review of the challenged claims based upon the same grounds authorized and for the same reasons discussed in our Institution Decision in IPR'884 (*see generally* IPR'884 DI) and to grant Petitioner's Motion for Joinder. This Decision does not constitute a final decision regarding the patentability of any challenged claim.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–30 of U.S. Patent 11,253,572 B2 is instituted with

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respect to all grounds and challenged claims as set forth in the Petition and shall commence on the entry date of this Decision, and notice is hereby given of the institution of trial;

FURTHER ORDERED that Petitioner's Motion for Joinder with IPR2023-00884 (Paper 2) is *granted*, IPR2024-00298 is terminated, and this proceeding is hereby joined with IPR2023-00884;

FURTHER ORDERED that the Scheduling Order entered in IPR2023-00884 (*see* Papers 14 and 18, and *see also* Paper 28 (stipulated modifications) in that proceeding) shall govern the trial schedule;

FURTHER ORDERED that Petitioner's role in IPR2023-00884 shall be limited as stated by Petitioner in the Motion for Joinder (Paper 2) unless and until Samsung is terminated from that proceeding;

FURTHER ORDERED that the case caption in IPR2023-00884 shall be changed, and a footnote added, to reflect joinder of Biocon Biologics Inc. as a petitioner in accordance with the attached example;

FURTHER ORDERED that a copy of this Decision will be entered into the record of IPR2023-00884; and

FURTHER ORDERED that all further filings shall be made in IPR2023-00884.

FOR PETITIONER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

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REGENERON PHARMACEUTICALS, INC., Patent Owner.

IPR2023-00884¹ Patent 11,253,572 B2

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