Gerard P. Norton
Jonathan R. Lagarenne
Paul W. Kalish
Joe G. Chen
Jonathan J. Madara
FOX ROTHSCHILD LLP
212 Carnegie Center, Suite 400
Princeton, NJ 08540
Telephone: 609-896-3600
Facsimile: 609-896-1469
Email: gnorton@foxrothschild.com
jlagarenne@foxrothschild.com
pkalish@foxrothschild.com
joechen@foxrothschild.com
jmadara@foxrothschild.com

Of Counsel:
Howard S. Suh (*pro hac vice*)
Erxin Du (*pro hac vice*)
101 Park Avenue, 17th Floor
New York, NY 10178
Phone: (212) 878-7900
hsuh@foxrothschild.com
edu@foxrothschild.com

Attorneys for Defendants/Counterclaim-Plaintiffs Conjupro Biotherapeutics, Inc., CSPC Pharmaceutical Group Limited, and CSPC Ouyi Pharmaceutical Co., Ltd.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IPSEN BIOPHARMACEUTICALS, INC. AND IPSEN BIOPHARM LTD., Plaintiffs, v. CONJUPRO BIOTHERAPEUTICS, INC., CSPC PHARMACEUTICAL GROUP LIMITED, AND CSPC OUYI PHARMACEUTICAL CO., LTD., Defendants.	Civil Action No. 24-4991 (RMB)(MJS) Civil Action No. 24-8723 (RMB)(MJS) Civil Action No. 25-13647 (RMB)(MJS) (Consolidated) **ANSWER TO COMPLAINT FOR PATENT INFRINGEMENT, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS** *(Filed Electronically)*

Defendants Conjupro Biotherapeutics, Inc. ("Conjupro"), CSPC Pharmaceutical Group Limited ("CSPC Group"), and CSPC Ouyi Pharmaceutical Co., Ltd. ("CSPC Ouyi") (collectively

"Defendants"), hereby file their answer ("Answer") to Plaintiffs Ipsen Biopharmaceuticals, Inc., and Ipsen BioPharm Ltd.'s (collectively "Plaintiffs" or "Ipsen") Complaint ("Complaint") for patent infringement (C.A. No. 25-13647 (RMB)(MJS), ECF No. 1). Each of the numbered paragraphs below regarding Defendants' Answer corresponds to the same numbered paragraphs in the Complaint. Additionally, Defendants hereby assert counterclaims for declaratory judgment of noninfringement and invalidity of U.S. Patent No. 12,364,691 ("the '691 patent" or "the patent-in-suit") against Ipsen.

Defendants deny all allegations in the Complaint, whether express or implied, that are not specifically admitted below. Defendants further deny that Plaintiffs are entitled to any relief, including the relief requested in the Complaint. With respect to the allegations made in the Complaint, upon knowledge with respect to Defendants' own acts, and upon information and belief as to other matters, Defendants respond and allege as follows:

RESPONSE TO PARAGRAPHS RELATING TO "THE PARTIES"

1. **Defendants' Response:** Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 1 and on that basis deny them.
2. **Defendants' Response:** Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2 and on that basis deny them.
3. **Defendants' Response:** Defendants admit the allegations of Paragraph 3.
4. **Defendants' Response:** Defendants admit the allegations of Paragraph 4.
5. **Defendants' Response:** Defendants admit the allegations of Paragraph 5.
6. **Defendants' Response:** Denied.
7. **Defendants' Response:** Defendants admit the allegations of Paragraph 7.
8. **Defendants' Response:** Defendants admit the allegations of Paragraph 8.

9. **Defendants' Response:** Denied.

RESPONSE TO PARAGRAPH RELATING TO "NATURE OF THE ACTION"

10. **Defendants' Response:** Defendants admit that Ipsen's Complaint asserts a claim for patent infringement of U.S. Patent No. 12,364,691 ("the '691 patent" or "the patent-in-suit") arising under the patent laws of the United States, 35 U.S.C. §100, et seq., as well as the Declaratory Judgement Act, 28 U.S.C. §§ 2201-02. Defendants deny that they have infringed the patent-in-suit or that Ipsen is entitled to any of the remedies specified under 35 U.S.C. §§ 281, 283-285, or under any other applicable provision or law.

RESPONSE TO PARAGRAPHS RELATING TO "JURISDICTION & VENUE"

11. **Defendants' Response:** The allegations in Paragraph 11 constitute conclusions of law to which no answer is required, and otherwise deny these allegations.
12. **Defendants' Response:** Defendants admit the allegations of Paragraph 12.
13. **Defendants' Response:** Defendants admit the allegations of Paragraph 13.
14. **Defendants' Response:** Defendants admit the allegations of Paragraph 14.
15. **Defendants' Response:** Defendants admit the allegations of Paragraph 15.
16. **Defendants' Response:** Denied.
17. **Defendants' Response:** Denied.
18. **Defendants' Response:** Denied.
19. **Defendants' Response:** Denied.
20. **Defendants' Response:** Denied. Defendants admits that, following FDA approval, Defendants may collaborate to distribute, or have distributed, the Proposed Conjupro Product in the United States. Defendants deny the remaining allegations in Paragraph 20.

21. **Defendants' Response:** Denied. The allegations in Paragraph 21 constitute conclusions of law to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction for the purposes of this action only.

22. **Defendants' Response:** Denied.

23. **Defendants' Response:** Denied. The allegations in Paragraph 23 constitute conclusions of law to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction for the purposes of this action only.

24. **Defendants' Response:** Denied. The allegations in Paragraph 24 constitute conclusions of law to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction for the purposes of this action only.

25. **Defendants' Response:** The allegations of Paragraph 25 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants do not contest venue for the purposes of this action only.

26. **Defendants' Response:** The allegations of Paragraph 26 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants do not contest venue for the purposes of this action only.

27. **Defendants' Response:** The allegations of Paragraph 27 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants do not contest venue for the purposes of this action only.

RESPONSE TO PARAGRAPHS RELATING TO "THE PATENT-IN-SUIT"

28. **Defendants' Response:** Defendants admit that a document purporting to be the '691 patent is attached to the Complaint as Exhibit A and that the face of the document indicates that it is titled "Methods For Treating Pancreatic Cancer Using Combination Therapies." Defendants admit that the document indicates that the '691 patent issued on July 22, 2025,

but deny that the '691 patent was duly and legally issued by the United States Patent and Trademark Office. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations in Paragraph 28 and on that basis deny them.

RESPONSE TO PARAGRAPHS RELATING TO "ACTS GIVING RISE TO THIS ACTION"

29. **Defendants' Response:** Paragraph 29 is not directed to Defendants and therefore does not require a response. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 29 and on that basis deny them.

30. **Defendants' Response:** Paragraph 30 is not directed to Defendants and therefore does not require a response. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 30 and on that basis deny them.

31. **Defendants' Response:** Paragraph 31 is not directed to Defendants and therefore does not require a response. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 31 and on that basis deny them.

32. **Defendants' Response:** Paragraph 32 is not directed to Defendants and therefore does not require a response. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 32 and on that basis deny them.

33. **Defendants' Response:** Conjupro admits submitting the NDA to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, sale,

and/or offer for sale within the United States, and/or importation into the United States, of the Proposed Conjupro Product. Defendants deny the remaining allegations in Paragraph 33.

34. **Defendants' Response:** Denied. The allegations in Paragraph 34 constitute conclusions of law to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 34.

COUNT I
(INFRINGEMENT BY CONJUPRO/CSPC OF U.S. PATENT NO. 12,364,691)

35. **Defendants' Response:** Defendants incorporate by reference preceding Paragraphs 1-34 of this Answer as if fully set forth herein.

36. **Defendants' Response:** Denied. The allegations of Paragraph 36 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 36.

37. **Defendants' Response:** Denied. The allegations of Paragraph 37 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 37.

38. **Defendants' Response:** Denied as stated. Defendants admit that Defendants intend to engage in the commercial manufacture, offer for sale, sale, and/or importation of the Proposed Conjupro Product following FDA approval of the Conjupro NDA. Defendants deny the remainder of the allegations in Paragraph 38.

39. **Defendants' Response:** Denied. The allegations of Paragraph 39 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 39.

40. **Defendants' Response:** Denied. The allegations of Paragraph 40 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 40.

41. **Defendants' Response:** Denied. The allegations of Paragraph 41 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 41.

42. **Defendants' Response:** Denied. Paragraph 42 is not directed to Defendants and therefore does not require a response. Additionally, the allegations of Paragraph 42 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 42.

43. **Defendants' Response:** Denied.

44. **Defendants' Response:** Denied. The allegations of Paragraph 44 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 44.

RESPONSE TO IPSEN'S PRAYER FOR RELIEF

Defendants deny that Ipsen is entitled to any of the relief it is seeking in this action.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Defendants hereby respectfully request a trial by jury of all issues so triable.

AFFIRMATIVE AND OTHER DEFENSES

By asserting these affirmative and other defenses, Defendants do not admit that they necessarily bear the burden of proof or persuasion for any of the defenses or issues alleged below. Moreover, at this time, Defendants have insufficient information and knowledge upon which to

form a belief as to whether additional defenses are or will later become available to them. Defendants reserve the right to amend their response to the Complaint to add, delete, or modify defenses based on additional facts and legal theories which they may or will learn, including that which may be divulged through clarification of the Complaint, through discovery, through change, or clarification of governing law, or through further analysis of Plaintiffs' allegations and claims in this litigation. Subject to the foregoing, and without prejudice to its denial of the allegations in Plaintiffs' Complaint, for its affirmative and other defenses in this action, Defendants hereby assert and allege the following:

FIRST DEFENSE – NON-INFRINGEMENT OF U.S. PATENT NO. 12,364,691

Defendants have not directly infringed, literally or under the doctrine of equivalents, any valid and enforceable claim of the '691 patent.

SECOND DEFENSE – INVALIDITY OF U.S. PATENT NO. 12,364,691

One or more of the claims of the '691 patent is invalid for failure to satisfy the conditions of patentability set forth in 35 U.S.C. §§ 101 *et seq.*, including but not limited to §§ 101, 102, 103, and/or 112.

THIRD DEFENSE – FAILURE TO STATE A CLAIM

The Complaint fails to state a claim upon which relief can be granted.

FOURTH DEFENSE – PROSECUTION HISTORY ESTOPPEL

By reason of amendments and/or statements made in and to the United States Patent and Trademark Office, during the prosecution of the applications that issued as the patent-in-suit, Plaintiff is estopped from construing the claims of the patent-in-suit in such a way as may cover Defendants' activities and/or products.

FIFTH DEFENSE – LIMITATION ON COSTS

Plaintiffs' claims for costs are barred, in whole or in part, by 35 U.S.C. § 288.

SIXTH DEFENSE – EQUITABLE DEFENSES

Plaintiffs' claims are barred by one or more of the doctrines of laches, waiver, equitable estoppel, acquiescence, implied license, unclean hands, unenforceability, and/or any other equitable remedy.

SEVENTH DEFENSE – NO INJUNCTIVE RELIEF

To the extent Plaintiffs purport to request injunctive relief, any such claim is barred because Plaintiffs have not suffered and will not suffer irreparable harm because of Defendants' conduct, and, instead, have adequate remedies at law.

EIGHTH DEFENSE – INEQUITABLE RELIEF

Plaintiffs' claims are barred, in whole or in part, because such relief would be inequitable.

NINTH DEFENSE – NO DAMAGES

Plaintiffs' claims are barred, in whole or in part, because there have been no damages in any amount by reason of any act alleged against the Defendants.

TENTH DEFENSE – NO EXCEPTIONAL CASE

Defendants have engaged in all relevant activities in good faith and, therefore, Defendants' actions do not give rise to an exceptional case under 35 U.S.C. § 285.

ELEVENTH DEFENSE – RESERVATION OF RIGHTS

Defendants presently have insufficient knowledge or information to form a belief as to whether additional affirmative defenses are available. Accordingly, Defendants hereby expressly reserve the right to assert additional affirmative defenses in the event that discovery indicates such defenses are appropriate.

WHEREFORE, having fully answered, Defendants prays that this Court deny all relief sought by Plaintiff, enter judgment in favor of the Defendants and against Plaintiffs, award Defendants their costs and attorneys' fees pursuant to 35 U.S.C. § 285, and grant Defendants such other relief as the Court deems just and proper.

COUNTERCLAIM-PLAINTIFFS' COUNTERCLAIMS

Without admitting any of the allegations in the Complaint, other than those allegations expressly admitted in the Answer *supra*, and without prejudice to Counterclaim-Plaintiffs' right to plead additional counterclaims as the facts of the matter warrant, Conjupro Biotherapeutics, Inc. ("Conjupro"), CSPC Pharmaceutical Group Limited ("CSPC Group"), and CSPC Ouyi Pharmaceutical Co., Ltd. ("CSPC Ouyi") (collectively "Counterclaim-Plaintiffs"), for their Counterclaims against Ipsen Biopharmaceuticals, Inc. ("Ipsen Biopharmaceuticals") and Ipsen Biopharm Ltd. ("Ipsen Biopharm") (collectively "Counterclaim-Defendants" or "Ipsen"), state as follows:

NATURE AND SUMMARY OF COUNTERCLAIMS

1. These counterclaims include claims for declaratory judgment that one or more claims of U.S. Patent No. 12,364,691 ("the '691 patent" or "the Counterclaim Patent-in-Suit") is invalid and/or not infringed.

2. Counterclaim-Plaintiffs repeat and incorporate by reference each of the foregoing paragraphs of Counterclaim-Plaintiffs' Answer and Affirmative Defenses to Counterclaim-Defendants' Complaint.

THE PARTIES

3. Counterclaim-Plaintiff Conjupro is an entity organized and existing under the laws of the State of New Jersey, having a principal place of business at 302 Carnegie Center, Princeton, New Jersey 08540.

4. Counterclaim-Plaintiff CSPC Group is an entity organized and existing under the laws of Hong Kong, having a principal place of business at Suite 3206, 32nd Floor, Central Plaza, 18 Harbour Road, Wan Chai, Hong Kong.

5. Counterclaim-Plaintiff CSPC Ouyi is an entity organized and existing under the laws of China, having a principal place of business at No. 88 Yangzi Road, Economic and Technological Development Zone, Shijiazhuang, Hebei 052160, China.

6. On information and belief, and based on the allegations in the Complaint, Counterclaim-Defendant Ipsen Biopharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware, having a place of business at 1 Main Street, Unit 700, Cambridge, Massachusetts 02142.

7. On information and belief, and based on the allegations in the Complaint, Counterclaim-Defendant Ipsen Biopharm Ltd. is a corporation organized and existing under the laws of England and Wales, having a place of business at Ash Road, Wrexham Industrial Estate, Wrexham, LL13 9UF, United Kingdom.

JURISDICTION AND VENUE

8. Counterclaim-Plaintiffs seek a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202.

9. This Court has subject matter jurisdiction over the Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 2201, 2202, 1331, 1338(a), and 1367, and/or 35 U.S.C. § 271(e)(2), based on an actual, substantial, and continuing justiciable case or controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants arising under the Patent Laws of the United States, 35 U.S.C. §§ 100 et seq.

10. This Court has personal jurisdiction over Counterclaim-Defendants because, on

information and belief, Counterclaim-Defendants transact business within the State of New Jersey and/or have engaged in systematic and continuous business contacts within the State of New Jersey. This Court further has personal jurisdiction over Counterclaim-Defendants because, among other reasons, Counterclaim-Defendants subjected themselves to the jurisdiction of this Court by filing their Complaint here.

11. Venue is proper in this District with respect to Counterclaim-Defendants as to these Counterclaims under 28 U.S.C. §§ 1391(b)-(c) and 1400(b) at least because the assertion of Counterclaim-Defendants' infringement action against Counterclaim-Plaintiffs in this District gave rise to these Counterclaims. Counterclaim-Defendants assert in their Complaint that venue is proper in this District.

12. In the alternative, this Court has personal jurisdiction over Plaintiff Ipsen Biopharm Ltd. because the requirements of Fed. R. Civ. P. 4(k)(2) are met as: (1) Counterclaim-Plaintiffs' claims arise under federal law; (2) Plaintiff Ipsen Biopharm Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (3) Plaintiff Ipsen Biopharm Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting NDAs to the FDA and/or manufacturing, importing, offering to sell, and/or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Plaintiff Ipsen Biopharm Ltd. satisfies due process.

13. At least because, on information and belief, Plaintiff Ipsen Biopharm Ltd. is a foreign company, venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(c).

BACKGROUND

Counterclaim Patent-in-Suit

14. On information and belief, on or about July 22, 2025, the United States Patent and Trademark Office ("USPTO") issued the '691 patent, titled "Methods for Treating Pancreatic

Cancer Using Combination Therapies." On information and belief, and based on the allegations in the Complaint, Ipsen Biopharm is the owner of the '691 patent. The '691 patent is attached as Exhibit A to the Complaint.

Ipsen's NDA

15. On information and belief, and based on the allegations of the Complaint, Ipsen Biopharmaceuticals is the holder of New Drug Application ("NDA") No. 207793 for irinotecan liposome injection, for intravenous use, which was approved by the Food and Drug Administration ("FDA") on October 22, 2015. Ipsen markets and sells this product in the United States under the brand name Onivyde® (irinotecan liposome injection).

16. On information and belief, on or about August 5, 2025, Counterclaim-Defendants caused the FDA to list the Counterclaim Patent-In-Suit in FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") in connection with NDA No. 207793.

17. By maintaining the listing of the Counterclaim Patent-In-Suit in the Orange Book, Counterclaim-Defendants represent that a claim of infringement of the Counterclaim Patent-In-Suit "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." *See* 21 U.S.C. § 355(b)(1)(G).

18. On information and belief, Counterclaim-Defendants have not caused the FDA to remove the Counterclaim Patent-In-Suit from the Orange Book in connection with NDA No. 207793.

Conjupro's Paragraph IV Patent Certification

19. In accordance with 21 U.S.C. § 355(b)(2), Conjupro notified Counterclaim-Defendants in writing that Conjupro's NDA No. 218923 was filed with a certification provided

for in 21 U.S.C. § 355(b)(2)(A)(iv) that inter alia, claims of U.S. Patent Nos. 8,329,213 ("the '213 patent"), 9,339,497 ("the '497 patent"), 9,364,473 ("the '473 patent"), 9,452,162 ("the '162 patent"), 9,492,442 ("the '442 patent"), 9,717,724 ("the '724 patent"), 10,980,795 ("the '795 patent"), 11,369,597 ("the '597 patent"), 8,147,867 ("the '867 Patent"), 10,456,360 ("the '360 Patent"), and 10,993,914 ("the '914 Patent") (collectively, the "Initial Patents-In-Suit") are invalid, unenforceable, and/or will not be infringed by Conjupro's NDA product ("Conjupro's Notice Letter").

20. Conjupro's Notice Letter met the statutory and regulatory requirements for such notice letters, and included a detailed statement of the factual and legal bases for Conjupro's opinion that the claims of the Initial Patents-In-Suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale, and/or importation of the Conjupro irinotecan NDA Product.

21. Conjupro's Notice Letter contained an Offer of Confidential Access that offered to provide Counterclaim-Defendants with confidential access to information from NDA No. 218923 for the purpose of Counterclaim-Defendants making a determination of whether an infringement action could be brought with respect to the Initial Patents-In-Suit.

The Instant Lawsuit

22. On April 15, 2024, Counterclaim-Defendants filed a first infringement action (Civil Action No. 24-4991 (RMB)(MJS)) against Counterclaim-Plaintiffs alleging infringement of the '213 patent, the '497 patent, the '473 patent, the '162 patent, the '442 patent, the '724 patent, the '795 patent, and the '597 patent.

23. Following the issuance of a new patent (U.S. Patent No. 12,059,497 (the "'59,497 patent")) on or about August 13, 2024, Counterclaim-Defendants filed a second infringement

action (Civil Action No. 24-8723 (RMB)(MJS)) on August 23, 2024 against Counterclaim-Plaintiffs alleging infringement of the '59,497 patent.

24. On October 18, 2024, the second infringement action was consolidated with the first infringement action.

25. Following the issuance of the '691 patent on or about July 22, 2025, Counterclaim-Defendants filed a third infringement action (C.A. No. 25-13647 (RMB)(MJS)) on July 22, 2025 against Counterclaim-Plaintiffs alleging infringement of the '691 patent.

26. On August 21, 2025, the third infringement action was consolidated with the first infringement action.

27. In view of the foregoing, there has been, and is now, an actual, substantial, and continuing, justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court with respect to noninfringement and/or invalidity of the '691 patent, and as to Counterclaim-Plaintiffs' right to obtain FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Conjupro's NDA Product.

COUNT 1
(DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '691 patent)

28. Counterclaim-Plaintiffs incorporate by reference the allegations of the preceding paragraphs of these Counterclaims.

29. Plaintiffs have accused Counterclaim-Plaintiffs of infringing claims of the '691 patent in connection with Conjupro's NDA No. 218923.

30. Counterclaim-Plaintiffs deny infringement of any valid, enforceable, properly construed claim of the '691 patent and allege that Counterclaim-Plaintiffs have not, and do not, infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by

inducement or contributorily), any valid, enforceable, properly construed claim of the '691 patent.

31. The manufacture, use, sale, or offer for sale within, and/or importation into, the United States of Conjupro's NDA Product will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid, enforceable, properly construed claim of the '691 patent.

32. Conjupro's NDA Product will not infringe any valid and/or enforceable claim of the '691 patent, at least because Conjupro's NDA Product does not satisfy the claims of the '691 patent, either literally or under the doctrine of equivalents.

33. There exists an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding whether Counterclaim-Plaintiffs infringe any valid claim of the '691 patent, and a judicial declaration of noninfringement is necessary and appropriate at this time.

34. Counterclaim-Plaintiffs are entitled to a declaration that they have not infringed the '691 Patent. Accordingly, Counterclaim-Plaintiffs respectfully request that the Court declare that the asserted claims of the '691 patent are not infringed.

COUNT 2
(DECLARATORY JUDGMENT OF INVALIDITY OF THE '691 patent)

35. Counterclaim-Plaintiffs incorporate by reference the allegations of the preceding paragraphs of these Counterclaims.

36. The '691 patent and each of the claims thereof are invalid for failure to comply with one of more conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, and/or double patenting, and/or based on other judicially-created bases for invalidation..

37. The alleged invention of the '691 patent was known or used by others in this

country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for the '691 patent.

38. The alleged invention of the '691 patent was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for the '691 patent in the United States.

39. The '691 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty, but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

40. The alleged invention of the '691 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '691 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '691 patent and would have had a reasonable expectation of success in doing so.

41. The '691 patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms to enable any person skilled in the art to practice the claims, as required by 35 U.S.C. § 112.

42. The claims of the '691 patent do not inform those skilled in the art about the scope of the invention with reasonable certainty, and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

43. There exists an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding the validity of the '691 patent, and a judicial declaration of invalidity is necessary and appropriate at this time.

44. Counterclaim-Plaintiffs are entitled to a declaration that the claims of the '691 patent are invalid.

PRAYER FOR RELIEF FOR COUNTERCLAIMS

(COUNTS 1 THROUGH 2)

WHEREFORE, Defendants/Counterclaim-Plaintiffs request that the Court enter judgment in its favor and against Counterclaim-Defendants as follows:

(A) Adjudging that Counterclaim-Plaintiffs have not and will not infringe any patent asserted by Counterclaim-Defendants in their Complaint;

(B) Adjudging that no patent asserted by Counterclaim-Defendants is valid;

(C) Enjoining Counterclaim-Defendants and their agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice hereof, from threatening or initiating infringement litigation against Counterclaim-Plaintiffs or their customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Counterclaim-Plaintiffs, or charging them either orally or in writing with infringement of any patent asserted herein against Counterclaim-Plaintiffs;

(D) Granting Counterclaim-Plaintiffs judgment in their favor on the Complaint and Counterclaims;

(E) Denying Counterclaim-Defendants' request for injunctive relief;

(F) Dismissing the Complaint with prejudice;

(G) Finding this case to be exceptional under 35 U.S.C. § 285 and awarding Defendants/Counterclaim-Plaintiffs their costs and reasonable attorneys' fees; and

(H) Awarding any other such relief as is just and proper.

JURY DEMAND

Defendants/Counterclaim-Plaintiffs hereby request a trial by jury on all issues triable to a jury.

Dated: September 10, 2025

By: */s/ Paul W. Kalish*

Gerard P. Norton
Jonathan R. Lagarenne
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FOX ROTHSCHILD LLP
gnorton@foxrothschild.com
jlagarenne@foxrothschild.com
pkalish@foxrothschild.com
joechen@foxrothschild.com
jmadara@foxrothschild.com
212 Carnegie Center, Suite 400
Princeton, NJ 08540
Phone: (609) 896-3600

Howard S. Suh (*pro hac vice*)
Erxin Du (*pro hac vice*)
FOX ROTHSCHILD LLP
101 Park Avenue, 17th Floor
New York, NY 10178
(212) 878-7900
hsuh@foxrothschild.com
edu@foxrothschild.com

Attorneys for Defendants/Counterclaim-Plaintiffs Conjupro Biotherapeutics, Inc., CSPC Pharmaceutical Group Limited, and CSPC Ouyi Pharmaceutical Co., Ltd.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that, on the below date, the foregoing was filed with the Court using the ECF system, which will provide notice and a copy to all Counsel of Record.

Dated: September 10, 2025

By: *s/ Paul W. Kalish*

Gerard P. Norton
FOX ROTHSCHILD LLP
212 Carnegie Center, Suite 400
Princeton, NJ 08540
Phone: (609) 896-3600
gnorton@foxrothschild.com

Attorneys for Defendants/Counterclaim-Plaintiffs Conjupro Biotherapeutics, Inc., CSPC Pharmaceutical Group Limited, and CSPC Ouyi Pharmaceutical Co., Ltd.