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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

OREXO AB and OREXO US, INC., Plaintiffs, v. SUN PHAMACEUTICAL INDUSTRIES LIMITED, SUN PHARMA GLOBAL FZE, SUN PHARMA GLOBAL, INC., and SUN PHARMACEUTICAL INDUSTRIES, INC. Defendants.	)	C.A. No.: _____ **COMPLAINT FOR PATENT INFRINGEMENT**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Orexo AB and Orexo US, Inc. ("Orexo US") (collectively, "Orexo" or "Plaintiffs"), for their Complaint against defendants Sun Pharmaceuticals Industries Limited ("Sun Ltd."), Sun Pharma Global FZE ("Sun FZE"), Sun Pharma Global, Inc. ("Sun Global"), and Sun Pharmaceutical Industries, Inc. ("Sun Inc.") (collectively, "Sun") hereby allege as follows:

NATURE OF THE ACTION

1. This 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. 214737 ("Sun's ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market generic versions of Orexo's ZUBSOLV® (buprenorphine/naloxone sublingual tablets) at doses of 1.4/0.36 mg, 2.9/0.71 mg, 5.7/1.4 mg, 8.6/2.1 mg, and 11.4/2.9 mg ("Sun's ANDA Products") prior to the expiration of United States Patent Nos. 8,470,361 ("the '361 patent"), 8,658,198 ("the '198 patent"), 8,940,330 ("the '330 patent"), 9,259,421 ("the '421 patent"), and 9,439,900 ("the '900 patent"), all owned by Orexo AB (collectively, the "patents-in-suit").

THE PARTIES

2. Plaintiff Orexo AB is a company organized and existing under the laws of Sweden, having its principal place of business at Virdings allé 32 A, 754 50 Uppsala, Sweden.

3. Plaintiff Orexo US is a corporation organized and existing under the laws of the state of Delaware, having its principal place of business at 150 Headquarters Plaza, East Tower, Morristown, New Jersey 07960. Orexo US is a wholly owned subsidiary of Orexo AB.

4. On information and belief, 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.

5. On information and belief, 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.

6. On information and belief, Sun Global is a corporation organized and existing under the laws of the British Virgin Islands, and maintains a post office box at International Trust Building, P.O. Box No. 659, Road Town, Tortola, British Virgin Islands. On information and belief, Sun Global is a wholly-owned subsidiary of Sun Ltd.

7. On information and belief, 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.

JURISDICTION AND VENUE

8. This is an action for patent infringement arising under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338, 2201, and/or 2202.

Sun Ltd.

9. This Court has personal jurisdiction over Sun Ltd. because it has purposely availed itself of the privilege of acting within New Jersey by committing an act of patent infringement under 35 U.S.C. § 271(e)(2), and has sent notice of that infringement to Orexo US in the State of New Jersey.

10. On information and belief, Sun Ltd. intends a future course of conduct that includes acts of patent infringement in New Jersey. On information and belief, Sun Ltd. knows and intends that, upon FDA approval of Sun's ANDA, Sun's ANDA Product will be distributed and sold, by Sun Ltd., in New Jersey and will thereby displace sales of ZUBSOLV®, causing injury to Plaintiffs in this District.

11. This Court has personal jurisdiction over Sun Ltd. also 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. is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through subsidiaries, agents, and/or alter egos, which Sun Ltd., either directly or indirectly, manufactures, distributes, markets and/or sells throughout the United States, including in this District.

12. Sun Ltd.'s website states that its "US headquarters are in Cranbury, New Jersey," that it has "distribution and customer service teams at multiple locations across the country," and that "Sun Pharma's latest acquisition of a majority interest in Ranbaxy Laboratories Limited (Ranbaxy) and its Ohm Laboratories facilities in the [sic] New Jersey makes it the largest Indian pharma company in the US market . . . ." Sun Pharma USA, http://www.sunpharma.com/usa (last visited August 21, 2020).

13. Sun Ltd. has done business in New Jersey, including through its wholly-owned subsidiary, agent, and/or alter ego, Sun Inc., a company registered as a 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. Sun Ltd. 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.

14. This Court has personal jurisdiction over Sun Ltd. also because it has taken advantage of the jurisdiction of this Court by filing claims and counterclaims in this Court. 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. For example, 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., Celgene Corporation v. Sun Pharmaceutical Industries, Inc., et al.*, Civil Action No. 18-11630 (SDW)(LDW); *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).

15. 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); *Sun Pharmaceutical Industries Ltd., et al. v. Novartis Pharmaceuticals Corp., et al.*, Civil Action No. 19-21733.

16. In the alternative to the foregoing, this Court has personal jurisdiction over Sun Ltd., because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a)

Plaintiffs' 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.

17. Venue is proper in this district for Sun Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Sun Ltd. is a corporation organized and existing under the laws of India and may be sued in any judicial district.

Sun FZE

18. This Court has personal jurisdiction over Sun FZE because it has purposely availed itself of the privilege of acting within New Jersey by committing an act of patent infringement. On information and belief, Sun FZE actively participated in the submission of Sun's ANDA.

19. On information and belief, Sun FZE intends a future course of conduct that includes acts of patent infringement in New Jersey. On information and belief, Sun FZE knows and intends that, upon FDA approval of Sun's ANDA, Sun's ANDA Product will be distributed and sold, by at least Sun FZE, in New Jersey and will thereby displace sales of ZUBSOLV®, causing injury to Plaintiffs in this District.

20. This Court has personal jurisdiction over Sun FZE also because Sun FZE 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 FZE has purposely conducted, and continues to conduct, business in this Judicial District. On information and belief, Sun FZE, in concert with at least 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.

21. This Court has personal jurisdiction over Sun FZE also because it has taken advantage of the jurisdiction of this Court by filing at least counterclaims in this Court; Sun FZE has also previously consented to this Court's jurisdiction. *See, e.g., Celgene Corporation v. Sun Pharmaceutical Industries, Inc., et al.*, Civil Action No. 18-11630 (SDW)(LDW); *Novartis Pharmaceuticals Corp., et al. v. Sun Pharma Sun 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).

22. Sun FZE has further availed itself of the jurisdiction of this Court by initiating litigation in this Judicial District. *See, e.g., Sun Pharma Global FZE et al. v. Lupin Ltd. et al.*, Civil Action No. 18-02213.

23. On information and belief Sun FZE acts for the benefit of and at the direction of Sun Ltd., and is an agent and/or alter ego of Sun Ltd.

24. In the alternative to the foregoing, this Court has personal jurisdiction over Sun FZE because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Celgene'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.

25. Venue is proper in this district for Sun FZE pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Sun FZE is a corporation organized and existing under the laws of the United Arab Emirates and may be sued in any judicial district.

Sun Global

26. This Court has personal jurisdiction over Sun Global because it has purposely availed itself of the privilege of acting within New Jersey by committing an act of patent infringement. On information and belief, Sun Global actively participated in the submission of Sun's ANDA.

27. On information and belief, Sun Global intends a future course of conduct that includes acts of patent infringement in New Jersey. On information and belief, Sun Global knows and intends that, upon FDA approval of Sun's ANDA, Sun's ANDA Product will be distributed and sold, by at least Sun Global, in New Jersey and will thereby displace sales of ZUBSOLV®, causing injury to Plaintiffs in this District.

28. This Court has personal jurisdiction over Sun Global also because Sun Global 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 Global has purposely conducted, and continues to conduct, business in this Judicial District. On information and belief, Sun Global, in concert with at least 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.

29. This Court has personal jurisdiction over Sun Global also because it has taken advantage of the jurisdiction of this Court by filing at least counterclaims in this Court; Sun Global has also previously consented to this Court's jurisdiction. *See, e.g., Celgene Corporation*

v. Sun Pharmaceutical Industries, Inc., et al., Civil Action No. 18-11630 (SDW)(LDW); *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., et al.*, Civil Action No. 14-6397 (JBS)(KMW); *Aventis Pharm. Inc., et al. v. Sun Pharma Global Inc., et al.*, Civil Action No. 09-325 (GEB)(MCA).

30. On information and belief Sun Global acts for the benefit of and at the direction of Sun Ltd., and is an agent and/or alter ego of Sun Ltd.

31. In the alternative to the foregoing, this Court has personal jurisdiction over Sun Global because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Plaintiffs' claims arise under federal law; (b) Sun Global is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Sun Global 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 Global satisfies due process.

32. Venue is proper in this district for Sun Global pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Sun Global is a corporation organized and existing under the laws of the British Virgin Islands and may be sued in any judicial district.

Sun Inc.

33. This Court has personal jurisdiction over Sun Inc. because it has purposely availed itself of the privilege of acting within New Jersey by committing an act of patent infringement and intends a course of conduct of patent infringement in this District. On information and belief, Sun Inc. actively participated in the submission of Sun's ANDA.

34. On information and belief, Sun Inc. intends a future course of conduct that includes acts of patent infringement in New Jersey. On information and belief, Sun Inc. knows

and intends that, upon FDA approval of Sun's ANDA, Sun's ANDA Product will be distributed and sold, by at least Sun Inc., in New Jersey and will thereby displace sales of ZUBSOLV®, causing injury to Plaintiffs in this District.

35. This Court has personal jurisdiction over Sun Inc. also because Sun Inc. 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 Inc. has purposely conducted, and continues to conduct, business in this Judicial District. On information and belief, Sun Inc., in concert with at least 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.

36. On information and belief, Sun Inc. maintains physical places of business in at least Princeton, New Jersey and Cranbury, New Jersey.

37. 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 a manufacturer and wholesaler with the New Jersey Department of Health under Registration No. 5003437.

38. This Court has personal jurisdiction over Sun Inc. because, *inter alia*, it has taken advantage of the jurisdiction of this Court by filing at least counterclaims in this Court; Sun Inc. has also previously consented to this Court's jurisdiction. *See, e.g., Celgene Corporation v. Sun Pharmaceutical Industries, Inc., et al.,* Civil Action No. 18-11630 (SDW)(LDW); *Janssen Pharm. 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).

39. Sun Inc. 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. Novartis Pharmaceuticals Corp., et al.*, Civil Action No. 19-21733; *Sun Pharma Global FZE et al. v. Lupin Ltd. et al.*, Civil Action No. 18-02213.

40. On information and belief Sun Inc. acts for the benefit of and at the direction of Sun Ltd., and is an agent and/or alter ego of Sun Ltd.

41. Venue is proper in this district for Sun Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Sun Inc. is subject to personal jurisdiction and has a principal place of business in this judicial district.

THE ZUBSOLV® DRUG PRODUCT

42. Orexo US holds approved New Drug Application ("NDA") No. 204242 for buprenorphine hydrochloride and naloxone hydrochloride sublingual tablets, which are prescribed and sold in the United States under the trademark ZUBSOLV®.

43. ZUBSOLV® sublingual tablets are indicated for the maintenance treatment of opioid dependence and for the induction of buprenorphine maintenance therapy in patients suffering from opioid dependence.

THE PATENTS-IN-SUIT

44. On June 25, 2013, the USPTO duly and lawfully issued the '361 patent, entitled, "Non-abusable pharmaceutical composition comprising opioids," to Orexo AB as assignee of the inventor Anders Pettersson. A copy of the '361 patent is attached hereto as Exhibit A. The '361 patent is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for ZUBSOLV® sublingual tablets (NDA No. 204242).

45. On February 25, 2014, the USPTO duly and lawfully issued the '198 patent, entitled, "Non-abusable pharmaceutical composition comprising opioids," to Orexo AB as

assignee of the inventor Anders Pettersson. A copy of the ’198 patent is attached hereto as Exhibit B. The ’198 patent is listed in the Orange Book for ZUBSOLV® sublingual tablets (NDA No. 204242).

46. On January 27, 2015, the USPTO duly and lawfully issued the ’330 patent, entitled, “Abuse-resistant pharmaceutical composition for the treatment of opioid dependence,” to Orexo AB as assignee of the inventor Andreas Fischer. A copy of the ’330 patent is attached hereto as Exhibit C. The ’330 patent is listed in the Orange Book for ZUBSOLV® sublingual tablets (NDA No. 204242).

47. On February 16, 2016, the USPTO duly and lawfully issued the ’421 patent, entitled, “Abuse-resistant pharmaceutical composition for the treatment of opioid dependence,” to Orexo AB as assignee of the inventor Andreas Fischer. A copy of the ’421 patent is attached hereto as Exhibit D. The ’421 patent is listed in the Orange Book for ZUBSOLV® sublingual tablets (NDA No. 204242).

48. On September 13, 2016, the USPTO duly and lawfully issued the ’900 patent, entitled, “Abuse-resistant pharmaceutical composition for the treatment of opioid dependence,” to Orexo AB as assignee of the inventor Andreas Fischer. A copy of the ’900 patent is attached hereto as Exhibit E. The ’900 patent is listed in the Orange Book for ZUBSOLV® sublingual tablets (NDA No. 204242).

ACTS GIVING RISE TO THIS SUIT

49. Pursuant to Section 505 of the Federal Food, Drug and Cosmetic Act, Sun Ltd. filed Sun’s ANDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Sun’s ANDA Products before the patents-in-suit expire.

50. On information and belief, Sun FZE, Sun Global, and Sun Inc. aided, abetted, and/or acted in concert with Sun Ltd. to file its ANDA.

51. On information and belief, following FDA approval of Sun's ANDA, Sun will make, use, sell, or offer to sell Sun's ANDA Products throughout the United States, or import such generic products into the United States.

52. On information and belief, in connection with the filing of its ANDA as described above, Sun Ltd. provided a written certification to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Sun's Paragraph IV Certification"), 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 August 3, 2020, Sun Ltd. sent written notice of its Paragraph IV Certification to Plaintiffs ("Sun's Notice Letter"). Sun's Notice Letter alleged that the claims of the patents-in-suit will not be infringed by the activities described in Sun's ANDA. Sun's Notice Letter also informed Plaintiffs that Sun seeks approval to market Sun's ANDA Products before the patents-in-suit expire. Sun specifically directed Sun's Notice Letter to Orexo US's headquarters in Morristown, New Jersey, in this Judicial District.

54. Sun's Notice Letter contained an "Offer of Confidential Access." Plaintiffs found the terms to the Offer of Confidential Access as unreasonable and attempted to negotiate access on more reasonable terms. While Plaintiffs negotiated with Defendants in good faith, Sun has not provided any Confidential Information as of the date of this Complaint

55. Based on its review of Sun's Paragraph IV Certification and other information, Plaintiffs are informed and believe Sun's ANDA infringes valid patent claims of the '361, '198, '330, '421, and '900 patents, and has therefore brought this action.

COUNT I
Infringement of the ’361 Patent

56. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

57. Sun, by the submission of its Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Sun’s ANDA Products, prior to the expiration of the ’361 patent.

58. Sun’s ANDA has been pending before the FDA since at least July 31, 2020, the date appearing on Sun’s Notice Letter to Plaintiffs.

59. Sun’s submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Sun’s ANDA Products, prior to the expiration of the ’361 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

60. There is a justiciable controversy between the parties hereto as to the infringement of the ’361 patent.

61. Unless enjoined by this Court, upon FDA approval of Sun’s ANDA, Sun will infringe one or more claims of the ’361 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Sun’s ANDA Products in the United States.

62. Unless enjoined by this Court, upon FDA approval of Sun’s ANDA, Sun will induce infringement of one or more claims of the ’361 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Sun’s ANDA Products 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 ’361 patent and knowledge that its acts are encouraging infringement.

63. Unless enjoined by this Court, upon FDA approval of Sun’s ANDA, Sun will contributorily infringe one or more claims of the ’361 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Sun’s ANDA Products in the United States. On information and belief, Sun has had and continues to have knowledge that Sun’s ANDA Products are especially adapted for a use that infringes one or more claims of the ’361 patent and that there is no substantial non-infringing use for Sun’s ANDA Products.

64. Sun’s ANDA Products are required in accordance with 21 U.S.C. 355(j)(2)(v) to have the same clinical instructions on use, be administered in the same manner, and achieve the same results as inventions claimed in the ’361 patent.

65. Plaintiffs will be substantially and irreparably damaged and harmed if Sun’s infringement of the ’361 patent is not enjoined.

66. Plaintiffs do not have an adequate remedy at law.

67. Sun did not contest the validity of any of the claims of the ’361 patent in Sun’s Notice Letter. If Sun had a factual or legal basis to contest the validity of the claims of the ’361 patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

68. This case is an exceptional one, and Plaintiffs are entitled to an award of its reasonable attorneys’ fees under 35 U.S.C. § 285.

COUNT II
Infringement of the ’198 Patent

69. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

70. Sun, by the submission of its Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Sun's ANDA Products, prior to the expiration of the '198 patent.

71. Sun's ANDA has been pending before the FDA since at least July 31, 2020, the date that Sun sent Sun's Notice Letter to Plaintiffs.

72. Sun's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Sun's ANDA Products, prior to the expiration of the '198 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

73. There is a justiciable controversy between the parties hereto as to the infringement of the '198 patent.

74. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will infringe one or more claims of the '198 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Sun's ANDA Products in the United States.

75. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will induce infringement of one or more claims of the '198 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Sun's ANDA Products 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 '198 patent and knowledge that its acts are encouraging infringement.

76. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will contributorily infringe one or more claims of the '198 patent under 35 U.S.C. § 271(c) by

making, using, offering to sell, selling, and/or importing Sun's ANDA Products in the United States. On information and belief, Sun has had and continues to have knowledge that Sun's ANDA Products are especially adapted for a use that infringes one or more claims of the '198 patent and that there is no substantial non-infringing use for Sun's ANDA Products.

77. Sun's ANDA Products are required in accordance with 21 U.S.C. 355(j)(2)(v) to have the same clinical instructions on use, be administered in the same manner, and achieve the same results as inventions claimed in the '198 patent.

78. Plaintiffs will be substantially and irreparably damaged and harmed if Sun's infringement of the '198 patent is not enjoined.

79. Plaintiffs do not have an adequate remedy at law.

80. Sun did not contest the validity of any of the claims of the '198 patent in Sun's Notice Letter. If Sun had a factual or legal basis to contest the validity of the claims of the '198 patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

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

COUNT III
Infringement of the '330 Patent

82. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

83. Sun, by the submission of its Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Sun's ANDA Products, prior to the expiration of the '330 patent.

84. Sun's ANDA has been pending before the FDA since at least July 31, 2020, the date that Sun sent Sun's Notice Letter to Plaintiffs.

85. Sun's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Sun's ANDA Products, prior to the expiration of the '330 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

86. There is a justiciable controversy between the parties hereto as to the infringement of the '330 patent.

87. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will infringe one or more claims of the '330 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Sun's ANDA Products in the United States.

88. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will induce infringement of one or more claims of the '330 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Sun's ANDA Products 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 '330 patent and knowledge that its acts are encouraging infringement.

89. Unless enjoined by this Court, upon FDA approval of Sun's ANDA, Sun will contributorily infringe one or more claims of the '330 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Sun's ANDA Products in the United States. On information and belief, Sun has had and continues to have knowledge that Sun's ANDA Products are especially adapted for a use that infringes one or more claims of the '330 patent and that there is no substantial non-infringing use for Sun's ANDA Products.

90. Sun's ANDA Products are required in accordance with 21 U.S.C. 355(j)(2)(v) to have the same clinical instructions on use, be administered in the same manner, and achieve the same results as inventions claimed in the '330 patent.

91. Plaintiffs will be substantially and irreparably damaged and harmed if Sun's infringement of the '330 patent is not enjoined.

92. Plaintiffs do not have an adequate remedy at law.

93. Sun did not contest the validity of any of the claims of the '330 patent in Sun's Notice Letter. If Sun had a factual or legal basis to contest the validity of the claims of the '330 patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

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

COUNT IV
Infringement of the '421 Patent

95. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

96. Sun, by the submission of its Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Sun's ANDA Products, prior to the expiration of the '421 patent.

97. Sun's ANDA has been pending before the FDA since at least July 31, 2020, the date that Sun sent Sun's Notice Letter to Plaintiffs.

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

expiration of the ’421 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

99. There is a justiciable controversy between the parties hereto as to the infringement of the ’421 patent.

100. Unless enjoined by this Court, upon FDA approval of Sun’s ANDA, Sun will infringe one or more claims of the ’421 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Sun’s ANDA Products in the United States.

101. Unless enjoined by this Court, upon FDA approval of Sun’s ANDA, Sun will induce infringement of one or more claims of the ’421 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Sun’s ANDA Products 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 ’421 patent and knowledge that its acts are encouraging infringement.

102. Unless enjoined by this Court, upon FDA approval of Sun’s ANDA, Sun will contributorily infringe one or more claims of the ’421 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Sun’s ANDA Products in the United States. On information and belief, Sun has had and continues to have knowledge that Sun’s ANDA Products are especially adapted for a use that infringes one or more claims of the ’421 patent and that there is no substantial non-infringing use for Sun’s ANDA Products.

103. Sun’s ANDA Products are required in accordance with 21 U.S.C. 355(j)(2)(v) to have the same clinical instructions on use, be administered in the same manner, and achieve the same results as inventions claimed in the ’421 patent.

104. Plaintiffs will be substantially and irreparably damaged and harmed if Sun's infringement of the '421 patent is not enjoined.

105. Plaintiffs do not have an adequate remedy at law.

106. Sun did not contest the validity of any of the claims of the '421 patent in Sun's Notice Letter. If Sun had a factual or legal basis to contest the validity of the claims of the '421 patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

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

COUNT V
Infringement of the '900 Patent

108. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

109. Sun, by the submission of its Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Sun's ANDA Products, prior to the expiration of the '900 patent.

110. Sun's ANDA has been pending before the FDA since at least July 31, 2020, the date that Sun sent Sun's Notice Letter to Plaintiffs.

111. Sun's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Sun's ANDA Products, prior to the expiration of the '900 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

112. There is a justiciable controversy between the parties hereto as to the infringement of the ’900 patent.

113. Unless enjoined by this Court, upon FDA approval of Sun’s ANDA, Sun will infringe one or more claims of the ’900 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Sun’s ANDA Products in the United States.

114. Unless enjoined by this Court, upon FDA approval of Sun’s ANDA, Sun will induce infringement of one or more claims of the ’900 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Sun’s ANDA Products 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 ’900 patent and knowledge that its acts are encouraging infringement.

115. Unless enjoined by this Court, upon FDA approval of Sun’s ANDA, Sun will contributorily infringe one or more claims of the ’900 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Sun’s ANDA Products in the United States. On information and belief, Sun has had and continues to have knowledge that Sun’s ANDA Products are especially adapted for a use that infringes one or more claims of the ’900 patent and that there is no substantial non-infringing use for Sun’s ANDA Products.

116. Sun’s ANDA Products are required in accordance with 21 U.S.C. 355(j)(2)(v) to have the same clinical instructions on use, be administered in the same manner, and achieve the same results as inventions claimed in the ’900 patent.

117. Plaintiffs will be substantially and irreparably damaged and harmed if Sun’s infringement of the ’900 patent is not enjoined.

118. Plaintiffs do not have an adequate remedy at law.

119. Sun did not contest the validity of any of the claims of the '900 patent in Sun's Notice Letter. If Sun had a factual or legal basis to contest the validity of the claims of the '900 patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment that Sun has infringed the patents-in-suit by submitting ANDA No. 214737;

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

C. An Order that the effective date of FDA approval of ANDA No. 214737 be a date which is not earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiffs are 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 ANDA Products until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become 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 buprenorphine/naloxone sublingual tablets or compositions 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 the patents-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

F. A Judgment that the commercial manufacture, use, importation into the United States, sale, and/or offer for sale of Sun's ANDA Products 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 to the inventions claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Plaintiffs damages for such acts;

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

I. A Judgment declaring that the patents-in-suit remain valid and enforceable;

J. A Judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Plaintiffs their attorneys' fees incurred in this action;

K. A Judgment awarding Plaintiffs their costs and expenses incurred in this action; and

L. Such further and other relief as this Court may deem just and proper.

GIBBONS P.C.

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