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and Ipsen Biopharm 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. _____

(Filed Electronically)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Ipsen Biopharmaceuticals, Inc. (“Ipsen Biopharmaceuticals”) and Ipsen Biopharm Ltd. (“Ipsen Biopharm”) (collectively “Ipsen”), for their Complaint against Defendants Conjupro Biotherapeutics, Inc. (“Conjupro”), CSPC Pharmaceutical Group Limited (“CSPC Group”), and CSPC Ouyi Pharmaceutical Co., Ltd. (“CSPC Ouyi”) (collectively, “Conjupro/CSPC”) hereby allege as follows:

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.

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.

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.

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.

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.

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.

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

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

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.

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.

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.

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

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.

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.

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

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.

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.

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.

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.

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.

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.

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.

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.

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

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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).

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.

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").

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").

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.

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.

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.

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.

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

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.

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).

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.

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.

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).

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.

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).

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.

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.

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.

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.

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).

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.

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.

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).

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.

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).

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.

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.

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.

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.

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).

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.

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.

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).

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.

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).

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.

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.

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.

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.

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).

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.

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.

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).

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.

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).

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.

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.

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.

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.

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).

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.

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.

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).

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.

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).

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.

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.

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.

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.

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).

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.

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.

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).

99. 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 '724 patent, or any later expiration of exclusivity for the '724 patent to which Ipsen is or becomes entitled.

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).

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.

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.

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.

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.

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).

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.

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.

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).

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.

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).

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.

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.

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.

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.

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).

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.

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.

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).

119. 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 '597 patent, or any later expiration of exclusivity for the '597 patent to which Ipsen is or becomes entitled.

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).

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.

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.

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.

PRAYER FOR RELIEF

WHEREFORE, Ipsen requests that the Court grant the following relief:

A. A Judgment decreeing that Conjupro/CSPC has infringed one or more claims of each of the patents-in-suit by submitting the Conjupro NDA;

B. A Judgment decreeing that Conjupro/CSPC will infringe one or more claims of each of the patents-in-suit if it commercially manufactures, uses, offers for sale, or sells the Proposed Conjupro Product within the United States, imports the Proposed Conjupro Product into the United States, or induces and/or contributes to such conduct;

C. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any FDA approval of the Conjupro NDA be a date not earlier than the latest expiration date of the patents-in-suit, or any later expiration of any patent term extension or exclusivity for the patents-in-suit to which Ipsen is or becomes entitled;

D. A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) or 35 U.S.C. § 283 restraining and enjoining Conjupro/CSPC, its directors, officers, agents, attorneys, affiliates, divisions, successors, and employees, and those acting in privity or concert with them, from commercially manufacturing, using, offering to sell, and/or selling within the United States, or importing into the United States the Proposed Conjupro Product and any other product that infringes or induces or contributes to the infringement of one or more of the patents-in-suit, prior to the expiration of the patents-in-suit, including any exclusivities or extensions to which Ipsen is or become entitled;

E. A declaration that this case is an exceptional case pursuant to 35 U.S.C. § 285 and Ipsen be awarded its attorneys' fees; and

F. Such other and further relief as this Court deems just and proper.

Dated: April 15, 2024

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy (1) is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding; and (2) does not involve the validity or infringement of any patent which is involved in a case previously pending in this Court.

Dated: April 15, 2024

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