

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' OPPOSITION TO
PATENT OWNER'S MOTION TO EXCLUDE**

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INTRODUCTION

Patent Owner Ipsen Biopharm Ltd.’s (“Patent Owner”) has failed to satisfy its burden in establishing that any of the evidence subject to its Motion to Exclude is inadmissible under the Federal Rules of Evidence (“FRE”). Petitioners CSPC Pharmaceutical Group Limited, CSPC Ouyi Pharmaceutical Co., Ltd., and Conjurpro Biotherapeutics, Inc. (collectively, “Petitioners”) respectfully request that the Board deny the request to exclude Exhibits 1004, 1017, 1002, and/or 2073.

STANDARD

The party bringing a motion to exclude “has the burden of proof to establish that it is entitled to the requested relief.” *Flir Sys., Inc. v. Leak Surveys, Inc.*, IPR2014-00411, Paper 113 at 3 (PTAB Sept. 3, 2015) (citing 37 C.F.R. § 42.20(c)). A party cannot base a motion to exclude on evidentiary grounds it did not previously assert in its objections. *See* 37 C.F.R. § 42.64; *HTC Corp. v. Advanced Auto Devices, LLC*, IPR2014-01155, Paper 36 at 26 (PTAB Dec. 29, 2015).

In opposing a motion to exclude, a party who previously served the moving party with evidence curing the evidentiary issue “may file the supplemental evidence with [its] Opposition to the Motion,” *Palo Alto Networks, Inc. v. Finjan, Inc.*, IPR2015-01979, Paper 27 at 2 (PTAB Aug. 11, 2016), in order to “support admissibility of the originally filed evidence and to defeat a Motion to Exclude that

evidence,” *Toyota Motor Corp. v. Blitzsafe Tx., LLC*, IPR2016-00418, Paper 16 at 7 (PTAB Aug. 2, 2016). If supplemental evidence cures the objection at issue, the motion to exclude should be denied. *Masterimage 3d, Inc. v. RealD Inc.*, IPR2015-00040, Paper 85 at 68 (PTAB Apr. 14, 2016) (“On this record, the deficiency alleged by Petitioner has been obviated by [PO’s] Supplemental Evidence. Accordingly, [the] Motion to Exclude is *denied*.”).

ARGUMENT

Patent Owner has not shown that evidence that it failed to object to or did not sufficiently articulate objections to should be excluded, especially when the evidence suggests the reliability of said information.

First, there is no dispute that Conroy (Ex. 1003) is an authentic article published in the well respected and reputable New England Journal of Medicine (“NEJM”) in 2011. Patent Owner does not challenge the authenticity of the NEJM publication or Conroy article itself (Ex. 1003) and both Exhibits 1004 and 1007 are referenced in Exhibit 1003. This underscores that the authenticity of these documents and citing practices are not actually in dispute.

Second, Patent Owner’s objections deployed categorical citations to FRE 401–403, 801–803, and 901–902 without the particularized “why and where” that the Board’s practice requires for curable objections. The rules require objectors to

articulate grounds “with sufficient particularity to allow correction in the form of supplemental evidence,” which necessarily includes the identification of the specific defect and the supplemental showing that would cure it. The record shows that, instead of pinpointing any concrete authentication gap or hearsay statement within the challenged documents, Patent Owner leveled generic assertions that do not identify what, if anything, is purportedly inauthentic or which statements are allegedly inadmissible hearsay, thereby depriving Petitioners of meaningful notice and frustrating the cure mechanism built into § 42.64(b)(2).

I. Exhibit 1004 – Conroy Protocol.

A. There Has Been No 37 C.F.R. § 42.63(b) Violation.

Patent Owner’s translation argument under 37 C.F.R. § 42.63(b) fails. Patent Owner falsely asserts that Petitioners did not serve supplemental evidence. (Paper 42 (herein “Mot.”) at 2.) In reality, Petitioners supplied a translator certification, first in Exhibit 1204 (prior to institution), and then—expressly to address Patent Owner’s concern—served updated translation materials and certifications as Exhibit A (filed herewith as **Exhibit 1004A**) with their timely response to Patent Owner’s objections under § 42.64(b)(2). (*See* Toft Decl. at ¶¶ 3-6.) That is, prior to the deadline to cure any form-of-evidence deficiencies, Petitioners had provided two certifications from professional translators attesting to the accuracy of the translation. The updated

translation and certifications—including either or both Exhibits 1204 and Exhibit 1004A—resolve the issue Patent Owner identifies.

B. Exhibit 1004 Has Been Authenticated And/Or Is Self-Authenticating and Patent Owner Has Not Shown Otherwise.

Exhibit 1004 contains multiple, robust indicia of authenticity that satisfy FRE 901(a) and the Board’s flexible evidentiary approach. *See Ericsson v. Intellectual Ventures I LLC*, IPR2014-00527, Paper 41 at 12 (PTAB May 18, 2015) (noting “the standard for admissibility under [FRE] 901(a) is slight.”). Patent Owner also provides no credible reason for questioning the authenticity of Exhibit 1004. *See Juniper Networks, Inc. v. Chrimar Sys., Inc.*, IPR2016-01397, Paper 66 at 62–63 (PTAB Dec. 29, 2017) (denying motion to exclude because movant did not provide adequate reason to question exhibit’s authenticity). Instead, the evidence suggests Exhibit 1004 is credible and authentic.

First, the record establishes that Conroy and the Conroy Protocol were published by the NEJM, which makes it self-authenticating under FRE 902(6). The Conroy NEJM article (Ex. 1003) includes reference to the Conroy Protocol, stating “[t]he protocol, including the statistical analysis plan, is available with the full text of this article at NEMJ.org. The first author vouches for the fidelity of the study to the protocol.” (Ex. 1003 at 3.) Patent Owner’s own expert, Dr. Oberstein, testified that vouching for the fidelity of the study is a common thing. (Ex. 2010 at 164:24-

165:19.) He also states that he had no reason to believe the protocol was not provided by NEJM with the publication of Conroy and that “if they say they provided it, then I think they probably provided it.” (*Id.* at 165:20-166:2.) Dr. Ratain also testified that “most top journals require that the protocol be submitted at the time of initial submission, and it’s always published alongside any major paper” and “certainly, New England Journal of Medicine does that.” (Ex. 2076 at 42:1-7.)

Second, the objective evidence shows that the Conroy Protocol (Ex. 1004) has been available since 2011. NEJM’s link to Conroy¹ and the Conroy Protocol² have been consistent since at least 2011. For example, Conroy (Ex. 1003) is archived on the Internet Archive’s Wayback Machine, including as of December 5, 2011. (*See* <https://web.archive.org/web/20111205071903/http://www.nejm.org:80/doi/full/10.1056/NEJMoa1011923#t=article>.) The first use of “protocol” (the same as the above quote) is a hyperlink. (See *id.*) Copying the link or hovering over the hyperlink reveals the destination:

https://web.archive.org/web/20111205071903/http://www.nejm.org/doi/suppl/10.1056/NEJMoa1011923/suppl_file/nejmoa1011923_protocol.pdf. The yellow

¹ Compare <http://www.nejm.org/doi/full/10.1056/NEJMoa1011923> with Exhibit 1003.

² Compare https://www.nejm.org/doi/suppl/10.1056/NEJMoa1011923/suppl_file/nejmoa1011923_protocol.pdf with Exhibit 1004.

highlighted portion of this link is the same as the Conroy Protocol link in Footnote 2, which demonstrates that the link NEJM associated with the protocol was the same in December 2011 as it is today. Courts routinely find webpages available through the Wayback Machine as authentic. *See UL LLC v. Space Chariot Inc.*, 250 F. Supp. 3d 596, 604 n.2 (C.D. Cal. 2017) (collecting cases and stating “In this district, the contents of web pages available through the Wayback Machine are generally proper subjects of judicial notice “as facts that can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned[.]”); Fed. R. Evid. 201(b)(2). Even Patent Owner has previously identified the Conroy Trial Protocol as being dated from 2011, on the face of the ‘552 Patent. (*See* Ex. 1001 at 33.)

Exhibit 1004 offers other indicia of authenticity. It is a clinical-trial protocol bearing a specific title, a coordinating investigator (Professor Thierry Conroy), an editorial committee, an identified sponsor (FNCLCC), and a unique EudraCT number, which are the hallmarks of a genuine study protocol document. (*See* FRE901(4).) The document details drug regimens and dose-modification algorithms with a level of technical specificity that strongly corroborates its authenticity and its identification as the operative Conroy study protocol. (*Id.*)

C. The Asserted Publication Date Does Not Constitute Hearsay Nor Support Exclusion.

Patent Owner's hearsay argument is procedurally and legally flawed. As an initial matter, Patent Owner's objections stated only that it "further objects to Exhibit 1004 as hearsay" without providing sufficient particularity to allow correction or explanation. *See* 37 C.F.R. § 42.64(b)(1); Paper 15 at 2. Indeed, even today, Petitioners are unaware of what statement in the 88-page Conroy Protocol that Patent Owner objects to. Because Patent Owner did not provide any particularity with respect to this objection, it must be denied. *See HTC Corp.*, IPR2014-01155, Paper 36 at 26 (denying motion to exclude when party did not previously identify grounds for objection). The Protocol does include dates, including when it contemplates the start and end of Phase II and III trials to be and the date of the end of the study, which span from June 2004 to June 2010. (*See* Ex. 1004 at 6.) Petitioners do not rely on any of these dates for the truth of when a study aspect began or ended, but these dates do align with the publication of the study results in 2011, after the end of the study. These dates are also exceptions to hearsay under FRE 803 (5) and (6).

In addition, Petitioners are not relying on any statement in Exhibit 1004 for the truth of any matter asserted within this business record; rather, they rely on the protocol for what it would have disclosed or suggested to a person of ordinary skill in the art (POSA).

Accordingly, Patent Owner's request to exclude Exhibits 1004 and 1204 should be denied.

II. Exhibit 1017 – Conroy Appendix.

Patent Owner's objections to Exhibit 1017 failed to identify the grounds for any objection with sufficient particularity under 37 C.F.R. § 42.64(b)(1). Patent Owner's only objections stated generically that Exhibit 1017 **and fifty-one other exhibits** have "not [been] established [as] an authentic copy," "as hearsay," or "the date by which it became publicly available" was not established. (Paper 15 at 2-3.) Patent Owner explained that the exhibits included titles, authors, and dates that could be verified and located online.

A. Exhibit 1017 Has Been Authenticated And/Or Is Self-Authenticating and Patent Owner Has Not Shown Otherwise.

Patent Owner again offers no credible reason for questioning the authenticity of Exhibit 1017, which supports denial. *Juniper Networks*, IPR2016-01397, Paper 66 at 62–63. Instead, the evidence suggests Exhibit 1017 is credible and authentic.

Like the Conroy Protocol, Exhibit 1017—the Conroy Appendix—was made available by NEJM through a distinct, article-associated hyperlink; Patent Owner's own motion describes as such. (Mot. at 10.) The fact that the Conroy Appendix was published by a publication like NEJM makes it self-authenticating under at least FRE 902(6). As above, the Conroy article (Ex. 1003), which is not objected to, includes

reference to the Conroy Appendix. (*See* Ex. 1003 at 1 (“Additional investigators are listed in the Supplementary Appendix, available at NEJM.org”) 3-8 (providing seven other cites or references to the “Supplementary Appendix” that was “available at NEJM.org”).) Patent Owner’s own expert, Dr. Oberstein, testified that by stating the Supplementary Appendix was available in Conroy, it was provided by NEJM. (Ex. 2010 at 166:3-16.)

Second, the objective evidence shows the Conroy Appendix (Ex. 1004) has been available since 2011. NEJM’s link to the Conroy Appendix³ has similarly been consistent since at least 2011. For example, when looking at the December 5, 2011 capture of Conroy (Ex. 1003) describe above, the reference to “Supplementary Appendix, available at NEJM.org” under “Treatment” is a hyperlink. (*See* <https://web.archive.org/web/20111205071903/http://www.nejm.org:80/doi/full/10.1056/NEJMoa1011923#t=article>.) Copying the link or hovering over the hyperlink reveals the destination:

https://web.archive.org/web/20111205071903/http://www.nejm.org/doi/suppl/10.1056/NEJMoa1011923/suppl_file/nejmoa1011923_appendix.pdf. The green highlighted portion of this link is the same as the Conroy Appendix link in Footnote

³ Compare https://www.nejm.org/doi/suppl/10.1056/NEJMoa1011923/suppl_file/nejmoa1011923_appendix.pdf with Exhibit 1017.

3, which demonstrates that the link NEJM associated with the Appendix was the same in December 2011 as it is today. This again suggests authenticity. *See UL LLC*, 250 F. Supp. 3d at 604 n.2.

Exhibit 1017 offers other indicia of authenticity. It includes the information that Conroy states that it would including additional investigators, (*compare* Ex. 1003 at 1 *with* Ex. 1017 at 2), modifications for predefined toxic events, (*compare* Ex. 1003 at 3 *with* Ex. 1017 at 4-8), Response Evaluation Criteria in Solid Tumors, (*compare* Ex. 1003 at 3 *with* Ex. 1017 at 9), a “sample size determination” section, (*compare* Ex. 1003 at 3 *with* Ex. 1017 at 13), a Fig. I and II, (*compare* Ex. 1003 at 4, 6 *with* Ex. 1017 at 16-17). These facts strongly corroborates its authenticity and its identification as the operative Conroy Appendix. *See, e.g.*, FRE 901(b)(5). Thus, no supplemental evidence was necessary to authenticate Exhibit 1017. *Ericsson*, IPR2014-00527, Paper 41 at 12.

B. The Asserted Publication Date Does Not Constitute Hearsay Nor Support Exclusion.

As with Exhibit 1004, the hearsay objection to Exhibit 1017 is undeveloped and misdirected. Patent Owner points to, for the first time, a statement within the Appendix about its purpose and posits that any associated but identified date would be hearsay. (*See* Paper 15 at 2-3 (objecting only to “hearsay”); Mot. at 9.) Yet Patent Owner never explains how any such statement is being used for the truth of the

matter asserted or why exceptions would not apply given the context of publisher-hosted supplementary scientific documentation.

Petitioners are not relying on any statement in Exhibit 1017 for the truth of any matter asserted but rather for what the statements would have suggested to a person of ordinary skill in the art (POSA).

C. Portions of Ratain Declaration and Deposition were Not Objected To.

Patent Owner attempts to exclude portions of Exhibit 1002, which it never objected to, and portions of never before objected to Exhibit 2073, which Patent Owner filed. Both should be rejected and the evidence should stand.

Patent Owner moves to exclude paragraphs 105 and 106 of Exhibit 1002 and any other unidentified “portions of Exhibit 1002 that rely exclusively on Exhibits 1004 and 1017. (Mot. at 13-14.) First, Patent Owner’s objections never identified either paragraphs 105 or 106 as objectionable. (Paper 15 at 4.) Second, Petitioners remain unaware of what other portions of Exhibit 1002 that Patent Owner is moving to exclude. Surely, if objections are meant to be stated with sufficient particularity under 37 C.F.R. 42.64(b)(1), so should motions to exclude said evidence. Therefore, Patent Owner’s request to exclude any part of Exhibit 1002 should be denied.

Patent Owner also moves to exclude pages 41:6 through 43:23 of Exhibit 2073. This is testimony elicited by Patent Owner and then later filed by Patent

Owner. (*See* Exhibit 2073 at 41:6-43:23.) Moreover, Patent Owner has never objected to this testimony prior to its Motion. For these reasons, this request to exclude should be denied.

In addition, for the reasons described *supra* Sections A-B, Exhibits 1004 and 1017 are credible and authenticated and therefore there is no reason to exclude expert testimony about what a POSA would have understood from such references.

CONCLUSION

For the reasons set forth above, and because the proper remedy for any residual dispute over public accessibility or authentication is to assign weight to the evidence rather than exclude it, Petitioners respectfully request the Board deny Patent Owner's Motion to Exclude any or all of Exhibits 1002, 1004, 1017, 1204, and 2073.

Respectfully submitted,

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR § 42.6(e), the undersigned hereby certifies that on May 4, 2026, the foregoing Petitioners' Opposition to Patent Owner's Motion to Exclude were served via email, as authorized by the Patent Owner, at the following email addresses:

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