Charles M. Lizza
William C. Baton
SAUL EWING ARNSTEIN & LEHR LLP
One Riverfront Plaza, Suite 1520
Newark, NJ 07102-5426
(973) 286-6700
clizza@saul.com

Attorneys for Plaintiff
Corcept Therapeutics, Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CORCEPT THERAPEUTICS, INC., **Plaintiff,** **v.** **SUN PHARMA GLOBAL FZE, SUN PHARMACEUTICAL INDUSTRIES, INC., and SUN PHARMACEUTICAL INDUSTRIES LIMITED,** **Defendants.**	**Civil Action No. 19-15678 (SDW)(CLW)** **(Filed Electronically)**

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT[1]

Plaintiff Corcept Therapeutics, Inc. ("Corcept"), by its undersigned attorneys, for its Complaint against Defendants Sun Pharma Global FZE ("Sun FZE"), Sun Pharmaceutical Industries, Inc. ("Sun Inc."), and Sun Pharmaceutical Industries Limited ("Sun Ltd.") (collectively, "Sun"), alleges as follows:

[1] Corcept files this Second Amended Complaint with consent from Sun pursuant to Fed. R. Civ. P. 15(a)(2).

Nature of the Action

1. This complaint is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Sun's filing of an Abbreviated New Drug Application ("ANDA") No. 213387 ("Sun's ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Corcept's 300 mg mifepristone drug product ("Sun's Proposed Product") prior to the expiration of United States Patent Nos. 8,921,348 ("the '348 Patent"),10,195,214 ("the '214 Patent"), 9,829,495 ("the '495 Patent"), 10,500,216 ("the '216 Patent"), 10,842,800 ("the '800 Patent"), and 10,842,801 ("the '801 Patent") (together, "the patents-in-suit"), owned by Corcept.

The Parties

2. Plaintiff Corcept is a biopharmaceutical company committed to improving the lives of patients worldwide. Corcept focuses on, and heavily invests in, the discovery and development of drugs that regulate the effects of cortisol for the treatment of severe and life-threatening conditions, including Cushing's syndrome. Corcept is an industry leader for the development of orphan-status rare disease drugs, including KORLYM®. Corcept is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 149 Commonwealth Dr., Menlo Park, California 94025.

3. On information and belief, defendant Sun FZE is a corporation organized and existing under the laws of the United Arab Emirates, having a principal place of business at Office # 43, Block Y, SAIF-Zone, P.O. Box #122304, Sharjah, United Arab Emirates. On information and belief, Sun FZE is a wholly-owned subsidiary of Sun Ltd.

4. On information and belief, defendant Sun Inc. is a corporation organized and existing under the laws of the State of Michigan, having a principal place of business at 2

Independence Way, Princeton, New Jersey 08540. On information and belief, Sun Inc. is a wholly-owned subsidiary of Sun Ltd.

5. On information and belief, defendant Sun Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai 400 063, Maharashtra, India.

The Patents-in-Suit

6. On December 30, 2014, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '348 Patent, entitled, "Optimizing Mifepristone Levels in Plasma Serum of Patients Suffering from Mental Disorders Treatable with Glucocorticoid Receptor Antagonists" to Corcept as assignee of the inventor Joseph K. Belanoff. A copy of the '348 Patent is attached hereto as Exhibit A.

7. On February 5, 2019, the USPTO duly and lawfully issued the '214 Patent, entitled, "Concomitant Administration of Glucocorticoid Receptor Modulators and CYP3A Inhibitors" to Corcept as assignee of the inventor Joseph K. Belanoff. A copy of the '214 Patent is attached hereto as Exhibit B.

8. On November 28, 2017, the USPTO duly and lawfully issued the '495 Patent, entitled, "Method for Differentially Diagnosing ACTH-Dependent Cushing's Syndrome" to Corcept as assignee of the inventor Andreas G. Moraitis. A copy of the '495 Patent is attached hereto as Exhibit C.

9. On December 10, 2019, the USPTO duly and lawfully issued the '216 Patent, entitled, "Optimizing Mifepristone Absorption" to Corcept as assignee of the inventors Joe Belanoff, Robert Roe, and Caroline Loewy. A copy of the '216 Patent is attached hereto as Exhibit D.

10. On November 24, 2020, the USPTO duly and lawfully issued the '800 Patent, entitled, "Concomitant administration of glucocorticoid receptor modulators and CYP3A inhibitors" to Corcept as assignee of the inventor Joseph K. Belanoff. A copy of the '800 Patent is attached hereto as Exhibit E.

11. On November 24, 2020, the USPTO duly and lawfully issued the '801 Patent, entitled, "Optimizing Mifepristone Absorption" to Corcept as assignee of the inventors Joseph K. Belanoff, Robert Roe, and Caroline Loewy. A copy of the '801 Patent is attached hereto as Exhibit F.

The KORLYM® Drug Product

12. Corcept holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for mifepristone tablets (NDA No. 202107), which it sells under the trade name KORLYM®. KORLYM® is a FDA-approved medication for the treatment of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. The claims of the patents-in-suit cover, *inter alia*, methods of use and administration of mifepristone.

13. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Product with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to KORLYM®.

Jurisdiction and Venue

14. This Court has jurisdiction over the subject matter of this Action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

15. The Court has personal jurisdiction over Sun by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.

16. On information and belief, Sun FZE, Sun Inc., and Sun Ltd. develop, manufacture, distribute, market, offer to sell, and sell generic drug products for sale and use throughout the United States, including within this Judicial District.

17. On information and belief, Sun FZE, Sun Inc., and Sun Ltd. prepare and/or aid in the submission of ANDAs to the FDA.

18. On information and belief, Sun FZE, Sun Inc., and Sun Ltd. derive substantial revenue from selling generic products throughout the United States, including in this Judicial District.

19. This Court has personal jurisdiction over Sun because, *inter alia*, it has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and, on information and belief, Sun intends a future course of conduct that includes acts of patent infringement in New Jersey.

20. On information and belief, Sun FZE, Sun Inc., and Sun Ltd. actively participated in the submission of Sun's ANDA. On information and belief, Sun Ltd. will work in concert with Sun FZE, Sun Inc., and/or other subsidiaries towards the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of generic pharmaceutical products, including Sun's Proposed Product, throughout the United States, including in New Jersey and in this Judicial District, prior to the expiration of the patents-in-suit.

21. On information and belief, Sun seeks approval from the FDA to sell Sun's Proposed Product throughout the United States, including in this Judicial District. On

information and belief, this Judicial District will be a destination for the generic drug product described in Sun's ANDA.

22. This Court has personal jurisdiction over Sun because Sun has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with the State of New Jersey. On information and belief, Sun regularly and continuously transacts business within New Jersey, directly or indirectly, including by making pharmaceutical products for sale in New Jersey and selling pharmaceutical products in New Jersey. For example, Sun's website states its "U.S. headquarters are in Princeton, New Jersey," and it has "distribution and customer service teams at multiple locations across the country." Sun Pharma USA, http://www.sunpharma.com/usa (last visited April 28, 2021).

23. This Court has personal jurisdiction over Sun FZE by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Sun FZE purposefully has conducted and continues to conduct business in this Judicial District.

24. On information and belief, Sun FZE is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

25. On information and belief, Sun FZE, alone or through Sun Inc. and/or Sun Ltd., or through distributors, retailers, and/or wholesalers, manufactures and/or distributes generic drugs for sale and use throughout the United States, including in this Judicial District.

26. On information and belief, Sun FZE has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this Judicial District. *See, e.g.*, *Novartis Pharmaceuticals*

Corp., et al. v. Sun Pharma Global FZE, et al., Civil Action No. 12-4393 (SDW)(MCA); *The Medicines Co. v. Sun Pharma Global FZE, et al.*, Civil Action No. 11-6819 (PGS)(DEA).

27. In the alternative, this Court has personal jurisdiction over Sun FZE because the requirements of Fed. R. Civ. P. 4(k)(2) are met as (a) Corcept's claims arise under federal law; (b) Sun FZE is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Sun FZE has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs 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 Sun FZE satisfies due process.

28. This Court has personal jurisdiction over Sun Inc. by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Sun Inc. purposefully has conducted and continues to conduct business in this Judicial District.

29. On information and belief, Sun Inc. is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

30. On information and belief, Sun Inc., alone or through Sun FZE and/or Sun Ltd., or through distributors, retailers, and/or wholesalers, manufactures and/or distributes generic drugs for sale and use throughout the United States, including in this Judicial District.

31. On information and belief, Sun, through at least Sun Inc., maintains a physical place of business in at least Princeton, New Jersey.

32. On information and belief, Sun Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under

Business ID Nos. 0100954087 and/or 0100970132 and is registered as manufacturer and wholesaler with the New Jersey Department of Health under Registration No. 5003437.

33. On information and belief, Sun Inc. has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this Judicial District. *See, e.g.*, *Janssen Pharms. Inc. v Sun Pharma Global FZE, et al.*, Civil Action No. 11-6089 (SRC)(CLW); *Otsuka Pharm. Co. v. Sun Pharm. Indus. Ltd., et al.*, Civil Action No. 14-4307 (JBS)(KMW); *Otsuka Pharm. Co. v. Sun Pharm. Indus. Ltd.*, Civil Action No. 14-6397 (JBS)(KMW).

34. On information and belief, Sun FZE and Sun Inc. act for the benefit of and at the direction of Sun Ltd., and are agents and/or alter egos of Sun Ltd.

35. This Court has personal jurisdiction over Sun Ltd. by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Sun Ltd. purposefully has conducted and continues to conduct business in this Judicial District.

36. On information and belief, Sun Ltd. is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

37. On information and belief, Sun Ltd., alone or through Sun FZE and/or Sun Inc., or through distributors, retailers, and/or wholesalers, manufactures and/or distributes generic drugs for sale and use throughout the United States, including in this Judicial District.

38. This Court also has personal jurisdiction over Sun Ltd. because Sun Ltd. has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with the State of New Jersey. On information and belief, Sun Ltd. regularly and continuously transacts business within New Jersey, including by making

pharmaceutical products for sale in New Jersey and selling pharmaceutical products in New Jersey.

39. This Court has personal jurisdiction over Sun Ltd. because, *inter alia*, it: (1) has purposefully availed itself of the privilege of doing business in New Jersey, including directly or indirectly through its subsidiary, agent, and/or alter ego, Sun Inc., a company registered as manufacturer and wholesaler with the New Jersey Department of Health under Registration No. 5003437 and registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID Nos. 0100954087 and/or 0100970132; and (2) maintains extensive and systematic contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey, including through, directly or indirectly, Sun Inc. On information and belief, Sun Inc. acts at the direction, and for the benefit, of Sun Ltd., and is controlled and/or dominated by Sun Ltd.

40. On information and belief, Sun Ltd. has previously invoked, stipulated, and/or consented to personal jurisdiction in this Judicial District in numerous prior patent cases.

41. Sun Ltd. has previously been sued in this Judicial District and has availed itself of New Jersey courts through the assertion of counterclaims in suits brought in New Jersey, and has not challenged personal jurisdiction. *See, e.g.*, *Jazz Pharmaceuticals, Inc., et al. v. Sun Pharmaceutical Industries Ltd., et al.*, Civil Action No. 15-8229 (ES)(JAD); *Boehringer Ingelheim Pharmaceuticals Inc., et al. v. Sun Pharmaceutical Industries Ltd., et al.*, Civil Action No. 15-5982 (PGS)(TJB); *Jazz Pharmaceuticals, Inc. v. Sun Pharmaceutical Industries Ltd., et al.*, Civil Action No. 15-3217 (ES)(JAD); *Otsuka Pharmaceutical Co., Ltd. v. Sun Pharmaceutical Industries Ltd., et al.*, Civil Action No. 14-6397 (JBS)(KMW); *Otsuka Pharmaceutical Co., Ltd. v. Sun Pharmaceutical Industries, Inc., et al.*, Civil Action No. 14-

4307 (JBS)(KMW); *Cephalon, Inc. v. Sun Pharmaceutical Industries, Inc., et al.*, Civil Action No. 11-5474 (FLW)(DEA); *Depomed, Inc., et al. v. Sun Pharmaceutical Industries, Inc., et al.*, Civil Action No. 11-3553 (JAP)(TJB).

42. Sun Ltd. has further availed itself of the jurisdiction of this Court by initiating litigation in this Judicial District. *See, e.g.*, *Sun Pharmaceutical Industries Ltd., et al. v. Altana Pharma AG, et al.*, Civil Action No. 05-2391 (KSH)(PS).

43. In the alternative, this Court has personal jurisdiction over Sun Ltd. because the requirements of Fed. R. Civ. P. 4(k)(2) are met as (a) Corcept's claims arise under federal law; (b) Sun Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Sun Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs 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 Sun Ltd. satisfies due process.

44. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and/or 1400(b).

Acts Giving Rise To This Suit

45. Pursuant to Section 505 of the FFDCA, Sun filed ANDA No. 213387 seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of Sun's Proposed Product, before the patents-in-suit expire.

46. No earlier than June 07, 2019, Sun sent written notice of a Paragraph IV Certification ("Sun's First Notice Letter") to Corcept. According to Sun's Notice Letter, Sun filed an ANDA pursuant to Section 505 of the FFDCA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sun's

Proposed Product before expiration of the patents listed in the Orange Book with respect to KORLYM®.

47. Sun's First Notice Letter alleges that the claims of the '348 Patent, the '495 Patent, and the '214 Patent are invalid and/or will not be infringed by the activities described in Sun's ANDA.

48. No earlier than May 22, 2020, Sun sent written notice of a second Paragraph IV Certification ("Sun's Second Notice Letter") to Corcept. According to Sun's Second Notice Letter, Sun filed an ANDA pursuant to Section 505 of the FFDCA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sun's Proposed Product before expiration of the patents listed in the Orange Book with respect to KORLYM®.

49. Sun's Second Notice Letter alleges that the claims of the '216 Patent are invalid and/or will not be infringed by the activities described in Sun's ANDA.

50. No earlier than February 4, 2021, Sun sent written notice of a third Paragraph IV Certification ("Sun's Third Notice Letter") to Corcept. According to Sun's Third Notice Letter, Sun filed an ANDA pursuant to Section 505 of the FFDCA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sun's Proposed Product before expiration of the patents listed in the Orange Book with respect to KORLYM®.

51. Sun's Third Notice Letter alleges that the claims of the '800 Patent and the '801 Patent are invalid and/or will not be infringed by the activities described in Sun's ANDA.

52. On information and belief, in connection with the filing of its ANDA as described above, Sun provided written certifications to the FDA, as called for by Section 505 of

the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Sun's Paragraph IV Certifications"), alleging that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Sun's ANDA.

53. On information and belief, following FDA approval of Sun's ANDA, Sun FZE, Sun Inc., and Sun Ltd. will work in concert with one another to make, use, offer to sell, or sell Sun's Proposed Product throughout the United States, or import such generic products into the United States.

Count I: Infringement of the '348 Patent

54. Corcept repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

55. Sun's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sun's Proposed Product, prior to the expiration of the '348 Patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

56. A justiciable controversy exists between the parties hereto as to the infringement of the '348 Patent.

57. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will infringe one or more claims of the '348 Patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Sun's Proposed Product in the United States.

58. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will induce infringement of one or more claims of the '348 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Sun's Proposed Product in the United States. On information and belief, upon FDA approval of Sun's ANDA, Sun will intentionally

encourage acts of direct infringement with knowledge of the '348 Patent and knowledge that its acts are encouraging infringement.

59. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will contributorily infringe one or more claims of the '348 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Sun's Proposed Product in the United States. On information and belief, Sun knew and knows that Sun's Proposed Product is designed for a use that infringes one or more claims of the '348 Patent, and Sun's Proposed Product lacks a substantial non-infringing use.

60. Failure to enjoin Sun's infringement of the '348 Patent will substantially and irreparably damage Corcept.

61. Corcept does not have an adequate remedy at law.

Count II: Infringement of the '214 Patent

62. Corcept repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

63. Sun's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sun's Proposed Product, prior to the expiration of the '214 Patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

64. A justiciable controversy exists between the parties hereto as to the infringement of the '214 Patent.

65. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will infringe one or more claims of the '214 Patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Sun's Proposed Product in the United States.

66. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will induce infringement of one or more claims of the '214 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Sun's Proposed Product in the United States. On information and belief, upon FDA approval of Sun's ANDA, Sun will intentionally encourage acts of direct infringement with knowledge of the '214 Patent and knowledge that its acts are encouraging infringement.

67. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will contributorily infringe one or more claims of the '214 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Sun's Proposed Product in the United States. On information and belief, Sun knew and knows that Sun's Proposed Product is designed for a use that infringes one or more claims of the '214 Patent, and Sun's Proposed Product lacks a substantial non-infringing use.

68. Failure to enjoin Sun's infringement of the '214 Patent will substantially and irreparably damage Corcept.

69. Corcept does not have an adequate remedy at law.

Count III: Infringement of the '495 Patent

70. Corcept repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

71. Sun's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sun's Proposed Product, prior to the expiration of the '495 Patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

72. A justiciable controversy exists between the parties hereto as to the infringement of the '495 Patent.

73. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will infringe one or more claims of the '495 Patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Sun's Proposed Product in the United States.

74. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will induce infringement of one or more claims of the '495 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Sun's Proposed Product in the United States. On information and belief, upon FDA approval of Sun's ANDA, Sun will intentionally encourage acts of direct infringement with knowledge of the '495 Patent and knowledge that its acts are encouraging infringement.

75. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will contributorily infringe one or more claims of the '495 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Sun's Proposed Product in the United States. On information and belief, Sun knew and knows that Sun's Proposed Product is designed for a use that infringes one or more claims of the '495 Patent, and Sun's Proposed Product lacks a substantial non-infringing use.

76. Failure to enjoin Sun's infringement of the '495 Patent will substantially and irreparably damage Corcept.

77. Corcept does not have an adequate remedy at law.

Count IV: Infringement of the '216 Patent

78. Corcept repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

79. Sun's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sun's Proposed Product, prior to the

expiration of the ’216 Patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

80. A justiciable controversy exists between the parties hereto as to the infringement of the ’216 Patent.

81. Unless enjoined by this Court, upon FDA approval of Sun’s ANDA, Sun will infringe one or more claims of the ’216 Patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Sun’s Proposed Product in the United States.

82. Unless enjoined by this Court, upon FDA approval of Sun’s ANDA, Sun will induce infringement of one or more claims of the ’216 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Sun’s Proposed Product in the United States. On information and belief, upon FDA approval of Sun’s ANDA, Sun will intentionally encourage acts of direct infringement with knowledge of the ’216 Patent and knowledge that its acts are encouraging infringement.

83. Unless enjoined by this Court, upon FDA approval of Sun’s ANDA, Sun will contributorily infringe one or more claims of the ’216 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Sun’s Proposed Product in the United States. On information and belief, Sun knew and knows that Sun’s Proposed Product is designed for a use that infringes one or more claims of the ’216 Patent, and Sun’s Proposed Product lacks a substantial non-infringing use.

84. Failure to enjoin Sun’s infringement of the ’216 Patent will substantially and irreparably damage Corcept.

85. Corcept does not have an adequate remedy at law.

Count V: Infringement of the '800 Patent

86. Corcept repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

87. Sun's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sun's Proposed Product, prior to the expiration of the '800 Patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

88. A justiciable controversy exists between the parties hereto as to the infringement of the '800 Patent.

89. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will infringe one or more claims of the '800 Patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Sun's Proposed Product in the United States.

90. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will induce infringement of one or more claims of the '800 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Sun's Proposed Product in the United States. On information and belief, upon FDA approval of Sun's ANDA, Sun will intentionally encourage acts of direct infringement with knowledge of the '800 Patent and knowledge that its acts are encouraging infringement.

91. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will contributorily infringe one or more claims of the '800 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Sun's Proposed Product in the United States. On information and belief, Sun knew and knows that Sun's Proposed Product is designed for a use that infringes one or more claims of the '800 Patent, and Sun's Proposed Product lacks a substantial non-infringing use.

92. Failure to enjoin Sun's infringement of the '800 Patent will substantially and irreparably damage Corcept.

93. Corcept does not have an adequate remedy at law.

Count VI: Infringement of the '801 Patent

94. Corcept repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

95. Sun's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sun's Proposed Product, prior to the expiration of the '801 Patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

96. A justiciable controversy exists between the parties hereto as to the infringement of the '801 Patent.

97. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will infringe one or more claims of the '801 Patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Sun's Proposed Product in the United States.

98. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will induce infringement of one or more claims of the '801 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Sun's Proposed Product in the United States. On information and belief, upon FDA approval of Sun's ANDA, Sun will intentionally encourage acts of direct infringement with knowledge of the '801 Patent and knowledge that its acts are encouraging infringement.

99. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will contributorily infringe one or more claims of the '801 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Sun's Proposed Product in the United

States. On information and belief, Sun knew and knows that Sun's Proposed Product is designed for a use that infringes one or more claims of the '801 Patent, and Sun's Proposed Product lacks a substantial non-infringing use.

100. Failure to enjoin Sun's infringement of the '801 Patent will substantially and irreparably damage Corcept.

101. Corcept does not have an adequate remedy at law.

PRAYER FOR RELIEF

102. WHEREFORE, Plaintiff Corcept respectfully requests the following relief:

(A) A Judgment that Sun infringed the patents-in-suit by submitting ANDA No. 213387;

(B) A Judgment that Sun has infringed, and that Sun's making, using, offering to sell, selling, or importing Sun's Proposed Product will infringe one or more claims of the patents-in-suit;

(C) An Order that the effective date of FDA approval of ANDA No. 213387 be a date no earlier than the later of the expiration of each patent-in-suit, or any later expiration of exclusivity to which Corcept is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Sun and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing Sun's Proposed Product until after the expiration of the each patent-in-suit, or any later expiration of exclusivity to which Corcept is or becomes entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Sun, its officers, agents, attorneys and employees, and those acting in privity or concert

with them, from practicing any method claimed in the patents-in-suit, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit, until after the expiration of each patent-in-suit, or any later expiration of exclusivity to which Corcept is or becomes entitled;

(F) A Judgment that the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of Sun's Proposed Product will directly infringe, induce and/or contribute to infringement of the patents-in-suit;

(G) To the extent that Sun has committed any acts with respect the methods claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Corcept damages for such acts;

(H) If Sun engages in the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of Sun's Proposed Product prior to the expiration of the patents-in-suit, a Judgment awarding damages to Corcept resulting from such infringement, together with interest;

(I) A Judgment declaring that the patent-in-suit remains valid and enforceable;

(J) A Judgment awarding Corcept its costs and expenses incurred in this action; and

(K) Such further and other relief as this Court may deem just and proper.

Dated: May 26, 2021

By: s/Charles M. Lizza

Charles M. Lizza
William C. Baton
SAUL EWING ARNSTEIN & LEHR LLP
One Riverfront Plaza, Suite 1520
Newark, New Jersey 07102-5426
(973) 286-6700
clizza@saul.com

Attorneys for Plaintiff
Corcept Therapeutics, Inc.

Of Counsel:

F. Dominic Cerrito
Eric C. Stops
Daniel C. Wiesner
John P. Galanek
Nicholas A. LoCastro
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010
(212) 849-7000