

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' REPLY IN SUPPORT OF ITS
MOTION TO EXCLUDE PATENT OWNER'S EVIDENCE
PURSUANT TO 37 C.F.R. § 42.64(c)**

Petitioners CSPC Pharmaceutical Group Limited, CSPC Ouyi Pharmaceutical Co., Ltd., and Conjurpro Biotherapeutics, Inc. (collectively, “Petitioners”) file this Reply in support of its Motion to Exclude Patent Owner’s Evidence Pursuant to 37 C.F.R. § 42.64(c) (Paper 43) (“Motion” or “Mot.”) and in response to Patent Owner Ipsen Biopharm Ltd.’s (“Patent Owner”) Opposition (Paper 44) (“Oppo.”).

ARGUMENT

The objected to exhibits pose serious risks under Federal Rule of Evidence (“FRE”) 403 and 801-802 because (1) their marginal probative value for the obviousness inquiry is substantially outweighed by the danger of confusing legal and factual issues, misleading the Board, and causing unfair prejudice and (2) because they are being offered for the truth of the matter asserted. Patent Owner offers misguided arguments in response thereto, as discussed below, and retreats to FRE 703 to attempt to save these exhibits. However, any reliance on Rule 703 is misplaced because Patent Owner uses the objected to exhibits as substantive proof of disputed facts, not merely as background inputs to an expert opinion. Rule 703 permits an expert to consider otherwise inadmissible material when forming an opinion, but it does not convert the underlying out-of-court statements into admissible evidence for the truth of the matters asserted, which is exactly how Patent Owner deploys these exhibits. Indeed, Patent Owner’s own authorities and framing

underscore that 703 speaks to expert reliance, not to the admission of the hearsay itself, and the Board may credit an expert's opinion while excluding or limiting the underlying hearsay for any truth-of-the-matter use. The retreat to FRE 703 also fails because Patent Owner offers no evidence that any of these exhibits are the type of material reasonably relied upon by experts in the field, especially for dosing instructions and/or reasonable likelihood of creating a drug that could treat pancreatic cancer (whether or not it was FDA approved).

Exhibit 2004

Patent Owner does not dispute that Exhibit 2004 teaches that “dose reductions were common” and a “standard approach” for FOLFIRINOX including reductions for “oxaliplatin, irinotecan and 5FU,” that most patients required dose reductions, and that those reductions “did not affect results.” (Compare Mot. at 2-3 with Oppo. at 1-3.) Despite this, Patent Owner doubles down that Exhibit 2004 is used to define that FOLFIRINOX includes 85 mg/m² oxaliplatin. (Oppo. at 2.) Thus, any reliance on this Exhibit for the dosing of oxaliplatin is being offered for the truth of the matter asserted and would be hearsay.

Even if not hearsay, the use of a selective statement within Exhibit 2004 is highly prejudicial and confusing. It is undisputed that Exhibit 2004 suggests and teaches that dose reductions were extremely common. Thus, Exhibit 2004 cannot

provide an understanding that 85 mg/m² oxaliplatin was always used in FOLFIRINOX treatments, as of the effective date for the '552 Patent. Accordingly, Patent Owner's selective use of Exhibit 2004 does not reflect what a POSA's understanding was and it would be confusing and prejudicial to allow Patent Owner to "define" the dosing of any drug based on its disclosures.

Exhibits 2008 and 2009

Patent Owner's admissions demonstrate that Exhibits 2008 and 2009 should be excluded. First, Patent Owner admits that it does not rely on Exhibits 2008 or 2009 in its briefing. That should end the inquiry. Second, Patent Owner does not dispute that these exhibits relate to FDA approval stats and admits they are being "offered to establish what was publicly understood about clinical development success rates in oncology." (Oppo. at 4.) That is, Patent Owner is relying on the truth of the matter asserted, i.e., what the success rates were. Regardless, inclusion of FDA approval stats when considering an obviousness inquiry is prejudicial and confusing. As Patent Owner argues, FDA approval is a long process with varying success rates. Whether a drug is given FDA approval may depend on how effectively it treats a patient population or not but also other factors not claimed by the '552 Patent, including but not limited to consideration of the number, type, and severity of complications or side-effects, study design concerns, patient population issues, etc.

FDA approval usually advances through Phase I, II, and III trials depending on these different considerations. That is, a new drug could treat patients and advance to Phase III trials but not gain FDA approval due to other concerns. Conversely, whether a POSA would reasonably expect a combination to treat a patient, i.e., provide more than a de minimis benefit to a patient, is all that is required to create a reasonable likelihood of success here. That is a far different and lower bar than FDA approval. By introducing this evidence, it also suggests that the POSA must be located in the United States and subject to clinical trial and FDA guidelines (as opposed to regulatory schemes or none at all).

The problem is aggravated by the studies' own caveats—such as excluded data and technology-specific effects noted in Exhibits 2008 and 2009—which heighten the danger that generalized statistics will be overread as dispositive on the obviousness question presented here. (Mot. at 3-4.)

By introducing this evidence, it risks confusing the standards (as Patent Owner continues to do here) and would severely prejudice these proceedings by heightening Petitioners' burden to show obviousness.

Exhibit 2010

Similar to Exhibits 2008-2009, Patent Owner relies on Exhibit 2010 to assert the low predictive value of phase II oncology results as compared to FDA approval,

which are again presented for their truth and thus remain hearsay. (Mot. at 5.) Again, both clinical trial success and FDA approval constitute a number of considerations not claimed by the ‘552 Patent (extent of treatment as compared to side effects or other concerns). Patent Owner again centers on population-level clinical development outcomes and U.S. based regulations—FDA approval dynamics, which are analytically distinct from the claim- and prior-art-specific reasonable-expectation-of-success analysis that governs obviousness under KSR and Federal Circuit law. Such evidence offers little to no insight into whether a particular drug combination offers more than a de minimis treatment benefit, which is all that is required for a reasonable expectation of success here.

At minimum, the Board should strictly limit any consideration to expert background only, with an express bar on using Exhibits 2004, 2008, 2009, and 2010 for the truth of any dosing constraints, success-rate figures, or predictiveness claims in assessing reasonable expectation of success.

EXHIBITS NOT RELIED UPON OR EXPLAINED

Patent Owner mischaracterizes both Petitioners’ argument and the evidence. Patent Owner does not dispute—or at least provide any citation in the record to show otherwise—that none of Exhibits 2002-2003, 2005-2011, 2013-2015, 2020-2028, 2030, 2033-2035, 2037, 2039-2042, 2047-2072, and 2074-2075 are not cited to

anywhere in Patent Owner’s Response (Paper 21) or Sur-Reply (Paper 38). (See Oppo. at 9-10.) Patent Owner also does not dispute that Exhibits 2006-2010, 2014-2015, 2023, 2026, 2030, 2033-2034, 2037, 2039-2042, 2047-2072, and 2074-2075 are not cite in any of Patent Owner’s Papers in this proceeding. (*See id.*) Instead, and as explained in the Motion, Patent Owner relies on a vague cites to multiple paragraphs or pages in Exhibit 2076 for each of these exhibits. (Mot. at 6.)

For example, Patent Owner admits the only “citation” to Exhibit 2006 is actually to paragraph 49 of Exhibit 2076 on page 34 of their Patent Owner Response (Paper 21). (Oppo. at 9.) There, Patent Owner states “[p]atients with metastatic pancreatic cancer are at an advanced stage of the disease” and then cite to 10 paragraphs, one of which—marked as a “see also” is paragraph 49. (Paper 21 at 33-34.) Exhibit 2006’s use in Exhibit 2076 does not support the argument in Paper 21. The same cite is also used for Exhibits 2014 and 2015, (Oppo. at 9), neither of which are explained or summarized.

In another example, Patent Owner cites to eighteen (18) paragraphs to argue the likelihood of success in developing new therapies is low. (Paper 21 at 48; Oppo. at 9.) One of those paragraph cites to Exhibits 2008 and 2009, but as explained above relate to the success of clinical trials and FDA approval not the success in developing new combination therapies capable of treating.

Accordingly, Patent Owner has not shown these Exhibits are relevant to these proceedings. Alternatively, they constitute an improper incorporation by reference.

CONCLUSION

For the reasons set forth above and in its Motion, Petitioners respectfully request that the Board exclude Exhibits 2004, 2008-2010 and all uncited or unexplained exhibits.

Respectfully submitted,

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR § 42.6(e), the undersigned hereby certifies that on May 11, 2026, the foregoing Petitioners' Reply in Support of Its Motion to Exclude Patent Owner's Evidence Pursuant to 37 C.F.R. § 42.64(c) were served via email, as authorized by the Patent Owner, at the following email addresses:

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