

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CONJUPRO BIOTHERAPEUTICS, INC.,
Petitioner,

v.

ASCLETIS PHARMA CHINA CO. LTD.,
Patent Owner.

Case No. PGR2025-00057
Patent No. 12,234,236
Title: GLP-1R agonist and therapeutic method thereof

**PETITIONER'S MOTION TO EXCLUDE EVIDENCE
PURSUANT TO 37 C.F.R. § 42.64(c)**

Pursuant to 37 C.F.R. § 42.64(c), and the Scheduling Order (Paper 17 at 12-13), Petitioner Conjupro Biotherapeutics, Inc. moves to exclude Patent Owner Ascletis Pharma China Co. Ltd. (“Patent Owner”) Exhibits 2032, 2035, 2035A, 2036, 2036A, 2037–43, 2044, 2044A, 2045, 2047, 2049, 2053–67, 2069, 2071, 2077, 2079–81, 2081A, 2082–83, and 2088–89 (“the Exhibits”), which are inadmissible under the Federal Rules of Evidence (“FRE”). The Exhibits were properly objected to, and Patent Owner was timely notified of the objections on March 12, 2026, and July 16, 2026. Therefore, Petitioner respectfully requests the Board to exclude the Exhibits.

ARGUMENT

A motion to exclude must explain why evidence is inadmissible under the FRE (*e.g.*, relevance or hearsay). *Legend3D, Inc. v. Prime Focus Creative Servs. Can. Inc.*, IPR2016-00806, Paper 73 at 8–9 (P.T.A.B. Sept. 18, 2017); *see* 37 C.F.R. §§ 42.62, 42.64; Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,758, 48,767 (Aug. 14, 2012). Evidence is relevant if it tends to make a fact of consequence more or less probable. Fed. R. Evid. 401. Irrelevant evidence is inadmissible. Fed. R. Evid. 402. Evidence may also be excluded if its probative value is substantially outweighed by unfair prejudice, confusion, or misleading the Board. Fed. R. Evid. 403.

Expert witnesses must be qualified by knowledge, skill, experience, training, or education and must offer testimony that will help the trier of fact. Fed. R. Evid. 702. Non-experts must have personal knowledge and may not offer specialized opinions. Fed. R. Evid. 602; 701. Hearsay—an out-of-court statement offered for the truth of the matter asserted—is inadmissible unless an exception applies. Fed. R. Evid. 801–02. Evidence must be authenticated by evidence demonstrating it is what the proponent claims. Fed. R. Evid. 901.

I. Exhibits 2080 and 2081 Should Be Excluded

John Gargiulo’s testimony (Ex. 2080) and Patent Owner’s Testing Data (Ex. 2081), which Mr. Gargiulo improperly attempts to authenticate, should be excluded.

Other than background, Mr. Gargiulo’s declaration purports to provide three categories of information. First, Mr. Gargiulo’s declaration provides the “results of in vitro activity” (of the EC₅₀) of certain compounds. (Ex. 2080, ¶¶6-8.) Second, he provides the “results of single-dose subcutaneous injection” to compare the pharmacokinetics, including the clearance (Cl_F) and observed concentration (C_{max}) of certain compounds. (*Id.*, ¶¶ 9-11.) Third, he authenticates the laboratory notebook provided as Exhibit 2081. (*Id.*, ¶¶ 12-13.) The lab notebook purports to document an HPLC-based solubility comparison of two compounds in pH 11 phosphate buffer conducted by Bin Liang on March 4, 2026. (Ex. 2081.) All of this information came from Bin Liang, who has not been shown to be unavailable. (*See*

Ex. 1039 at 17:2-7 (Gargiulo stating he talked to Mr. Liang the night before his deposition).)

a. Exhibit 2080: Declaration of John Gargiulo

Mr. Gargiulo's testimony should be excluded because he is not qualified, has no direct knowledge regarding the information he conveys, and relies entirely on hearsay.

First, Mr. Gargiulo is not a POSA and lacks the credentials, education, or experience to perform the tests or analyze the data he provides. Mr. Gargiulo is the Chief Business Officer ("CBO") of Ascletis Pharma Inc., with an MBA from Duke University's Fuqua School of Business and a B.A. in Economics from Boston College. (Ex. 2080, ¶¶ 3–4.) He is not a scientist, chemist, or pharmacologist and has no foundation for performing laboratory tests, analyzing results, reviewing scientific articles or patent-related documents, or preparing lab notebooks. (*Id.*; Gargiulo Dep. Ex. 1039 at 27:23–29:8 (admitting he does not perform laboratory tests, analyze test results, review scientific articles, review patent applications, or prepare laboratory notebooks); 113:13-14 (confirming he is "not a scientist"); 148:12-24 (stating same and stating he has no idea how the information in his declaration could be used).)

Despite this, Mr. Gargiulo testifies regarding in vitro activity evaluation results (EC50 data comparing challenged compounds to orforglipron) (Ex. 2080, ¶¶

6–8), pharmacokinetic study data (clearance, Cmax values for Compounds 1 and 19) (Ex. 2080, ¶¶ 9–11), and authentication of a laboratory notebook (Ex. 2081; Ex. 2080, ¶¶ 12–13). He lacks the requisite qualifications for testimony assessing the accuracy or reliability of scientific data proffered, as required under FRE 701–02. (*See, e.g.*, Ex. 1039 at 133:23-134:7 (confirming limited understanding of data).)

Second, Mr. Gargiulo’s declaration is based entirely on hearsay. He presents experimental data generated by others. He was not present for, did not supervise, and was not involved in directing any testing. (Gargiulo Dep. Ex. 1039 at 60:16–24; 84:1–17 (confirming not involved in testing and only knowledge is based on conversation with another), 85:25-87:18 (confirming no involvement).) He states that Bin Liang oversaw some of the scientific testing and data analysis but does not know who performed other testing. (Gargiulo Dep. Ex. 1039 at 90:19-92:2 (confirming no knowledge of testing); 92:15-98:22 (confirming no knowledge of testing); 126:17-127:22 (same); 134:8–20 (same); 137:23-138:10 (stating he does not know names of third-party testers).) Rather, Mr. Gargiulo received the data from Bin Liang and has only Mr. Liang’s assurances regarding its accuracy. (Gargiulo Dep. Ex. 1039 at 85:5-24 (confirming he only talked to an individual but has “not verified” data or reviewed “source documentation”), 136:21–137:6 (received info from Liang); 156:5-158:20 (stating he doesn’t need scientific knowledge to know the accuracy of information but that he only knows the information is accurate

because Mr. Liang told him so and he believes him); 159:8-160:10 (received notebook from Mr. Liang without other info); 167:4-21; *see also id.* at 24:2-6 (confirming there are no documents he reviewed that were not cited in declaration); 133:14-16 (admitting unawareness of any documents that would include PK information).)

Patent Owner chose not to rely on Bin Liang—a named inventor on the ‘236 Patent who purportedly conducted or oversaw the testing—and instead offers only Mr. Gargiulo’s secondhand account. These out-of-court statements are offered for the truth of the matter asserted and are inadmissible hearsay under FRE 801-803. Moreover, the source of Bin Liang’s information is unknown. (*See* Ex. 1039 at 93:11-98:22 (confirming an unnamed third party conducted assay testing); 135:12-137:3 (confirming same regarding clearance and Cmax data); 137:23-138:10.) Because Bin Liang obtained the underlying data from documents or conversations with unnamed third parties before relaying it to Mr. Gargiulo, this constitutes hearsay within hearsay under FRE 805. Patent Owner has not demonstrated that either level of hearsay qualifies for any exception.

Third, because Mr. Gargiulo has no personal knowledge he cannot authenticate the test data. *See* FRE 602, 901; *TRW Auto. U.S. LLC v. Magna Elecs. Inc.*, IPR2014-01348, Paper 25 at 5-12 (PTAB Jan. 15, 2016). He confirmed he does not even understand how the test data is generated. (*See, e.g.*, Ex. 1039 at 50:24-

51:1; 92:3-14; 119:25-121:3 (confirming no personal knowledge).) Further, he does not provide adequate details about the testing, as required by 37 C.F.R. § 42.65.

Fourth, Mr. Gargiulo's declaration is more prejudicial than probative. As discussed, the declaration does not identify who conducted the experiments, the protocols followed, or any quality assurance measures. Mr. Gargiulo cannot offer scientific evidence or verify its accuracy and relies entirely on Mr. Liang, whom he does not know or interact with, (*see* Ex. 1039 at 184:23-187:2), which further calls into question the reliability of the data and denies Petitioner the opportunity to cross those who could speak to the data. Thus, the declaration prejudices Petitioner more than it helps resolve any fact issue and should be excluded under FRE 403.

Accordingly, Exhibit 2080 should be excluded from evidence.

b. Exhibits 2081 and 2081A: Solubility Test

Petitioner moves to exclude Exhibits 2081¹ because it is not properly authenticated, constitutes hearsay, and its probative value is substantially outweighed by unfair prejudice.

First, Exhibit 2081 has not been properly authenticated. The exhibit purports to be a laboratory notebook documenting solubility testing of compounds GLC02-

¹ Petitioner similarly moves to exclude Exhibit 2081A, to the extent it is filed in response to this motion. Exhibit 2081A provides an English translation of the Chinese language included in the lab notebook entry but otherwise does not materially address any of the objections raised by Petitioner.

521 (Compound 1) and GLC02-568 (Compound 65) in phosphate buffer at pH 11. (Ex. 2081A, 1; Ex. 2080, ¶¶ 12–13.) Mr. Gargiulo attempted to authenticate this document by claiming it is “a true and correct copy of Ascletis laboratory notebook GLNB007230-3” maintained “in the regular course of business at Ascletis.” (Ex. 2080, ¶ 12.) However, Mr. Gargiulo admits these statements were made before he discussed this exhibit with anyone. (*See* Ex. 1039 at 16:19-18:10 (confirming first conversation with Mr. Liang regarding Ex. 2081 was day before deposition).)

The reality is, the laboratory notebook entry was created on March 4, 2026—***one day before*** Patent Owner’s Response was filed on March 5, 2026. (Ex. 2081, 1 (“创建时间:2026/03/04 16:16:04 创建人:梁斌”).) Mr. Gargiulo did not conduct or oversee the experiment, does not know who decided to undertake the testing, has no understanding of the software used, did not access the laboratory notebook database or know where notebooks are stored, and has no idea if other versions exist or what changes were made to it. (Ex. 1039 at 27:11-30:21; 160:11-165:11.)

Second, the laboratory notebook constitutes hearsay under FRE 801-803 and qualifies for no exception. (*See id.*) The notebook does not qualify as a business record under FRE 803(6) because it was created one day before the filing deadline, in anticipation of litigation rather than in the regular course of business. (*See also* Ex. 1039 at 166:17-167:3 (confirming it was created one day before submission and

no business reason to conduct test).) No qualified witness has testified as to the regular practice of making, keeping, or securing the notebook.

Third, the test results in the notebook are not relevant to the facts at issue here and/or have a probative value that is substantially outweighed by the danger of unfair prejudice and misleading the Board. For one, the solubility data was generated at a single pH value (pH 11) without explanation of why that pH was selected or how it relates to physiologically relevant conditions, e.g., the pH of the human body or gastric fluid, which is significantly below pH 11. (*See* Ex. 1039 at 179:5-183:7.) The testing appears to have been conducted specifically for purposes of this proceeding and under non-physiologically relevant conditions. Further, the “-3” in the lab notebook’s identification number, GLNB007230-3, suggests this is the third version of this entry. Any other versions of this lab notebook or audit trail have not been provided. Petitioner has had no opportunity to examine the individual(s) who conducted the testing, to review the full experimental protocols or record, or verify the accuracy of the results.

Accordingly, Exhibit 2081 should be excluded because the exhibit is unauthenticated, constitutes hearsay, and any probative value is substantially outweighed by the danger of unfair prejudice.

II. Exclude Exhibits or Parts of Exhibits Never Relied Upon

Petitioner moves to exclude Exhibits and testimony not cited or relied upon by Patent Owner and therefore as irrelevant and prejudicial under FRE 401-403 and an improper attempt to incorporate arguments by reference.

First, significant portions of testimony contained in Exhibit 2079 are not cited to or relied upon by Patent Owner. *See* 37 C.F.R. §§ 42.22-42.23; *see also* § 42.204; *Actifo, Inc. v. Delphix Corp.*, IPR2015-00108, Paper 56 at 57 (PTAB Apr. 29, 2016) (excluding evidence not relied upon). Paragraphs 32–46, 48, 50–51, 53–60, 65, 67–69, 71, 78, 82–83, 85–87, 89–91, 93–94, 97–98, 100–102, 106, 108, 110–20, 122, 125–26, 129–30, 132–39, 143, 148–52, 154–65, 168–76, 179–80, 182–83, 189–90, 192–93, 199–201, 204–06, 211–13, 218, 220–21, 223, 231–54, 257, 259–73, 275, 278, 282, 285, 287–88, 292–93, 296–97, 302–05, 309–10, 319, and 328–33 contain substantive testimony but are not cited in Patent Owner’s Response.

Relatedly, Exhibits 2032, 2035, 2035A, 2036, 2036A, 2037–41, 2043, 2044, 2044A, 2045, 2047, 2049, 2065, 2067, 2069, 2071, 2077, 2082-83, and 2087–89 were not cited in Patent Owner’s substantive briefing. These exhibits are not discussed in Patent Owner’s Response (Paper 26) or Sur-Reply (Paper 39).

Because Patent Owner has not cited or relied upon these exhibits, they have no tendency to make any fact of consequence more or less probable, are likely to cause confusion, and create undue prejudice. Permitting Patent Owner to introduce

dozens of uncited exhibits risks the Board inadvertently considering evidence Petitioner has had no meaningful opportunity to address. Because Patent Owner never explained these exhibits' significance, Petitioner could not respond to any intended arguments. Allowing such evidence would be fundamentally unfair. Accordingly, they are irrelevant, misleading, and confusing under FRE 401–03.

In addition, Dr. Wipf's uncited testimony and reliance on uncited exhibits constitutes improper incorporation by reference under 37 C.F.R. § 42.6(a)(3). Patent Owner elected not to rely on this testimony; thus, it is not part of Patent Owner's Response and need not be addressed by Petitioner in its Reply. To the extent Patent Owner attempts to rely on this testimony, Petitioner has not been given the opportunity to assess how Patent Owner intends to use it or which arguments it supports, resulting in substantial prejudice.

These exhibits and portions of Dr. Wipf's testimony should be excluded.

III. Exhibit 2079: Declaration of Dr. Wipf

Petitioner further moves to exclude Exhibit 2079 under FRE 401–03 and 702 for the following additional reasons. Portions of Exhibit 2079 should also be excluded under FRE 702 as far as those portions offer opinions beyond Dr. Wipf's qualifications. First, Dr. Wipf offers opinions based on his own analysis of the three-dimensional cryo-EM model of orforglipron bound to the GLP-1 receptor deposited in the Protein Data Bank (PDB ID: 6XOX). (*See* Ex. 2079, ¶¶ 88–98 (citing Ex.

2035).) Dr. Wipf is allegedly a synthetic organic and medicinal chemist, but nothing in his qualifications establishes expertise in structural biology, cryo-electron microscopy, or computational analysis of protein-ligand binding pocket geometry sufficient to render reliable opinions on the three-dimensional spatial environment of the GLP-1R binding pocket. (*See* Ex. 2079, ¶¶ 3–12.) Specifically, Dr. Wipf’s opinions in paragraphs 88–98 of his declaration must be excluded because he opines that the binding pocket is not “spacious” and could not accommodate a bulkier substituent, based on his visualization of the 3D cryo-EM model. (Ex. 2079, ¶¶ 88–98, 169–181; Ex. 2035, 1–11.) However, Dr. Wipf is not qualified to offer such an opinion as evidence because he cannot be considered an expert in this area under FRE 702. Accordingly, this testimony is misleading, confusing, and unfairly prejudicial under FRE 401–403, and it should be excluded.

Second, Dr. Wipf offers opinions in portions of Exhibit 2079 on the clinical significance of Ascletis’s ASC30 clinical trial results, including its Phase 1 and Phase 2 data. (Ex. 2079, ¶¶ 326–27; Ex. 2042; Ex. 2066.) Dr. Wipf is not a clinician, pharmacologist, or clinical trial specialist, (*see* Ex. 2079, ¶¶ 3–12), and he therefore lacks the qualifications to offer reliable expert opinions on the clinical significance of weight loss data, gastrointestinal tolerability comparisons, or the implications of pharmacokinetic profiles for human dosing regimens. These opinions are beyond the scope of his expertise and should be given no weight. Accordingly, this testimony is

misleading, confusing, and unfairly prejudicial under FRE 401–403, and it should be excluded.

Third, portions of Exhibit 2079 also rely on data presented in the Gargiulo Declaration (Ex. 2080) and the Ascleitis laboratory notebook (Ex. 2081) as a basis for his expert opinions on unexpected results and solubility. (*See, e.g.*, Ex. 2079, ¶¶ 311–25; Ex. 2080, ¶¶ 6–13; Ex. 2081.) As set forth above, the Gargiulo Declaration and laboratory notebook themselves suffer from authentication, hearsay, and foundation deficiencies that render them unreliable bases for expert opinion under FRE 703. Accordingly, this testimony is confusing, misleading, and unfairly prejudicial under FRE 401–403 and should be excluded.

Accordingly, Exhibit 2079 should be excluded because it contains testimony not relied upon by Patent Owner, offers improper expert opinion, improperly relies on Exhibits 2080 and 2081, and is unfairly prejudicial to Petitioner.

IV. Exhibits 2053–64

Petitioner moves to exclude Exhibits 2053–64 under FRE 401–03, 702, and 801–03 because they are irrelevant, more prejudicial than probative, and constitute hearsay. Patent Owner and Dr. Wipf cite these exhibits—general review articles about heterocyclic groups in medicinal chemistry—solely to argue that a skilled artisan would be “just as likely” to consider alternative modifications. (Papers 26, 29–33; Ex. 2079, ¶ 284.) However, none of these articles addresses the specific

structural modifications claimed in the '236 Patent—namely, the substitution patterns at issue. General review articles discussing heterocyclic chemistry in the abstract do not make any fact of consequence regarding the specific claimed compounds more or less probable. FRE 401, 402. Patent Owner's failure to identify any particular teaching in these articles, invoking them only in bulk, further demonstrates their lack of relevance. Accordingly, this evidence is irrelevant and unfairly prejudicial under FRE 401–403.

Exhibits 2053–64 also constitute impermissible hearsay under FRE 801–05. These articles are offered for the truth of the matters asserted therein—that certain heterocyclic modifications are common or preferred in medicinal chemistry—and contain citations to other sources that themselves constitute hearsay within hearsay. No exception applies. Therefore, these exhibits should be excluded.

V. Exhibit 2042

Petitioner moves to exclude Exhibit 2042 under Fed. R. Evid. 401–03, 801–03, 805, and 901–02 because it constitutes hearsay and its probative value is substantially outweighed by unfair prejudice. Exhibit 2042 is a press release issued by Ascletis Pharma Inc. on December 8, 2025, announcing Phase II clinical trial results for ASC30. (Ex. 2042.) This constitutes hearsay under FRE 801–03 as an out-of-court statement offered to prove ASC30 achieved certain weight loss and

safety endpoints. (*See* Ex. 2079, ¶¶ 127, 326.) No peer review or independent verification supports this data.

The promotional nature of the press release creates substantial danger of misleading the Board. Press releases are designed to generate favorable publicity and investor interest, not to provide objective accounts of clinical findings. Patent Owner uses this exhibit to argue ASC30 has a “best-in-class profile” and compares it favorably to orforglipron, but cross-trial comparisons are inherently unreliable without access to underlying data, patient populations, and study designs. Exhibit 2042 should be excluded.

CONCLUSION

For the reasons set forth above, Petitioner respectfully requests that the Board exclude Exhibits 2032, 2035, 2035A, 2036, 2036A, 2037–43, 2044, 2044A, 2045, 2047, 2049, 2053–67, 2069, 2071, 2077, 2079–81, 2081A, 2082–83, and 2088–89.

Dated: August 10, 2026

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR § 42.6(e), I hereby certify that on August 10, 2026, I caused a true and correct copy of the foregoing **Petitioner's Motion to Exclude Evidence Pursuant to 37 C.F.R. § 42.64(c)** to be served by electronic mail, as authorized by Patent Owner, at the following email addresses:

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Dated: August 10, 2026

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