UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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CSPC PHARMACEUTICAL GROUP LMITED,
CSPC OUYI PHARMACEUTICAL CO., LTD., AND
CONJUPRO BIOTHERAPEUTICS, INC.,
Petitioners,

v.

IPSEN BIOHARM LTD.,
Patent Owner.

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Case No. IPR2025-00505
Patent No. 11,344,552

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PETITIONERS OBJECTIONS TO PATENT OWNER'S EVIDENCE PURSUANT TO 37 C.F.R. § 42.64(b)(1)

Pursuant to 37 C.F.R. § 42.64 and the Federal Rules of Evidence, as applied by the Board, Petitioners CSPC Pharmaceutical Group Limited, CSPC Ouyi Pharmaceutical Co., Ltd., and Conjupro Biotherapeutics, Inc. (collectively "Petitioner") provides the following objections to evidence submitted by Patent Owner Ipsen Biopharm Ltd., ("Patent Owner"). These objections are timely served within ten (10) business days of the Board's Institution Decision, (Paper 13).

Petitioner serves Patent Owner with these objections to provide notice that Patent Owner may move to exclude the challenged evidence under 37 C.F.R. § 42.64(c) unless Patent Owner cures the defects associated with the challenged evidence identified below. In addition, Petitioner reserves the right to present further objections to this or additional evidence submitted by Patent Owner, as allowed by the applicable rules or other authority.

I. Objections to Exhibits 2001-2003, 2005, 2011-2013.

Patent Owner objects to Exhibits 2001-2003, 2005, 2011-2013 to the extent the exhibits are not cited to or relied upon by Patent Owner in its Preliminary Patent Owner Response. Accordingly, this evidence is irrelevant, misleading, and confusing under Fed. R. Evid. 401-403.

II. Objections to Exhibits 2004, 2006-2010, 2014, 2017-2019, and 2022-2035.

Petitioner objects to Exhibits 2004, 2006-2010, 2014, 2017-2019, and 2022-2035 to the extent they contain hearsay under FRE 801-802 and/or are irrelevant, misleading, and/or confusing under FRE 401-403.

- Patent Owner relies on Exhibit 2004 to reflect an unidentified "understanding" of what the FOLFIRINOX regimen includes and what would have allegedly motivated a POSA and therefore Patent Owner is relying on the statements for the truth of the matter asserted. (Paper 9 at 30.) Exhibit 2004 also fails to indicate that any individual understood FOLFIRINOX regimens to be limited to any particular dosing and is therefore irrelevant, misleading, and confusing.
- Patent Owner relies on Exhibits 2006-2007 for the truth of the matter asserted, i.e., what treatment options existed. (Paper 9 at 3, 25.) In addition, whether the identified treatment options existed is irrelevant to the obviousness inquiry presented here. Patent Owner also relies on Exhibit 2007 to negative trial results in a handful of studies. (Paper 9 at 45-46.) Not only does Patent Owner rely on the truth of the matter asserted, Petitioner objects to the extent the results in any unrelated trial are irrelevant, misleading, and confusing.
- Patent Owner relies on Exhibits 2008-2009 for the truth of the matter asserted, i.e., the development success rates or failure rates for oncology drugs as well as for other diseases. (Paper 9 at 43.) Whether certain drugs pass regulatory hurdles is a different inquiry than an obviousness analysis and therefore this information is also irrelevant, misleading, and confusing.

- Patent Owner relies on Exhibit 2010 for the truth of the matter asserted, i.e., the correlation between predictive value and likelihood of approval. (Paper 9 at 45.) The cited quote is also taken out of context and is therefore irrelevant, misleading, and confusing.
- Patent Owner relies on Exhibit 2014 for the truth of the mater asserted, i.e., what the treatment goals for advanced-stage or metastatic pancreatic cancer are. (Paper 9 at 2.)
- Patent Owner relies on Exhibits 2017-2019 for the truth of the matter asserted, i.e., the understood definition of "treatment." (Paper 9 at 7-8.)
- Patent Owner relies on Exhibit 2022 for the truth of the matter asserted, i.e., what Exhibit 2022 states. (Paper 9 at 19-20.)
- Patent Owner relies on Exhibit 2023 for the truth of the matter asserted, i.e., that certain drug characteristics result in unpredictable clinical effects. (Paper 9 at 38-39.) In addition, Patent Owner does not provide evidence that the prior art or obvious combination had such characteristics and therefore this is irrelevant, misleading, and confusing.
- Patent Owner relies on Exhibits 2024-2028 for the truth of the matter asserted, i.e., the inter-patient variability of different drugs or drug combinations. (Paper 9 at 39-40.)
- Patent Owner relies on Exhibits 2029-2035 for the truth of the matter asserted, i.e., the survival rates, superiority, and/or economic value

associated with different drug regimens. (Paper 9 at 49-50.) Exhibits 2029-2030 also published after the effective filing date of the '552 Patent are therefore irrelevant, misleading, and confusing.

III. Objections to Exhibits 2001-2035.

Petitioner objects to Exhibits 2001-2035 as lacking authentication as required under Fed. R. Evid. 901, which requires that "the proponent must produce evidence sufficient to support a finding that the item is what the proponent claims it is." Patent Owner has failed to provide any evidentiary foundation for any of these Exhibits.

Dated: August 28, 2025

By: /s/ Luke Toft

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR § 42.6(e), the undersigned hereby certifies that on August 28, 2025, the foregoing Petitioner's Objections to Patent Owner's Evidence Pursuant to 37 C.F.R. § 42.64(b)(1) was served via e-mail, as authorized by the Patent Owner, at the following email correspondence address of record as follows:

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