

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

APOTEX INC.,
Petitioner,

v.

ALKERMES PHARMA IRELAND LIMITED,
Patent Owner.

IPR2025-00514
Patent 7,919,499 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

Alkermes Pharma Ireland Limited (“Patent Owner”) filed a request for discretionary denial (Paper 6, “DD Req.”) in the above-captioned case, and Apotex Inc. (“Petitioner”) filed an opposition (Paper 8, “DD Opp.”).

After considering the parties’ arguments and the record, and in view of all relevant considerations, discretionary denial of institution is appropriate in this proceeding. This determination is based on the totality of the evidence and arguments the parties have presented.

In particular, the challenged patent has been in force for more than 14 years, creating strong settled expectations, and Petitioner does not provide any persuasive reasoning why an *inter partes* review is an appropriate use of Board resources. *Dabico Airport Solutions Inc. v. Axa Power Aps*, IPR2025-00408, Paper 21 at 2–3 (Director June 18, 2025); *Intel Corporation v. Proxense*, IPR2025-00327, Paper 12, 2–3 (Director June 26, 2025); Ex. 1001. Furthermore, *ex parte* reexamination has been ordered on the challenged patent. The reexamination includes substantially overlapping art and nearly identical issues as Petitioner seeks to raise in this *inter partes* review. *See* DD Req. 6–15, 33–35. It is not an appropriate use of Office resources to review a patent in two separate, concurrent Office proceedings, especially when the issues and evidence in those proceedings has substantial overlap. Accordingly, discretionary denial is appropriate.

Although certain arguments are highlighted above, the determination to exercise discretion to deny institution is based on a holistic assessment of all of the evidence and arguments presented. Accordingly, the Petition is denied under 35 U.S.C. § 314(a).

In consideration of the foregoing, it is:

ORDERED that Patent Owner’s request for discretionary denial is *granted*; and

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

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