

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

Petitioners,

v.

IPSEN BIOPHARM LTD.,

Patent Owner.

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

**PATENT OWNER'S NOTICE OF OBJECTIONS TO
PETITIONERS' SUPPLEMENTAL 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 supplemental evidence served by Petitioners CSPC Pharmaceutical Group Limited, CSPC Ouyi Pharmaceutical Co., Ltd., and Conjupro Biotherapeutics, Inc. (collectively, “CSPC”) on March 4, 2026, in connection with Petitioners' Response and Notice of Supplemental Evidence in Response to Patent Owner’s Objections to Petitioners’ Evidence Dated February 18, 2026. As required by 37 C.F.R. § 42.62, Patent Owner’s objections below apply the Federal Rules of Evidence (“FRE”).

The supplemental evidence consists of the March 3, 2026 Declaration of Lukas D. Toft (“Toft Declaration”) and the March 3, 2026 Affidavit of Alexander J.W. Sappington (“Updated Sappington Declaration”), submitted purportedly to cure Ipsen’s evidentiary objections to Exhibits 1211–1222. As set forth below, the Toft Declaration and Updated Sappington Declaration are themselves independently objectionable, and neither cures the outstanding objections to the underlying exhibits.

II. OBJECTIONS TO THE TOFT DECLARATION

Ground for Objection: FRE 401-403, 602, 701-702, 801-803, 901-902; 37 C.F.R. § 42.64(b)(2).

Ipsen objects to the admissibility of the Toft Declaration in its entirety and to specific paragraphs as set forth below.

A. **The Toft Declaration Exceeds the Permissible Scope of Supplemental Evidence Under 37 C.F.R. § 42.64(b)(2)**

Ipsen objects to the Toft Declaration to the extent it contains substantive factual assertions and arguments beyond what is necessary to support the admissibility of the underlying exhibits. Such content exceeds the permissible scope of supplemental evidence under 37 C.F.R. § 42.64(b)(2) and is therefore inadmissible. The Toft Declaration goes far beyond authentication and cure. It contains substantive factual assertions concerning: the content of the OncLive video (¶¶ 3, 5); events at Dr. Oberstein's deposition (¶ 3); the process by which CSPC's staff prepared a transcript and Toft himself edited it (¶ 7); and detailed descriptions of the OpenPayments, OIG, ASCO, and NCCN websites (¶¶ 8–14). These paragraphs constitute new substantive evidence that exceeds the permissible cure function and is therefore inadmissible under 37 C.F.R. § 42.64(b)(2).

B. **Paragraphs 3-7 (Exhibits 1211, 1212, 1213): Attorney-as-Witness; Lack of Personal Knowledge; Improper Authentication**

Grounds for Objection: FRE 602, 701, 801-803, 901-902.

Ipsen objects to paragraphs 3-7 of the Toft Declaration, which purport to authenticate Exhibits 1211, 1212, and 1213 through the personal observations of CSPC's lead trial counsel, Lukas D. Toft.

First, Mr. Toft is the lead attorney of record for Petitioners in this proceeding and remains actively engaged as trial counsel. His declaration constitutes substantive factual testimony offered by an interested advocate on behalf of the party he represents. The Board should afford this declaration diminished weight accordingly.

Second, with respect to Exhibit 1213 (the transcript of the OncLive video), Toft declares that he “directed [his] staff to transcribe the video” and that he “personally reviewed and revised the transcript while watching the video.” (Toft Decl. ¶ 7.) This is not authentication—it is the creation of a new document by opposing counsel and their staff, offered as a purportedly accurate representation of the video’s content. The transcript is a document prepared entirely by CSPC and revised by CSPC’s counsel. No independent or neutral transcriptionist certified its accuracy. Authentication of Exhibit 1213 requires evidence sufficient to support a finding that the transcript is what CSPC claims it to be—a “fair and accurate” representation of the video—but the only basis offered is the *ipse dixit* of interested counsel. This is insufficient under FRE 901(a). Ipsen further objects to Exhibit 1213 under FRE 801-803 as a hearsay document created by counsel in anticipation of this litigation.

Third, Toft’s personal attestation that he “watched” the video and that Exhibit 1211 is a “fair and accurate copy” does not satisfy FRE 901 for digital

video content. Toft provides no technical foundation establishing the integrity of the video file, including whether the Page Vault capture process faithfully preserved the video's content without alteration, compression, or loss of data.

C. **Paragraphs 3–7: Objections to Exhibits 1211–1213 Are Not Cured**

Even accepting the Toft Declaration at face value, the authentication attempts in paragraphs 3-7 do not cure Ipsen's outstanding objections to Exhibits 1211–1213. Specifically:

- Ipsen's hearsay objections under FRE 801-803 to Exhibits 1211 and 1213 are not cured by authentication testimony. CSPC's assertion that these exhibits are "not offered for the truth of the matter asserted" is a merits argument for briefing, not a cure under § 42.64(b)(2);
- Ipsen's relevance objection under FRE 401-403 to Exhibits 1211-1213 is not cured. CSPC's argument that credibility and bias evidence is "always relevant" is a legal argument for briefing, not supplemental evidence; and
- Ipsen's objection under 37 C.F.R. § 42.23(b) that Exhibits 1211-1213 constitute new evidence supporting arguments not made in the Petition is not cured. The Toft Declaration does not address whether these exhibits are cited in support of new arguments.

D. **Paragraph 8 (Exhibit 1214): Objections Not Cured**

Grounds for Objection: FRE 401-403, 801-803, 37 C.F.R. § 42.23(b).

Toft's attestation that he personally searched the OpenPayments website and retrieved Exhibit 1214 does not cure Ipsen's relevance objection under FRE 401-403. The probative value of 2024 physician payment records with respect to a proceeding involving an August 21, 2015 effective filing date is at best marginal and is substantially outweighed by the danger of unfair prejudice, confusion of the issues, and undue delay. CSPC's assertion that credibility evidence is "always relevant" is a legal argument, not supplemental evidence constituting a cure. Ipsen's objection under 37 C.F.R. § 42.23(b) is also not cured.

E. **Paragraph 9 (Exhibit 1215): Objections Not Cured**

Grounds for Objection: FRE 401-403, 801-803, 37 C.F.R. § 42.23(b).

Toft's navigation of the OIG website to locate the November 16, 2020 Special Fraud Alert does not cure Ipsen's relevance objection under FRE 401-403. A government fraud alert issued in 2020 has no relevance to the patentability of a pharmaceutical compound with an August 21, 2015 filing date, and its probative value, if any, is substantially outweighed by the danger of unfair prejudice, confusion of the issues, and undue delay. Ipsen's objection under 37 C.F.R. § 42.23(b) is also not cured.

F. **Paragraphs 11–14 (Exhibits 1217–1221): Objections Not Cured; Exhibit Number Inconsistencies**

Grounds for Objection: FRE 401-403, 801-803, 901-902, 37 C.F.R. § 42.23(b).

Toft’s personal attestation to having located and downloaded the ASCO abstract (Ex. 1217) and NCCN submissions and panel discussions (Exs. 1218-1221) does not cure Ipsen’s outstanding objections. None of these exhibits predates the August 21, 2015 effective filing date. Authentication does not cure relevance, hearsay, or § 42.23(b) objections.

Moreover, paragraph 13 of the Toft Declaration refers to “Exhibit 2020” as Ipsen’s September 12, 2023 NCCN Submission, and paragraph 14 refers to “Exhibit 2019” and “Exhibit 2021” as NCCN transparency documents. These exhibits are filed in this proceeding as Exhibits 1220, 1219, and 1221, respectively. The Toft Declaration thus fails to correctly identify the exhibits it purports to authenticate. A declaration that misidentifies the exhibits being authenticated is insufficient to establish under FRE 901(a) that those exhibits are what CSPC claims them to be.

III. **OBJECTIONS TO THE UPDATED SAPPINGTON DECLARATION**

Grounds for Objection: FRE 602, 801-803, 901-902; 37 C.F.R. § 42.64(b)(2).

Ipsen objects to the admissibility of the Updated Sappington Declaration (March 3, 2026) on the following grounds.

A. **The Updated Sappington Declaration Is Not Authorized Supplemental Evidence Under 37 C.F.R. § 42.64(b)(2)**

The Updated Sappington Declaration is CSPC's second attempt to authenticate Exhibits 1211 and 1212, offered to cure deficiencies in the original Sappington Affidavit (Exhibit 1222) that was already submitted with CSPC's Reply. Section 42.64(b)(2) provides one opportunity for a party to serve supplemental evidence to cure timely objections. It does not authorize iterative rounds of supplemental evidence to shore up deficiencies in previously submitted cure evidence. The Updated Sappington Declaration is therefore outside the scope of permissible supplemental evidence under § 42.64(b)(2) and should be excluded.

B. **Paragraph 13: Lack of Personal Knowledge Regarding Exhibit Identity**

Grounds for Objection: FRE 602, 901-902.

The critical paragraph of the Updated Sappington Declaration—paragraph 13—states that the attached captures are “true and correct cop[ies]” of the captured webpage and video, and that Sappington “understand[s]” they “were filed in the above captioned proceeding as Exhibit 1212” and “Exhibit 1211,” respectively.

The use of “I understand” rather than a statement of personal knowledge reveals that Sappington does not personally know that the attached documents were filed as Exhibits 1211 and 1212. He is relying on what someone else told him.

Authentication under FRE 901(a) requires a witness with personal knowledge to testify that an item is what the proponent claims it to be. Secondhand understanding does not satisfy this standard. Ipsen objects to the Updated

Sappington Declaration under FRE 602 (lack of personal knowledge) and FRE 901-902 (insufficient authentication).

C. **Exhibit 1211 (Video) Is Not Adequately Authenticated**

Grounds for Objection: FRE 901-902.

The Updated Sappington Declaration attests to the capture of a “webpage” and a “video available at the above URL.” The Page Vault process described in paragraphs 4–12 concerns the capture of web content through the Page Vault Capturing Server. However, the declaration provides no explanation of the technical methodology used to capture a video file embedded in a webpage, whether that methodology differs from a static webpage capture, how the integrity of the video file was preserved, or how one can confirm the captured video matches the video that appeared on the website. For video content—a distinct digital object from a webpage—this foundation is insufficient under FRE 901(a).

D. **Neither Declaration Authenticates Exhibit 1213**

Grounds for Objection: FRE 901-902.

Neither the Toft Declaration nor the Updated Sappington Declaration provides competent authentication for Exhibit 1213 (the transcript of the OncLive video). Sappington makes no reference to Exhibit 1213. Toft acknowledges that the transcript was prepared by CSPC’s own counsel and revised by him personally.

No independent or neutral authenticating witness attests to the accuracy of Exhibit 1213. Ipsen's objections to Exhibit 1213 remain uncured.

IV. RENEWED AND CONTINUING OBJECTIONS TO UNDERLYING EXHIBITS

For the avoidance of doubt, Ipsen renews and maintains all objections previously stated in Patent Owner's Notice of Objections to Evidence dated February 18, 2026, to Exhibits 1211-1222. The supplemental evidence served by CSPC does not cure the following categories of objections:

- FRE 401-403 as to Exhibits 1211-1215 and 1217-1221, to the extent the probative value of these exhibits, if any, is substantially outweighed by the danger of unfair prejudice, confusion of the issues, misleading the Board, undue delay, and wasting time;
- FRE 801-803 as to Exhibits 1211-1215 and 1217-1221, to the extent they contain hearsay not subject to any applicable exception. CSPC's conclusory assertion that these exhibits are "not offered for the truth of the matter asserted" is a merits argument that does not constitute supplemental evidence curing a hearsay objection;
- FRE 901-902 as to Exhibits 1211-1213, as set forth above; and
- 37 C.F.R. § 42.23(b) as to Exhibits 1211-1215 and 1217-1221, to the extent they constitute new evidence offered in support of new arguments not made in the Petition. CSPC's assertion that these

exhibits “support arguments initially raised in the Petition” is a legal argument for briefing, not supplemental evidence.

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

The undersigned hereby certifies that on March 11, 2026 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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