UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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CSPC PHARMACEUTICAL GROUP LIMITED,
CSPC OUYI PHARMACEUTICAL CO., LTD.,
AND CONJUPRO BIOTHERAPEUTICS, INC.,
Petitioners,

v.

IPSEN BIOPHARM LTD.,
Patent Owner.

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Case No. IPR2025-00505
U.S. Patent No. 11,344,552

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PATENT OWNER'S NOTICE OF OBJECTIONS TO EVIDENCE

I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.64(b)(1), Patent Owner Ipsen Biopharm Ltd. ("Ipsen") submits the following objections to the following exhibits of Petitioners CSPC Pharmaceutical Group Limited, CSPC Ouyi Pharmaceutical Co., Ltd., and Conjupro Biotherapeutics, Inc. (collectively, "CSPC"). Exhibits 1002-1005 1007-1014, 1016-1019, 1021-1023, 1025, 1027, 1033-1060, and 1200-1207. As required by 37 C.F.R. § 42.62, Patent Owner's objections below apply the Federal Rules of Evidence ("FRE").

II. OBJECTIONS

A. Objections to Exhibit 1004 – Alleged English Translation of Conroy Protocol

Grounds for Objection: FRE 401-403, 801-803, and 901-902

Ipsen objects to the admissibility of Exhibit 1004, which CSPC describes as a "Certified English Translation of the Protocol of Conroy, et al, https://www.nejm.org, (2011)," under FRE 401-403, 801-803, and 901-902. Paper 1 at iii. Exhibit 1004 does not contain, and CSPC did not include with its Petition, any certification attesting to the accuracy of the translation of Exhibit 1004. CSPC's failure to provide such certification is in violation of 37 C.F.R. § 42.63, which governs the form of evidence in *inter partes* review proceedings. To the extent that Exhibit 1004 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that CSPC failed to

submit the required certificate of translation with its Petition. Further, CSPC has not produced evidence sufficient to support a finding that Exhibit 1004 is what CSPC claims it is. Ipsen further objects to Exhibit 1004 as hearsay.

B. Objections to Exhibit 1204 – Translation Certification of the Alleged English Translation of Conroy Protocol

Grounds for Objection: FRE 401-403 and 801-803

Ipsen objects to the admissibility of Exhibit 1204 under FRE 401-403 and 801-803. Ipsen objects to Exhibit 1204, as it is not cited by the Petition. Because the Petition does not rely on the exhibit, it is not relevant to the instituted grounds of review. Further, to the extent that Exhibit 1204 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the Petition. Ipsen further objects to Exhibit 1204 as hearsay.

C. Objections to Exhibits 1003, 1005, 1007-1014, 1016-1019, 1021-1023, 1025, 1027, 1033-1059, 1061, 1201-1203, and 1206-1207

Grounds for Objection: FRE 801-803, 901-902.

Ipsen objects to the admissibility of Exhibits 1003, 1005, 1007-1014, 1016-1019, 1021-1023, 1025, 1027, 1033-1059, 1061, 1201-1203, and 1206-1207 under FRE 801-803 and 901-902. As to each of Exhibits 1003, 1005, 1007-1014, 1016-1019, 1021-1023, 1025, 1027, 1033-1059, 1061, 1201-1203, and 1206-1207, CSPC has not established that it is an authentic copy. Ipsen further objects to each

of Exhibits 1003, 1005, 1007-1014, 1016-1019, 1021-1023, 1025, 1027, 1033-1059, 1061, 1201-1203, and 1206-1207 as hearsay. Ipsen further objects to each of Exhibits 1003, 1005, 1007-1014, 1016-1019, 1021-1023, 1025, 1027, 1033-1059, 1061, 1201-1203, and 1206-1207 as CSPC has not established that the exhibit is a printed publication, including the date by which it became publicly available. As to each of Exhibits 1003, 1005, 1007-1014, 1016-1019, 1021-1023, 1025, 1027, 1033-1059, 1061, 1201-1203, and 1206-1207, CSPC has not produced evidence sufficient to support a finding that the item is what CSPC claims it is.

D. Objections to Exhibits 1027, 1042-1060, and 1201-1207

Grounds for Objection: FRE 401-403, 801-803

Ipsen objects to the admissibility of Exhibits 1027, 1042-1060, and 1201-1207 under FRE 401-403. Ipsen objects to each of Exhibits 1027, 1042-1060, and 1201-1207 as it is not cited by the Petition. As to each of Exhibits 1027, 1042-1060, and 1201-1207, because the Petition does not rely on the exhibit, it is not relevant to the instituted grounds of review. Further, to the extent any one of Exhibits 1027, 1042-1060, and 1201-1207 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the Petition. Ipsen further objects to the admissibility of each of Exhibits 1027, 1042-1060, and 1201-1207 under FRE 801-803 to the extent it includes hearsay.

E. Objections to Exhibit 1002 – Expert Declaration of Mark J. Ratain, MD

Grounds for Objection: FRE 401-403, 801-803

Patent Owner objects to the admissibility of certain portions of Exhibit 1002 under FRE 401-403 and 801-803. Patent Owner objects to Exhibit 1002 to the extent that it is not cited by the Petition, including but not limited to, paragraphs 47, 48, 61, 163, 171-173, 176-191, and 214-215. Because the Petition does not rely on those portions of Exhibit 1002, they are not relevant to the instituted grounds of review. Further, to the extent the uncited portions of Exhibit 1002 are deemed relevant, their admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that they are not cited in the Petition. Ipsen further objects to the admissibility of Exhibit 1002 under FRE 801-803 to the extent it includes hearsay.

F. Objections to Exhibit 1200 – Supplemental Expert Declaration of Mark J. Ratain, MD

Grounds for Objection: FRE 401-403, 801-803

Ipsen objects to the admissibility of Exhibit 1200 under FRE 401-403 and 801-803. Ipsen objects to Exhibit 1200 as it is not cited in the Petition and/or is not responsive to argument presented in Ipsen's request for discretionary denial. Because the Petition does not rely on Exhibit 1200, it is not relevant to the instituted grounds of review. Further, to the extent that Exhibit 1200 is deemed

relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it is not cited in the Petition. Ipsen further objects to the admissibility of Exhibit 1200 under FRE 801-803 to the extent it includes hearsay.

G. Objections to Exhibits 1010-1011, 1013-1014, 1018-1019, 1020-1021, 1026, 1061, 1201-1203, and 1205-1207

Grounds for Objection: FRE 401-403, 801-803

Ipsen objects to the admissibility of Exhibits 1010-1011, 1013-1014, 1018-1019, 1020-1021, 1026, 1061, 1201-1203, and 1205-1207 as prior art under FRE 401-403. Each of Exhibits 1010-1011, 1013-1014, 1018-1019, 1020-1021, 1026, 1061, 1201-1203, and 1205-1207 purports to reflect a publication date that is after the August 21, 2015 effective filing date found by the Board in its Institution Decision. *See* Paper 13 at 45. Accordingly, each of Exhibits 1010-1011, 1013-1014, 1018-1019, 1020-1021, 1026, 1061, 1201-1203, and 1205-1207 is not prior art under 35 U.S.C. § 102. Further to the extent that any of Exhibits 1010-1011, 1013-1014, 1018-1019, 1020-1021, 1026, 1061, 1201-1203, and 1205-1207 is deemed relevant, its admission as prior art would be unduly prejudicial, misleading, and a waste of time. Ipsen further objects to the admissibility of Exhibits 1010-1011, 1013-1014, 1018-1019, 1020-1021, 1026, 1061, 1201-1203, and 1205-1207 under FRE 801-803 to the extent it includes hearsay.

Date: August 28, 2025

By: */s/ Angus Chen*

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CERTIFICATE OF SERVICE (37 C.F.R. §§ 42.6(E), 42.105(A))

The undersigned hereby certifies that on August 28, 2025 copies of the foregoing document was served upon the following parties via electronic mail, with a copy to ipdocket@foxrothschild.com (referencing Attorney Docket No. 340008.00021):

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