

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 REPLY IN SUPPORT OF ITS MOTION
TO EXCLUDE EVIDENCE**

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

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I. EXHIBIT 1004 SHOULD BE EXCLUDED

A. The § 42.63(b) Violation Was Not Timely Cured

Petitioners assert that the § 42.63(b) deficiency has been cured by two translation certifications: Ex. 1204, filed with Petitioners' Discretionary Denial opposition, and Ex. 1004A, served with Petitioners' response to Patent Owner's post-institution objections. Paper 45 ("Opp.") at 3. Neither satisfies the rule.

Petitioners characterize Ex. 1204 as having been filed "prior to institution," as though that timing is sufficient. It is not. Section 42.63(b) requires a certified translation to accompany the foreign-language document it translates—meaning it must be filed with the Petition itself. *See Zhongshan Broad Ocean Motor Co. v. Nidec Motor Corp.*, IPR2014-01123, Paper 20 at 3-8 (PTAB Jan. 21, 2015) (denying institution where a translation affidavit was not included with the original petition and was only obtained after Patent Owner identified the deficiency in its Preliminary Response). That Petitioners filed Ex. 1204 only after Patent Owner identified the deficiency in its Response confirms the violation.

Petitioners also point to Ex. 1004A as an independent cure, but Ex. 1004A is deficient. The two translator certifications attached as Ex. 1004A attest to the accuracy of only pages 1-37 and 61-88 of Ex. 1004. *See* Ex. 1004A at 89-90. Pages 38-60—a substantial portion of the exhibit—are left entirely without certification.

An attempted cure that covers only part of a document does not satisfy § 42.63(b)'s requirement that a certified translation accompany the document.

The certifications also fail to identify the foreign-language source document. Neither the certifications in Exs. 1204 and 1004A nor the translation itself (Ex. 1004) identifies the specific foreign-language document provided to the translators. Without linking the certifications to an identified source document, there is no basis to find that Ex. 1004 is an accurate translation of the protocol accompanying Ex. 1003.

B. Exhibit 1004 Has Not Been Authenticated

Petitioners invoke *Ericsson* and *Juniper* for the proposition that the authentication standard is “slight” and that Patent Owner has offered no credible basis for challenging authenticity. Opp. at 4. Neither case supports them. *Ericsson* involved a printed publication bearing an “IEEE copyright line contain[ing] a publication date, a price, and what appears to be an ISSN code.” IPR2014-00527 Paper 41 at 10. Petitioners cite no authority that the internal characteristics of a clinical trial protocol they rely on for Ex. 1004 (*see* Opp. at 6) rise to the same level, especially here where Petitioner only relies on the translated copy and not the original French-language version. *Juniper* involved documents maintained on a public server, authenticated through testimony from a witness with personal knowledge of how those documents were maintained. IPR2016-01397, at 62-63.

Here, no declarant with personal knowledge has attested that Ex. 1004 is the same document available at the NEJM hyperlink in 2011. Petitioners' Wayback Machine argument is attorney argument unsupported by any declaration from a person with personal knowledge of Wayback or NEJM's publication practices. Attorney argument is not evidence. *Neste Oil Oyj v. REG Synthetic Fuels, LLC*, IPR2013-00578, Paper 53 at 3-4 (PTAB Mar. 12, 2015) (excluding Wayback printouts offered through counsel, who lacked personal knowledge of the websites). And *UL LLC v. Space Chariot Inc.*, 250 F. Supp. 3d 596 (C.D. Cal. 2017), cited by Petitioners, is a district court opinion addressing judicial notice of advertising in a trademark action—not a foreign-language protocol in an IPR.

Further, Petitioners' reliance on Wayback highlights the authentication issue with Ex. 1004. Petitioners' provided a link to Conroy (Ex. 1003) as allegedly archived "including as of December 5, 2011," and points to a sub-link therein allegedly directing to Ex. 1004. Opp. at 5. That sub-link, however, when clicked on, does not return any webpage, let alone Ex. 1004. Petitioners' apparently concede this issue, as they claim that if one "hover[s] over the hyperlink" to the alleged Ex. 1004 in the Wayback archive of Conroy (Ex. 1003), *part* of that hyperlink is the same as a hyperlink Petitioners' provided to the version of the Conroy Protocol as it appears on the NEJM webpage *today*. *Id.* at 5-6.

The relied-upon expert testimony fares no better. Opp. at 4-5. Dr. Oberstein and Dr. Ratain testified generally about journal practices, not with personal knowledge of Ex. 1004 specifically. FRE 901(a) requires the latter.

Petitioners have also made no showing that the original French-language document is the same document that was translated to produce Ex. 1004. The certifications do not identify the source document, *supra*. Ex. 1004 is therefore unauthenticated as to what it purports to be *and* as to what it purports to translate.

C. Statements in Exhibit 1004 Are Hearsay

Petitioners' Opposition confirms the hearsay problem. Petitioners argue that Ex. 1004 contains dates that "align with the publication of the study results in 2011, after the end of the study." Opp. at 7. That hearsay use under FRE 801(c): relying on the truth of the dates to establish that it is prior art. *See Toyota Motor Corp. v. Am. Vehicular Scis. LLC*, IPR2013-00417, Paper 78 at 13-14 (PTAB Jan. 2015) (excluding documents offered to corroborate a publication date is inadmissible hearsay). Petitioners' invocation of FRE 803(5) and (6) also fails: no foundation has been laid establishing a business record under FRE 803(6), and no sponsoring witness has been identified as required by FRE 803(5).

II. EXHIBIT 1017 SHOULD BE EXCLUDED

On authentication, Petitioners again rely exclusively on attorney argument—this time pointing to references in Ex. 1003 to the Appendix and Wayback

evidence of a consistent hyperlink. Opp. at 8-9. While the alleged sub-link to the Appendix found within Wayback does return a webpage (unlike the sub-link to the Protocol as noted *supra*), that sub-link returns a copy of the Appendix with a capture date of January 20, 2022, further highlighting the authentication issue. As with Ex. 1004, no declarant with personal knowledge has attested that Ex. 1017 is the document NEJM made available at that hyperlink in 2011. *See Neste*, IPR2013-00578, Paper 53 at 3-4. Dr. Oberstein's statement was a generalization, not one with the requisite personal knowledge per FRE 901(a). Ex. 1210 at 166:3-16.

On hearsay, Petitioners again claim they rely on Ex. 1017 only for what it would have disclosed to a POSA. Opp. at 11. But Petitioners' Opposition relies on the Appendix hyperlink since 2011 to establish public availability—precisely the hearsay use the Board rejected in *Toyota*, IPR2013-00417, Paper 78 at 13-14. Petitioners' FRE 803(5) and (6) arguments fail for the same reasons as *supra*.

III. PORTIONS OF THE RATAIN DECLARATION AND DEPOSITION SHOULD BE EXCLUDED

Expert testimony that rests on inadmissible evidence lacks the factual foundation required by FRE 702 and should be given no weight. *See* 37 C.F.R. § 42.65(a). Paragraphs 105, 106, and 241 of the Ratain Declaration (Ex. 1002) cite only Exs. 1004 and 1017. If those exhibits are excluded, the opinions built exclusively on them must be disregarded. Patent Owner's motion to exclude pages 41:6–43:23 of Ex. 2073 follows for the same reason.

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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 5 pages and thus complies with the applicable word limit.

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

The undersigned hereby certifies that on May 11, 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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