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Paper 8
Date: January 30, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CELLTRION, INC.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

IPR2024-00260
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 14, 2023, Celltrion, Inc. ("Petitioner" or "Celltrion") 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 3 ("Motion" or "Mot."). On January 26, 2024, a conference call was held between the Panel, Celltrion, Biocon Biologics Inc. ("Biocon," the petitioner in related IPR2024-00298), Samsung Bioepis Co., Ltd. ("Samsung," the petitioner in related IPR'884), and Regeneron. *See* Paper 7. 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 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, "[t]he real part[ies]-in-interest for Petitioner [are] Celltrion Inc., Celltrion Healthcare Co. Ltd. [a]nd Celltrion Healthcare U.S.A., Inc." Pet. 16. Patent Owner identifies itself, Regeneron, as the real party-in-interest. Paper 3, 1.

B. RELATED MATTERS

Regarding related matters, Petitioner states:

> Apotex filed an IPR Petition on September 9, 2022 asserting five grounds for invalidating the non-DME claims of the '572 patent, all of which recite "results limitations." Ex.1008 ("Apotex Petition"). Grounds 1-4 of Apotex's petition were based on anticipation: (1) anticipation of claims 1-5, 8-11, 14, and 26-30 based on Dixon; (2) anticipation of claims 1-5, 8-11, 14, and 26-30 based on a May 8, 2008 Regeneron Press Release; (3) anticipation of claims 1-5, 8-11, 14, and 26-30 based on NCT-795 (i.e., VIEW 1 ClinicalTrials.gov entry); and (4) anticipation of claims 1-5, 8-11, 14, and 26-30 based on NCT-377 (i.e., VIEW 2 ClinicalTrials.gov entry). Ex.1008, 12.
>
> With respect to the "results limitations" in these claims, Apotex argued that they (1) were not entitled to patentable weight (*id*., 17-20); or (2) were inherently anticipated by practice of the claimed method (*id*., 35-68). Notably, Apotex did not rely on obviousness to address the visual acuity limitations in any of the claims.
>
> Apotex only asserted obviousness for claims 6, 7, 12, and 13 in its Ground 5. For those claims, Apotex relied on any of the above anticipatory references in view of Hecht. Ex.1008, 12. Apotex's obviousness argument in Ground 5 was solely directed to the "isotonic solution" limitation in dependent claims 6 and 12 and the "nonionic surfactant" limitation in dependent claims 7 and 13—not the "results limitations." Ex.1008, 68-71.
>
> In its Institution Decision, the Board determined that the "results limitations" were entitled to patentable weight.

Ex.1004 ("Apotex '572 ID"), 14-18. The Board then went on to determine that the prior art did not inherently disclose the "results limitations" for at least two reasons: (1) less than all of the patients in the VIEW 1/2 trials achieved the claimed visual acuity limitations; and (2) the patient population reported in the prior art as achieving the recited gains was not the same as that described in the '572 patent. *Id*, 30-36. It therefore denied institution. *Id.*

The '572 patent is in the same family as U.S. Patent Nos. 9,254,338 ("'338 patent"), 9,669,069 ("'069 patent"), 10,130,681 ("'681 patent"), and 10,888,601 ("'601 patent"). Ex.1001.

In May 2021, Mylan Pharmaceuticals Inc. filed petitions requesting *inter partes* review of the '338 and '069 patents. *See* IPR2021-00881 ("'338 IPR") and IPR2021-00880 ("'069 IPR"). The Board instituted review for the '338 and '069 patents, and Celltrion filed joinder petitions to both of those proceedings—IPR2022-00258 and IPR2022-00257, respectively. The Board found all challenged claims of those patents unpatentable in Final Written Decisions issued on November 9, 2022. *See* Ex.1011, '338 IPR, Paper 94 ("'338 FWD"); '069 IPR, Paper 89. Regeneron appealed the Board's Final Written Decisions to the Court of Appeals for the Federal Circuit—Consolidated Appeal Nos. 2023-1395 and -001396.

Mylan filed a petition requesting IPR of the '681 patent on July 1, 2022 (IPR2022-01225) ("Mylan '681 IPR"). The Mylan '681 IPR was instituted on January 11, 2023. Ex.1012 ("'681 ID"). Celltrion filed a "copycat" petition and a motion for joinder on February 10, 2023. *See, Celltrion, Inc. v. Regeneron Pharmaceuticals, Inc.*, IPR2023-00532, Papers 2-3. The petition was granted on March 22, 2023. *See id.* Paper 7. Samsung Bioepis filed a petition against the '681 patent on January 6, 2023 (IPR2023-00442) asserting different grounds of invalidity than in the Mylan '681 IPR. The Board instituted review on July 19. 2023.

Mylan filed a petition requesting IPR of the non-DME claims of the '601 patent on July 1, 2022. *See* IPR2022-01226

("Mylan '601 IPR"). The Mylan 601 IPR was instituted on January 11, 2023. Ex.1013 ('601 ID). Celltrion filed a "copycat" petition and a motion for joinder on February 10, 2023. *See, Celltrion, Inc. v. Regeneron Pharmaceuticals, Inc.*, IPR2023-00533, Papers 2-3. The petition was granted on March 22, 2023. *See id.* Paper 7. Samsung Bioepis filed a "copycat" IPR petition on February 10, 2023. *See, Samsung Bioepis Co., Ltd. v. Regeneron Pharmaceuticals, Inc.*, IPR2023-00566, Papers 2-3. The Board instituted Samsung Bioepis' IPR petition and granted its motion for joinder on March 22, 2023 in IPR2023-00566. *Id.*, Paper 10.

Samsung Bioepis filed a petition requesting IPR of the DME claims of the '601 patent on March 26, 2023. *See Samsung Bioepis Co., Ltd. v. Regeneron Pharmaceuticals, Inc.*, IPR2023-00739. Institution was granted on October 20, 2023.

In the interest of completeness, Petitioner notes that it filed IPR2023-00462, challenging claims 1-18 of US Patent No. 10,464,992, which claims formulations of VEGF antagonists, i.e., formulations of aflibercept. Review was instituted on July 20, 2023. Samsung Bioepis filed a "copycat" IPR petition on August 18, 2023. *See, Samsung Bioepis Co., Ltd. v. Regeneron Pharmaceuticals, Inc.,* IPR2023-01312, Papers 1-2. The Board instituted Samsung Bioepis' IPR petition and granted its motion for joinder on December 11, 2023 in IPR2023-01312. *Id*., Paper 30.

To the best of Petitioner's knowledge, the following are judicial or administrative matters that potentially would affect, or be affected by, a decision in this proceeding: *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.*, NDWV-1-22-cv-00061 ("Mylan Litigation"), *United States v. Regeneron Pharms., Inc.*, No. 1:20-cv-11217-FDS (D. Mass.).

Pet. 16–20.

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 *Biocon Biologics Inc. v. Regeneron Pharmaceuticals, Inc.*, Case No. IPR202400298.

Related U.S. Patent No. 10,888,601 is being challenged in *Mylan Pharmaceuticals Inc. v. Regeneron Pharmaceuticals, Inc.*, Case No. IPR202201226 (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. IPR202201225 (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. IPR202100880 (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. IPR202100881 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. 20231396 (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. 1:23-cv-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. PGR202100035 (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 3, 1–3.

C. THE '572 PATENT

The '572 patent is summarized in our Institution Decision 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.[1]

[1] 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. §[2]	Reference(s)/Basis
1	15, 24	102(a)	2009 PR[3] ***or*** Dec. 2010 PR,[4] individually
2	1–5, 8–11, 16, 17, 20, 21	102(a)	Dec. 2010 PR
3	26–30	102(a)	Nov. 2010 PR[5]
4	1–5, 8–11, 26–30	103(a)	Dixon,[6] 2006 PR[7]

[2] The priority date to be accorded the '572 patent is contested (*see* Pet. 25); however, as discussed in our Institution Decision in IPR2023-00884 (Paper 13, 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.

[3] 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").

[4] 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").

[5] 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").

[6] 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").

[7] 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. §[2]	Reference(s)/Basis
5	16, 17, 20, 21	103(a)	2009 PR, 2007 ARVO,[8] Dixon, 2010 ARVO[9]
6	6, 7, 12, 13	103(a)	Dixon, Hecht,[10] 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,[11] PIER,
9	25	103(a)	2009 PR, Shams,[12] Elman 2010[13]
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").

[8] 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").

[9] 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").

[10] 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").

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

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

[13] 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. 22–24. We instituted trial in IPR'884 on all of the above-listed grounds. *See* IPR'884 DI.

In support of these grounds for unpatentability Petitioner submits, *inter alia*, the Declaration of Christine Kay, MD. Ex. 1002. Petitioner certifies in its Motion that "[t]he conclusions and underlying reasoning of [Dr. Kay and Dr. Chaum, Samsung's declaration witness in IPR'884,] are identical." Mot. 1 n.1.

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 a substantially "identical" expert declaration). *See generally* Pet.; *see also* Mot. 1 (Petitioner certifies that "[t]he instant Petition is substantially the same as the Samsung IPR['884]: it involves the same patent, same claims, same grounds of unpatentability, and the same evidence[] (including the same prior art combinations) as the Samsung IPR['884]."). Petitioner seeks institution of the same claims and grounds for which the Board instituted trial in IPR'884, stating that the "Petition does not raise any new grounds of unpatentability" and that the

> Petition is substantially identical to the petition in the Samsung IPR, challenging the same claims of the '572 Patent on the same grounds and relying on the same testimony from an expert declarant. Thus, the only difference between Celltrion's Petition and the petition filed in the Samsung IPR are the sections on Real Party-In-Interest, Related Matters, and Counsel, which have been appropriately updated.

Mot. 4, 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 that Petitioner is similarly 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*.

Based on the record before us, 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 inter partes 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/america-invents-act-aia/america-invents-act-aia-frequently-asked#type-inter-partes-review_3244 (last visited February 2, 2022).

B. JOINDER IS WARRANTED

Petitioner filed its Petition and Motion for Joinder on December 14, 2023, which was within one month of our IPR'884 DI (entered Nov. 17, 2023), thus, the Motion is timely. 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; *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. Patent Owner waives its right to file a preliminary response in this proceeding, for the sake of efficiency. *See* Paper 7, 2.

Petitioner also certifies that it will be a "silent understudy" 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. 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 6–7.

Petitioner asserts that Patent Owner will not be prejudiced by joinder. *Id.* at 7. As noted above, Patent Owner does not oppose the motion and, so, does not expressly disagree. Paper 7.

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 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 3) is *granted*, IPR2024-00260 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 3) 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 Celltrion 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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[joined case caption]

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

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IPR2023-00884[1]
Patent 11,253,572 B2

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