

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

PETITIONER'S OBJECTIONS TO EVIDENCE

I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.64(b)(1), Azurity Pharmaceuticals, Inc. (“Azurity”) submits the following objections to Helsinn Healthcare S.A. (“Helsinn”) Exhibits EX2001-EX2037, EX2039, EX2042-EX2066, and EX2069, and any reference to or reliance on these exhibits.

II. OBJECTIONS

A. Objections to EX2001-EX2004, EX2037, and Their Use

Grounds for Objection: Federal Rules of Evidence (“F.R.E.”) 105, 401-403, 602, 801-802.

Azurity objects to EX2001-EX2004 and EX2037 as irrelevant, and their unfair prejudice and confusion of the issues substantially outweigh any probative value. F.R.E. 401-403. Azurity also objects to these exhibits as lacking foundation (F.R.E. 602) and as hearsay or containing hearsay (F.R.E. 801-802). Even if admissible for some purpose, these exhibits must be restricted to their proper scope. F.R.E. 105.

B. Objections to EX2005, EX2007-EX2009, EX2011, EX2014-EX2015, and Their Use

Grounds for Objection: F.R.E. 105, 401-403, 602, 801-802, 901.

Azurity objects to EX2005, EX2007-EX2009, EX2011, and EX2014-EX2015, which do not purport to be available prior to the critical date. Helsinn relies upon these exhibits solely in its discretionary denial briefing, which was

denied. Helsinn fails to authenticate these exhibits as prior art publications (F.R.E. 901). Moreover, they are irrelevant, and their unfair prejudice and confusion of the issues substantially outweigh any probative value. F.R.E. 401-403. Azurity also objects to these exhibits as lacking foundation (F.R.E. 602) and as hearsay or containing hearsay. F.R.E. 801-802. Even if admissible for some purpose, these exhibits must be restricted to their proper scope. F.R.E. 105.

C. Objections to EX2006, EX2012, and Their Use

Grounds for Objection: F.R.E. 105, 106, 401-403, 602, 801-802, 901.

Azurity objects to EX2006 and EX2012, which do not purport to be available prior to the critical date. Helsinn relies upon these exhibits solely in its discretionary denial briefing, which was denied. Helsinn fails to authenticate these exhibits as prior art publications (F.R.E. 901). Moreover, they are irrelevant, and their unfair prejudice and confusion of the issues substantially outweigh any probative value. F.R.E. 401-403. Azurity also objects to these exhibits as lacking foundation (F.R.E. 602), lacking completeness (F.R.E. 106), and as hearsay or containing hearsay. F.R.E. 801-802. Even if admissible for some purpose, these exhibits must be restricted to their proper scope. F.R.E. 105.

D. Objections to EX2010 and Its Use

Grounds for Objection: F.R.E. 105, 401-403, 602, 801-802.

Azurity objects to EX2010. Helsinn relies upon this exhibit solely in its discretionary denial briefing, which was denied; hence, it is irrelevant, and its unfair prejudice and confusion of the issues substantially outweigh any probative value. F.R.E. 401-403. Azurity also objects to this exhibit as lacking foundation (F.R.E. 602) and as hearsay or containing hearsay. F.R.E. 801-802. Even if admissible for some purpose, this exhibit must be restricted to its proper scope. F.R.E. 105.

E. Objections to EX2013 and Its Use

Grounds for Objection: F.R.E. 105, 401-403, 602, 801-802, 901.

Azurity objects to EX2013. Helsinn relies upon this exhibit solely in its discretionary denial briefing, which was denied. Helsinn fails to authenticate this exhibit (F.R.E. 901). Moreover, it is irrelevant, and its unfair prejudice and confusion of the issues substantially outweigh any probative value. F.R.E. 401-403. Azurity also objects to this exhibit as lacking foundation (F.R.E. 602) and as hearsay or containing hearsay. F.R.E. 801-802. Even if admissible for some purpose, this exhibit must be restricted to its proper scope. F.R.E. 105.

F. Objections to EX2016 and Its Use

Grounds for Objection: F.R.E. 105, 401-403, 602, 801-802, 901.

Azurity objects to EX2016. Helsinn admits “the underlying data is the same” as Azurity’s EX1030. Helsinn fails to authenticate this exhibit (F.R.E. 901).

Moreover, it is irrelevant, and its unfair prejudice and confusion of the issues substantially outweigh any probative value. F.R.E. 401-403. Azurity also objects to this exhibit as lacking foundation (F.R.E. 602) and as hearsay or containing hearsay. F.R.E. 801-802. Even if admissible for some purpose, this exhibit must be restricted to its proper scope. F.R.E. 105.

G. Objections to EX2017-EX2031, EX2033-EX2034, and Their Use

Grounds for Objection: F.R.E. 105, 401-403, 602, 801-802, 901.

Azurity objects to EX2017-EX2031 and EX2033-EX2034. EX2017-EX2019 and EX2022-EX2031, which do not purport to be available prior to the critical date, purport to show details from clinical studies. EX2020-EX2021 and EX2033-EX2034 purport to show webpage printouts and do not purport to be available prior to the critical date. EX2017-EX2031 and EX2033-EX2034 are not cited in Helsinn's briefing. Helsinn fails to authenticate EX2017-EX2031 and EX2033-EX2034 as prior art publications (F.R.E. 901). Moreover, they are irrelevant, and their unfair prejudice and confusion of the issues substantially outweigh any probative value. F.R.E. 401-403. Azurity also objects to these exhibits as lacking foundation (F.R.E. 602) and as hearsay or containing hearsay. F.R.E. 801-802. Even if admissible for some purpose, these exhibits must be restricted to their proper scope. F.R.E. 105.

H. Objections to EX2032 and Its Use

Grounds for Objection: F.R.E. 105, 401-403, 602, 801-802.

Azurity objects to EX2032, which is not cited in Helsinn's briefing; hence, it is irrelevant, and its unfair prejudice and confusion of the issues substantially outweigh any probative value. F.R.E. 401-403. Azurity also objects to this exhibit as lacking foundation (F.R.E. 602) and as hearsay or containing hearsay. F.R.E. 801-802. Even if admissible for some purpose, this exhibit must be restricted to its proper scope. F.R.E. 105.

I. Objections to EX2035 and Its Use

Grounds for Objection: F.R.E. 105, 401-403, 602, 801-802, 901.

Azurity objects to EX2035, which is not cited in Helsinn's briefing. Helsinn fails to authenticate this exhibit (F.R.E. 901). Moreover, it is irrelevant, and its unfair prejudice and confusion of the issues substantially outweigh any probative value. F.R.E. 401-403. Azurity also objects to this exhibit as lacking foundation (F.R.E. 602) and as hearsay or containing hearsay. F.R.E. 801-802. Even if admissible for some purpose, this exhibit must be restricted to its proper scope. F.R.E. 105.

J. Objections to EX2039 and Its Use

Grounds for Objection: F.R.E. 105, 401-403, 602, 801-802, 901.

Azurity objects to EX2039, which does not purport to be available prior to the critical date. Helsinn fails to authenticate this exhibit as a prior art publication

(F.R.E. 901). Moreover, it is irrelevant, and its unfair prejudice and confusion of the issues substantially outweigh any probative value. F.R.E. 401-403; *see also* Paper 12 (Institution Decision) at 18-19 (“The fact that multiple solutions to the problem of treating CINV may have been obvious is not probative that the combination proposed by Petitioner is non-obvious.”). Azurity also objects to this exhibit as lacking foundation (F.R.E. 602) and as hearsay or containing hearsay. F.R.E. 801-802. Even if admissible for some purpose, this exhibit must be restricted to its proper scope. F.R.E. 105.

K. Objections to EX2042-EX2043 and Their Use

Grounds for Objection: F.R.E. 105, 401-403, 602, 801-802, 901.

Azurity objects to EX2042-EX2043. Helsinn fails to authenticate these exhibits (F.R.E. 901). Moreover, they are irrelevant, and their unfair prejudice and confusion of the issues substantially outweigh any probative value. F.R.E. 401-403; *see also* Paper 12 (Institution Decision) at 18-19 (“The fact that multiple solutions to the problem of treating CINV may have been obvious is not probative that the combination proposed by Petitioner is non-obvious.”). Azurity also objects to these exhibits as lacking foundation (F.R.E. 602) and as hearsay or containing hearsay. F.R.E. 801-802. Even if admissible for some purpose, these exhibits must be restricted to their proper scope. F.R.E. 105.

L. Objections to EX2036, EX2045-EX2055, EX2057, EX2059-EX2066, and Their Use

Grounds for Objection: F.R.E. 105, 401-403, 602, 801-802.

Azurity objects to EX2036, EX2045-EX2055, EX2057, and EX2059-EX2066 as irrelevant, and their unfair prejudice and confusion of the issues substantially outweigh any probative value. F.R.E. 401-403; *see also* Paper 12 (Institution Decision) at 18-19 (“The fact that multiple solutions to the problem of treating CINV may have been obvious is not probative that the combination proposed by Petitioner is non-obvious.”). Azurity also objects to these exhibits as lacking foundation (F.R.E. 602) and as hearsay or containing hearsay. F.R.E. 801-802. Even if admissible for some purpose, these exhibits must be restricted to their proper scope. F.R.E. 105.

M. Objections to EX2056, EX2058, and Their Use

Grounds for Objection: F.R.E. 105, 401-403, 602, 801-802.

Azurity objects to EX2056 and EX2058. Helsinn fails to authenticate these documents (F.R.E. 901). Moreover, they are irrelevant, and their unfair prejudice and confusion of the issues substantially outweigh any probative value. F.R.E. 401-403; *see also* Paper 12 (Institution Decision) at 18-19 (“The fact that multiple solutions to the problem of treating CINV may have been obvious is not probative that the combination proposed by Petitioner is non-obvious.”). Azurity also objects to these exhibits as lacking foundation (F.R.E. 602) and as hearsay or containing

hearsay. F.R.E. 801-802. Even if admissible for some purpose, these exhibits must be restricted to their proper scope. F.R.E. 105.

N. Objections to EX2069, EX2044, and Their Use

Grounds for Objection: F.R.E. 401-403, 602, 701-703, 801-802, 37 C.F.R. §§ 42.6, 42.65, and PTAB Consolidated Trial Practice Guide November 2019.

Azurity objects to EX2069 (Dr. Navari's testimony) as not rationally based on his own personal and percipient knowledge (F.R.E. 602, 701) and as not providing an opinion within his knowledge, skill, experience, training, or education that is based on sufficient facts or data and is the product of reliable principles and methods reliably applied to the facts of this case (F.R.E. 702-703; 37 C.F.R. §42.65). Azurity objects to EX2069 because Dr. Navari relies on facts or data that are not the kinds of facts or data an expert in his particular field would rely on in forming an opinion on the subject. Azurity also objects to EX2069 because the probative value of Dr. Navari's testimony is substantially outweighed by unfair prejudice and confusion of the issues (F.R.E. 401-403). This includes any reliance on any portion of EX2069 that is cited for a different purpose than that for which it is relied on in the Patent Owner Preliminary Response. Even if admissible for some purpose, this exhibit must be restricted to its proper scope. F.R.E. 105.

Azurity additionally objects to all portions of Dr. Navari's declaration that are not cited in the Patent Owner Preliminary Response including, e.g., ¶¶1-18, 20-

22, 51-58, 64, and 66. F.R.E. 401-403. Azurity also objects to these uncited portions of EX2069 where Helsinn relies on them via an improper incorporation by reference. 37 C.F.R. §42.6(a)(3); *see also* PTAB Consolidated Trial Practice Guide, 35 (November 2019).

Furthermore, Azurity objects to portions of Dr. Navari’s declaration concerning alternative therapeutics—including, *inter alia*, ¶¶41-50 and 81-95—because such excerpts are irrelevant, and their unfair prejudice and confusion of the issues substantially outweigh any probative value. F.R.E. 401-403; *see also* Paper 12 (Institution Decision) at 18-19 (“The fact that multiple solutions to the problem of treating CINV may have been obvious is not probative that the combination proposed by Petitioner is non-obvious.”).

Azurity also objects to EX2044 and EX2069 as hearsay or containing hearsay. F.R.E. 801-802.

III. CONCLUSION

These exhibits were filed together with the Patent Owner’s Preliminary Response and Patent Owner’s Request for Discretionary Denial. These objections are made within 10 business days of institution of the trial. 37 C.F.R. §42.64.

Respectfully submitted,

Dated: 4 December 2025

/Richard Torczon/

Richard Torczon, Lead Counsel

Reg. No. 34,448

CERTIFICATE OF SERVICE

The undersigned certifies that this paper was served today on the following electronic-service addresses:

Eric W. Dittmann
Naveen Modi
Melanie R. Rupert
Isaac S. Ashkenazi
Chetan Bansal
Justin T. Fleischacker
PAUL HASTINGS LLP
ericdittmann@paulhastings.com
naveenmmodi@paulhastings.com
melanierupert@paulhastings.com
isaacashkenazi@paulhastings.com
chetalbansal@paulhastings.com
justinflischacker@paulhastings.com
PH-Azurity-Helsinn-IPR@paulhastings.com

Respectfully submitted,

Dated: 4 December 2025

/Richard Torczon/
Richard Torczon, Lead Counsel
Reg. No. 34,448