

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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BIOCON BIOLOGICS, INC. and  
BIOCON BIOLOGICS LIMITED,  
Petitioners

v.

REGENERON PHARMACEUTICALS, INC.,  
Patent Owner

U.S. Patent No. 12,168,036 to Graham  
Issue Date: December 12, 2024  
Title: Methods for Treating Angiogenic Eye Disorders  
with High Doses of VEGF Receptor Fusion Proteins

Post Grant Review No. PGR2026-00039

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**PETITIONERS' REPLY TO  
PATENT OWNER'S OPPOSITION TO  
PETITIONERS' MOTION FOR JOINDER**

## **I. INTRODUCTION**

Pursuant to 37 C.F.R. §§ 42.23-42.25, Petitioners Biocon Biologics, Inc. and Biocon Biologics Limited (together, “Biocon”) submit this reply to the first three arguments<sup>1</sup> in Patent Owner Regeneron Pharmaceuticals, Inc. (“PO”)’s Opposition (Paper 7, “Opp.”) to Biocon’s Motion for Joinder (Paper 3). PO never argues that Biocon’s motion for joinder itself was untimely or that the joinder factors weigh against joinder. Instead, PO opposes joinder only by arguing that Biocon’s underlying *petition* is untimely and then takes issue with the governing regulation for allowing joinder in this instance. PO’s position would essentially eliminate joinder in PGRs, and consequently leave potential challengers with no available relief whatsoever during the entire pendency of a PGR proceeding. That would not only be highly inefficient but would also open the door to inappropriate gamesmanship. The Board can and should grant Biocon’s motion for joinder.

## **II. ARGUMENT**

PO does not deny that Biocon’s motion for joinder is proper under 37 C.F.R. § 42.222(b), because it was “filed . . . no later than one month after the institution date.” Rather, PO relies on 35 U.S.C. § 321(c) to argue that joinder should also require the movant to have filed its copycat PGR petition within 9 months of the patent grant. PO acknowledges, and in fact expressly argues, that its position would

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<sup>1</sup> Biocon does not oppose the limitations discussed in PO’s fourth argument.

render Section 42.222(b) invalid for lacking this additional requirement. PO's position is both legally mistaken and unsound from a public policy perspective.

While section 321(c) states that a PGR petition “may only be filed not later than” 9 months after the patent grant, section 311(c) states that an IPR petition “shall be filed after the later of either (1) the date that is 9 months after the grant of a patent; or (2) if a post-grant review is instituted . . . *the termination of such post-grant review.*” 35 U.S.C. §§ 321(c), 311(c) (emphasis added). Both provisions, however, are *silent* with respect to joinder and neither addresses the intervening period after the 9-month date but when an IPR is not yet available due to a pending PGR.

The Director is expressly authorized under section 326(a)(4), a statute that PO ignores altogether, to prescribe regulations “establishing and governing a post-grant review under [chapter 35] and the relationship of such review to other proceedings under this title [i.e., IPRs].” 35 U.S.C. § 326(a)(4). Thus, the Director had broad discretion to promulgate 37 C.F.R. § 42.222(b), allowing a copycat PGR petition to be filed with a motion for joinder within one month of a PGR being instituted, during the period when that already-pending PGR makes an IPR unavailable.

None of PO's counterarguments are persuasive. PO first points to the Board's decision in *Apple Inc. v. RF Cyber Corp.*, Opp. at 4, but that decision actually favors Biocon's position. In *Apple*, the Board first extensively considered the timeliness of the joinder motion itself—which differs from the present case in that it was filed

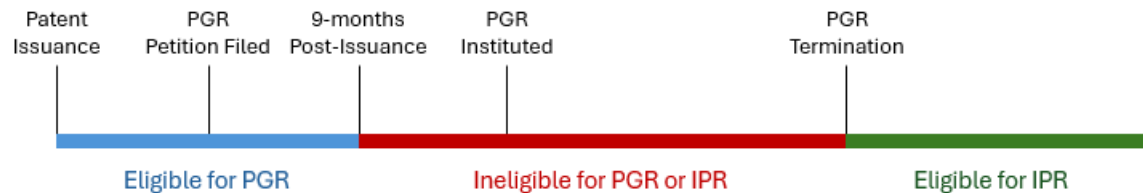
after the one-month period set by 37 C.F.R. § 42.222(b). Furthermore, only after denying joinder did the Board go on to address the underlying petition, where it simply denied it “in view of our decision to deny Petitioner’s Motion for Joinder.” *Apple Inc. v. RFCyber Corp.*, PGR2022-00003, Paper 10, at 8 (P.T.A.B. Mar. 24, 2022). PO argues that in *Apple*, the timing of the underlying petition was dispositive such that the large bulk of that decision considering joinder was all for naught. Opp. at 12. The Board clearly thought otherwise.

PO next points to section 315(b), which both sets forth a requirement to file an IPR petition within a year of a district court complaint and then negates that requirement in the case of a joinder motion. Opp. at 6-7. But that section is inopposite, because there is no corresponding requirement based on a district court complaint imposed on PGRs in the first place, and thus nothing to negate. *Compare* 35 U.S.C. § 315(b) *with* 35 U.S.C. § 325(b).

PO then argues that allowing a petition to be joined more than nine months after patent issuance would “flaunt *Congress*’ intended policy of ensuring that patents are never simultaneously eligible for both PGR and IPR.” Opp. at 8. But Petitioners did not file an IPR (nor could it have in view of the pending PGR) and is not attempting to make PO’s patent simultaneously eligible for an IPR and PGR. Instead, as illustrated below, PO’s interpretation would leave a period of time—including the period directly following a determination that there is a reasonable

likelihood a patent is invalid—when a patent is not eligible for *any* new review and a potential challenger would have *no* available recourse before the PTAB.

Under Plaintiffs' Interpretation:



This cannot be what Congress intended. The precursor version of section 311 allowed *inter partes* reexamination “at any time,” 35 U.S.C. § 311(a) (1999), and it would be incongruous to believe that Congress replaced that regime with one where a patent is entirely insulated from new challengers during a PGR proceeding.<sup>2</sup> PO’s position that a motion for joinder must be based on a PGR petition filed before the nine-month mark would all but eliminate post-institution joinder, because institution decisions are due six months after the petition and thus nearly always issue after the nine-month date. Preventing joinder in this way is highly inefficient.

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<sup>2</sup> Notably, PGRs were modeled on EPO Opposition proceedings, where parties are allowed to intervene after the 9-month filing deadline. *See* Art. 105 EPC (allowing “interven[tion] in opposition proceedings after the opposition period has expired”); *see Patent Quality Improvement: Post-Grant Opposition Hr’g*, 108th Cong. 2 (2004) (noting European Opposition proceeding that “permits challengers to contest a wider range of issues” but “must be made within 9 months of a patent’s issuance”).

PO's position would also enable inappropriate gamesmanship. For example, a patent owner facing a pending PGR institution could quickly file a new district court case against other opponents so that the IPR time bar begins at the same time as the PGR proceeding. In so doing, the patent owner would be able to run out the clock with the one-year time bar fully blocked by the one-year-long PGR proceeding, such that the district court defendants would have no opportunity at all to participate in any review proceeding.

Ensuring that questionable patents, especially those where institution of a PGR petition is granted, are subject to review serves the public interest to improve patent quality. *Magnolia Medical Techs., Inc. v. Kurin, Inc.*, IPR2026-00097, Paper 17 (“the central purpose of IPRs is to determine whether the patent at issue may have been improvidently granted and whether and to what extent that right should continue to be recognized at all”). PO's interpretation of the statutes and regulations leaves a weak patent immune from joinder by additional parties. This would be highly inefficient and detrimental to the public's interest in improving patent quality. Accordingly, PO's attack on 37 C.F.R. § 42.222(b) should be rejected and Petitioners' motion for joinder should be granted.

### **III. CONCLUSION**

For these reasons, Biocon respectfully requests that its Motion be granted.

Respectfully submitted,

Dated: May 29, 2026

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**CERTIFICATION UNDER 37 C.F.R. § 42.24(c)(2)**

The undersigned certifies that Petitioners' Reply to Patent Owner's Opposition to Petitioners' Motion for Joinder complies with the 5-page limit provided in 37 C.F.R. § 42.24(c)(2).

Dated: May 29, 2026

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**CERTIFICATE OF SERVICE**  
**(37 C.F.R. § 42.6(e))**

The undersigned hereby certifies that on May 29, 2026, I caused true and correct copies of the following materials:

- Petitioners' Reply to Patent Owner's Opposition to Petitioners' Motion for Joinder

to be served via e-mail on the following:

| Name                 | E-Mail Address                                          |
|----------------------|---------------------------------------------------------|
| David I. Berl        | <u><a href="mailto:dberl@wc.com">dberl@wc.com</a></u>   |
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