

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AZURITY PHARMACEUTICALS, INC.,
Petitioner,

v.

HELSINN HEALTHCARE S.A.,
Patent Owner.

Case IPR2025-00948
Patent No. 9,943,515 B2

**PATENT OWNER'S OBJECTIONS
TO EVIDENCE PURSUANT TO 37 C.F.R. § 42.64**

Pursuant to 37 C.F.R. § 42.64, Patent Owner submits the following objections to evidence served with the Petition for *inter partes* review ("Petition"). Patent Owner's objections apply equally to Petitioner's reliance on these exhibits in any subsequently filed documents. These objections are timely, having been filed within ten business days of the Institution Decision (November 19, 2025).

Exhibit 1009 (Declaration of Stephen J. Peroutka, M.D., Ph.D.):

Patent Owner objects to Exhibit 1009 as misleading, incomplete, and lacking relevance and because any probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the fact finder, undue delay, wasting time, and/or needlessly presenting cumulative evidence. *See* Fed. R. Evid. 106, 401, 402, and 403. In particular, Patent Owner objects to:

- ¶¶ 29-35, 50-56, 62-67, 70-73, 87-94, 102-110, 123-124, 127-503, and 717-1328 as misleading, incomplete, and irrelevant because they relate to and/or involve alleged grounds of unpatentability for patents other than the '515 patent.

Exhibits 1015 and 1029

Patent Owner objects to Exhibits 1015 and 1029 under FRE 901 for lacking authentication. A package insert and a corporate press release lacks the necessary indicia of reliability and Petitioner has not produced evidence sufficient to support a

finding that the exhibit is what Petitioner claims it is. Petitioner has not established when, where, and how the exhibit was published.

Exhibits 1031, 1036, 1050-1054, and 1058

Patent Owner objects to Exhibits 1031, 1036, 1050-1054, and 1058 under FRE 901 for lacking authentication. The exhibits consist of web pages or archived copies of web pages. Petitioner has not produced evidence sufficient to support a finding that the exhibit is what Petitioner claims it is. Petitioner has not established when, where, and how the exhibit was published.

Exhibits 1010-1061

Patent Owner objects to these exhibits under FRE 802 to the extent the Petition and/or Dr. Peroutka rely on them to prove the truth of the matter asserted. Patent Owner further objects to certain exhibits (1015, 1018, 1026, 1028-1029, 1033, 1036, 1038, 1041, 1045-1046, 1050-1054, 1058-1061) under FRE 403 because they were not cited in the Petition or Dr. Peroutka's declaration (Ex. 1009) in the paragraphs pertaining to IPR2025-00948. The probative value of exhibits not cited in the Petition or the relevant paragraphs of Dr. Peroutka's declaration (Ex. 1009) is substantially outweighed by the danger of unfair prejudice, confusing the issues, undue delay, wasting time, or needlessly presenting cumulative evidence.

Dated: December 4, 2025

Respectfully submitted,

By: /Eric W. Dittmann/
Eric W. Dittmann (Reg. No. 51,188)
Counsel for Patent Owner

CERTIFICATE OF SERVICE

I certify that I caused to be served on the counsel identified below a true and correct copy of the foregoing Patent Owner's Objections to Evidence Pursuant To 37 C.F.R. § 42.64 by electronic means on December 4, 2025:

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