

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

AMNEAL PHARMACEUTICALS, INC.,
Petitioner,

v.

NIVAGEN PHARMACEUTICALS, INC.,
Patent Owner.

IPR2025-00731 (Patent 11,925,661 B2)
IPR2025-00779 (Patent 11,813,291 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 cases, and Amneal Pharmaceuticals, Inc. (“Petitioner”) filed an opposition (Paper 12, “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 these proceedings. This determination is based on the totality of the evidence and arguments the parties have presented.

Some considerations weigh against discretionary denial. For example, the challenged patents have not been in force for a significant period of time (issued in 2023 and 2024). Furthermore, no trial date has been set in the related district court proceeding, and Petitioner persuasively argues that a trial is unlikely to take place before the projected final written decision date. DD Opp. 6–9.

Other considerations, however, favor discretionary denial. In particular, the district court granted Patent Owner’s Motion for Preliminary Injunction in the parallel litigation based on a preliminary adjudication of the validity of the challenged patent. *See* Ex. 2003. Specifically, the district court was “persuaded that the sterility and ready-to-use properties of the patented invention alone make it more likely than not that [US 11,925,661 B2] is not obvious over the [asserted reference].” *Id.* at 10. Patent Owner persuasively argues that the sterility and ready-to-use properties arguments in the parallel litigation are similar to the arguments presented in these proceedings. *See* DD Req. 21–24. Likewise, Patent Owner persuasively

¹ Citations are to papers in IPR2025-00731. The parties filed similar papers in IPR2025-00779.

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argues that the district court has made a preliminary adjudication addressing Petitioner’s anticipation argument in IPR2025-00731. *Id.* at 20–21.

Specifically, “the Court is not persuaded at this juncture that it is more likely than not that [US 2022/0110969 A1] and [US 11,925,661 B2] do not share a priority date.” Ex. 2003, 12. Under these circumstances, where the Board essentially would be taking up the same preliminary issues as the district court, it is not an efficient use of Office resources to revisit substantially similar subject matter that has already been considered in the parallel proceeding.

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 Petitions are 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

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

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