

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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AZURITY PHARMACEUTICALS, INC.,  
Petitioner,

v.

HELSINN HEALTHCARE S.A.,  
Patent Owner.

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

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**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 EX2073-EX2087, EX2090, and EX2092-EX2103, and any reference to or reliance on these exhibits.

## **II. OBJECTIONS**

### **A. Objections to EX2073, EX2075-EX2076, EX2078-EX2079, EX2081-EX2082, EX2084-EX2085, EX2092, EX2096, and EX2103, and Their Use**

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

Azurity objects to EX2073, EX2075-EX2076, EX2078-EX2079, EX2081-EX2082, EX2084-EX2085, EX2092, EX2096, and EX2103 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 EX2074 and Its Use**

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

Azurity objects to EX2074 as irrelevant, and its unfair prejudice and confusion of the issues substantially outweighs any probative value. F.R.E. 401-403. Azurity also objects to this exhibit 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, this exhibit must be restricted to its proper scope. F.R.E. 105.

**C. Objections to EX2077, EX2080, EX2093-EX2094, EX2097-EX2099, EX2102, and Their Use**

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

Azurity objects to EX2077, EX2080, EX2093-EX2094, EX2097-EX2099, and EX2102. 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. 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.

**D. Objections to EX2083 and Its Use**

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

Azurity objects to EX2083. 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), lacking completeness (F.R.E. 106), 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 EX2095, EX2100, and Their Use**

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

Azurity objects to EX2095 and EX2100. 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 its proper scope. F.R.E. 105.

### **F. Objections to EX2086 and Its Use**

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

Azurity objects to EX2086. Helsinn fails to authenticate this exhibit (F.R.E. 901). Moreover, Azurity maintains its scope and relevance objections in EX2086, specifically including 16:18-22, 18:12-20, 21:11-22:2, 24:9-16, 28:16-23, 29:8-16, 32:5-33:1, 36:17-37:11, 38:8-39:24, 38:22-42:5, 39:12-15, 42:2-5, 52:02-60:8, 60:10-61:22, 62:12-24, 63:25-64:21, 78:15-79:12, 83:5-22, 86:11-90:12, 100:16-

23, 101:21-102:1, 107:17-25, 119:15-22, 122:20-123:19, 126:17-24, 127:5-10, 130:11-137:1, 132:4-18, 134:1-16, 134:23-135:4, 136:15-21, 138:25-139:11, 140:20-141:7, 153:16-154:21, 155:9-13, 156:10-17, 158:16-24, 170:18-172:4, 173:2-23, 174:12-177:23, 178:15-179:10, 179:18-181:3, 182:3-184:10, 193:19-194:19, 194:21-196:22, 200:8-19, 200:21-201:21, 202:21-203:14, 206:24-209:22, 210:20-211:1, 230:9-231:6, 240:25-241:3, 242:25-243:5, 243:18-245:15, 251:13-19, 253:7-255:15, 261:2-9, 269:14-270:3, 271:14-273:17, 275:9-14, 279:5-280:8, 280:21-281:18, 289:23-292:9, 293:19-24, 294:1-10, and 295:4-296:14, which testimony is irrelevant, and its unfair prejudice and confusion of the issues substantially outweigh any probative value. F.R.E. 401-403. Even if admissible for some purpose, this exhibit must be restricted to its proper scope. F.R.E. 105.

### **G. Objections to EX2087, EX2090, 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 EX2090 (Dr. Roeland'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 EX2090 because Dr. Roeland 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 specifically includes in its objection testimony incorporated from Dr. Navari's declarations. Azurity also objects to EX2090 because the probative value of Dr. Roeland'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 EX2090 that is cited for a different purpose than that for which it is relied on in the Patent Owner 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. Roeland's declaration (EX2090) that are not cited in the Patent Owner Response including, e.g., ¶¶21-23, 70-71, 156, 164, 202, and 224-230. F.R.E. 401-403. Azurity also objects to these uncited portions of EX2090 where Helsinn relies on them via an improper incorporation by reference, as well as to all portions of Dr. Roeland's declarations that Helsinn improperly incorporates by reference including, e.g., ¶¶49-51, 72-87, 89, 96, 118, 143-148, and 172-175. 37 C.F.R. §42.6(a)(3); *see also* PTAB Consolidated Trial Practice Guide November 2019, 35.

Furthermore, Azurity objects to portions of Dr. Roeland's declaration concerning alternative therapeutics—including, *inter alia*, ¶¶45, 70-86, 193-201, and 215-218—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* Institution Decision at 18 (“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 EX2087 and EX2090 as hearsay or containing hearsay. F.R.E. 801-802.

#### **H. Objections to EX2101 and Its Use**

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

Exhibit EX2101 is not cited in Patent Owner’s briefing. Azurity objects to EX2101 as irrelevant, and its unfair prejudice and confusion of the issues substantially outweighs 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.

### **III. CONCLUSION**

These exhibits were filed together with the Patent Owner’s Response. These objections are made within 5 business days of institution of the trial. 37 C.F.R. §42.64.

Respectfully submitted,

Dated: 4 March 2026

/Richard Torczon/  
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## **CERTIFICATE OF SERVICE**

The undersigned certifies that this paper was served today to the following  
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Respectfully submitted,

Dated: 4 March 2026

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