

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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BIOCON BIOLOGICS INC.,  
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,  
Patent Owner.

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*Inter Partes* Review No.: IPR2024-00298

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U.S. Patent No. 11,253,572  
Filed: June 21, 2021  
Issued: February 22, 2022  
Inventor: George D. Yancopoulos

Title: USE OF A VEGF ANTAGONIST TO TREAT  
ANGIOGENIC EYE DISORDERS

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**PETITIONER'S MOTION FOR JOINDER PURSUANT TO 35 U.S.C.  
§ 315(c) AND 37 C.F.R. §§ 42.22 AND 42.122(b)**

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## **I. STATEMENT OF THE PRECISE RELIEF REQUESTED.**

Petitioner Biocon Biologics Inc. (“Biocon”) filed the present petition for *inter partes* review (the “Biocon IPR”) and respectfully submits this Motion for Joinder. Pursuant to 35 U.S.C. § 315(c), 37 C.F.R. §§ 42.22, and 42.122(b), Biocon requests institution of *inter partes* review concerning U.S. Patent No. 11,253,572 (“the ‘572 patent”) and joinder with the *inter partes* review concerning the same patent in *Samsung Bioepis Co., Ltd. v. Regeneron Pharmaceuticals, Inc.*, assigned Case No. IPR2023-00884 (the “Samsung IPR”), which was instituted on November 17, 2023. Samsung Bioepis Co., Ltd. (“Samsung”) indicated it does not oppose Petitioner’s motion.

In accordance with the Patent Trial and Appeal Board’s (“Board”) Representative Order identifying matters to be addressed in a motion for joinder, *Kyocera Corp. v. Softview LLC*, IPR2013-00004, Paper 15 (P.T.A.B. Apr. 24, 2013), Biocon submits that: (1) joinder is appropriate because it will promote efficient determination of the validity of the ‘572 patent without prejudice to the prior petitioner, Samsung, or to the owner of the ‘572 patent, Regeneron Pharmaceuticals, Inc. (“Regeneron” or “Patent Owner”); (2) Biocon’s Petition raises the same grounds of unpatentability over the same prior art as those instituted by the Board in the Samsung IPR; (3) joinder would not affect the pending schedule in the Samsung IPR nor increase the complexity of that proceeding, thereby minimizing costs; and (4)

Biocon is willing to agree to consolidated filings with Samsung to minimize the burden and the impact on the schedule. *See, e.g., Motorola Mobility LLC v. Softview LLC*, IPR2013-00256, Paper 10 (P.T.A.B. June 20, 2013) (granting motion for joinder under similar circumstance); *Amneal Pharms. LLC v. Yeda Rsch. & Dev. Co., Ltd.*, IPR2015-01976, Paper 9 (P.T.A.B. Dec. 28, 2015) (same).

This Motion for Joinder is timely under 37 C.F.R. §§ 1.7, 42.22 and 42.122(b), as it is submitted within one month of November 17, 2023, the date on which the Samsung IPR was instituted.

## **II. STATEMENT OF MATERIAL FACTS.**

Biocon requests institution of an *inter partes* review on the ‘572 patent and asserts the same grounds of unpatentability that were instituted in the Samsung IPR.

On November 17, 2023, the Board instituted trial on claims 1-30 (the “Challenged Claims”) of the ‘572 patent in the Samsung IPR based on several grounds of unpatentability raised by Samsung. The instant petition for IPR filed by Biocon challenges the same patent claims,<sup>1</sup> contains the same grounds of

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<sup>1</sup> Following a finding of no patentable weight for the results limitations, Patent Owner stipulated to summary judgment on claims 1-5, 8-11, 14, and 26-28 in the associated district court litigation, *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, 1:22-cv-00061-TSK (N.D.W. Va.) (“Mylan Litigation”), but subject to all “appellate

unpatentability, and those grounds are the same in all substantive aspects as the Samsung IPR. Both petitions contain the same analysis and exhibits, and rely upon the same expert declaration.

### **III. STATEMENT OF REASONS FOR RELIEF REQUESTED.**

Biocon respectfully requests that the Board exercise its discretion and grant joinder of the Biocon IPR and the Samsung IPR proceedings pursuant to 35 U.S.C. § 315(c), 37 C.F.R. § 42.22, and 37 C.F.R. § 42.122(b). In support of this motion, Biocon proposes consolidated filings and other procedural accommodations designed to streamline the proceedings.

The Leahy-Smith America Invents Act (AIA) permits joinder of *inter partes* review proceedings. The statutory provision governing joinder of *inter partes* review proceedings is 35 U.S.C. § 315(c), which reads as follows:

(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

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rights, including but not limited to rights of appeal concerning claim construction.”

Ex.1068, 1.

expiration of the time for filing such a response, determines warrants the institution of an inter partes review under section 314.

Congress further clarified that the one-year litigation time bar, “shall not apply to a request for joinder under subsection (c).” 35 U.S.C. § 315(b).

In exercising its discretion to grant joinder, the Board considers the impact of substantive and procedural issues on the proceedings, as well as other considerations, while being “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 Dell Inc. v. Network-1 Sec. Sols., Inc.*, IPR2013-00385, Paper 17, 3 (P.T.A.B. July 29, 2013). The Board should consider “the policy preference for joining a party that does not present new issues that might complicate or delay an existing proceeding.” *Id.*, 10. Under this framework, joinder of the present Biocon IPR with the Samsung IPR is appropriate.

“A motion for joinder should: (1) set forth the reasons why joinder is appropriate; (2) identify any new grounds of unpatentability asserted in the petition; (3) explain what impact (if any) joinder would have on the trial schedule for the existing review; and (4) address specifically how briefing and discovery may be simplified.” *Id.*, 4. Each of these is addressed fully below.



**A. Reasons Why Joinder is Appropriate.**

Joinder 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. *See* 35 U.S.C. § 316(b); 37 C.F.R. § 42.1(b). Joinder will allow the Board to resolve the unpatentability of the Challenged Claims without any significant impact on the Samsung IPR. Intentionally, the Biocon IPR is substantively identical with respect to the grounds in the Samsung IPR in an effort to avoid multiplication of issues before the Board. Given the duplicative nature of these petitions, joinder of the related proceedings is appropriate and conserves Board resources. Further, Biocon will agree to consolidated filings and discovery, and procedural concessions, so that in this matter Biocon will be bound by the schedule set forth in the Samsung IPR.

**1. Substantively Identical Petitions.**

The 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, aside from minor non-substantive edits to accommodate word count.<sup>2</sup> Both petitions contain the same analysis and exhibits, and Biocon

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<sup>2</sup> Petitioner Biocon is mindful of the Board's findings in its Institution Decision, and that its findings in-part conflict with the decision of the Court in the Mylan Litigation with regard to the patentable weight of the Results Limitations. Biocon also is aware

intends to rely upon the same expert declaration. The only differences are in the party-specific portions of the petition (*e.g.*, discretionary denial, mandatory notices, etc.). Because the Board has already instituted trial in the Samsung IPR, *see Samsung Bioepis Co., Ltd. v. Regeneron Pharms., Inc.*, IPR2023-00884, Paper 13 (P.T.A.B. Nov. 17, 2023), the substantively identical Biocon IPR will not require additional Board resources to determine that institution on the same grounds as in the Samsung IPR institution decision is appropriate here. Indeed, in circumstances such as these, the PTO anticipated that joinder would be granted as a matter of right. *See* 157 CONG. REC. S1376 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl).

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that the Board expressed skepticism about some of the Grounds initially asserted in the Samsung Petition. Given Biocon’s limited understudy role, and for as long as Samsung remains a party in its IPR, Biocon will defer to Samsung with regard to these arguments and Grounds. To be clear, the inclusion of all arguments and Grounds included in the Samsung Petition in the Biocon Petition is for purposes of providing a “copycat” petition along with Biocon’s concurrent joinder motion, and is not intended to signal that Biocon will present additional argument or modify the Samsung Petition Grounds, or, for the purposes of this IPR only, contest the Board’s decision regarding the patentable weight of the Results Limitations, while in its limited understudy role.

## **2. Simplification of Briefing and Discovery as an “Understudy.”**

Because the grounds of unpatentability and the prior art relied on in the Biocon IPR and the instituted Samsung IPR are the same, Biocon is amenable to undertaking the role of an “understudy” to simplify the proceeding. As an “understudy,” Biocon agrees that, if joined, the following conditions will apply so long as Samsung remains an active party:

- All filings by Biocon in the joined proceeding will be consolidated with the filings of IPR2023-00884, unless a filing solely concerns issues that do not involve Samsung;
- Going forward, in the event of joinder, Biocon agrees to consolidated filings and discovery;
- Biocon shall not be permitted to raise any new grounds, or art combinations, not instituted by the Board in the Samsung IPR, or introduce any argument not already introduced by Samsung;
- With regard to taking of testimony, Biocon will abide by 37 C.F.R. § 42.53 or any agreement between the Patent Owner and Samsung.

*See Mylan Pharms. Inc. v. Novartis AG*, IPR2015-00268, Paper 17, 5-6 (P.T.A.B. Apr. 10, 2015) (defining the aforementioned conditions as “consistent with the ‘understudy’ role that [Biocon] agrees to assume”); *see also Celltrion, Inc. v. Regeneron Pharms., Inc.*, IPR2022-00257, Paper 3, 6 (P.T.A.B. Dec. 9, 2021)

(motion requesting the same granted in related Regeneron patent proceedings). Biocon further agrees that Samsung will manage all depositions and will lead in all discovery matters, and that Biocon will not receive any separate cross-examination or redirect time from that of Samsung, and will not have separate oral argument time at the hearing, unless agreed to by the parties or requested by the Board.

Should joinder be granted, Biocon is prepared to rely solely on the testimony of Samsung's expert, Dr. Chaum. To be clear, as long as the Samsung IPR remains pending following joinder, no additional discovery from Biocon would be needed, and Biocon would agree to a subordinate role, allowing Samsung to take lead in all discovery matters and the cross-examination of any witness produced by Patent Owner.

### **3. No New Grounds of Unpatentability.**

The Biocon IPR contains the same grounds of unpatentability instituted in the Samsung IPR. In fact, the grounds of unpatentability are identical in all substantive respects. The Biocon IPR contains the same analysis and exhibits, and relies on the same expert opinions. The Biocon IPR does not alter, nor otherwise seek to supplement the arguments or prior art combinations instituted in the Samsung IPR, nor in Dr. Chaum's expert opinions already submitted in the Samsung IPR. As a result, the Biocon IPR raises no new grounds of unpatentability from those of the Samsung IPR.

#### **4. No Impact on IPR Trial Schedule.**

The difference between the filing date of the Biocon IPR and the Samsung IPR is without consequence should the proceedings be joined. The trial schedule for the Samsung IPR would not need to be delayed to effect joinder based on Patent Owner's preliminary response and later-filed Biocon IPR, and Biocon agrees to be bound by the Scheduling Order in the Samsung IPR. Indeed, given that the Biocon IPR asserts substantively identical grounds of unpatentability as those instituted in the Samsung IPR, and presents no new invalidity arguments or evidence for the Board or Patent Owner to address, there should be no need for the Patent Owner to submit a preliminary response, and because no new issues are being raised, there will be no need for the Board to alter or extend any of the current deadlines. The joint proceeding would allow the Board and parties to focus on the merits in one consolidated proceeding, and in a timely manner.

#### **5. Joinder Will Not Prejudice Patent Owner or Samsung.**

Biocon's participation in this proceeding does not result in any prejudice to Patent Owner for several reasons. First, no additional grounds or arguments are being introduced. Second, no new evidence or issues are being added and no additional briefing should be necessary. Third, joinder preserves judicial economy

without prejudice to Patent Owner, who will be involved in the Samsung IPR regardless of Biocon's participation.

#### **IV. PROPOSED ORDER.**

Petitioner proposes a joinder order for consideration by the Board as follows:

- The Biocon IPR will be instituted and joined with the Samsung IPR on the same grounds as those for which review was instituted in the Samsung IPR.
- The scheduling order for the Samsung IPR will apply to the joined proceeding.
- Biocon will take an "understudy" role to Samsung in the proceeding.

#### **V. CONCLUSION.**

For the foregoing reasons, Biocon respectfully requests that its Petition for *inter partes* review of claims 1-30 of U.S. Patent No. 11,253,572 be instituted and that the proceeding be joined with *Samsung Bioepis Co., Ltd. v. Regeneron Pharmaceuticals, Inc.*, IPR2023-00884. Although no additional fee is believed to be required for this Motion, the Commissioner is hereby authorized to charge any additional fees which may be required for this Motion to Deposit Acct. No. 503626.

Dated: December 18, 2023

Respectfully Submitted,

RAKOCZY MOLINO MAZZOCHI SIWIK LLP

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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a true and correct copy of the foregoing **Petitioner's Motion for Joinder Pursuant to 35 U.S.C. § 315(c) and 37 C.F.R. §§ 42.22 and 42.122(b)** was served on December 18, 2023, via FedEx Priority Overnight on the Patent Owner at the correspondence address of record for U.S. Patent No. 11,253,572 as evidenced in Patent Center:

A&P - Regeneron (Prosecution)  
601 Massachusetts Ave., NW  
Washington, DC 20001-3743

/Paul J. Molino/  
\_\_\_\_\_  
Paul J. Molino (Reg. No. 45,350)