Gerard P. Norton
Jonathan R. Lagarenne
Paul W. Kalish
Joe G. Chen
Jonathan J. Madara
FOX ROTHSCHILD LLP
Princeton Pike Corporate Center
997 Lenox Drive
Lawrenceville, NJ 08648
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* application forthcoming)
Erxin Du (*pro hac vice* application forthcoming)
101 Park Avenue, 17th Floor
New York, NY 10178
Phone: (212) 878-7900
hsuh@foxrothschild.com
edu@foxrothschild.com

Attorneys for Defendants 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.: 1:24-cv-04991-RMB-MJS **ANSWER TO COMPLAINT FOR PATENT INFRINGEMENT, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS** *(Documents Filed Electronically)*

Defendants Conjupro Biotherapeutics, Inc. ("Conjupro"), CSPC Pharmaceutical Group Limited ("CSPC Group"), and CSPC Ouyi Pharmaceutical Co., Ltd. ("CSPCY 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 (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 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 "Counterclaim Patents-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. Ipsen Biopharmaceuticals 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.

   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. Ipsen Biopharm 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.

   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. On information and belief, 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.

Defendants' Response: Defendants admit the allegations of Paragraph 3.

4. On information and belief, 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.

Defendants' Response: Defendants admit the allegations of Paragraph 4.

5. On information and belief, 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.

Defendants' Response: Defendants admit the allegations of Paragraph 5.

6. On information and belief, Conjupro develops, manufactures, markets, sells, distributes, and/or imports generic pharmaceutical versions of branded products throughout the United States, including in this Judicial District.

Defendants' Response: Defendants admit the allegations of Paragraph 6.

7. On information and belief, Conjupro is a subsidiary of CSPC Group.

Defendants' Response: Defendants admit the allegations of Paragraph 7.

8. On information and belief, CSPC Ouyi is a wholly owned subsidiary of CSPC Group.

Defendants' Response: Defendants admit the allegations of Paragraph 8.

9. On information and belief, CSPC Group and CSPC Ouyi, themselves and/or in cooperation with Conjupro and/or as alter egos of Conjupro, develop, manufacture, market, sell, distribute, and/or import generic pharmaceutical versions of branded products throughout the United States, including in this Judicial District.

Defendants' Response: Denied as stated. Defendants admit that CSPC Group and CSPC Ouyi, themselves and/or in cooperation with Conjupro, develop, manufacture, market, sell, distribute, and/or import generic pharmaceuticals throughout the United States, including in this Judicial District. Defendants deny the remaining allegations of Paragraph 9.

RESPONSE TO PARAGRAPH RELATING TO "NATURE OF THE ACTION"

10. This is a civil action for infringement of United States 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"), and 11,369,597 ("the '597 patent") (collectively, "the patents-in-suit"). This action arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 et seq., as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

Defendants' Response: Defendants admit that Ipsen's Complaint asserts claims for patent infringement of the Patents-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 Patents-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. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and 35 U.S.C. § 271. This Court may declare the rights and other legal relationships of the parties under 28 U.S.C. §§ 2201-02 because this case is an actual controversy within the Court's jurisdiction.

Defendants' Response: Defendants admit that this Court has original federal question jurisdiction over the subject matter of actions for patent infringement. Defendants otherwise deny that any patent infringement occurred, or that Ipsen is entitled to any damages or relief in this action.

12. On information and belief, Conjupro has its principal place of business in New Jersey at 302 Carnegie Center, Princeton, New Jersey 08540.

Defendants' Response: Defendants admit the allegations of Paragraph 12.

13. On information and belief, Conjupro is registered with the State of New Jersey's Division of Revenue & Enterprise Services as a business in the State of New Jersey under Entity ID No. 0450121860.

Defendants' Response: Defendants admit the allegations of Paragraph 13.

14. On information and belief, Conjupro markets, sells, and/or distributes pharmaceutical products (including generic versions of branded drug products) throughout the United States, including within New Jersey.

Defendants' Response: Defendants admit the allegations of Paragraph 14.

15. On information and belief, Conjupro prepared and submitted New Drug Application ("NDA") No. 218923 (the "Conjupro NDA") from within New Jersey.

Defendants' Response: Defendants admit the allegations of Paragraph 15.

16. On information and belief, Conjupro prepared and submitted a certification under 21 U.S.C. § 355(b)(2)(A)(iv), which it included in its submission of the Conjupro NDA ("the Conjupro PIV Certification"), from within New Jersey.

Defendants' Response: Defendants admit the allegations of Paragraph 16.

17. On information and belief, Conjupro sent Ipsen Biopharmaceuticals and Ipsen Biopharm a letter notifying them of the Conjupro PIV Certification (the "Conjupro Notice Letter") from within New Jersey.

Defendants' Response: Defendants admit the allegations of Paragraph 17.

18. On information and belief, CSPC Group and CSPC Ouyi, themselves and/or in cooperation with Conjupro and/or as alter egos of Conjupro, develop, manufacture, market, sell, distribute, and/or import pharmaceutical products (including generic versions of branded drug products) throughout the United States, including in this Judicial District.

Defendants' Response: Denied as stated. Defendants admit that CSPC Group and CSPC Ouyi, themselves and/or in cooperation with Conjupro, develop, manufacture, market, sell, distribute, and/or import pharmaceutical products (including generic versions of branded drug products) throughout the United States, including in this Judicial District. Defendants deny the remaining allegations of Paragraph 18.

19. On information and belief, CSPC Group and CSPC Ouyi aided, abetted, cooperated, participated, and/or assisted Conjupro in its preparation and/or submission of the Conjupro NDA, the Conjupro PIV Certification, and/or the Conjupro Notice Letter.

Defendants' Response: Denied as stated. Defendants admit that CSPC Group and CSPC Ouyi aided, cooperated, participated, and assisted Conjupro in its preparation and/or

submission of the Conjupro NDA, the Conjupro PIV Certification, and the Conjupro Notice Letter. Defendants deny the remaining allegations of Paragraph 19.

20. On information and belief, Conjupro/CSPC will, itself and/or through its agents, distribute, or have distributed, the irinotecan liposome injection product described in the Conjupro NDA (the "Proposed Conjupro Product") from and within New Jersey.

Defendants' Response: Denied. Defendants admit that, following FDA approval of the Conjupro NDA, 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. This Court has personal jurisdiction over Conjupro, CSPC Group, and CSPC Ouyi because, on information and belief, they intend to market, sell, and/or distribute drug products within this state and to residents of this state, including the Proposed Conjupro Product. The preparation and submission of the Conjupro NDA, the Conjupro PIV Certification, and the Conjupro Notice Letter were conducted from within this Judicial District. Additionally, the distribution of the Proposed Conjupro Product will be from within this Judicial District. The marketing, offer for sale, sale, distribution, and/or importation of the Proposed Conjupro Product infringes the patents-in-suit and will lead to foreseeable harm and injury to Ipsen in this Judicial District.

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. This Court further has personal jurisdiction over CSPC Group in this action pursuant to Fed. R. Civ. P. 4(k)(2) because, on information and belief, CSPC Group is organized under the laws of Hong Kong and is not subject to any state's courts of general jurisdiction, and exercising jurisdiction over CSPC Group is consistent with the Constitution and laws of the United States.

Defendants' Response: Denied. The allegations in Paragraph 22 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.

23. This Court further has personal jurisdiction over CSPC Ouyi in this action pursuant to Fed. R. Civ. P. 4(k)(2) because, on information and belief, CSPC Ouyi is organized under the

laws of China and is not subject to any state's courts of general jurisdiction, and exercising jurisdiction over CSPC Ouyi is consistent with the Constitution and laws of the United States.

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. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and 1400.

Defendants' Response: The allegations of Paragraph 24 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.

25. Venue is proper in this Judicial District with respect to Conjupro because, inter alia, Conjupro has a regular and established place of business in New Jersey and because Conjupro has committed acts of infringement in this Judicial District, and, on information and belief, Conjupro will commit further acts of infringement in this Judicial District.

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. Venue is proper in this Judicial District with respect to CSPC Group and CSPC Ouyi because they are not residents of the United States, they have committed acts of infringement in this Judicial District, and, on information and belief, they will commit further acts of infringement in this Judicial District.

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.

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

27. Ipsen Biopharm is the owner of the '213 patent, titled "Liposomes Useful For Drug Delivery." The '213 patent was duly and legally issued on December 11, 2012. A copy of the '213 patent is attached as Exhibit A.

Defendants' Response: Defendants admit that a document purporting to be the '213 patent is attached to the Complaint as Exhibit A and that the face of the document indicates that it is titled "Liposomes Useful For Drug Delivery." Defendants admit that the document indicates that the '213 patent issued on December 11, 2012, but deny that the '213 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 27.

28. Ipsen Biopharm is the owner of the '497 patent, titled "Methods For Treating Pancreatic Cancer Using Combination Therapies Comprising Liposomal Irinotecan." The '497 patent was duly and legally issued on May 17, 2016. A copy of the '497 patent is attached as Exhibit B.

Defendants' Response: Defendants admit that a document purporting to be the '497 patent is attached to the Complaint as Exhibit B and that the face of the document indicates that it is titled "Methods For Treating Pancreatic Cancer Using Combination Therapies Comprising Liposomal Irinotecan." Defendants admit that the document indicates that the '497 patent issued on May 17, 2016, but deny that the '497 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.

29. Ipsen Biopharm is the owner of the '473 patent, titled "Methods For Treating Pancreatic Cancer Using Combination Therapies Comprising Liposomal Irinotecan." The '473 patent was duly and legally issued on June 14, 2016. A copy of the '473 patent is attached as Exhibit C.

Defendants' Response: Defendants admit that a document purporting to be the '473 patent is attached to the Complaint as Exhibit C and that the face of the document indicates that it is titled "Methods For Treating Pancreatic Cancer Using Combination

Therapies Comprising Liposomal Irinotecan." Defendants admit that the document indicates that the '473 patent issued on June 14, 2016, but deny that the '473 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 29.

30. Ipsen Biopharm is the owner of the '162 patent, titled "Methods For Treating Pancreatic Cancer Using Combination Therapies Comprising Liposomal Irinotecan." The '162 patent was duly and legally issued on September 27, 2016. A copy of the '162 patent is attached as Exhibit D.

Defendants' Response: Defendants admit that a document purporting to be the '162 patent is attached to the Complaint as Exhibit D and that the face of the document indicates that it is titled "Methods For Treating Pancreatic Cancer Using Combination Therapies Comprising Liposomal Irinotecan." Defendants admit that the document indicates that the '162 patent issued on September 27, 2016, but deny that the '162 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 30.

31. Ipsen Biopharm is the owner of the '442 patent, titled "Methods For Treating Pancreatic Cancer Using Combination Therapies Comprising Liposomal Irinotecan." The '442 patent was duly and legally issued on November 15, 2016. A copy of the '442 patent is attached as Exhibit E.

Defendants' Response: Defendants admit that a document purporting to be the '442 patent is attached to the Complaint as Exhibit E and that the face of the document indicates that it is titled "Methods For Treating Pancreatic Cancer Using Combination Therapies Comprising Liposomal Irinotecan." Defendants admit that the document indicates that the '442 patent issued on November 15, 2016, but deny that the '442 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 31.

32. Ipsen Biopharm is the owner of the ’724 patent, titled “Methods For Treating Pancreatic Cancer Using Combination Therapies.” The ’724 patent was duly and legally issued on August 1, 2017. A copy of the ’724 patent is attached as Exhibit F.

Defendants’ Response: Defendants admit that a document purporting to be the ’724 patent is attached to the Complaint as Exhibit F 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 ’724 patent issued on August 1, 2017, but deny that the ’724 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 32.

33. Ipsen Biopharm is the owner of the ’795 patent, titled “Methods For Treating Pancreatic Cancer Using Combination Therapies Comprising Liposomal Irinotecan.” The ’795 patent was duly and legally issued on April 20, 2021. A copy of the ’795 patent is attached as Exhibit G.

Defendants’ Response: Defendants admit that a document purporting to be the ’795 patent is attached to the Complaint as Exhibit G and that the face of the document indicates that it is titled “Methods For Treating Pancreatic Cancer Using Combination Therapies Comprising Liposomal Irinotecan.” Defendants admit that the document indicates that the ’795 patent issued on April 20, 2021, but deny that the ’795 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 33.

34. Ipsen Biopharm is the owner of the '597 patent, titled "Methods For Treating Pancreatic Cancer Using Combination Therapies." The '597 patent was duly and legally issued on June 28, 2022. A copy of the '597 patent is attached as Exhibit H.

Defendants' Response: Defendants admit that a document purporting to be the '597 patent is attached to the Complaint as Exhibit H 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 '597 patent issued on June 28, 2022, but deny that the '597 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 34.

RESPONSE TO PARAGRAPHS RELATING TO

"ACTS GIVING RISE TO THIS ACTION"

35. Ipsen Biopharmaceuticals holds 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).

Defendants' Response: Paragraph 35 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 35 and on that basis deny them.

36. On November 17, 2014, FDA granted fast track designation for the investigation of Onivyde® (irinotecan liposome injection), in combination with 5-fluorouracil and leucovorin, for the treatment of metastatic adenocarcinoma of the pancreas in patients previously treated with gemcitabine, to demonstrate an improvement in overall survival.

Defendants' Response: Paragraph 36 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 36 and on that basis deny them.

37. Onivyde® (irinotecan liposome injection) is indicated: (1) in combination with oxaliplatin, fluorouracil and leucovorin, for the first-line treatment of adult patients with metastatic pancreatic adenocarcinoma, in combination with fluorouracil and leucovorin ("first line treatment"), and (2) for the treatment of adult patients with metastatic pancreatic adenocarcinoma after disease progression following gemcitabine-based therapy ("second-line treatment").

Defendants' Response: Paragraph 37 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 37 and on that basis deny them.

38. The composition of Onivyde® and the use of Onivyde® for second-line treatment are embodiments of one or more claims of the patents-in-suit. Pursuant to 21 U.S.C. § 355(b)(1), the patents-in-suit are listed for Onivyde® in the FDA publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book").

Defendants' Response: Paragraph 38 is not directed to Defendants and therefore does not require a response. To the extent a response is required, the Orange Book speaks for itself, and Defendants deny any allegations that misstate or mischaracterize its contents. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 38 and on that basis deny them.

39. On information and belief, Conjupro/CSPC submitted the Conjupro NDA to the FDA under 21 U.S.C. § 355(b)(2) seeking FDA approval to engage in the commercial manufacture, use, sale, and/or offer for sale within the United States, and/or importation into the United States, of the Proposed Conjupro Product prior to the expiration of the patents-in-suit.

Defendants' Response: Denied. Defendants admit submitting the Conjupro 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 39.

40. On information and belief, Conjupro/CSPC certified in the Conjupro NDA, pursuant to 21 U.S.C. § 355(b)(2)(A)(iv), that the claims of the patents-in-suit are invalid and/or would not be infringed by the commercial manufacture, use, sale, or offer for sale within the United States, and/or importation into the United States, of the Proposed Conjupro Product.

Defendants' Response: Denied. The Conjupro NDA speaks for itself, and Defendants deny any allegations that misstate or mischaracterize its contents. Defendants deny the remaining allegations of Paragraph 40.

41. On or after March 5, 2024, Ipsen received the Conjupro Notice Letter by Federal Express, notifying Ipsen of the Conjupro NDA and the Conjupro PIV Certification.

Defendants' Response: Paragraph 41 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 41 and on that basis deny them.

42. On information and belief, any commercial manufacture, use, sale, and/or offer to sell the Proposed Conjupro Product within the United States, and/or any importation into the United States of the Proposed Conjupro Product, meets or embodies all elements of one or more claims of each of the patents-in-suit, either literally and/or under the doctrine of equivalents.

Defendants' Response: Denied. The allegations in Paragraph 42 constitute conclusions of law to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 42.

43. This action was filed within 45 days of Ipsen receiving Conjupro's Notice Letter.

Defendants' Response: Paragraph 43 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 43 and on that basis deny them.

COUNT I
(INFRINGEMENT BY CONJUPRO/CSPC OF U.S. PATENT NO. 8,329,213)

44. Ipsen re-alleges paragraphs 1-43 as if fully set forth herein.

Defendants' Response: Defendants incorporate by reference preceding Paragraphs 1-43 of this Answer as if fully set forth herein.

45. Conjupro/CSPC's submission of the Conjupro NDA, including the Conjupro PIV Certification, constitutes infringement of the '213 patent under 35 U.S.C. § 271(e)(2)(A).

Defendants' Response: Denied. The allegations of Paragraph 45 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 45.

46. On information and belief, the manufacture, use, sale, and/or offer for sale within the United States, and/or importation into the United States, of the Proposed Conjupro Product infringes all elements of one or more claims of the '213 patent.

Defendants' Response: Denied. The allegations of Paragraph 46 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 46.

47. On information and belief, Conjupro/CSPC intends to and will engage in the commercial manufacture, use, sale, and/or offer for sale, within the United States, and/or importation into the United States, of the Proposed Conjupro Product if it receives FDA approval of the Conjupro NDA.

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 47.

48. On information and belief, the commercial manufacture, use, sale, and/or offer for sale, within the United States, and/or importation into the United States, of the Proposed Conjupro Product prior to the expiration of the '213 patent will infringe and/or induce and/or contribute to the infringement of the '213 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

Defendants' Response: Denied. The allegations of Paragraph 48 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 48.

49. Ipsen is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of the Conjupro NDA be a date that is not earlier than the expiration of the '213 patent, or any later expiration of exclusivity for the '213 patent to which Ipsen is or becomes entitled.

Defendants' Response: Denied. The allegations of Paragraph 49 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 49.

50. Ipsen is entitled to a declaration that, if Conjupro/CSPC commercially manufactures, uses, offers for sale, and/or sells the Proposed Conjupro Product within the United States, imports the Proposed Conjupro Product into the United States, and/or induces and/or contributes to such conduct, Conjupro will infringe one or more claims of the '213 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

Defendants' Response: Denied. The allegations of Paragraph 50 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 50.

51. Ipsen will be irreparably harmed by Conjupro/CSPC's infringing activities unless those activities are enjoined by this Court. Ipsen does not have an adequate remedy at law.

Defendants' Response: Denied. Paragraph 51 is not directed to Defendants and therefore does not require a response. Additionally, the allegations of Paragraph 51 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 51.

52. On information and belief, Conjupro/CSPC was aware of the existence of the '213 patent and was aware that the filing of the Conjupro NDA, including the Conjupro PIV Certification, constitutes an act of infringement of that patent.

Defendants' Response: Defendants deny the allegations of Paragraph 52.

53. This case is an exceptional one, and Ipsen is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Defendants' Response: Denied. The allegations of Paragraph 53 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 53.

COUNT II

INFRINGEMENT BY CONJUPRO/CSPC OF U.S. PATENT NO. 9,339,497

54. Ipsen re-alleges paragraphs 1-43 as if fully set forth herein.

Defendants' Response: Defendants incorporate by reference preceding Paragraphs 1-43 of this Answer as if fully set forth herein.

55. Conjupro/CSPC's submission of the Conjupro NDA, including the Conjupro PIV Certification, constitutes infringement of the '497 patent under 35 U.S.C. § 271(e)(2)(A).

Defendants' Response: Denied. The allegations of Paragraph 55 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 55.

56. On information and belief, the manufacture, use, sale, and/or offer for sale within the United States, and/or importation into the United States, of the Proposed Conjupro Product infringes all elements of one or more claims of the '497 patent.

Defendants' Response: Denied. The allegations of Paragraph 56 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 56.

57. On information and belief, Conjupro/CSPC intends to and will engage in the commercial manufacture, use, sale, and/or offer for sale, within the United States, and/or importation into the United States, of the Proposed Conjupro Product if it receives FDA approval of the Conjupro NDA.

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 57.

58. On information and belief, the commercial manufacture, use, sale, and/or offer for sale, within the United States, and/or importation into the United States, of the Proposed Conjupro Product prior to the expiration of the '497 patent will infringe and/or induce and/or contribute to the infringement of the '497 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

Defendants' Response: Denied. The allegations of Paragraph 58 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 58.

59. Ipsen is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of the Conjupro NDA be a date that is not earlier than the expiration of the '497 patent, or any later expiration of exclusivity for the '497 patent to which Ipsen is or becomes entitled.

Defendants' Response: Denied. The allegations of Paragraph 59 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 59.

60. Ipsen is entitled to a declaration that, if Conjupro/CSPC commercially manufactures, uses, offers for sale, and/or sells the Proposed Conjupro Product within the United States, imports the Proposed Conjupro Product into the United States, and/or induces and/or contributes to such conduct, Conjupro will infringe one or more claims of the '497 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

Defendants' Response: Denied. The allegations of Paragraph 60 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 60.

61. Ipsen will be irreparably harmed by Conjupro/CSPC's infringing activities unless those activities are enjoined by this Court. Ipsen does not have an adequate remedy at law.

Defendants' Response: Denied. Paragraph 61 is not directed to Defendants and therefore does not require a response. Additionally, the allegations of Paragraph 61

constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 61.

62. On information and belief, Conjupro/CSPC was aware of the existence of the '497 patent and was aware that the filing of the Conjupro NDA, including the Conjupro PIV Certification, constitutes an act of infringement of that patent.

Defendants' Response: Defendants deny the allegations of Paragraph 62.

63. This case is an exceptional one, and Ipsen is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Defendants' Response: Denied. The allegations of Paragraph 63 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 63.

COUNT III
INFRINGEMENT BY CONJUPRO/CSPC OF U.S. PATENT NO. 9,364,473

64. Ipsen re-alleges paragraphs 1-43 as if fully set forth herein.

Defendants' Response: Defendants incorporate by reference preceding Paragraphs 1-43 of this Answer as if fully set forth herein.

65. Conjupro/CSPC's submission of the Conjupro NDA, including the Conjupro PIV Certification, constitutes infringement of the '473 patent under 35 U.S.C. § 271(e)(2)(A).

Defendants' Response: Denied. The allegations of Paragraph 65 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 65.

66. On information and belief, the manufacture, use, sale, and/or offer for sale within the United States, and/or importation into the United States, of the Proposed Conjupro Product infringes all elements of one or more claims of the '473 patent.

Defendants' Response: Denied. The allegations of Paragraph 66 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 66.

67. On information and belief, Conjupro/CSPC intends to and will engage in the commercial manufacture, use, sale, and/or offer for sale, within the United States, and/or importation into the United States, of the Proposed Conjupro Product if it receives FDA approval of the Conjupro NDA.

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 67.

68. On information and belief, the commercial manufacture, use, sale, and/or offer for sale, within the United States, and/or importation into the United States, of the Proposed Conjupro Product prior to the expiration of the '473 patent will infringe and/or induce and/or contribute to the infringement of the '473 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

Defendants' Response: Denied. The allegations of Paragraph 68 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 68.

69. Ipsen is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of the Conjupro NDA be a date that is not earlier than the expiration of the '473 patent, or any later expiration of exclusivity for the '473 patent to which Ipsen is or becomes entitled.

Defendants' Response: Denied. The allegations of Paragraph 69 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 69.

70. Ipsen is entitled to a declaration that, if Conjupro/CSPC commercially manufactures, uses, offers for sale, and/or sells the Proposed Conjupro Product within the United States, imports the Proposed Conjupro Product into the United States, and/or induces and/or contributes to such conduct, Conjupro will infringe one or more claims of the '473 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

Defendants' Response: Denied. The allegations of Paragraph 70 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 70.

71. Ipsen will be irreparably harmed by Conjupro/CSPC's infringing activities unless those activities are enjoined by this Court. Ipsen does not have an adequate remedy at law.

Defendants' Response: Denied. Paragraph 71 is not directed to Defendants and therefore does not require a response. Additionally, the allegations of Paragraph 71 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 71.

72. On information and belief, Conjupro/CSPC was aware of the existence of the '473 patent and was aware that the filing of the Conjupro NDA, including the Conjupro PIV Certification, constitutes an act of infringement of that patent.

Defendants' Response: Defendants deny the allegations of Paragraph 72.

73. This case is an exceptional one, and Ipsen is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Defendants' Response: Denied. The allegations of Paragraph 73 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 73.

COUNT IV
INFRINGEMENT BY CONJUPRO/CSPC OF U.S. PATENT NO. 9,452,162

74. Ipsen re-alleges paragraphs 1-43 as if fully set forth herein.

Defendants' Response: Defendants incorporate by reference preceding Paragraphs 1-43 of this Answer as if fully set forth herein.

75. Conjupro/CSPC's submission of the Conjupro NDA, including the Conjupro PIV Certification, constitutes infringement of the '162 patent under 35 U.S.C. § 271(e)(2)(A).

Defendants' Response: Denied. The allegations of Paragraph 75 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 75.

76. On information and belief, the manufacture, use, sale, and/or offer for sale within the United States, and/or importation into the United States, of the Proposed Conjupro Product infringes all elements of one or more claims of the '162 patent.

Defendants' Response: Denied. The allegations of Paragraph 76 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 76.

77. On information and belief, Conjupro/CSPC intends to and will engage in the commercial manufacture, use, sale, and/or offer for sale, within the United States, and/or importation into the United States, of the Proposed Conjupro Product if it receives FDA approval of the Conjupro NDA.

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 77.

78. On information and belief, the commercial manufacture, use, sale, and/or offer for sale, within the United States, and/or importation into the United States, of the Proposed Conjupro Product prior to the expiration of the '162 patent will infringe and/or induce and/or contribute to the infringement of the '162 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

Defendants' Response: Denied. The allegations of Paragraph 78 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 78.

79. Ipsen is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of the Conjupro NDA be a date that is not earlier than the expiration of the '162 patent, or any later expiration of exclusivity for the '162 patent to which Ipsen is or becomes entitled.

Defendants' Response: Denied. The allegations of Paragraph 79 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 79.

80. Ipsen is entitled to a declaration that, if Conjupro/CSPC commercially manufactures, uses, offers for sale, and/or sells the Proposed Conjupro Product within the United States, imports the Proposed Conjupro Product into the United States, and/or induces and/or contributes to such conduct, Conjupro will infringe one or more claims of the '162 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

Defendants' Response: Denied. The allegations of Paragraph 80 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 80.

81. Ipsen will be irreparably harmed by Conjupro/CSPC's infringing activities unless those activities are enjoined by this Court. Ipsen does not have an adequate remedy at law.

Defendants' Response: Denied. Paragraph 81 is not directed to Defendants and therefore does not require a response. Additionally, the allegations of Paragraph 81 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 81.

82. On information and belief, Conjupro/CSPC was aware of the existence of the '162 patent and was aware that the filing of the Conjupro NDA, including the Conjupro PIV Certification, constitutes an act of infringement of that patent.

Defendants' Response: Defendants deny the allegations of Paragraph 82.

83. This case is an exceptional one, and Ipsen is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Defendants' Response: Denied. The allegations of Paragraph 83 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 83.

COUNT V
INFRINGEMENT BY CONJUPRO/CSPC OF U.S. PATENT NO. 9,492,442

84. Ipsen re-alleges paragraphs 1-43 as if fully set forth herein.

Defendants' Response: Defendants incorporate by reference preceding Paragraphs 1-43 of this Answer as if fully set forth herein.

85. Conjupro/CSPC's submission of the Conjupro NDA, including the Conjupro PIV Certification, constitutes infringement of the '442 patent under 35 U.S.C. § 271(e)(2)(A).

Defendants' Response: Denied. The allegations of Paragraph 85 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 85.

86. On information and belief, the manufacture, use, sale, and/or offer for sale within the United States, and/or importation into the United States, of the Proposed Conjupro Product infringes all elements of one or more claims of the '442 patent.

Defendants' Response: Denied. The allegations of Paragraph 86 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 86.

87. On information and belief, Conjupro/CSPC intends to and will engage in the commercial manufacture, use, sale, and/or offer for sale, within the United States, and/or importation into the United States, of the Proposed Conjupro Product if it receives FDA approval of the Conjupro NDA.

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 87.

88. On information and belief, the commercial manufacture, use, sale, and/or offer for sale, within the United States, and/or importation into the United States, of the Proposed Conjupro Product prior to the expiration of the '442 patent will infringe and/or induce and/or contribute to the infringement of the '442 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

Defendants' Response: Denied. The allegations of Paragraph 88 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 88.

89. Ipsen is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of the Conjupro NDA be a date that is not earlier than the expiration of the '442 patent, or any later expiration of exclusivity for the '442 patent to which Ipsen is or becomes entitled.

Defendants' Response: Denied. The allegations of Paragraph 89 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 89.

90. Ipsen is entitled to a declaration that, if Conjupro/CSPC commercially manufactures, uses, offers for sale, and/or sells the Proposed Conjupro Product within the United States, imports the Proposed Conjupro Product into the United States, and/or induces and/or contributes to such conduct, Conjupro will infringe one or more claims of the '442 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

Defendants' Response: Denied. The allegations of Paragraph 90 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 90.

91. Ipsen will be irreparably harmed by Conjupro/CSPC's infringing activities unless those activities are enjoined by this Court. Ipsen does not have an adequate remedy at law.

Defendants' Response: Denied. Paragraph 91 is not directed to Defendants and therefore does not require a response. Additionally, the allegations of Paragraph 91 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 91.

92. On information and belief, Conjupro/CSPC was aware of the existence of the '442 patent and was aware that the filing of the Conjupro NDA, including the Conjupro PIV Certification, constitutes an act of infringement of that patent.

Defendants' Response: Defendants deny the allegations of Paragraph 92.

93. This case is an exceptional one, and Ipsen is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Defendants' Response: Denied. The allegations of Paragraph 93 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 93.

COUNT VI
INFRINGEMENT BY CONJUPRO/CSPC OF U.S. PATENT NO. 9,717,724

94. Ipsen re-alleges paragraphs 1-43 as if fully set forth herein.

Defendants' Response: Defendants incorporate by reference preceding Paragraphs 1-43 of this Answer as if fully set forth herein.

95. Conjupro/CSPC's submission of the Conjupro NDA, including the Conjupro PIV Certification, constitutes infringement of the '724 patent under 35 U.S.C. § 271(e)(2)(A).

Defendants' Response: Denied. The allegations of Paragraph 95 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 95.

96. On information and belief, the manufacture, use, sale, and/or offer for sale within the United States, and/or importation into the United States, of the Proposed Conjupro Product infringes all elements of one or more claims of the '724 patent.

Defendants' Response: Denied. The allegations of Paragraph 96 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 96.

97. On information and belief, Conjupro/CSPC intends to and will engage in the commercial manufacture, use, sale, and/or offer for sale, within the United States, and/or importation into the United States, of the Proposed Conjupro Product if it receives FDA approval of the Conjupro NDA.

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 97.

98. On information and belief, the commercial manufacture, use, sale, and/or offer for sale, within the United States, and/or importation into the United States, of the Proposed Conjupro Product prior to the expiration of the '724 patent will infringe and/or induce and/or contribute to the infringement of the '724 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

Defendants' Response: Denied. The allegations of Paragraph 98 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 98.

99. Ipsen is entitled to relief provided by 35 U.S.C. § 271€(4), including an order of this Court that the effective date of the approval of the Conjupro NDA be a date that is not earlier than the expiration of the '724 patent, or any later expiration of exclusivity for the '724 patent to which Ipsen is or becomes entitled.

Defendants' Response: Denied. The allegations of Paragraph 99 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 99.

100. Ipsen is entitled to a declaration that, if Conjupro/CSPC commercially manufactures, uses, offers for sale, and/or sells the Proposed Conjupro Product within the United States, imports the Proposed Conjupro Product into the United States, and/or induces and/or contributes to such conduct, Conjupro will infringe one or more claims of the '724 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

Defendants' Response: Denied. The allegations of Paragraph 100 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 100.

101. Ipsen will be irreparably harmed by Conjupro/CSPC's infringing activities unless those activities are enjoined by this Court. Ipsen does not have an adequate remedy at law.

Defendants' Response: Denied. Paragraph 101 is not directed to Defendants and therefore does not require a response. Additionally, the allegations of Paragraph 101

constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 101.

102. On information and belief, Conjupro/CSPC was aware of the existence of the '724 patent and was aware that the filing of the Conjupro NDA, including the Conjupro PIV Certification, constitutes an act of infringement of that patent.

Defendants' Response: Defendants deny the allegations of Paragraph 102.

103. This case is an exceptional one, and Ipsen is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Defendants' Response: Denied. The allegations of Paragraph 103 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 103.

COUNT VII
INFRINGEMENT BY CONJUPRO/CSPC OF U.S. PATENT NO. 10,980,795

104. Ipsen re-alleges paragraphs 1-43 as if fully set forth herein.

Defendants' Response: Defendants incorporate by reference preceding Paragraphs 1-43 of this Answer as if fully set forth herein.

105. Conjupro/CSPC's submission of the Conjupro NDA, including the Conjupro PIV Certification, constitutes infringement of the '795 patent under 35 U.S.C. § 271(e)(2)(A).

Defendants' Response: Denied. The allegations of Paragraph 105 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 105.

106. On information and belief, the manufacture, use, sale, and/or offer for sale within the United States, and/or importation into the United States, of the Proposed Conjupro Product infringes all elements of one or more claims of the '795 patent.

Defendants' Response: Denied. The allegations of Paragraph 106 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 106.

107. On information and belief, Conjupro/CSPC intends to and will engage in the commercial manufacture, use, sale, and/or offer for sale, within the United States, and/or importation into the United States, of the Proposed Conjupro Product if it receives FDA approval of the Conjupro NDA.

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 107.

108. On information and belief, the commercial manufacture, use, sale, and/or offer for sale, within the United States, and/or importation into the United States, of the Proposed Conjupro Product prior to the expiration of the '795 patent will infringe and/or induce and/or contribute to the infringement of the '795 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

Defendants' Response: Denied. The allegations of Paragraph 108 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 108.

109. Ipsen is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of the Conjupro NDA be a date that is not earlier than the expiration of the '795 patent, or any later expiration of exclusivity for the '795 patent to which Ipsen is or becomes entitled.

Defendants' Response: Denied. The allegations of Paragraph 109 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 109.

110. Ipsen is entitled to a declaration that, if Conjupro/CSPC commercially manufactures, uses, offers for sale, and/or sells the Proposed Conjupro Product within the United States, imports the Proposed Conjupro Product into the United States, and/or induces and/or contributes to such conduct, Conjupro will infringe one or more claims of the '795 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

Defendants' Response: Denied. The allegations of Paragraph 110 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 110.

111. Ipsen will be irreparably harmed by Conjupro/CSPC's infringing activities unless those activities are enjoined by this Court. Ipsen does not have an adequate remedy at law.

Defendants' Response: Denied. Paragraph 111 is not directed to Defendants and therefore does not require a response. Additionally, the allegations of Paragraph 111 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 111.

112. On information and belief, Conjupro/CSPC was aware of the existence of the '795 patent and was aware that the filing of the Conjupro NDA, including the Conjupro PIV Certification, constitutes an act of infringement of that patent.

Defendants' Response: Defendants deny the allegations of Paragraph 112.

113. This case is an exceptional one, and Ipsen is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Defendants' Response: Denied. The allegations of Paragraph 113 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 113.

COUNT VIII
INFRINGEMENT BY CONJUPRO/CSPC OF U.S. PATENT NO. 11,369,597

114. Ipsen re-alleges paragraphs 1-43 as if fully set forth herein.

Defendants' Response: Defendants incorporate by reference preceding Paragraphs 1-43 of this Answer as if fully set forth herein.

115. Conjupro/CSPC's submission of the Conjupro NDA, including the Conjupro PIV Certification, constitutes infringement of the '597 patent under 35 U.S.C. § 271(e)(2)(A).

Defendants' Response: Denied. The allegations of Paragraph 115 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 115.

116. On information and belief, the manufacture, use, sale, and/or offer for sale within the United States, and/or importation into the United States, of the Proposed Conjupro Product infringes all elements of one or more claims of the '597 patent.

Defendants' Response: Denied. The allegations of Paragraph 116 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 116.

117. On information and belief, Conjupro/CSPC intends to and will engage in the commercial manufacture, use, sale, and/or offer for sale, within the United States, and/or importation into the United States, of the Proposed Conjupro Product if it receives FDA approval of the Conjupro NDA.

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 117.

118. On information and belief, the commercial manufacture, use, sale, and/or offer for sale, within the United States, and/or importation into the United States, of the Proposed Conjupro Product prior to the expiration of the '597 patent will infringe and/or induce and/or contribute to the infringement of the '597 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

Defendants' Response: Denied. The allegations of Paragraph 118 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 118.

119. Ipsen is entitled to relief provided by 35 U.S.C. § 271e(4), including an order of this Court that the effective date of the approval of the Conjupro NDA be a date that is not earlier than the expiration of the '597 patent, or any later expiration of exclusivity for the '597 patent to which Ipsen is or becomes entitled.

Defendants' Response: Denied. The allegations of Paragraph 119 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 119.

120. Ipsen is entitled to a declaration that, if Conjupro/CSPC commercially manufactures, uses, offers for sale, and/or sells the Proposed Conjupro Product within the United States, imports the Proposed Conjupro Product into the United States, and/or induces and/or contributes to such conduct, Conjupro will infringe one or more claims of the '597 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

Defendants' Response: Denied. The allegations of Paragraph 120 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 120.

121. Ipsen will be irreparably harmed by Conjupro/CSPC's infringing activities unless those activities are enjoined by this Court. Ipsen does not have an adequate remedy at law.

Defendants' Response: Denied. Paragraph 121 is not directed to Defendants and therefore does not require a response. Additionally, the allegations of Paragraph 121 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 121.

122. On information and belief, Conjupro/CSPC was aware of the existence of the '597 patent and was aware that the filing of the Conjupro NDA, including the Conjupro PIV Certification, constitutes an act of infringement of that patent.

Defendants' Response: Defendants deny the allegations of Paragraph 122.

123. This case is an exceptional one, and Ipsen is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Defendants' Response: Denied. The allegations of Paragraph 123 constitute conclusions of law to which no answer is required. To the extent that a response is required, Defendants deny the allegations of Paragraph 123.

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. 8,329,213

Defendants have not directly infringed, literally or under the doctrine of equivalents, any valid and enforceable claim of the '213 Patent.

SECOND DEFENSE – INVALIDITY OF U.S. PATENT NO. 8,329,213

One or more of the claims of the '213 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 – NON-INFRINGEMENT OF U.S. PATENT NO. 9,339,497

Defendants have not directly infringed, literally or under the doctrine of equivalents, any valid and enforceable claim of the ’497 Patent.

FOURTH DEFENSE – INVALIDITY OF U.S. PATENT NO. 9,339,497

One or more of the claims of the ’497 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.

FIFTH DEFENSE – NON-INFRINGEMENT OF U.S. PATENT NO. 9,364,473

Defendants have not directly infringed, literally or under the doctrine of equivalents, any valid and enforceable claim of the ’473 Patent.

SIXTH DEFENSE – INVALIDITY OF THE U.S. PATENT NO. 9,364,473

One or more of the claims of the ’473 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.

SEVENTH DEFENSE – NON-INFRINGEMENT OF U.S. PATENT NO. 9,452,162

Defendants have not directly infringed, literally or under the doctrine of equivalents, any valid and enforceable claim of the ’162 Patent.

EIGHTH DEFENSE – INVALIDITY OF THE U.S. PATENT NO. 9,452,162

One or more of the claims of the ’162 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.

NINTH DEFENSE – NON-INFRINGEMENT OF U.S. PATENT NO. 9,492,442

Defendants have not directly infringed, literally or under the doctrine of equivalents, any valid and enforceable claim of the ’442 Patent.

TENTH DEFENSE – INVALIDITY OF U.S. PATENT NO. 9,492,442

One or more of the claims of the ’442 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.

ELEVENTH DEFENSE – NON-INFRINGEMENT OF U.S. PATENT NO. 9,717,724

Defendants have not directly infringed, literally or under the doctrine of equivalents, any valid and enforceable claim of the ’724 Patent.

TWELFTH DEFENSE – INVALIDITY OF U.S. PATENT NO. 9,717,724

One or more of the claims of the ’724 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.

THIRTEENTH DEFENSE – NON-INFRINGEMENT OF U.S. PATENT NO. 10,980,795

Defendants have not directly infringed, literally or under the doctrine of equivalents, any valid and enforceable claim of the ’795 Patent.

FOURTEENTH DEFENSE – INVALIDITY OF U.S. PATENT NO. 10,980,795

One or more of the claims of the ’795 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.

FIFTEENTH DEFENSE – NON-INFRINGEMENT OF U.S. PATENT NO. 11,369,597

Defendants have not directly infringed, literally or under the doctrine of equivalents, any valid and enforceable claim of the '597 Patent.

SIXTEENTH DEFENSE – INVALIDITY OF U.S. PATENT NO. 11,369,597

One or more of the claims of the '597 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.

SEVENTEENTH DEFENSE – FAILURE TO STATE A CLAIM

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

EIGHTEENTH 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 Asserted Patents, Plaintiff is estopped from construing the claims of the Asserted Patents in such a way as may cover Defendants' activities and/or products.

NINETEENTH DEFENSE – LIMITATION ON COSTS

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

TWENTIETH 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.

TWENTY-FIRST 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, has adequate remedies at law.

TWENTY-SECOND DEFENSE – INEQUITABLE RELIEF

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

TWENTY-THIRD 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.

TWENTY-FOURTH 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.

TWENTY-FIFTH 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.

PRAYER FOR RELIEF

No answer is required to the allegations contained in Plaintiffs' prayer for relief. To the extent a response is required, Defendants deny that they engaged in any of the alleged conduct and deny that Plaintiff is entitled to any of the relief that it seeks.

WHEREFORE, having fully answered, Defendants prays that this Court deny all relief sought by Plaintiff, enter judgment in favor of the Defendants and against Plaintiff, award

Defendants its costs and attorneys' fees pursuant to 35 U.S.C. § 285, and grant Defendants such other relief as the Court deems just and proper.

DEFENDANTS' COUNTERCLAIMS

Without admitting any of the allegations in the Complaint, other than those allegations expressly admitted in the Answer *supra*, and without prejudice to Defendants/Counterclaim-Plaintiffs' right to plead additional counterclaims as the facts of the matter warrant, Defendants/Counterclaim-Plaintiffs Conjupro Biotherapeutics, Inc. ("Conjupro"), CSPC Pharmaceutical Group Limited ("CSPC Group"), and CSPC Ouyi Pharmaceutical Co., Ltd. ("CSPCY 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 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 "Counterclaim Patents-in-Suit") are invalid and/or not infringed.

2. Defendants repeat and incorporate by reference each of the foregoing paragraphs of Defendants' Answer and Affirmative Defenses to Plaintiffs' 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 Counterclaim-Defendant 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) Counterclaim-Defendant Ipsen Biopharm Ltd is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (3) Counterclaim-Defendant 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 Counterclaim-Defendant Ipsen Biopharm Ltd. satisfies due process.

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

BACKGROUND

Counterclaim Patents-In-Suit

14. On information and belief, on or about December 11, 2012, the United States Patent and Trademark Office ("USPTO") issued the '213 patent, titled "Liposomes Useful for Drug Delivery." On information and belief, and based on the allegations in the Complaint, Ipsen Biopharm is the owner of the '213 patent. The '213 patent is attached as Exhibit A to the Complaint.

15. On information and belief, on or about May 17, 2016, the USPTO issued the '497 patent, titled "Methods For Treating Pancreatic Cancer Using Combination Therapies Comprising Liposomal Irinotecan." On information and belief, and based on the allegations in the Complaint, Ipsen Biopharm is the owner of the '497 patent. The '497 patent is attached as Exhibit B to the Complaint.

16. On information and belief, on or about June 14, 2016, the USPTO issued the '473 patent, titled "Methods For Treating Pancreatic Cancer Using Combination Therapies Comprising Liposomal Irinotecan." On information and belief, and based on the allegations in the Complaint, Ipsen Biopharm is the owner of the '473 patent. The '473 patent is attached as Exhibit C to the Complaint.

17. On information and belief, on or about September 27, 2016, the USPTO issued the '162 patent, titled "Methods For Treating Pancreatic Cancer Using Combination Therapies Comprising Liposomal Irinotecan." On information and belief, and based on the allegations in the Complaint, Ipsen Biopharm is the owner of the '162 patent. The '162 patent is attached as Exhibit D to the Complaint.

18. On information and belief, on or about November 15, 2016, the USPTO issued the '442 patent, titled "Methods For Treating Pancreatic Cancer Using Combination Therapies Comprising Liposomal Irinotecan." On information and belief, and based on the allegations in the

Complaint, Ipsen Biopharm is the owner of the ’442 patent. The ’442 patent is attached as Exhibit E to the Complaint.

19. On information and belief, on or about August 1, 2017, the USPTO issued the ’724 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 ’724 patent. The ’724 patent is attached as Exhibit F to the Complaint.

20. On information and belief, on or about April 20, 2021, the USPTO issued the ’795 patent, titled “Methods For Treating Pancreatic Cancer Using Combination Therapies Comprising Liposomal Irinotecan.” On information and belief, and based on the allegations in the Complaint, Ipsen Biopharm is the owner of the ’795 patent. The ’795 patent is attached as Exhibit G to the Complaint.

21. On information and belief, on or about June 28, 2022, the USPTO issued the ’597 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 ’597 patent. The ’597 patent is attached as Exhibit H to the Complaint.

22. On information and belief, on or about April 3, 2012, the USPTO issued the ’867 patent, titled “Liposomes Useful for Drug Delivery.” On information and belief, Ipsen Biopharm is the owner of the ’867 patent. A true and correct copy of the ’867 patent is attached as Exhibit 1 to these Counterclaims.

23. On information and belief, on or about October 29, 2019, the USPTO issued the ’360 patent, titled “Stabilizing Campothecin Pharmaceutical Compositions.” On information and belief, Ipsen Biopharm is the owner of the ’360 patent. A true and correct copy of the ’360 patent is attached as Exhibit 2 to these Counterclaims.

24. On information and belief, on or about May 4, 2021, the USPTO issued the '914 patent, titled "Stabilizing Campothecin Pharmaceutical Compositions." On information and belief, Ipsen Biopharm is the owner of the '914 patent. A true and correct copy of the '914 patent is attached as Exhibit 3 to these Counterclaims.

Ipsen's NDA

25. 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).

26. On information and belief, Counterclaim-Defendants caused the FDA to list the Counterclaim Patents-In-Suit in FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") in connection with NDA No. 207793.

27. By maintaining the listing of the Counterclaim Patents-In-Suit in the Orange Book, Counterclaim-Defendants represent that a claim of infringement of the Counterclaim Patents-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).

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

Conjupro's Paragraph IV Patent Certification

29. 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, the ’213 patent, the ’497 patent, the ’473 patent, the ’162 patent, the ’442 patent, the ’724 patent, the ’795 patent, the ’597 patent, the ’867 patent, the ’360 patent, and the ’914 patent are invalid, unenforceable, and/or will not be infringed by Conjupro’s NDA product (“Conjupro’s Notice Letter”).

30. 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 Counterclaim 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. Counterclaim-Plaintiffs incorporate by reference the Conjupro Notice Letter.

31. 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 Counterclaim Patents-In-Suit.

The Instant Lawsuit

32. On April 15, 2024, Counterclaim-Defendants filed an infringement action 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. Upon information and belief, Counterclaim-Defendants have not sued Counterclaim-Plaintiffs for infringement of the ’867 patent, the ’360 patent, or the ’914 patent.

33. More than forty-five (45) days have elapsed since Counterclaim-Defendants’ receipt of the Conjupro Notice Letter, which was received at the latest by March 7, 2024.

34. 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 ’213 patent, the ’497 patent, the ’473 patent, the ’162 patent, the ’442 patent, the ’724 patent, the ’795 patent, the ’597 patent, the ’867 patent, the ’360 patent, and the ’914 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 ’213 PATENT)

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

36. Counterclaim-Defendants have accused Counterclaim-Plaintiffs of infringing claims of the ’213 patent in connection with Conjupro’s NDA No. 218923.

37. Counterclaim-Plaintiffs deny infringement of any valid, enforceable, properly construed claim of the ’213 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 ’213 patent, including for at least the reasons set forth in the detailed statement included with Conjupro’s Notice Letter.

38. 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 ’213 patent.

39. Conjupro’s NDA Product will not infringe any valid and/or enforceable claim of

the ’213 patent, at least because Conjupro’s NDA Product does not satisfy the claims of the ’213 patent, either literally or under the doctrine of equivalents.

40. There exists an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding whether Counterclaim-Plaintiffs infringe any valid claim of the ’213 Patent, and a judicial declaration of noninfringement is necessary and appropriate at this time.

41. Counterclaim-Plaintiffs are entitled to a declaration that they have not infringed the ’213 Patent. Accordingly, Counterclaim-Plaintiffs respectfully request that the Court declare that the asserted claims of the ’213 Patent are not infringed.

COUNT 2
(DECLARATORY JUDGMENT OF INVALIDITY OF THE ’213 PATENT)

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

43. The ’213 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, and including at least the reasons set forth in the detailed statement included with Conjupro’s Notice Letter.

44. The alleged invention of the ’213 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 ’213 patent.

45. The alleged invention of the ’213 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 ’213 patent in the United States.

46. The ’213 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.

47. The alleged invention of the ’213 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 ’213 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 ’213 patent and would have had a reasonable expectation of success in doing so.

48. The ’213 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.

49. The claims of the ’213 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.

50. There exists an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding the validity of the ’213 Patent, and a judicial declaration of invalidity is necessary and appropriate at this time.

51. Counterclaim-Plaintiffs are entitled to a declaration that the claims of the ’213 patent are invalid.

COUNT 3
(DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’497 PATENT)

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

53. Counterclaim-Defendants have accused Counterclaim-Plaintiffs of infringing claims of the ’497 patent in connection with Conjupro’s NDA No. 218923.

54. Counterclaim-Plaintiffs deny infringement of any valid, enforceable, properly construed claim of the ’497 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 ’497 patent, including for at least the reasons set forth in the detailed statement included with Conjupro’s Notice Letter.

55. 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 ’497 patent.

56. Conjupro’s NDA Product will not infringe any valid and/or enforceable claim of the ’497 patent, at least because Conjupro’s NDA Product does not satisfy the claims of the ’497 patent, either literally or under the doctrine of equivalents.

57. There exists an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding whether Counterclaim-Plaintiffs infringe any valid claim of the ’497 patent, and a judicial declaration of noninfringement is necessary and appropriate at this time.

58. Counterclaim-Plaintiffs are entitled to a declaration that they have not infringed the ’497 patent. Accordingly, Counterclaim-Plaintiffs respectfully request that the Court declare that the asserted claims of the ’497 patent are not infringed.

COUNT 4
(DECLARATORY JUDGMENT OF INVALIDITY OF THE '497 PATENT)

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

60. The '497 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, and including at least the reasons set forth in the detailed statement included with Conjupro's Notice Letter.

61. The alleged invention of the '497 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 '497 patent.

62. The alleged invention of the '497 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 '497 patent in the United States.

63. The '497 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.

64. The alleged invention of the '497 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 '497 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 '497 patent and would have had a reasonable expectation of success in doing so.

65. The ’497 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.

66. The claims of the ’497 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.

67. There exists an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding the validity of the ’497 Patent, and a judicial declaration of invalidity is necessary and appropriate at this time.

68. Counterclaim-Plaintiffs are entitled to a declaration that the claims of the ’497 patent are invalid.

COUNT 5
(DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’473 PATENT)

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

70. Counterclaim-Defendants have accused Counterclaim-Plaintiffs of infringing claims of the ’473 patent in connection with Conjupro’s NDA No. 218923.

71. Counterclaim-Plaintiffs deny infringement of any valid, enforceable, properly construed claim of the ’473 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 ’473 patent, including for at least the reasons set forth in the detailed statement included with Conjupro’s Notice Letter.

72. 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 '473 patent.

73. Conjupro's NDA Product will not infringe any valid and/or enforceable claim of the '473 patent, at least because Conjupro's NDA Product does not satisfy the claims of the '473 patent, either literally or under the doctrine of equivalents.

74. There exists an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding whether Counterclaim-Plaintiffs infringe any valid claim of the '473 patent, and a judicial declaration of noninfringement is necessary and appropriate at this time.

75. Counterclaim-Plaintiffs are entitled to a declaration that they have not infringed the '473 patent. Accordingly, Counterclaim-Plaintiffs respectfully request that the Court declare that the asserted claims of the '473 patent are not infringed.

COUNT 6
(DECLARATORY JUDGMENT OF INVALIDITY OF THE '473 PATENT)

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

77. The '473 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, and including at least the reasons set forth in the detailed statement included with Conjupro's Notice Letter.

78. The alleged invention of the '473 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 ’473 patent.

79. The alleged invention of the ’473 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 ’473 patent in the United States.

80. The ’473 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.

81. The alleged invention of the ’473 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 ’473 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 ’473 patent and would have had a reasonable expectation of success in doing so.

82. The ’473 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.

83. The claims of the ’473 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.

84. There exists an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding the validity of the ’473 patent, and a judicial declaration of invalidity is necessary and appropriate at this time.

85. Counterclaim-Plaintiffs are entitled to a declaration that the claims of the ’473

patent are invalid.

COUNT 7
(DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’162 PATENT)

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

87. Counterclaim-Defendants have accused Counterclaim-Plaintiffs of infringing claims of the ’162 patent in connection with Conjupro’s NDA No. 218923.

88. Counterclaim-Plaintiffs deny infringement of any valid, enforceable, properly construed claim of the ’162 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 ’162 patent, including for at least the reasons set forth in the detailed statement included with Conjupro’s Notice Letter.

89. 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 ’162 patent.

90. Conjupro’s NDA Product will not infringe any valid and/or enforceable claim of the ’162 patent, at least because Conjupro’s NDA Product does not satisfy the claims of the ’162 patent, either literally or under the doctrine of equivalents.

91. There exists an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding whether Counterclaim-Plaintiffs infringe any valid claim of the ’162 patent, and a judicial declaration of noninfringement is necessary and appropriate at this time.

92. Counterclaim-Plaintiffs are entitled to a declaration that they have not infringed the ’162 patent. Accordingly, Counterclaim-Plaintiffs respectfully request that the Court declare that the asserted claims of the ’162 patent are not infringed.

COUNT 8
(DECLARATORY JUDGMENT OF INVALIDITY OF THE ’162 PATENT)

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

94. The ’162 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, and including at least the reasons set forth in the detailed statement included with Conjupro’s Notice Letter.

95. The alleged invention of the ’162 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 ’162 patent.

96. The alleged invention of the ’162 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 ’162 patent in the United States.

97. The ’162 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.

98. The alleged invention of the ’162 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 ’162 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 ’162 patent and would have had a reasonable expectation of success in doing so.

99. The ’162 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.

100. The claims of the ’162 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.

101. There exists an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding the validity of the ’162 patent, and a judicial declaration of invalidity is necessary and appropriate at this time.

102. Counterclaim-Plaintiffs are entitled to a declaration that the claims of the ’162 patent are invalid.

COUNT 9
(DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’442 PATENT)

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

104. Counterclaim-Defendants have accused Counterclaim-Plaintiffs of infringing claims of the ’442 patent in connection with Conjupro’s NDA No. 218923.

105. Counterclaim-Plaintiffs deny infringement of any valid, enforceable, properly construed claim of the ’442 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 ’442 patent,

including for at least the reasons set forth in the detailed statement included with Conjupro's Notice Letter.

106. 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 '442 patent.

107. Conjupro's NDA Product will not infringe any valid and/or enforceable claim of the '442 patent, at least because Conjupro's NDA Product does not satisfy the claims of the '442 patent, either literally or under the doctrine of equivalents.

108. There exists an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding whether Counterclaim-Plaintiffs infringe any valid claim of the '442 patent, and a judicial declaration of noninfringement is necessary and appropriate at this time.

109. Counterclaim-Plaintiffs are entitled to a declaration that they have not infringed the '442 patent. Accordingly, Counterclaim-Defendants respectfully request that the Court declare that the asserted claims of the '442 patent are not infringed.

COUNT 10
(DECLARATORY JUDGMENT OF INVALIDITY OF THE '442 PATENT)

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

111. The '442 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, and including at least the reasons set forth

in the detailed statement included with Conjupro's Notice Letter.

112. The alleged invention of the '442 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 '442 patent.

113. The alleged invention of the '442 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 '442 patent in the United States.

114. The '442 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.

115. The alleged invention of the '442 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 '442 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 '442 patent and would have had a reasonable expectation of success in doing so.

116. The '442 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.

117. The claims of the '442 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.

118. There exists an actual controversy between Counterclaim-Plaintiffs and

Counterclaim-Defendants regarding the validity of the ’442 patent, and a judicial declaration of invalidity is necessary and appropriate at this time.

119. Counterclaim-Plaintiffs are entitled to a declaration that the claims of the ’442 patent are invalid.

COUNT 11
(DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’724 PATENT)

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

121. Counterclaim-Defendants have accused Counterclaim-Plaintiffs of infringing claims of the ’724 patent in connection with Conjupro’s NDA No. 218923.

122. Counterclaim-Plaintiffs deny infringement of any valid, enforceable, properly construed claim of the ’724 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 ’724 patent, including for at least the reasons set forth in the detailed statement included with Conjupro’s Notice Letter.

123. 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 ’724 patent.

124. Conjupro’s NDA Product will not infringe any valid and/or enforceable claim of the ’724 patent, at least because Conjupro’s NDA Product does not satisfy the claims of the ’724 patent, either literally or under the doctrine of equivalents.

125. There exists an actual controversy between Counterclaim-Plaintiffs and

Counterclaim-Defendants regarding whether Counterclaim-Plaintiffs infringe any valid claim of the ’724 patent, and a judicial declaration of noninfringement is necessary and appropriate at this time.

126. Counterclaim-Plaintiffs are entitled to a declaration that they have not infringed the ’724 patent. Accordingly, Counterclaim-Plaintiffs respectfully request that the Court declare that the asserted claims of the ’724 patent are not infringed.

COUNT 12
(DECLARATORY JUDGMENT OF INVALIDITY OF THE ’724 PATENT)

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

128. The ’724 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, and including at least the reasons set forth in the detailed statement included with Conjupro’s Notice Letter.

129. The alleged invention of the ’724 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 ’724 patent.

130. The alleged invention of the ’724 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 ’724 patent in the United States.

131. The ’724 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.

132. The alleged invention of the ’724 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 ’724 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 ’724 patent and would have had a reasonable expectation of success in doing so.

133. The ’724 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.

134. The claims of the ’724 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.

135. There exists an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding the validity of the ’724 patent, and a judicial declaration of invalidity is necessary and appropriate at this time.

136. Counterclaim-Plaintiffs are entitled to a declaration that the claims of the ’724 patent are invalid.

COUNT 13
(DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’795 PATENT)

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

138. Counterclaim-Defendants have accused Counterclaim-Plaintiffs of infringing claims of the ’795 patent in connection with Conjupro’s NDA No. 218923.

139. Counterclaim-Plaintiffs deny infringement of any valid, enforceable, properly

construed claim of the ’795 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 ’795 patent, including for at least the reasons set forth in the detailed statement included with Conjupro’s Notice Letter.

140. 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 ’795 patent.

141. Conjupro’s NDA Product will not infringe any valid and/or enforceable claim of the ’795 patent, at least because Conjupro’s NDA Product does not satisfy the claims of the ’795 patent, either literally or under the doctrine of equivalents.

142. There exists an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding whether Counterclaim-Plaintiffs infringe any valid claim of the ’795 patent, and a judicial declaration of noninfringement is necessary and appropriate at this time.

143. Counterclaim-Plaintiffs are entitled to a declaration that they have not infringed the ’795 patent. Accordingly, Counterclaim-Plaintiffs respectfully request that the Court declare that the asserted claims of the ’795 patent are not infringed.

COUNT 14
(DECLARATORY JUDGMENT OF INVALIDITY OF THE ’795 PATENT)

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

145. The ’795 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, and including at least the reasons set forth in the detailed statement included with Conjupro's Notice Letter.

146. The alleged invention of the '795 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 '795 patent.

147. The alleged invention of the '795 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 '795 patent in the United States.

148. The '795 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.

149. The alleged invention of the '795 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 '795 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 '162 patent and would have had a reasonable expectation of success in doing so.

150. The '795 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.

151. The claims of the '795 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.

152. There exists an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding the validity of the ’795 patent, and a judicial declaration of invalidity is necessary and appropriate at this time.

153. Counterclaim-Plaintiffs are entitled to a declaration that the claims of the ’795 patent are invalid.

COUNT 15
(DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’597 PATENT)

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

155. Counterclaim-Defendants have accused Counterclaim-Plaintiffs of infringing claims of the ’597 patent in connection with Conjupro’s NDA No. 218923.

156. Counterclaim-Plaintiffs deny infringement of any valid, enforceable, properly construed claim of the ’597 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 ’597 patent, including for at least the reasons set forth in the detailed statement included with Conjupro’s Notice Letter.

157. 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 ’597 patent.

158. Conjupro’s NDA Product will not infringe any valid and/or enforceable claim of

the ’597 patent, at least because Conjupro’s NDA Product does not satisfy the claims of the ’597 patent, either literally or under the doctrine of equivalents.

159. There exists an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding whether Counterclaim-Plaintiffs infringe any valid claim of the ’597 patent, and a judicial declaration of noninfringement is necessary and appropriate at this time.

160. Counterclaim-Plaintiffs are entitled to a declaration that they have not infringed the ’597 patent. Accordingly, Counterclaim-Plaintiffs respectfully request that the Court declare that the asserted claims of the ’597 patent are not infringed.

COUNT 16
(DECLARATORY JUDGMENT OF INVALIDITY OF THE ’597 PATENT)

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

162. The ’597 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, and including at least the reasons set forth in the detailed statement included with Conjupro’s Notice Letter.

163. The alleged invention of the ’597 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 ’597 patent.

164. The alleged invention of the ’597 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 ’597 patent in the United States.

165. The ’597 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.

166. The alleged invention of the ’597 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 ’597 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 ’597 patent and would have had a reasonable expectation of success in doing so.

167. The ’597 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.

168. The claims of the ’597 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.

169. There exists an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding the validity of the ’597 patent, and a judicial declaration of invalidity is necessary and appropriate at this time.

170. Counterclaim-Plaintiffs are entitled to a declaration that the claims of the ’597 patent are invalid.

COUNT 17
(DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’867 PATENT)

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

172. More than forty-five (45) days have elapsed since Counterclaim-Defendants' receipt of Conjupro's Notice Letter, which was received at the latest by March 7, 2024.

173. To date, and upon information and belief, even though Counterclaim-Defendants have not sued Counterclaim-Plaintiffs for infringement of the '867 patent, Counterclaim-Defendants have not delisted this patent from the Orange Book and have not entered into any agreements and/or covenants that they will not assert this patent in this case or in any future case, even though, as stated above, Counterclaim-Plaintiffs have certified this patent under paragraph IV of the Hatch-Waxman Act and provided notice of this certification to Counterclaim-Defendants.

174. 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 '867 patent, including for at least the reasons set forth in the detailed statement included with Conjupro's Notice Letter.

175. 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 '867 patent.

176. Conjupro's NDA Product will not infringe any valid and/or enforceable claim of the '867 patent, at least because Conjupro's NDA Product does not satisfy the claims of the '867 patent, either literally or under the doctrine of equivalents.

177. There exists an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding whether Counterclaim-Plaintiffs infringe any valid claim of the '867 patent, and a judicial declaration of noninfringement is necessary and appropriate at this time.

178. Counterclaim-Plaintiffs are entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Conjupro's NDA Product does not, and would not if marketed, infringe any valid and/or enforceable claim of the '867 patent.

COUNT 18
(DECLARATORY JUDGMENT OF INVALIDITY OF THE '867 PATENT)

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

180. More than forty-five (45) days have elapsed since Counterclaim-Defendants' receipt of Conjupro's Notice Letter, which was received at the latest by March 7, 2024.

181. To date, and upon information and belief, even though Counterclaim-Defendants have not sued Counterclaim-Plaintiffs for infringement of the '867 patent, Counterclaim-Defendants have not delisted this patent from the Orange Book and have not entered into any agreements and/or covenants that they will not assert this patent in this case or in any future case, even though, as stated above, Counterclaim-Plaintiffs have certified this patent under paragraph IV of the Hatch-Waxman Act and provided notice of this certification to Counterclaim-Defendants.

182. The '867 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, and including at least the reasons set forth in the detailed statement included with Conjupro's Notice Letter.

183. The alleged invention of the '867 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 '867 patent.

184. The alleged invention of the '867 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 ’867 patent in the United States.

185. The ’867 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.

186. The alleged invention of the ’867 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 ’867 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 ’867 patent and would have had a reasonable expectation of success in doing so.

187. The claims of the ’867 patent are invalid at least under the doctrine of obviousness-type double patenting because its claims are not patentably distinct from the earlier expiring claims of at least the commonly owned U.S. Patent No. 8,703,181 and/or U.S. Patent No. 9,724, 303.

188. The claims of the ’867 patent are also invalid at least under 35 U.S.C. §§ 102 and/or 103 in view of the prior art, including, but not limited to: Chou et al., Journal of Bioscience and Bioengineering, Vol. 95, No. 4, 2003, pages 405-408 (“Chou et al.”); U.S. Patent No. 5,783,568 to Schlessinger et al. (“Schlessinger et al.”); U.S. Patent No. 5,785,987 to Hope et al. (“Hope et al.”); Katsu et al., Anal. Chem., Vol. 73, No. 8, 2001, pages 1849–1854 (“Katsu et al.”); US Patent Application Publication No. 2002/0146450 A1 to Slater et al. (“Slater et al.”); US Patent Application Publication No. 2003/0138481 A1 to Zadi et al. (“Zadi et al.”); and WO 2003/030864 A1 to Rahman et al. (“Rahman et al.”). The differences between the subject matter claimed in the ’867 patent and the prior art are such that the subject matter as a whole was either fully

anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

189. The ’867 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.

190. The claims of the ’867 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.

191. There exists an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding the validity of the ’867 patent, and a judicial declaration of invalidity is necessary and appropriate at this time.

192. Counterclaim-Plaintiffs are entitled to a declaration that the claims of the ’867 patent are invalid.

COUNT 19
(DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’360 PATENT)

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

194. More than forty-five (45) days have elapsed since Counterclaim-Defendants’ receipt of Conjupro’s Notice Letter, which was received at the latest by March 7, 2024.

195. To date, and upon information and belief, even though Counterclaim-Defendants have not sued Counterclaim-Plaintiffs for infringement of the ’360 patent, Counterclaim-Defendants have not delisted this patent from the Orange Book and have not entered into any agreements and/or covenants that they will not assert this patent in this case or in any future case,

even though, as stated above, Counterclaim-Plaintiffs have certified this patent under paragraph IV of the Hatch-Waxman Act and provided notice of this certification to Counterclaim-Defendants.

196. 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 ’360 patent, including for at least the reasons set forth in the detailed statement included with Conjupro’s Notice Letter.

197. 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 ’360 patent.

198. Conjupro’s NDA Product will not infringe any valid and/or enforceable claim of the ’360 patent, at least because Conjupro’s NDA Product does not satisfy the claims of the ’360 patent, either literally or under the doctrine of equivalents.

199. There exists an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding whether Counterclaim-Plaintiffs infringe any valid claim of the ’360 patent, and a judicial declaration of noninfringement is necessary and appropriate at this time.

200. Counterclaim-Plaintiffs are entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Conjupro’s NDA Product does not, and would not if marketed, infringe any valid and/or enforceable claim of the ’360 patent.

COUNT 20
(DECLARATORY JUDGMENT OF INVALIDITY OF THE ’360 PATENT)

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

202. More than forty-five (45) days have elapsed since Counterclaim-Defendants' receipt of Conjupro's Notice Letter, which was received at the latest by March 7, 2024.

203. To date, and upon information and belief, even though Counterclaim-Defendants have not sued Counterclaim-Plaintiffs for infringement of the '360 patent, Counterclaim-Defendants have not delisted this patent from the Orange Book and have not entered into any agreements and/or covenants that they will not assert this patent in this case or in any future case, even though, as stated above, Counterclaim-Plaintiffs have certified this patent under paragraph IV of the Hatch-Waxman Act and provided notice of this certification to Counterclaim-Defendants.

204. The '360 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, and including at least the reasons set forth in the detailed statement included with Conjupro's Notice Letter.

205. The alleged invention of the '360 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 '360 patent.

206. The alleged invention of the '360 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 '360 patent in the United States.

207. The '360 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.

208. The alleged invention of the '360 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 ’360 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 ’360 patent and would have had a reasonable expectation of success in doing so.

209. The claims of the ’360 patent are invalid at least under 35 U.S.C. §§ 102 and/or 103 in view of the prior art, including, but not limited to: the ’867 Patent. The differences between the subject matter claimed in the ’360 patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

210. The ’360 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.

211. The claims of the ’360 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.

212. There exists an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding the validity of the ’360 patent, and a judicial declaration of invalidity is necessary and appropriate at this time.

213. Counterclaim-Plaintiffs are entitled to a declaration that the claims of the ’360 patent are invalid.

COUNT 21
(DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’914 PATENT)

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

215. More than forty-five (45) days have elapsed since Counterclaim-Defendants' receipt of Conjupro's Notice Letter, which was received at the latest by March 7, 2024.

216. To date, and upon information and belief, even though Counterclaim-Defendants have not sued Counterclaim-Plaintiffs for infringement of the '914 patent, Counterclaim-Defendants have not delisted this patent from the Orange Book and have not entered into any agreements and/or covenants that they will not assert this patent in this case or in any future case, even though, as stated above, Counterclaim-Plaintiffs have certified this patent under paragraph IV of the Hatch-Waxman Act and provided notice of this certification to Counterclaim-Defendants.

217. 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 '914 patent, including for at least the reasons set forth in the detailed statement included with Conjupro's Notice Letter.

218. 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 '914 patent.

219. Conjupro's NDA Product will not infringe any valid and/or enforceable claim of the '914 patent, at least because Conjupro's NDA Product does not satisfy the claims of the '914 patent, either literally or under the doctrine of equivalents.

220. There exists an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding whether Counterclaim-Plaintiffs infringe any valid claim of

the ’914 patent, and a judicial declaration of noninfringement is necessary and appropriate at this time.

221. Counterclaim-Plaintiffs are entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Conjupro’s NDA Product does not, and would not if marketed, infringe any valid and/or enforceable claim of the ’914 patent.

COUNT 22
(DECLARATORY JUDGMENT OF INVALIDITY OF THE ’914 PATENT)

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

223. More than forty-five (45) days have elapsed since Counterclaim-Defendants’ receipt of Conjupro’s Notice Letter, which was received at the latest by March 7, 2024.

224. To date, and upon information and belief, even though Counterclaim-Defendants have not sued Counterclaim-Plaintiffs for infringement of the ’914 patent, Counterclaim-Defendants have not delisted this patent from the Orange Book and have not entered into any agreements and/or covenants that they will not assert this patent in this case or in any future case, even though, as stated above, Counterclaim-Plaintiffs have certified this patent under paragraph IV of the Hatch-Waxman Act and provided notice of this certification to Counterclaim-Defendants.

225. The ’914 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, and including at least the reasons set forth in the detailed statement included with Conjupro’s Notice Letter.

226. The alleged invention of the ’914 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 ’914 patent.

227. The alleged invention of the ’914 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 ’914 patent in the United States.

228. The ’914 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.

229. The alleged invention of the ’914 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 ’914 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 ’914 patent and would have had a reasonable expectation of success in doing so.

230. The claims of the ’914 patent are invalid at least under 35 U.S.C. §§ 102 and/or 103 in view of the prior art, including, but not limited to: the ’867 Patent. The differences between the subject matter claimed in the ’914 patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

231. The ’914 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.

232. The claims of the ’914 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.

233. There exists an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding the validity of the ’914 patent, and a judicial declaration of invalidity is necessary and appropriate at this time.

234. Counterclaim-Plaintiffs are entitled to a declaration that the claims of the ’914 patent are invalid.

PRAYER FOR RELIEF FOR COUNTERCLAIMS

(COUNTS 1 THROUGH 22)

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

(A) Adjudging that Defendants/Counterclaim-Plaintiffs have not and will not infringe any patent asserted by Plaintiffs in their Complaint and/or certified against by Defendants/Counterclaim-Plaintiffs in the Conjupro Notice Letter;

(B) Adjudging that no patent asserted by Plaintiffs and/or certified against by Defendants/Counterclaim-Plaintiffs in the Conjupro Notice Letter 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 and/or certified against by

Defendants/Counterclaim-Plaintiffs in the Conjupro Notice Letter;

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

(E) Denying Plaintiffs' 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: July 8, 2024

By: */s/ Gerard P. Norton*

Gerard P. Norton
Jonathan R. Lagarenne
Paul W. Kalish
Joe G. Chen
Jonathan J. Madara
FOX ROTHSCHILD LLP
gnorton@foxrothschild.com
jlagarenne@foxrothschild.com
pkalish@foxrothschild.com
joechen@foxrothschild.com
jmadara@foxrothschild.com
Princeton Pike Corporate Center
997 Lenox Drive
Lawrenceville, NJ 08648
Phone: (609) 896-3600

Howard S. Suh (*pro hac vice* application forthcoming)
Erxin Du (*pro hac vice* application forthcoming)
FOX ROTHSCHILD LLP

101 Park Avenue, 17th Floor
New York, NY 10178
(212) 878-7900
hsuh@foxrothschild.com
edu@foxrothschild.com

Attorneys for Defendants 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 forgoing was filed with the Court using the ECF system, which will provide notice and a copy to all Counsel of Record.

Dated: July 8, 2024

By: *s/ Gerard P. Norton*

Gerard P. Norton
FOX ROTHSCHILD LLP
Princeton Pike Corporate Center
997 Lenox Drive
Lawrenceville, NJ 08648
Phone: (609) 896-3600
gnorton@foxrothschild.com

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