

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE OFFICE OF THE UNDER SECRETARY OF COMMERCE  
FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE  
UNITED STATES PATENT AND TRADEMARK OFFICE

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AZURITY PHARMACEUTICALS, INC.,  
Petitioner,

v.

HELSINN HEALTHCARE S.A.,  
Patent Owner.

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IPR2025-00945 (Patent 8,623,826 B2)  
IPR2025-00946 (Patent 9,186,357 B2)  
IPR2025-00947 (Patent 9,186,357 B2)  
IPR2025-00948 (Patent 9,943,515 B2)  
IPR2025-00949 (Patent 10,828,297 B2)

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

DECISION  
Referring the Petitions to the Board

IPR2025-00945 (Patent 8,623,826 B2)  
IPR2025-00946 (Patent 9,186,357 B2)  
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Helsinn Healthcare S.A. (“Patent Owner”) filed a request for discretionary denial (Paper 7, “DD Req.”) in the above-captioned cases, and Azurity Pharmaceuticals, Inc. (“Petitioner”) filed an opposition (Paper 8, “DD Opp.”).<sup>1</sup>

After considering the parties’ arguments and the record, and in view of all relevant considerations, discretionary denial of institution is not appropriate in these proceedings. This determination is based on the totality of the evidence and arguments the parties have presented.

Some considerations favor discretionary denial. In particular, the challenged patents have been in force for several years (2014, 2015, 2018, and 2020), creating strong settled expectations for Patent Owner. DD Req. 10. Additionally, Patent Owner has commercialized the challenged patents in IPR2025-00945 in the form of a drug product approved by the FDA, and has asserted the patents challenged in IPR2025-00946, IPR2025-00947, and IPR2025-00949 against a generic drug company. *Id.* at 12–13.

Other considerations, however, counsel against discretionary denial. For example, the parties are not currently engaged in a parallel proceeding involving the challenged patents. Additionally, although the grounds set forth in the Petition rely on the same or substantially the same art that was considered by the patent examiner during prosecution of the challenged patents, the patent examiner allowed the claims in view of the “evidence of

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<sup>1</sup> Citations are to papers in IPR2025-00945. The parties filed similar papers in IPR2025-00946, IPR2025-00947, IPR2025-00948, and IPR2025-00949.

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synergy (unexpected result) from the combination of netupitant and palonosetron in regard to the claimed method.” Ex. 1005, 369; DD Req. 18–24. The evidence included a Rule 132 declaration from the inventors stating that “we have generated unexpectedly superior results when using netupitant against CINV instead of aprepitant.” Ex. 1005, 345. Petitioner, however, persuasively argues that the data and evidence presented to the patent examiner indicates that the results may not have been unexpected, but rather may have been consistent with prior art disclosures of the claimed compounds and their use. DD Opp. 16–21; Ex. 1030, 3–5; Ex. 1005, 346; Ex. 1009 ¶¶ 1336, 1382–83. For example, data showed that the overall effect for no nausea and no significant nausea for palonosetron and netupitant was nearly the same as that of palonosetron and aprepitant. Ex. 1005, 345 (Table 2); Ex. 1009 ¶¶ 1382–1384. Under these circumstances, it is an appropriate use of Office resources to review the Petitions to determine whether or not the Office made a material error.

Although certain arguments are highlighted above, the determination not to exercise discretion to deny institution is based on a holistic assessment of all of the evidence and arguments presented. Accordingly, the Petitions are referred to the Board to handle the cases 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 request for discretionary denial is *denied*;

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FURTHER ORDERED that the Petitions are referred to the Board;  
and

FURTHER ORDERED that neither party shall file a request for rehearing or Director Review of this decision until the Board issues a decision on institution.

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