

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.,  
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,  
Patent Owner.

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IPR2023-01312  
Patent 10,464,992 B2

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Before JOHN G. NEW, SUSAN L.C. MITCHELL, and JAMIE T. WISZ,  
*Administrative Patent Judges.*

WISZ, *Administrative Patent Judge.*

DECISION

Granting Institution of *Inter Partes* Review

35 U.S.C. § 314

Granting Motion for Joinder

35 U.S.C. § 315(c); 37 C.F.R. § 42.122

## I. INTRODUCTION

Samsung Bioepis Co., Ltd. (“Petitioner” or “Samsung”) has timely filed a Petition (“Samsung Petition” or “Pet.”) requesting *inter partes* review of claims 1–18 of U.S. Patent No. 10,464,992 B2 (Ex. 1001, “the ’992 patent”). Paper 1 (“Pet.”). Petitioner also timely filed a Motion for Joinder (“Motion” or “Mot.” (Paper 2)) requesting to join this proceeding with *Celltrion, Inc. v. Regeneron Pharms., Inc.*, IPR2023-00462, filed January 17, 2023, and instituted on July 20, 2023 (the “*Celltrion* IPR”). See *Celltrion* IPR, Paper 11. Regeneron Pharmaceuticals, Inc. (“Patent Owner”) did not timely file a preliminary response or oppose the Motion.

For the reasons set forth below, we (1) institute *inter partes* review based on the same grounds as instituted in the *Celltrion* IPR, and (2) GRANT Petitioner’s Motion for Joinder, subject to the conditions detailed herein.

## II. INSTITUTION OF INTER PARTES REVIEW

In the *Celltrion* IPR, we instituted trial on the following grounds:

Ground	Claims Challenged	35 U.S.C. §	Reference(s)
1	1–18	102	Fraser <sup>1</sup>

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<sup>1</sup> Fraser, Hamish M. et al., *Single Injections of Vascular Endothelial Growth Factor Trap Block Ovulation in the Macaque and Produce a Prolonged, Dose-Related Suppression of Ovarian Function*, J. Clin. Endocrinology & Metabolism, Vol. 90, No. 2, 1114–1122 (2005).

Ground	Claims Challenged	35 U.S.C. §	Reference(s)
2	1–18	103	Fraser, Wulff <sup>2</sup> , Holash <sup>3</sup> , '319 Publication <sup>4</sup> , '309 Publication <sup>5</sup> , McNally 2000 <sup>6</sup> , FDA Guidance <sup>7</sup>

*Celltrion* IPR, Paper 11, 7–8, 41.

The Samsung Petition is substantially identical to the petition in the *Celltrion* IPR, challenging the same claims of the same patent, based on the same grounds of unpatentability, and relying upon the same evidence (including the same prior art combinations supported by the same expert declaration). *See* Mot. 1, 3; Pet. 40–41. At this stage of the instant proceeding, Patent Owner has not raised any arguments in response to the substantive grounds of the Samsung Petition. Petitioner undertakes, if the Motion is granted, to assume a “limited ‘understudy’ role,” so long as

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<sup>2</sup> Wulff, Christine et al., *Prevention of Thecal Angiogenesis, Antral Follicular Growth, and Ovulation in the Primate by Treatment with Vascular Endothelial Growth Factor Trap R1R2*, *Endocrinology*, Vol. 143, No. 7, 2797–2807 (2002).

<sup>3</sup> Holash, Jocelyn et al., *VEGF-Trap: A VEGF blocker with potent antitumor effects*, *PNAS*, Vol. 99, No. 17, 11393–11398 (2002).

<sup>4</sup> Papadopoulos et al., WO 00/75319 A1, published Dec. 14, 2000.

<sup>5</sup> Kandel et al., US 2004/0265309 A1, published Dec. 30, 2004.

<sup>6</sup> Paul McGoff & David S. Scher, *Solution Formulation of Proteins/Peptides in PROTEIN FORMULATION AND DELIVERY* vol. 99, 139–58 (Eugene J. McNally ed., 2000).

<sup>7</sup> Food & Drug Administration, *Guidance for Industry, Container Closure Systems for Packaging Human Drugs and Biologics* (May 1999).

Celltrion, Inc. (“Celltrion”), the petitioner in the *Celltrion* IPR, remains as an active party in that proceeding. Mot. 1. Petitioner asserts that the proposed joinder will neither create additional burdens for the Board nor impact the schedule of the *Celltrion* IPR, and, accordingly, will promote judicial efficiency. *Id.*

In view of these representations by Petitioner, and having reviewed the petition in the *Celltrion* IPR, we determine that, under the current circumstances, it is appropriate to exercise our discretion 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 the *Celltrion* IPR. *See Celltrion* IPR, Paper 11.

### III. JOINDER OF *INTER PARTES* REVIEWS

An *inter partes* review may be joined with another *inter partes* review, subject to the provisions 35 U.S.C. § 315(c), which governs joinder of *inter partes* review proceedings:

(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.

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: set forth the reasons joinder is appropriate; identify any new grounds of unpatentability asserted in the petition; and 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](https://uspto.gov/patents/laws/america-invents-act-aia/america-invents-act-aia-frequently-asked#type-inter-partes-review_3244) (last visited February 2, 2022).

Petitioner timely filed its Motion within one month of the institution of the *Celltrion* IPR, as required by 37 C.F.R. § 42.122(b). In the Motion, Petitioner asserts that “[j]oinder is appropriate in this case because it is the most expedient way to secure the just, speedy, and inexpensive resolution of the two related proceedings,” the Samsung Petition “is *identical* with respect to the grounds instituted in the *Celltrion* IPR,” and “[j]oinder will not impact the Board’s ability to complete its review in a timely manner and would have no impact on the *Celltrion* IPR schedule.” Mot. 5–6.

Having considered the unopposed Motion for Joinder, and in light of our decision to institute on the same grounds as in the *Celltrion* IPR, we determine that Petitioner has persuasively established that joinder is appropriate and will have little to no impact on the timing, cost, or presentation of the trial in the *Celltrion* IPR. Thus, in consideration of the foregoing, and in the manner set forth in the following Order, the Motion for Joinder is GRANTED.

#### IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that a trial is instituted in IPR2023-01312 on the following grounds:

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Ground I: Claims 1–18 of the '992 patent under 35 U.S.C. § 102 as anticipated by Fraser.

Ground II: Claims 1–18 of the '992 patent under 35 U.S.C. § 103 as obvious over Fraser, Wulff, Holash, '319 Publication, '309 Publication, McNally 2000, and FDA Guidance.

FURTHER ORDERED that Petitioner's Motion for Joinder with IPR2023-00462 is GRANTED;

FURTHER ORDERED that IPR2023-01312 is terminated and joined with IPR2023-00462, pursuant to 37 C.F.R. §§ 42.72, 42.122, wherein Samsung will maintain a secondary role in the proceeding, unless and until Celltrion ceases to participate as a petitioner in the *inter partes* review;

FURTHER ORDERED that the Scheduling Order in place for IPR2023-00462, along with modifications appropriately stipulated to by the parties, shall govern the joined proceeding;

FURTHER ORDERED that all future filings in the joined proceeding are to be made only in IPR2023-00462;

FURTHER ORDERED that the case caption in IPR2023-00462 for all further submissions shall be changed to add Samsung Bioepis Co., Ltd. as a named petitioner after the Celltrion petitioner, and a footnote shall be added to indicate the joinder of IPR2023-001312 to that proceeding, as shown in the attached sample case caption; and

FURTHER ORDERED that a copy of this Decision shall be entered into the record of IPR2023-00462.

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Joined Case Caption

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<sup>1</sup> IPR2023-01312 has been joined with this proceeding.