

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

BIOFRONTERA INC., BIOFRONTERA BIOSCIENCE GMBH, and
BIOFRONTERA AG,
Petitioner,

v.

SUN PHARMACEUTICAL INDUSTRIES, INC.,
Patent Owner.

IPR2025-00287
Patent 11,446,512 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

Sun Pharmaceutical Industries, Inc. (“Patent Owner”) filed a request for discretionary denial (Paper 7, “DD Req.”) in the above-captioned case, and Biofrontera Inc., Biofrontera Bioscience GmbH, and Biofrontera AG (collectively, “Petitioners”) 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 projected final written decision due date for this proceeding is August 12, 2026. DD Req. 3. The parallel U.S. International Trade Commission (“ITC”) scheduled final determination date is February 2, 2026. *Id.* at 7–8. As such, it is unlikely that a final written decision in this proceeding will issue before the final determination in the ITC investigation. Additionally, there is insufficient evidence that the ITC is likely to stay its proceeding even if the Board were to institute trial. *Id.* at 5–7. Furthermore, there has been meaningful investment in the parallel proceeding by the parties. *Id.* at 8–10. For example, final contentions and expert reports have been exchanged and a hearing at the ITC will have concluded before a decision on institution is due. *Id.*

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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