

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

AMGEN INC.,
Petitioner,

v.

BRISTOL-MYERS SQUIBB COMPANY,
Patent Owner.

IPR2025-00601 (Patent 9,856,320 B2)
IPR2025-00602 (Patent 10,174,113 B2)
IPR2025-00603 (Patent 11,332,529 B2)

Before COKE MORGAN STEWART, *Acting Under Secretary of
Commerce for Intellectual Property and Acting Director of the United States
Patent and Trademark Office.*

DECISION

Denying Institution of *Inter Partes* Review in IPR2025-00601 and
IPR2025-00602 and Referring the Petition in IPR2025-00603 to the Board

IPR2025-00601 (Patent 9,856,320 B2)
IPR2025-00602 (Patent 10,174,113 B2)
IPR2025-00603 (Patent 11,332,529 B2)

Bristol-Myers Squibb Company (“Patent Owner”) filed a request for discretionary denial (Paper 6, “DD Req.”) in each of the above-captioned cases, and Amgen Inc. (“Petitioner”) filed an opposition (Paper 8, “DD Opp.”).¹

After considering the parties’ arguments and the record, and in view of all relevant considerations, discretionary denial of institution is appropriate in IPR2025-00601 and IPR2025-00602, but is not appropriate in IPR2025-00603. This determination is based on the totality of the evidence and arguments the parties have presented.

Some factors counsel against discretionary denial. For example, the parties are not currently engaged in a parallel proceeding involving the challenged patents. DD Opp. 21. As a result, there is currently no concern of inconsistent outcomes and duplication of efforts resulting from two proceedings operating in parallel.

Additionally, the patent challenged in IPR2025-00603 has not been in force for a significant amount of time (issued in 2022). Although there may be good reasons why a patent owner has strong settled expectations in a patent that has only been in force for three years, for example an explanation of how an extraordinary amount of investment, time, and resources dedicated to research, development, trials, and regulatory approval correlates to settled expectations, Patent Owner has not sufficiently articulated such reasons in these proceedings. In the absence of such information, Patent

¹ Citations are to papers in IPR2025-00601. The parties filed similar papers in IPR2025-00602 and IPR2025-00603.

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Owner has not demonstrated that it has developed strong settled expectations that favor discretionary denial for the patent challenged in IPR2025-00603.

The patents challenged in IPR2025-00601 and IPR2025-00602 present different circumstances. In particular, the challenged patents have been in force for seven and six years, respectively, creating strong settled expectations for Patent Owner, and Petitioner does not provide persuasive reasoning why an *inter partes* review is an appropriate use of Board resources. *Dabico Airport Sols. Inc. v. AXA Power ApS*, IPR2025-00408, Paper 21 at 2–3 (Director June 18, 2025). In the absence of any such information, the Office is disinclined to disturb the strong settled expectations of Patent Owner.

Both parties present arguments about the exercise of discretion in view of the Biologics Price Competition and Innovation Act. DD Req. 40–42; DD Opp. 16–17. These arguments are not persuasive.

Although certain arguments are highlighted above, the determinations in this Decision are based on a holistic assessment of all of the evidence and arguments presented. Accordingly, the Petitions in IPR2025-00601 and IPR2025-00602 are denied under 35 U.S.C. § 314(a), and the Petition in IPR2025-00603 is referred to the Board to handle the case in the normal course, including by issuing a decision on institution addressing the merits and other non-discretionary considerations, as appropriate.

In consideration of the foregoing, it is:

ORDERED that Patent Owner’s requests for discretionary denial in IPR2025-00601 and IPR2025-00602 are *granted*;

FURTHER ORDERED that the Petitions in IPR2025-00601 and IPR2025-00602 are *denied*, and no trial is instituted;

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IPR2025-00603 (Patent 11,332,529 B2)

FURTHER ORDERED that Patent Owner's request for discretionary denial in IPR2025-00603 is *denied*;

FURTHER ORDERED that the Petition in IPR2025-00603 is referred to the Board; and

FURTHER ORDERED that neither party shall file a request for rehearing or Director Review of the decision to deny Patent Owner's request for discretionary denial in IPR2025-00603 until the Board issues a decision on institution.

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IPR2025-00602 (Patent 10,174,113 B2)
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