

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

Patent No. 11,344,552

**PETITIONERS' RESPONSE AND NOTICE
OF SUPPLEMENTAL EVIDENCE IN RESPONSE TO
PATENT OWNER'S OBJECTIONS DATED AUGUST 25, 2025**

Pursuant to 37 C.F.R. § 42.64(b)(2), Petitioners provides the accompanying supplemental evidence and response to “Patent Owner’s Notice of Objections to Evidence” dated and served August 28, 2025. This supplemental evidence is timely served within ten (10) business days.

The Rules require that “[o]nce a trial has been instituted, any objection must be filed within five business days of service of evidence to which the objection is directed” and that such evidentiary objections made by a party “must identify the grounds for the objection *with sufficient particularity to allow correction in the form of supplemental evidence.*” 37 C.F.R. § 42.64(b)(1) (emphasis added); *see also* 77 Fed. Reg. 48676 (Aug. 14, 2012). Patent Owner’s objections lack sufficient particularity, are confusing and inaccurate, and contain only conclusory references to the Federal Rules. Additionally, the vast majority of Patent Owner’s objections go to the weight, rather than the admissibility, of the evidence.

Despite Patent Owner’s failure to comply with the Board’s rules of practice, Petitioners have made efforts to respond and/or provide supplemental evidence. Petitioners reserve all rights to respond to any further explanations that Patent Owner may attempt to provide regarding its evidentiary objections and to address Patent Owner’s non-compliance with the rules should any motion to exclude be filed with the Board.

Exhibit 1004 – English Translation of Conroy Protocol

Patent Owner objects to Exhibit 1004 on various grounds (FRE 401-403, 801-803, and 901-902) but fails to provide the particularity required under 37 C.F.R. § 42.64(b)(1). The thrust of Patent Owner’s objections is that Exhibit 1004 did not contain a translator certification, but acknowledges that such a translator certification was provided in Exhibit 1204. Therefore, this objection is not warranted.

Patent Owner also claims the admission of Exhibit 1004, without a translator certification, would be unduly prejudicial, misleading, and a waste of time but fails to explain or identify any prejudice, why the exhibit/admission thereof would be misleading, or how it would result in a waste of time.

Patent Owner next objects that Petitioners have not provided evidence to show that Exhibit 1004 is what Petitioners claim it is, but Patent Owner does not contest Petitioners’ claim nor suggest Exhibit 1004 is not the Protocol to Conroy (Exhibit 1003). Therefore, this objection lacks merit. Regardless, Conroy was available online in 2011 and included a link to the referenced protocol. See <https://web.archive.org/web/20111205071903/http://www.nejm.org:80/doi/full/10.1056/NEJMoa1011923#t=articleMethods>. The link to the referenced protocol is the same today as it was in 2011. (*Compare id.* at hyperlinked “protocol” with <https://www.nejm.org/doi/full/10.1056/NEJMoa1011923#APPNEJMoa1011923P>

[RO](#) (containing hyperlink to download the “Protocol” today).) The hyperlink for the protocol was and still is: http://www.nejm.org/doi/suppl/10.1056/NEJMoa1011923/suppl_file/nejmoa1011923_protocol.pdf.

Finally Patent Owner objects to Exhibit 1004 as hearsay, but does not explain its objection. Regardless, Exhibit 1004 is not being relied upon for the truth of the matter asserted but rather what it would suggest to person of ordinary skill in the art.

Patent Owner’s objections go to weight, not admissibility. However, without waiving any arguments and in an effort to address any of Patent Owner’s concerns, Petitioners attach here to **Exhibit A**, which includes an updated translation and certification of Exhibit 1004 and which fixes a couple typos identified by Patent Owner in their briefing.

Exhibit 1204 – Translation Certification

Patent Owner objects to Exhibit 1204 on various grounds (FRE 401-403 and 801-803) but fails to provide the particularity required under 37 C.F.R. § 42.64(b)(1). Patent Owner acknowledges Exhibit 1204 is translator’s certification, which should have alleviated its concerns with Exhibit 1004. Patent Owner argues that the admission of this exhibit would also be unduly prejudicial, misleading, and a waste of time but again fails to explain or identify any prejudice, why the

exhibit/admission thereof would be misleading, or how it would result in a waste of time.

Patent Owner objects to Exhibit 1004 as hearsay, but does not explain its objection, why one of the several exceptions to hearsay does not apply, or why it could not seek a deposition to address its concerns.

Patent Owner's objections go to weight, not admissibility.

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

Patent Owner objects to each of the above referenced exhibits on the grounds that they are inadmissible under FRE 801-803 and 901-902. But other than conclusory assertions Patent Owner does not provide the particularity required under 37 C.F.R. § 42.64(b)(1). For example, Patent Owner claims it is unclear when various exhibits became publicly available but the objected to exhibits include a title, authors, and dates, which can be verified and located online and/or in various libraries or other public repositories so it unclear what Patent Owner is objecting to. (*See, e.g.*, Ex. 1003 (stating on its face that it was published in the New England Journal of Medicine on May 12, 2011 and available online at NEJM.ORG). In addition, and as described above, these publications can be found on the internet archive. Patent Owner also objects on hearsay grounds but fails to identify what is allegedly hearsay or otherwise explain its hearsay objection.

Patent Owner's objections go to weight, not admissibility.

Exhibits 1027, 1042-1060, and 1201-1207

Patent Owner objects to each of these exhibits under FRE 401-403 and 801-803. Patent Owner again makes conclusory relevance and admissibility objections without explaining what would be prejudicial, misleading, or cause a waste of time if these exhibits were admitted. Patent Owner objects on hearsay grounds but fails to identify what is allegedly hearsay or otherwise explain its hearsay objection. The relevance of these exhibits is explained by Dr. Ratain and/or in Petitioners' Opposition to Patent Owner's Discretionary Denial Request. Patent Owner's objections go to weight, not admissibility.

Exhibits 1002 and 1200

Patent Owner objects to Exhibits 1002 and 2000 (Dr. Ratain declarations) on various grounds (FRE 401-403, 801-803, and 901-902) but fails to provide the particularity required under 37 C.F.R. § 42.64(b)(1). Patent Owner claims parts of Dr. Ratain's testimony is not relevant and, if it is, it would be unduly prejudicial, misleading, or a waste of time. Unsurprisingly, there is no explanation for these claims.

Patent Owner also objects to these exhibits as including hearsay but fail to identify any hearsay in either exhibit that is purportedly objectionable. Moreover, these declarations are both signed under oath and Patent Owner may cross-examine Dr. Ratain, making this objection even more confusing.

Patent Owner's objections go to weight, not admissibility.

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

Patent Owner objects to the above exhibits on various grounds including FRE 401-403 and 801-803 but fails to provide the particularity required under 37 C.F.R. § 42.64(b)(1). As an initial matter, Patent Owner does not explain how certain relevant objections and/or hearsay objections made to these exhibits differ, if at all, from other objections on the same grounds made to the same exhibits.

Patent Owner objects to the above exhibits as purportedly published after August 21, 2015 and not prior art under § 102 but of the listed exhibits only Exs. 1013-1014 are asserted in a ground against the '552 Patent so it is unclear what Patent Owner is objecting to. In addition, Petitioners explained that Exhibits 1013-1014 are prior art if the effective date is November 10, 2017. (*See* Pet. at 14.)

Patent Owner's objections go to weight, not admissibility.

Petitioners provide Exhibit A below and find that no further supplemental evidence is necessary. Petitioners reserve all rights.

Respectfully submitted,

Dated: September 12, 2025

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR § 42.6(e), the undersigned hereby certifies that on September 12, 2025, the foregoing Petitioners' Response and Notice of Supplemental Evidence was served via e-mail, as authorized by the Patent Owner, at the following email correspondence address of record:

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