IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PERNIX IRELAND PAIN LTD and PERNIX THERAPEUTICS, LLC,	)	
Plaintiffs,	)	
v.	)	
	)	C.A. No. 16-139-GMS
ALVOGEN MALTA OPERATIONS LTD.,	)	
Defendant.	)	

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Pernix Ireland Pain Ltd. ("Pernix Ireland") and Pernix Therapeutics, LLC ("Pernix Therapeutics") (collectively, "Plaintiffs"), for their Second Amended Complaint against Defendant Alvogen Malta Operations Ltd. ("Alvogen"), hereby allege as follows:

THE PARTIES

1. Pernix Ireland is a corporation organized and existing under the laws of Ireland, having its principal place of business at Pembroke House, Dublin 2, Ireland.

2. Pernix Therapeutics is a corporation organized and existing under the laws of Louisiana having its principal place of business at 10 North Park Place, Suite 201, Morristown, New Jersey 07960.

3. On information and belief, Alvogen is a corporation organized and existing under the laws of Malta.

4. On information and belief, Alvogen, is in the business of among other things, manufacturing, marketing, importing, preparing, and selling generic pharmaceutical products that it distributes in the State of Delaware and throughout the United States.

NATURE OF ACTION

5. This is an action for infringement of United States Patent Nos. 9,265,760 ("the '760 patent"), 9,326,982 ("the '982 patent"), 9,333,201 ("the '201 patent"), 9,339,499 ("the '499 patent"), 9,421,200 ("the '200 patent"), and 9,433,619 ("the '619 patent") under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*, including 35 U.S.C. § 271(e)(2). True and correct copies of the '760, '982, '201, '499, '200, and '619 patents are attached as Exhibits A-F, respectively.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

7. This Court has personal jurisdiction over Alvogen by virtue of the fact that, *inter alia*, it has committed the tortious act of patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A) that has led to foreseeable harm and injury to Plaintiffs in the State of Delaware, and throughout the United States.

8. This Court also has personal jurisdiction over Alvogen by virtue of the fact that Alvogen previously submitted to the jurisdiction of this Court and availed itself of this Court by consenting to this Court's jurisdiction and asserting counterclaims in a civil action initiated in this jurisdiction involving the same Abbreviated New Drug Application ("ANDA") and pharmaceutical product at issue here. *See, e.g.*, *Recro Gainesville LLC v. Alvogen Malta Operations Ltd.*, C.A. No. 14-cv-1364-GMS, D.I. 7 (D. Del. Nov. 25, 2014), D.I. 42 (D. Del. Dec. 2, 2015) (consenting to suit regarding ANDA No. 206986 and Zohydro® ER).

9. This Court also has personal jurisdiction over Alvogen by virtue of the fact that Alvogen is at home in Delaware as reflected by the fact that, on information and belief, it

regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, including by selling its pharmaceutical products in Delaware and, therefore, can reasonably expect to be subject to jurisdiction in the Delaware courts. Among other things, on information and belief, Alvogen conducts marketing and sales activities in the State of Delaware, including, but not limited to, distribution, marketing, and sales of pharmaceutical products to Delaware residents that are continuous and systematic.

10. On information and belief, this Court also has personal jurisdiction over Alvogen under Federal Rule of Civil Procedure 4(k)(2).

11. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

FACTUAL BACKGROUND

12. Pernix Ireland is the holder of an approved New Drug Application ("NDA") No. 202880 for Zohydro® ER extended-release capsules. The United States Food and Drug Administration ("FDA") approved NDA No. 202880 on October 25, 2013. Zohydro® ER capsules contain hydrocodone bitartrate and are indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

13. U.S. Patent Nos. 6,228,398 ("the '398 patent"), 6,902,742 ("the '742 patent"), and 9,132,096 ("the '096 patent") are also listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") for Zohydro® ER capsules.

14. On information and belief, Alvogen submitted ANDA No. 206986 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval

to engage in the commercial manufacture, use, and sale of hydrocodone bitartrate extended-release capsules in 10, 15, 20, 30, 40, and 50 mg strengths ("Alvogen Generic Product"), as generic versions of the Zohydro® ER 10, 15, 20, 30, 40, and 50 mg capsules.

15. By letters dated September 26, 2014 and December 15, 2015 ("the Alvogen-Recro Notice Letters"), Alvogen advised Recro Tech., LLC ("Recro"), the owner of the '398, '742, and '096 patents, and Pernix Ireland that it had submitted ANDA No. 206986 to the FDA seeking approval to manufacture, use, or sell the Alvogen Generic Product prior to the expiration of the '398, '742, and '096 patents.

16. The Alvogen-Recro Notice Letters also advised Recro and Pernix Ireland that Alvogen's ANDA submission included a certification under 21 U.S.C. § 355(j)(2)(B)(iv) that, in Alvogen's opinion, the claims of the '398, '742, and '096 patents are invalid, unenforceable and/or not infringed.

17. Recro and its predecessors previously filed an action in this Court asserting that Alvogen's submission of ANDA No. 206986 to the FDA seeking approval to manufacture, use, or sell the Alvogen Generic Product constitutes infringement of the '398 and '742 patents. This action was filed on November 3, 2014 (C.A. No. 14-cv-1364-GMS), and this Court ordered a stipulation of dismissal on September 30, 2016.

18. The 30-month stay of FDA approval on the Alvogen Generic Product pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) is set to expire on March 29, 2017.

19. The '760, '982, '201, '499, '200, and '619 patents had not issued at the time Alvogen submitted its certifications under 21 U.S.C. § 355(j)(2)(B) with respect to the '398, '742, and '096 patents.

20. On February 23, 2016, the '760 patent, entitled "Treating Pain in Patients with

Hepatic Impairment," was duly and legally issued to Pernix Ireland. The '760 patent is listed in the Orange Book for Zohydro® ER capsules. Pernix Therapeutics is the exclusive licensee of the '760 patent and is the sole distributor of Zohydro® ER capsules in the United States.

21. On February 23, 2016, Plaintiffs notified Alvogen of the existence of the '760 patent. Alvogen did not respond to Plaintiffs' notification. Plaintiffs commenced this action on March 4, 2016. At the time Plaintiffs commenced this action, the '982, '201, '499, '200, and '619 patents had not issued.

22. On May 3, 2016, the '982 patent, entitled "Treating Pain in Patients with Hepatic Impairment," was duly and legally issued to Pernix Ireland. The '982 patent is listed in the Orange Book for Zohydro® ER capsules. Pernix Therapeutics is the exclusive licensee of the '982 patent.

23. On May 10, 2016, the '201 patent, entitled "Treating Pain in Patients with Hepatic Impairment," was duly and legally issued to Pernix Ireland. The '201 patent is listed in the Orange Book for Zohydro® ER capsules. Pernix Therapeutics is the exclusive licensee of the '201 patent.

24. On May 17, 2016, the '499 patent, entitled "Treating Pain in Patients with Hepatic Impairment," was duly and legally issued to Pernix Ireland. The '499 patent is listed in the Orange Book for Zohydro® ER capsules. Pernix Therapeutics is the exclusive licensee of the '499 patent.

25. By letter dated May 19, 2016 ("the May 19, 2016 Alvogen-Pernix Notice Letter"), Alvogen advised Plaintiffs that it had submitted ANDA No. 206986 to the FDA seeking approval to manufacture, use, or sell the Alvogen Generic Product prior to the expiration of the '760 and '982 patents.

26. The May 19, 2016 Alvogen-Pernix Notice Letter also advised Plaintiffs that Alvogen's ANDA submission included a certification under 21 U.S.C. § 355(j)(2)(B)(iv) that, in Alvogen's opinion, the claims of the '760 and '982 patents are invalid, unenforceable and/or not infringed.

27. The First Amended Complaint was filed before the expiration of forty-five days from the date Plaintiffs received the May 19, 2016 Alvogen-Pernix Notice Letter.

28. On August 23, 2016, the '200 patent, entitled "Treating Pain in Patients with Hepatic Impairment," was duly and legally issued to Pernix Ireland. The '200 patent is listed in the Orange Book for Zohydro® ER capsules. Pernix Therapeutics is the exclusive licensee of the '200 patent.

29. On September 6, 2016, the '619 patent, entitled "Treating Pain in Patients with Hepatic Impairment," was duly and legally issued to Pernix Ireland. The '619 patent is listed in the Orange Book for Zohydro® ER capsules. Pernix Therapeutics is the exclusive licensee of the '619 patent.

30. By letter dated September 14, 2016 ("the September 14, 2016 Alvogen-Pernix Notice Letter"), Alvogen advised Plaintiffs that it had amended ANDA No. 206986 to include a certification under 21 U.S.C. § 355(j)(2)(B)(iv) that, in Alvogen's opinion, the claims of the '201 and '499 patents are invalid, unenforceable and/or not infringed.

31. This Second Amended Complaint is being filed before the expiration of forty-five days from the date Plaintiffs received the September 14, 2016 Alvogen-Pernix Notice Letter.

32. Although as of the filing of this Second Amended Complaint, Plaintiffs have not yet received certifications under 21 U.S.C. § 355(j)(2)(B) with respect to the '200 and '619 patents, Plaintiffs anticipate that Alvogen will make noninfringement and invalidity arguments

similar to those set forth in the May 19, 2016 and September 14, 2016 Alvogen-Pernix Notice Letters with respect to these newly-listed patents.

33. On information and belief, Alvogen has made and will continue to make substantial and meaningful preparations to engage in the commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States a product that will be administered to patients using the methods of treatment patented by the '760, '982, '201, '499, '200, and '619 patents prior to their expiration.

34. On information and belief, Alvogen's preparations include, but are not limited to, the development of the Alvogen Generic Product and the filing of ANDA No. 206986. These preparations indicate a refusal to change its course of action in the face of acts by Plaintiffs.

35. On information and belief, Alvogen continues to seek approval of ANDA No. 206986, and upon approval by the FDA, Alvogen intends to immediately engage in the commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States the Alvogen Generic Product that will be administered to patients using the methods of treatment patented by the '760, '982, '201, '499, '200, and '619 patents prior to their expiration.

36. On information and belief, the methods of treatment patented by the '760, '982, '201, '499, '200, and '619 patents are an essential component of administering the Alvogen Generic Product to patients.

37. On information and belief, Alvogen will direct or control the treatment of patients using the Alvogen Generic Product with methods claimed in the '760, '982, '201, '499, '200, and '619 patents, after the FDA approves ANDA No. 206986. On information and belief, this will occur at Alvogen's active behest and with its intent, knowledge and encouragement. On information and belief, Alvogen will actively encourage, aid and abet this treatment with

knowledge that it is in contravention of Plaintiffs' rights under the '760, '982, '201, '499, '200, and '619 patents.

38. On information and belief, Alvogen will knowingly provide the Alvogen Generic Product with instructions for use that substantially copy the instructions for Zohydro® ER capsules, including instructions for treating patients using methods claimed in the '760, '982, '201, '499, '200, and '619 patents.

39. On information and belief, Alvogen knows the instructions that will accompany the Alvogen Generic Product will induce and/or contribute to others using the Alvogen Generic Product in the manner set forth in the instructions.

40. On information and belief, physicians, health care providers, and/or patients will directly infringe one or more claims of the '760, '982, '201, '499, '200, and '619 patents by using the Alvogen Generic Product in accordance with the instructions provided by Alvogen, after the FDA approves ANDA No. 206986.

41. On information and belief, Alvogen specifically intends that physicians, health care providers, and/or patients will use the Alvogen Generic Product in accordance with the instructions provided by Alvogen to directly infringe one or more claims of the '760, '982, '201, '499, '200, and '619 patents. Alvogen therefore will actively induce and/or contribute to infringement of the '760, '982, '201, '499, '200, and '619 patents.

42. On information and belief, Alvogen knowingly has taken and intends to take active steps to induce and/or contribute to physicians, health care providers, and/or patients using the Alvogen Generic Product in a manner that directly infringes at least one claim of the '760, '982, '201, '499, '200, and '619 patents.

43. On information and belief, Alvogen designed the Alvogen Generic Product for

use in a way that would infringe the '760, '982, '201, '499, '200, and '619 patents and will instruct users of the Alvogen Generic Product to use the Alvogen Generic Product in a way that would infringe the '760, '982, '201, '499, '200, and '619 patents.

COUNT I

Infringement of the '760 Patent Under 35 U.S.C. § 271(e)(2)

44. Plaintiffs incorporate each of the preceding paragraphs 1 to 43 as if fully set forth herein.

45. Alvogen submitted ANDA No. 206986 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use or have used, offer for sale, sale, and/or importation of the Alvogen Generic Product throughout the United States, including Delaware, prior to patent expiry. By submitting and maintaining the application, Alvogen committed an act of infringement with respect to one or more claims of the '760 patent, under 35 U.S.C. § 271(e)(2)(A).

46. By submitting ANDA No. 206986, Alvogen has necessarily represented to the FDA that, upon approval, the Alvogen Generic Product will have the same active ingredient, method of administration, dosage form, and strength as Zohydro® ER, and will be bioequivalent to Zohydro® ER.

47. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry will constitute direct infringement, contributory infringement and/or active inducement of infringement of the '760 patent.

48. The use of the Alvogen Generic Product by physicians, health care providers, and/or patients prior to patent expiry will directly infringe one or more claims of the '760 patent.

49. Alvogen will direct, control, encourage, aid and/or abet the direct infringement

of one or more claims of the ’760 patent by and through the commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry.

50. On information and belief, Alvogen knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry will actively induce direct infringement of one or more claims of the ’760 patent.

51. Alvogen’s acts described in paragraphs 49-50 will be performed with knowledge of the ’760 patent and with intent to encourage infringement prior to patent expiry.

52. On information and belief, Alvogen knows or should know the Alvogen Generic Product will be especially made or especially adapted for use in an infringement of the ’760 patent, and it is not a staple article or commodity of commerce suitable for substantial non-infringing use.

53. On information and belief, Alvogen knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry will contribute to the direct infringement of one or more claims of the ’760 patent.

54. Alvogen’s acts described in paragraphs 52-53 will be performed with knowledge of the ’760 patent and with intent to encourage infringement prior to patent expiry.

COUNT II

Infringement of the ’982 Patent Under 35 U.S.C. § 271(e)(2)

55. Plaintiffs incorporate each of the preceding paragraphs 1 to 43 as if fully set forth herein.

56. Alvogen submitted ANDA No. 206986 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use or have used, offer for sale, sale, and/or importation of the Alvogen Generic Product throughout the United States,

including Delaware, prior to patent expiry. By submitting and maintaining the application, Alvogen committed an act of infringement with respect to one or more claims of the '982 patent, under 35 U.S.C. § 271(e)(2)(A).

57. By submitting ANDA No. 206986, Alvogen has necessarily represented to the FDA that, upon approval, the Alvogen Generic Product will have the same active ingredient, method of administration, dosage form, and strength as Zohydro® ER, and will be bioequivalent to Zohydro® ER.

58. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry will constitute direct infringement, contributory infringement and/or active inducement of infringement of the '982 patent.

59. The use of the Alvogen Generic Product by physicians, health care providers, and/or patients prior to patent expiry will directly infringe one or more claims of the '982 patent.

60. Alvogen will direct, control, encourage, aid and/or abet the direct infringement of one or more claims of the '982 patent by and through the commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry.

61. On information and belief, Alvogen knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry will actively induce direct infringement of one or more claims of the '982 patent.

62. Alvogen's acts described in paragraphs 60-61 will be performed with knowledge of the '982 patent and with intent to encourage infringement prior to patent expiry.

63. On information and belief, Alvogen knows or should know the Alvogen Generic Product will be especially made or especially adapted for use in an infringement of the '982 patent, and it is not a staple article or commodity of commerce suitable for substantial non-

infringing use.

64. On information and belief, Alvogen knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry will contribute to the direct infringement of one or more claims of the '982 patent.

65. Alvogen's acts described in paragraphs 63-64 will be performed with knowledge of the '982 patent and with intent to encourage infringement prior to patent expiry.

COUNT III

Infringement of the '201 Patent Under 35 U.S.C. § 271(e)(2)

66. Plaintiffs incorporate each of the preceding paragraphs 1 to 43 as if fully set forth herein.

67. Alvogen submitted ANDA No. 206986 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use or have used, offer for sale, sale, and/or importation of the Alvogen Generic Product throughout the United States, including Delaware, prior to patent expiry. By submitting and maintaining the application, Alvogen committed an act of infringement with respect to one or more claims of the '201 patent, under 35 U.S.C. § 271(e)(2)(A).

68. By submitting ANDA No. 206986, Alvogen has necessarily represented to the FDA that, upon approval, the Alvogen Generic Product will have the same active ingredient, method of administration, dosage form, and strength as Zohydro® ER, and will be bioequivalent to Zohydro® ER.

69. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry will constitute direct infringement, contributory infringement and/or active inducement of infringement of the '201 patent.

70. The use of the Alvogen Generic Product by physicians, health care providers, and/or patients prior to patent expiry will directly infringe one or more claims of the '201 patent.

71. Alvogen will direct, control, encourage, aid and/or abet the direct infringement of one or more claims of the '201 patent by and through the commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry.

72. On information and belief, Alvogen knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry will actively induce direct infringement of one or more claims of the '201 patent.

73. Alvogen's acts described in paragraphs 71-72 will be performed with knowledge of the '201 patent and with intent to encourage infringement prior to patent expiry.

74. On information and belief, Alvogen knows or should know the Alvogen Generic Product will be especially made or especially adapted for use in an infringement of the '201 patent, and it is not a staple article or commodity of commerce suitable for substantial non-infringing use.

75. On information and belief, Alvogen knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry will contribute to the direct infringement of one or more claims of the '201 patent.

76. Alvogen's acts described in paragraphs 74-75 will be performed with knowledge of the '201 patent and with intent to encourage infringement prior to patent expiry.

COUNT IV

Infringement of the '499 Patent Under 35 U.S.C. § 271(e)(2)

77. Plaintiffs incorporate each of the preceding paragraphs 1 to 43 as if fully set forth herein.

78. Alvogen submitted ANDA No. 206986 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use or have used, offer for sale, sale, and/or importation of the Alvogen Generic Product throughout the United States, including Delaware, prior to patent expiry. By submitting and maintaining the application, Alvogen committed an act of infringement with respect to one or more claims of the '499 patent, under 35 U.S.C. § 271(e)(2)(A).

79. By submitting ANDA No. 206986, Alvogen has necessarily represented to the FDA that, upon approval, the Alvogen Generic Product will have the same active ingredient, method of administration, dosage form, and strength as Zohydro® ER, and will be bioequivalent to Zohydro® ER.

80. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry will constitute direct infringement, contributory infringement and/or active inducement of infringement of the '499 patent.

81. The use of the Alvogen Generic Product by physicians, health care providers, and/or patients prior to patent expiry will directly infringe one or more claims of the '499 patent.

82. Alvogen will direct, control, encourage, aid and/or abet the direct infringement of one or more claims of the '499 patent by and through the commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry.

83. On information and belief, Alvogen knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry will actively induce direct infringement of one or more claims of the '499 patent.

84. Alvogen's acts described in paragraphs 82-83 will be performed with knowledge of the '499 patent and with intent to encourage infringement prior to patent expiry.

85. On information and belief, Alvogen knows or should know the Alvogen Generic Product will be especially made or especially adapted for use in an infringement of the '499 patent, and it is not a staple article or commodity of commerce suitable for substantial non-infringing use.

86. On information and belief, Alvogen knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry will contribute to the direct infringement of one or more claims of the '499 patent.

87. Alvogen's acts described in paragraphs 85-86 will be performed with knowledge of the '499 patent and with intent to encourage infringement prior to patent expiry.

COUNT V

Infringement of the '200 Patent Under 35 U.S.C. § 271(e)(2)

88. Plaintiffs incorporate each of the preceding paragraphs 1 to 43 as if fully set forth herein.

89. Alvogen submitted ANDA No. 206986 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use or have used, offer for sale, sale, and/or importation of the Alvogen Generic Product throughout the United States, including Delaware, prior to patent expiry. By submitting and maintaining the application, Alvogen committed an act of infringement with respect to one or more claims of the '200 patent, under 35 U.S.C. § 271(e)(2)(A).

90. By submitting ANDA No. 206986, Alvogen has necessarily represented to the FDA that, upon approval, the Alvogen Generic Product will have the same active ingredient, method of administration, dosage form, and strength as Zohydro® ER, and will be bioequivalent to Zohydro® ER.

91. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry will constitute direct infringement, contributory infringement and/or active inducement of infringement of the '200 patent.

92. The use of the Alvogen Generic Product by physicians, health care providers, and/or patients prior to patent expiry will directly infringe one or more claims of the '200 patent.

93. Alvogen will direct, control, encourage, aid and/or abet the direct infringement of one or more claims of the '200 patent by and through the commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry.

94. On information and belief, Alvogen knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry will actively induce direct infringement of one or more claims of the '200 patent.

95. Alvogen's acts described in paragraphs 93-94 will be performed with knowledge of the '200 patent and with intent to encourage infringement prior to patent expiry.

96. On information and belief, Alvogen knows or should know the Alvogen Generic Product will be especially made or especially adapted for use in an infringement of the '200 patent, and it is not a staple article or commodity of commerce suitable for substantial non-infringing use.

97. On information and belief, Alvogen knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry will contribute to the direct infringement of one or more claims of the '200 patent.

98. Alvogen's acts described in paragraphs 96-97 will be performed with knowledge of the '200 patent and with intent to encourage infringement prior to patent expiry.

COUNT VI

Infringement of the '619 Patent Under 35 U.S.C. § 271(e)(2)

99. Plaintiffs incorporate each of the preceding paragraphs 1 to 43 as if fully set forth herein.

100. Alvogen submitted ANDA No. 206986 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use or have used, offer for sale, sale, and/or importation of the Alvogen Generic Product throughout the United States, including Delaware, prior to patent expiry. By submitting and maintaining the application, Alvogen committed an act of infringement with respect to one or more claims of the '619 patent, under 35 U.S.C. § 271(e)(2)(A).

101. By submitting ANDA No. 206986, Alvogen has necessarily represented to the FDA that, upon approval, the Alvogen Generic Product will have the same active ingredient, method of administration, dosage form, and strength as Zohydro® ER, and will be bioequivalent to Zohydro® ER.

102. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry will constitute direct infringement, contributory infringement and/or active inducement of infringement of the '619 patent.

103. The use of the Alvogen Generic Product by physicians, health care providers, and/or patients prior to patent expiry will directly infringe one or more claims of the '619 patent.

104. Alvogen will direct, control, encourage, aid and/or abet the direct infringement of one or more claims of the '619 patent by and through the commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry.

105. On information and belief, Alvogen knows or should know that its commercial

manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry will actively induce direct infringement of one or more claims of the '619 patent.

106. Alvogen's acts described in paragraphs 104-105 will be performed with knowledge of the '619 patent and with intent to encourage infringement prior to patent expiry.

107. On information and belief, Alvogen knows or should know the Alvogen Generic Product will be especially made or especially adapted for use in an infringement of the '619 patent, and it is not a staple article or commodity of commerce suitable for substantial non-infringing use.

108. On information and belief, Alvogen knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to patent expiry will contribute to the direct infringement of one or more claims of the '619 patent.

109. Alvogen's acts described in paragraphs 107-108 will be performed with knowledge of the '619 patent and with intent to encourage infringement prior to patent expiry.

* * *

110. Alvogen was aware of the existence of the '760, '982, '201, '499, '200, and '619 patents prior to the filing date of this Second Amended Complaint. This is an exceptional case.

111. Alvogen's commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product prior to the expiration of the '760, '982, '201, '499, '200, and '619 patents in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

112. Unless Alvogen is enjoined from infringing, contributing to the infringement, and/or actively inducing the infringement of the '760, '982, '201, '499, '200, and '619 patents,

sales of the Alvogen Generic Product prior to the expiration of the '760, '982, '201, '499, '200, and '619 patents will cause Plaintiffs irreparable injury for which damages are an inadequate remedy.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. that judgment be entered that Alvogen has infringed the '760, '982, '201, '499, '200, and '619 patents;

B. that an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 206986 shall be a date that is not earlier than the expiration dates of the '760, '982, '201, '499, '200, and '619 patents, inclusive of any extensions;

C. that, prior to March 29, 2017 (the expiration of the 30-month stay referenced in paragraph 18), a preliminary injunction be issued enjoining Alvogen, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product within or into the United States until the resolution of the claims associated with this lawsuit, including any appeals;

D. that an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Alvogen, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of the Alvogen Generic Product within or into the United States prior to the expiration dates of the '760, '982, '201, '499, '200, and '619 patents, inclusive of any extensions;

E. that damages or other monetary relief be awarded to Plaintiffs under 35 U.S.C. §

271(e)(4)(C) as appropriate with respect to the '760, '982, '201, '499, '200, and '619 patents;

F. that judgment be entered that this is an exceptional case and an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

G. costs and expenses in this action; and

H. such other and further relief as the Court may deem just and proper.

Dated: October 12, 2016

MCCARTER & ENGLISH LLP

/s/ Daniel M. Silver

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