

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

Petitioners,

v.

IPSEN BIOPHARM LTD.,

Patent Owner.

Case No. IPR2025-00505¹
U.S. Patent No. 11,344,552

PATENT OWNER’S MOTION TO EXCLUDE

¹ Apotex Inc., which filed a petition in IPR2025-01531, has been joined as a petitioner in this proceeding.

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I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.64(c), Patent Owner Ipsen Biopharm Ltd. (“Ipsen”) moves to exclude Exhibit 1004 (“Conroy Protocol”) and Exhibit 1017 (“Conroy Appendix”). Both exhibits are central to Petitioners’ case: CSPC identifies the Conroy Protocol and Conroy Appendix in every ground of its Petition as the primary prior art source for the claimed 60 mg/m² oxaliplatin dose. *See* Paper 1 at 5-6 (identifying Ex. 1004 and Ex. 1017 with a May 12, 2011 purported publication date); *id.* at 41 (claim chart citing Ex. 1004, 16-18 and Ex. 1017, 3-7 for the 60 mg/m² oxaliplatin limitation).

Both exhibits are inadmissible. Exhibit 1004 is a purported English translation of a French-language clinical trial protocol that CSPC submitted without the certification of translation accuracy required by 37 C.F.R. § 42.63(b). Although CSPC later filed Exhibit 1204—a translation certification—as part of its pre-institution discretionary denial briefing, that filing does not cure the defect. Exhibit 1204 was not served as supplemental evidence under 37 C.F.R. § 42.64(b)(2) in response to a timely evidentiary objection, and it therefore cannot function as a cure under the Board’s rules. In any event, Exhibit 1204 addresses only translation accuracy and says nothing about when or how either document was publicly accessible as a printed publication.

Exhibit 1017 is a supplementary appendix to the Conroy article, accessible only through a separate URL, for which CSPC has never provided any authentication or public-accessibility evidence. As to both exhibits, Ipsen timely served objections under FRE 801-803 and 901-902. CSPC did not respond to those objections with any supplemental evidence. The exhibits therefore lack the foundational showing required for admission.

II. STATEMENT OF FACTS AND PROCEDURAL HISTORY

A. The Exhibits and Their Role in the Petition

Exhibit 1004 is described in the Petition as the “Certified English Translation of the Protocol of Conroy, *et al.*, <https://www.nejm.org>, (2011).” Paper 1 at iii. Exhibit 1017 is described as the “Conroy Supplementary Appendix, N. Engl. J. Med., 364(19): 1817-25 Supplementary Appendix (2011).” *Id.* CSPC filed both exhibits with its Petition on January 17, 2025.

CSPC alleged in its Petition that “[b]oth the Conroy Protocol and the Conroy Appendix disclose that patients were to be given dose reduction of oxaliplatin from 85 mg/m² to 60 mg/m² based on various hematological toxicities, neutropenia, diarrhea, or any other grade 2 toxicities.” Paper 1 at 16 (citing Ex. 1004, 16-18; Ex. 1017, 3-7.). The Petition’s claim chart further states that the 60 mg/m² oxaliplatin limitation is disclosed by “Ex. 1004, 16-18; Ex. 1017, 3-7.” Paper 1 at 41.

B. Exhibit 1004: Filed Without Required Translation Certificate

Exhibit 1004 is purportedly a translation of a French-language clinical trial protocol. The underlying source document is not itself an English-language publication—it is a protocol document accessible through a URL at NEJM.org. *See* Paper 1 at iii (describing Ex. 1004 as a “Certified English Translation of the Protocol of Conroy, *et al.*, <https://www.nejm.org>”). Rule 42.63(b) provides that “[w]hen a party relies on a document or is required to produce a document in a language other than English, a translation of the document into English and an affidavit attesting to the accuracy of the translation must be filed with the document.” 37 C.F.R. § 42.63(b). CSPC filed no such affidavit with its Petition.

CSPC later filed Exhibit 1204—described as a “Translation Certification of the Alleged English Translation of Conroy Protocol”—as part of its opposition to Ipsen’s motion for discretionary denial, prior to institution. Exhibit 1204 purports to attest to the accuracy of the English translation. It says nothing, however, about the public accessibility of the Conroy Protocol, when it was made available to the public, or through what means it could be located by a person of ordinary skill in the art.

C. **Exhibit 1017: Filed Without Any Authentication or Accessibility**

Evidence

Exhibit 1017 is purportedly the supplementary appendix to the Conroy article. Unlike the Conroy article itself (Ex. 1003), which was published in the New England Journal of Medicine, the Conroy Appendix is accessible only through a separate URL hyperlinked from the article. The Petition provides no evidence—no declaration, no librarian testimony, no affidavit from anyone with knowledge of the NEJM’s electronic supplementary material practices—establishing that Exhibit 1017 was publicly accessible as of any date, let alone as of May 12, 2011. CSPC’s identification of Exhibit 1017 in the Petition’s prior art table as having a “May 12, 2011” publication date rests on nothing more than that bare assertion. Paper 1 at 6.

D. **Ipsen’s Timely Objections and CSPC’s Failure to Supplement**

Pursuant to 37 C.F.R. § 42.64(b)(1), Ipsen timely served its Notice of Objections to Evidence on August 28, 2025. *See* Paper 15. Ipsen objected to Exhibit 1004 under FRE 401-403, 801-803, and 901-902, stating that the exhibit does not contain, and CSPC did not include with its Petition, any certification attesting to the accuracy of the translation, in violation of 37 C.F.R. § 42.63, and that CSPC had not produced evidence sufficient to support a finding that Exhibit 1004 is what CSPC claims it is. *Id.* Ipsen separately objected to Exhibit 1204 as

irrelevant under FRE 401-403 because it is not cited in the Petition. *Id.* Ipsen further objected to Exhibit 1017 under FRE 801-803 and 901-902 as part of a broader objection covering all non-patent literature exhibits for which CSPC had not established authenticity, hearsay status, or public accessibility as printed publications. *Id.*

Under 37 C.F.R. § 42.64(b)(2), CSPC had ten business days from service of the objections to respond with supplemental evidence. CSPC did not serve any supplemental evidence in response to Ipsen’s objections to Exhibit 1004 or Exhibit 1017. No librarian declaration, no affidavit from a person with knowledge of the NEJM’s supplementary material practices, no Wayback Machine declaration, and no other authentication evidence was ever provided for either exhibit.

III. **ARGUMENT**

A. **Legal Standards**

A motion to exclude must “identify where in the record the objection originally was made” and “explain each objection.” 37 C.F.R. § 42.64(c); Consolidated Trial Practice Guide at 79 (Nov. 2019). A motion to exclude “must explain why the evidence is not admissible (e.g., relevance or hearsay).” *Id.* Ipsen satisfies both requirements here.

Under FRE 901(a), the proponent of evidence “must produce evidence sufficient to support a finding that the item is what the proponent claims it is.” To

be admissible as prior art, a non-patent literature reference must be shown to be a printed publication—meaning it was publicly accessible to persons skilled in the art before the critical date. *In re Wyer*, 655 F.2d 221, 227 (C.C.P.A. 1981). Public accessibility is “the touchstone” of the printed publication inquiry. *SRI Int’l, Inc. v. Internet Sec. Sys., Inc.*, 511 F.3d 1186, 1194 (Fed. Cir. 2008). The date printed on a document’s face does not establish public accessibility. *In re Lister*, 583 F.3d 1307, 1316-17 (Fed. Cir. 2009). A copyright date or publication date on a document, offered to prove the document was publicly accessible on that date, is hearsay because it is an out-of-court statement offered to prove the truth of the matter asserted. FRE 801; *Standard Innovation Corp. v. LELO, Inc.*, IPR2014-00148, Paper 41 at 13-17 (PTAB Apr. 23, 2015).

When a petitioner fails to respond to a timely evidentiary objection with supplemental evidence under 37 C.F.R. § 42.64(b)(2), that failure forecloses any attempt to cure the objection through later-filed evidence. *TRW Automotive U.S. LLC v. Magna Electronics Inc.*, IPR2014-01348, Paper 25 at 3-4, 12 (PTAB Jan. 15, 2016) (granting motion to exclude where petitioner “did not serve any supplemental evidence in response to [the] objections”); *Toyota Motor Corp. v. American Vehicular Sciences LLC*, IPR2013-00417, Paper 78 at 13-15 (PTAB Jan. 7, 2015) (granting motion to exclude where proponent’s supplemental

authentication evidence failed to establish the document was what the proponent claimed it to be).

B. Exhibit 1004 Should Be Excluded

1. Exhibit 1004 Violates 37 C.F.R. § 42.63(b)

Rule 42.63(b) requires that when a party relies on a non-English document, a translation and an affidavit attesting to the accuracy of the translation must be filed with the document. The Conroy Protocol (Ex. 1004) is translated from French. CSPC filed no attesting affidavit with its Petition. This is a violation of the applicable rule governing the form of evidence in inter partes review proceedings. To the extent the Exhibit is deemed relevant, its admission would be unduly prejudicial, misleading, and wasteful under FRE 403 in view of CSPC's failure to comply with the governing rules.

Although CSPC filed Exhibit 1204—a translation certification—prior to institution as part of its response to Ipsen's discretionary denial motion, that pre-institution filing does not cure CSPC's non-compliance. Exhibit 1204 was not filed with the Petition as required by Rule 42.63(b). Moreover, after Ipsen served its timely objection to Exhibit 1004, CSPC did not respond by serving supplemental evidence within the ten business days permitted by 37 C.F.R. § 42.64(b)(2). The window for cure has closed. *See* 37 C.F.R. § 42.64(b)(2) (providing ten business days to respond with supplemental evidence); *TRW Automotive*, IPR2014-01348,

Paper 25 at 3-4, 12 (granting motion to exclude where petitioner served no supplemental evidence in response to timely objections).

2. Exhibit 1004 Has Not Been Authenticated

Even setting aside the translation certification defect, CSPC has produced no evidence sufficient under FRE 901(a) to support a finding that Exhibit 1004 is what CSPC claims it is—a printed publication publicly accessible as of May 12, 2011. The Petition identifies Exhibit 1004 only by a URL at NEJM.org. Paper 1 at iii, 6. No witness with personal knowledge of how the NEJM makes its clinical trial protocols accessible, when they were first made publicly available, or through what mechanism they can be located and retrieved has provided any testimony. The bare URL citation in the Petition, even if treated as implicit evidence of online availability today, says nothing about public accessibility as of the asserted prior art date. *In re Lister*, 583 F.3d at 1316-17; *Standard Innovation*, IPR2014-00148, Paper 41 at 13-17.

CSPC did not serve any supplemental evidence after Ipsen timely objected on authentication and hearsay grounds. No librarian declaration, no declaration from an NEJM representative with knowledge of the journal’s protocol-publication practices, and no internet archive authentication evidence was ever filed. Without any such evidence, the date appearing in the Petition’s prior art table for Exhibit 1004—“May 12, 2011”—is an unsubstantiated attorney assertion. Attorney

argument is not evidence and cannot substitute for the foundational showing required by FRE 901.

3. The Asserted Publication Date of Exhibit 1004 is Hearsay

To the extent CSPC relies on any date printed on or associated with Exhibit 1004 to establish that the Conroy Protocol was publicly accessible as a printed publication in 2011, that date is hearsay. It is an out-of-court statement offered to prove the truth of the matter asserted—namely, that the document was accessible on that date. FRE 801(c); *Standard Innovation*, IPR2014-00148, Paper 41 at 13-17. No hearsay exception applies: the date was not placed on the document by a custodian or qualified witness testifying in this proceeding, and CSPC has offered no business records foundation or other FRE 803 showing.

4. Exhibit 1204 Does Not Cure These Defects

Exhibit 1204 addresses only translation accuracy—it does not speak to public accessibility. Even if Exhibit 1204 were considered, it would cure at most the translation certification defect. It leaves entirely unaddressed whether the Conroy Protocol, accessible through a NEJM.org URL, was publicly available as a printed publication as of May 12, 2011. The authentication and hearsay objections to Exhibit 1004 stand regardless of Exhibit 1204.

Furthermore, Ipsen timely objected to Exhibit 1204 itself as irrelevant and hearsay. *See* Paper 15 at Section II.B. Exhibit 1204 is not cited in the Petition and

was not relied upon in the instituted grounds of review. Because the Petition does not rely on Exhibit 1204, it is not relevant to the proceedings and should be given no consideration in evaluating the admissibility of Exhibit 1004.

C. **Exhibit 1017 Should Be Excluded**

1. **Exhibit 1017 Has Not Been Authenticated**

Exhibit 1017 is the Conroy Supplementary Appendix. Unlike the Conroy article itself, which appears in the body of a printed journal, the supplementary appendix is accessible only through a separate hyperlink from the article page. The Petition provides no evidence establishing that Exhibit 1017 is an authentic copy of a document that was publicly accessible as of May 12, 2011 or any other date. CSPC provides nothing more than a bare citation in its prior art table. Paper 1 at 6. No declaration from any witness with personal knowledge of the NEJM's supplementary appendix publication practices—how such materials are hosted, when they are made available alongside the corresponding article, whether the URL was active as of the claimed priority date, or how the document was indexed and retrievable—has been offered.

FRE 901(a) requires the proponent to produce evidence sufficient to support a finding that the item is what the proponent claims it is. Supplementary online materials present distinct authentication challenges from the journal article to which they are appended: they are separately hosted, accessible through distinct

URLs, and their posting dates may differ from the article’s publication date. CSPC has offered nothing to bridge the gap. The situation is directly analogous to cases where courts have excluded website printouts and other electronic materials for lack of authentication when the proponent provided no testimony from a person with knowledge of the website’s publication or preservation practices. *See Riverbed Tech., Inc. v. Realtime Data LLC*, IPR2016-00978, Paper 67 at 40-41 (PTAB Oct. 30, 2017) (excluding exhibit where expert did not “explain[] where he found it, when and where it was published, or if the copy of the document filed . . . is an unaltered, true, and correct copy.”).

After Ipsen served timely objections, CSPC served no supplemental evidence. No librarian declaration, no affidavit from NEJM confirming the supplementary appendix’s publication history, and no internet archive evidence was provided.

2. The Asserted Publication Date of Exhibit 1017 is Hearsay

As with Exhibit 1004, any reliance on a date appearing on or associated with Exhibit 1017 to establish public accessibility as a printed publication is hearsay. The supplementary appendix itself states: “This appendix has been provided by the authors to give readers additional information about their work.” Ex. 1017 at 1. This statement—like any date appearing on or associated with the document—is an out-of-court statement offered to prove the truth of the matter asserted, and no

hearsay exception applies. FRE 801-802; *Standard Innovation*, IPR2014-00148, Paper 41 at 13-17.

3. CSPC's Failure to Supplement is Dispositive

CSPC's failure to respond to Ipsen's objections with any supplemental evidence forecloses any attempt to rehabilitate either exhibit. In *TRW Automotive*, the Board excluded a prior art reference where the petitioner did not serve supplemental evidence after timely objections were served, holding that the Board must assess admissibility based only on the evidence provided with the original filing. IPR2014-01348, Paper 25 at 3-4, 12. There, as here, the petitioner's only showing of authenticity was a bare footnote in its petition asserting that the document qualified as prior art. *Id.* at 5-6. The Board rejected this, explaining that TRW had "not cited any evidence" to support its authentication claim and that its argument was "attorney argument, not supported with evidence." *Id.* at 7-8. The same is true here: neither the Petition nor the Ratain Declaration provides any firsthand knowledge of the publication, online availability, or public accessibility of the Conroy Protocol or the Conroy Appendix. *See* Paper 1 at 16-17; Ex. 1002, ¶¶104-106 (citing the exhibits' contents without addressing how or when they were made publicly accessible).

Critically, CSPC has not submitted a librarian declaration or any declaration from a publisher representative for any exhibit in this proceeding. CSPC relied

solely on attorney assertion and expert citation to establish the prior art status of both Exhibit 1004 and Exhibit 1017. That is insufficient. *See Toyota Motor*, IPR2013-00417, Paper 78 at 15-18 (finding that librarian testimony based on personal knowledge of a publisher's records and procedures was the critical evidence establishing public accessibility, while other corroborating evidence was excluded as hearsay); *TRW Automotive*, IPR2014-01348, Paper 25 at 9-10; *Riverbed Technology*, IPR2016-00978, Paper 67 at 40-41.

D. Portions of the Ratain Declaration and Deposition Relying on Exhibits 1004 and 1017 Should Also Be Excluded

Because Exhibits 1004 and 1017 are inadmissible, those portions of the Ratain Declaration (Ex. 1002) and Ratain Deposition (Ex. 2073) that rely expressly on Exhibits 1004 and 1017 for the proposition that the Conroy Protocol and Appendix disclosed dose reductions of oxaliplatin to 60 mg/m² should likewise be excluded. *See* Ex. 1002, ¶¶105-106, 241 (citing Ex. 1004 and Ex. 1017 for the alleged 60 mg/m² oxaliplatin disclosure); Ex. 2073 at 41:6-43:23; Paper 1 at 16, 32-33, 40-44 (citing Ex. 1002, ¶105 together with Ex. 1004, 16-18 and Ex. 1017, 3-7). Specifically, Ipsen moves to exclude paragraphs 105 and 106 of Exhibit 1002, pages 41:6 through 43:23 of Exhibit 2073, and any portions of Exhibit 1002 that rely exclusively on Exhibits 1004 or 1017 to support the 60 mg/m² oxaliplatin

limitation. *See Riverbed Technology*, IPR2016-00978, Paper 67 at 41 (excluding portions of expert declaration that relied on excluded exhibit).

IV. **CONCLUSION**

For the foregoing reasons, the Board should exclude Exhibits 1004 and 1017 from evidence, together with the identified portions of Exhibits 1002 and 2073 that rely upon them.

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CERTIFICATE OF LENGTH (37 C.F.R. § 42.24(D))

The undersigned hereby certifies that, according to the word-processing system used to prepare the foregoing document, this document is 14 pages and thus complies with the applicable word limit.

Date: April 27, 2026

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

The undersigned hereby certifies that on April 27, 2026 copies of the foregoing document were 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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