

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE OFFICE OF THE UNDER SECRETARY OF COMMERCE
FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE
UNITED STATES PATENT AND TRADEMARK OFFICE

BIOCON BIOLOGICS, INC. and
BIOCON BIOLOGICS LIMITED,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

PGR2026-00039
Patent 12,168,036 B2

Before JOHN A. SQUIRES, *Under Secretary of Commerce for Intellectual
Property and Director of the United States Patent and Trademark Office.*

DECISION
Denying Institution of Post-Grant Review

Biocon Biologics, Inc. and Biocon Biologics Limited (collectively “Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting post-grant review of claims 1–38 of U.S. Patent No. 12,168,036 B2 (Ex. 1001, “the ’036 patent”). Petitioner also filed a Motion for Joinder (Paper 3, “Mot.”) requesting to join as a party to PGR2025-00085 (the “Alvotech PGR”) filed by Alvotech USA Inc. and Alvotech hf. (collectively, “Alvotech”). Mot. 1. Regeneron Pharmaceuticals, Inc. (“Patent Owner”) filed an Opposition to Petitioner’s Motion for Joinder (Paper 7, “Opp.”), and Petitioner filed a Reply in support of its Motion for Joinder (Paper 8, “Reply”).

Patent Owner filed a request for discretionary denial (Paper 9, “DD Req.”), and Petitioner filed an opposition (Paper 15, “DD Opp.”). On August 6, 2026, after considering the parties’ arguments and the record, and in view of all relevant considerations, I issued a Notice indicating that institution was denied in this proceeding. Paper 17.

The ’036 patent issued on December 17, 2024. Alvotech properly filed its petition in the Alvotech PGR on September 17, 2025, and institution was granted on March 3, 2026. PGR2025-00085, Paper 10. Petitioner filed its Petition for post-grant review on April 2, 2026, within one month of institution in the Alvotech PGR, but more than nine months from the issue date of the ’036 patent.

Petitioner acknowledges that the ’036 patent issued more than nine months before it filed the Petition, but argues that institution should be granted “under 37 C.F.R. § 42.222(b), which permits requests for joinder ‘no later than one month after the institution date of any post-grant review for which joinder is requested.’” Mot. 7. Patent Owner argues that institution is barred because the Petition was filed more than nine months after the ’036 patent issued. Opp. 4. Patent Owner further contends that any interpretation

of 37 C.F.R. § 42.222(b) permitting joinder after nine months from issuance, but within one month of institution of a timely petition, “would render that regulation invalid as contrary to the plain text of 35 U.S.C. § 321(c).” *Id.* at 11.

I agree with Patent Owner that the Petition is barred by § 321(c). Section 321(c) provides that “[a] petition for a post-grant review may only be filed not later than the date that is 9 months after the date of the grant of the patent or of the issuance of a reissue patent (as the case may be).” Joinder is authorized under 35 U.S.C. § 325(c), which provides that “[i]f more than 1 petition for a post-grant review under this chapter is properly filed against the same patent and the Director determines that more than 1 of these petitions warrants the institution of a post-grant review under section 324, the Director may consolidate such reviews into a single post-grant review.” Notably, the statutory authorization for joinder under § 325(c) does not provide an exception to the nine-month statutory bar, as it requires any petition considered for joinder to be “properly filed,” i.e., to meet the statutory filing requirements including the nine-month filing deadline recited in § 321(c). Petitioner argues that I have broad discretion to promulgate rules and permit exceptions, such as here where institution would increase efficiency. *See* Reply 2–3. I agree that my institution discretion is broad. But § 325(c) provides no exception to the time period in which a petition for post-grant review may be filed.¹ The board rule on which Petitioner relies cannot override a clear statutory requirement, and Petitioner does not point

¹ Although the Office continues to encourage joinder and early challenges to increase efficiency and resolve patentability challenges early in the life of the patent, these considerations must follow the statute.

to any statutory provision that would create an exception to the filing deadline in § 321(c).²

In consideration of the foregoing, it is:

ORDERED that the Petition is *denied*, and no trial is instituted.

² Although a party seeking joinder typically files its petition after institution of the lead case, I note that 37 C.F.R. § 42.222(b) provides only a deadline for a request for joinder. Given the limited time frame for filing a request for post-grant review, parties should consider filing their petition and motion for joinder before a decision on institution in the lead case.

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FOR PETITIONER:

Alexander Ott
Jovial Wong
Alison King
WINSTON TAYLOR LLP
alexander.ott@winstontaylor.com
jovial.wong@winstontaylor.com
alison.king@winstontaylor.com

FOR PATENT OWNER:

David Berl
Andrew Trask
WILLIAMS & CONNOLLY LLP
dberl@wc.com
atrask@wc.com