

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

SUN PHARMACEUTICALS INDUSTRIES INC.,
Petitioner,

v.

NIVAGEN PHARMACEUTICALS, INC.,
Patent Owner.

IPR2025-00893
Patent 11,878,076 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

Nivagen Pharmaceuticals, Inc. (“Patent Owner”) filed a request for discretionary denial (Paper 7, “DD Req.”) in the above-captioned case, and Sun Pharmaceutical Industries, Inc. (“Petitioner”) filed an opposition (Paper 14, “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.

Some considerations weigh against discretionary denial. In particular, the projected final written decision due date is in November 2026. DD Req. 15; DD Opp. 21. The district court has not yet scheduled a trial date, and the time-to-trial statistics suggest trial would not begin before 2029.¹ DD Opp. 21. As such, it is likely that a final written decision in this proceeding will issue before a district court trial occurs, reducing the concern of inconsistent outcomes or significant duplication of efforts. Furthermore, the challenged patent has not been in force for a significant period of time (issued in 2024). Accordingly, Patent Owner has not developed strong settled expectations that favor discretionary denial. Additionally, early challenges favor robust, predictable patent rights and weigh against discretionary denial.

Other factors, however, favor discretionary denial. Petitioner has taken different claim construction positions in this proceeding and the parallel district court proceeding. DD Req. 31–32. In particular, Petitioner contends in this proceeding that the term “composition” should be given its

¹ The district court complaint was originally filed in the Eastern District of Texas. DD Req. 13. On August 8, 2025, the court granted Petitioner’s motion to transfer the case to the District of New Jersey. Ex. 1053.

plain and ordinary meaning, whereas in the parallel proceeding Petitioner asserted that the term “composition” was narrower than its plain and ordinary meaning. *Id.* (citing Ex. 2004, 3). Although a party is not necessarily precluded from arguing different claim construction positions before a district court and the Board, a party should explain why different positions are warranted. *See Cambridge Mobile Telematics, Inc. v. Sfara, Inc.*, IPR2024-00966, Paper 12 at 8 (PTAB Dec. 13, 2024) (informative); *see also* 83 Fed. Reg. 51342 (noting that the Board adopted the same standard for claim construction used in district courts to improve “uniformity and predictability,” “improve the integrity of the patent system,” and “increase judicial efficiency overall”). For example, if a party advances a narrow construction in the district court and the district court declines to adopt the narrow construction, the party would have sufficient reason for advancing the broader, court-adopted construction in a proceeding before the Board. Here, however, Petitioner does not sufficiently explain why it advanced a narrow construction in district court and advances a broader construction in its Petition. The considerations favoring denial, therefore, outweigh the considerations that counsel against it.

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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