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and Arius Two, Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BIODELIVERY SCIENCES INTERNATIONAL, INC. and ARIUS TWO, INC., Plaintiffs, v. CHEMO RESEARCH, S.L.; INSUD PHARMA S.L.; INTELGENX CORP.; and INTELGENX TECHNOLOGIES CORP., Defendants.	Civil Action No. 19-8660 *Document Electronically Filed*

COMPLAINT FOR PATENT INFRINGEMENT

1. Plaintiffs BioDelivery Sciences International, Incorporated and Arius Two, Incorporated (collectively, "Plaintiffs"), file this Complaint for patent infringement against Defendants Chemo Research, S.L., Insud Pharma S.L., IntelGenx Corp., and IntelGenx Technologies Corp. (collectively, "Defendants"), under 35 U.S.C. §§ 271(e)(2), (a), (b) and (c). This patent action concerns the pharmaceutical drug product Belbuca® (buprenorphine buccal film), CIII. Plaintiffs hereby state as follows:

JURISDICTION AND PARTIES

2. Plaintiff BioDelivery Sciences International, Inc. ("BDSI") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 4131 ParkLake Ave., Suite 225, Raleigh, North Carolina, 27612. Plaintiff BDSI is a specialty pharmaceutical company engaged in the research, development, sale, and marketing of prescription pharmaceuticals with a focus in the areas of pain management and addiction medicine. Plaintiff BDSI is also the holder of New Drug Application ("NDA") No. 207932 for Belbuca®, and is the distributer of Belbuca® in the United States.

3. Plaintiff Arius Two, Incorporated ("Arius") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 4131 ParkLake Ave., Suite 225, Raleigh, North Carolina, 27612. Plaintiff Arius is a wholly owned subsidiary of Plaintiff BDSI.

4. On information and belief, Defendant Chemo Research, S.L. ("Chemo Research") is a corporation organized and existing under the laws of Spain, having a principal place of business at Manuel Pombo Angulo, 28 4a Planta (Fourth Floor), Madrid 28050 Spain. On information and belief, Defendant Chemo Research is a wholly owned subsidiary of Defendant Insud Pharma S.L.

5. On information and belief, Defendant Chemo Research is a pharmaceutical company that formulates, manufactures, packages, and markets generic drug products for distribution in the District of New Jersey and throughout the United States.

6. On information and belief, Defendant Chemo Research maintains an office in New Jersey at 180 Park Ave., Suite 101, Florham Park, New Jersey, 07932. On information and belief, Defendant Chemo Research regularly does or solicits business in New Jersey, engages in other persistent courses of conduct in New Jersey, and/or derives substantial revenue from services or

things used or consumed in New Jersey, demonstrating that Defendant Chemo Research has continuous and systematic contacts with New Jersey.

7. In addition, in the Notice Letter, dated January 31, 2019, Defendant Chemo Research did not identify a U.S. agent as required under 21 C.F.R. § 314.95(c)(9).

8. This Court has personal jurisdiction over Defendant Chemo Research by virtue of, among other things, the facts alleged in paragraphs 5-7 of this Complaint.

9. In the alternative, this Court has personal jurisdiction over Defendant Chemo Research because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (1) Plaintiffs' claims arise under federal law; (2) Defendant Chemo Research is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (3) Defendant Chemo Research has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting Abbreviated New Drug Applications ("ANDAs") to the U.S. Food and Drug Administration ("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 Defendant Chemo Research satisfies due process.

10. On information and belief, Defendant Insud Pharma S.L. ("Insud") is a corporation organized and existing under the laws of Spain with a principal place of business at Manuel Pombo Angulo, 28 3rd Floor, Madrid 28050 Spain.

11. On information and belief, Defendant Insud regularly does or solicits business in the District of New Jersey, engages in other persistent courses of conduct in the District of New Jersey, and/or derives substantial revenue from services or things used or consumed in the District of New Jersey, demonstrating that Defendant Insud has continuous and systematic contacts with the District of New Jersey.

12. On information and belief, Defendant Insud purposefully has conducted and continues to conduct business in this judicial district by directly, or indirectly through its wholly owned subsidiaries, manufacturing, marketing, and selling generic drug products, including generic drug products manufactured by Defendant Insud throughout the United States and in this judicial district.

13. On information and belief, the acts of Defendant Chemo Research complained of herein were done at the direction of, with the authorization of, or with the cooperation, participation or assistance of, or at least in part for the benefit of Defendant Insud.

14. This Court has personal jurisdiction over Defendant Insud by virtue of, among other things, the facts alleged in paragraphs 11-13 of this Complaint.

15. In the alternative, this Court has personal jurisdiction over Defendant Insud because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (1) Plaintiffs' claims arise under federal law; (2) Defendant Insud is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (3) Defendant Insud 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 Defendant Insud satisfies due process.

16. On information and belief, Defendant IntelGenx Corp. ("IntelGenx Corp.") is a corporation organized and existing under the laws of Canada, having a principal place of business at 6420 Rue Abrams, Ville Saint-Laurent, Quebec H4S 1Y2, Canada. On information and belief, Defendant IntelGenx Corp. is a wholly owned subsidiary of Defendant IntelGenx Technologies Corp.

17. On information and belief, Defendant IntelGenx Corp. is a pharmaceutical company that formulates, manufactures, packages, and markets generic drug products for distribution in the District of New Jersey and throughout the United States.

18. On information and belief, Defendant IntelGenx Corp. regularly does or solicits business in New Jersey, engages in other persistent courses of conduct in New Jersey, and/or derives substantial revenue from services or things used or consumed in New Jersey, demonstrating that Defendant IntelGenx Corp. has continuous and systematic contacts with New Jersey.

19. On information and belief, Defendant IntelGenx Corp. is amenable to litigating in this forum based on its conduct in other litigations in this District. For example, Defendant IntelGenx Corp. has filed suit and sought relief in other civil actions initiated in this jurisdiction, including but not limited to: *IntelGenx Corp. v. Wockhardt Bio, AG et al.*, C.A. No. 1:13-cv-05074-JBS-JS (D.N.J. 2013). Defendant IntelGenx Corp. has thus purposefully availed itself of this forum.

20. This Court has personal jurisdiction over Defendant IntelGenx Corp. by virtue of, among other things, the facts alleged in paragraphs 17-19 of this Complaint.

21. In the alternative, this Court has personal jurisdiction over Defendant IntelGenx Corp. because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (1) Plaintiffs' claims arise under federal law; (2) Defendant IntelGenx Corp. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (3) Defendant IntelGenx Corp. 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 Defendant IntelGenx Corp. satisfies due process.

22. On information and belief, Defendant IntelGenx Technologies Corp. ("IntelGenx Tech.") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 6420 Rue Abrams, Ville Saint-Laurent, Quebec H4S 1Y2, Canada.

23. On information and belief, Defendant IntelGenx Tech. is a pharmaceutical company that formulates, manufactures, packages, and markets generic drug products for distribution in the District of New Jersey and throughout the United States.

24. On information and belief, Defendant IntelGenx Tech. regularly does or solicits business in New Jersey, engages in other persistent courses of conduct in New Jersey, and/or derives substantial revenue from services or things used or consumed in New Jersey, demonstrating that Defendant IntelGenx Tech. has continuous and systematic contacts with New Jersey.

25. This Court has personal jurisdiction over Defendant IntelGenx Tech. by virtue of, among other things, the facts alleged in paragraphs 23-24 of this Complaint.

26. On information and belief, the acts of Defendant IntelGenx Corp. complained of herein were done at the direction of, with the authorization of, or with the cooperation, participation or assistance of, or at least in part for the benefit of Defendant IntelGenx Tech.

27. On information and belief, the acts of Defendant IntelGenx Corp. and Defendant IntelGenx Tech. complained of herein were done at the direction of, with the authorization of, or with the cooperation, participation or assistance of, or at least in part for the benefit of, Defendant Insud and/or Defendant Chemo Research.

28. On information and belief, and consistent with their practice with respect to other generic products, following FDA approval of ANDA No. 212036, Defendants will market, distribute, sell, and derive revenue from Defendants' generic buprenorphine buccal film product described in ANDA No. 212036 throughout the United States, including in New Jersey.

29. This patent infringement action arises under the United States Patent Laws, Title 35 U.S.C. § 100 *et seq*. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

COUNT I FOR PATENT INFRINGEMENT
(Infringement of U.S. Patent No. 8,147,866 ("the '866 patent") under 35 U.S.C. § 271(e)(2))

30. Plaintiffs reallege and incorporate by reference paragraphs 1-29.

31. The '866 patent, titled "Transmucosal Delivery Devices with Enhanced Uptake," was duly and legally issued to inventors Andrew Finn and Niraj Vasisht by the United States Patent and Trademark Office ("PTO") on April 3, 2012. The '866 patent is currently assigned to Plaintiff BDSI and expires on July 23, 2027. A true and correct copy of the '866 patent is attached as Exhibit A.

32. NDA No. 207932 is directed to the use of Belbuca® in the treatment of pain by transmucosal delivery of buprenorphine. The FDA approved NDA No. 207932 on October 23, 2015. The '866 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 207932.

33. On information and belief, Defendants filed, or caused to be filed, ANDA No. 212036 with the FDA under 21 U.S.C. § 355(j), seeking to obtain approval for the commercial manufacture, use, and sale of Buprenorphine Buccal Film, 75 mcg, 150 mcg, 300 mcg, 450 mcg, and 900 mcg in the United States before the expiration of the '866 patent.

34. On information and belief, ANDA No. 212036 contains a Paragraph IV certification alleging that the claims of the ’866 patent are invalid and/or not infringed.

35. Defendants sent, or caused to be sent, to Plaintiffs a letter dated January 31, 2019 (“the Notice Letter”) notifying Plaintiffs that Defendants had submitted ANDA No. 212036 and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). The Notice Letter alleges invalidity and noninfringement of claims 1-12 of the ’866 patent.

36. Under 35 U.S.C. § 271(e)(2)(A), Defendants infringed one or more claims of the ’866 patent, in violation of Plaintiffs’ patent rights, by submitting to the FDA ANDA No. 212036 that seeks approval to commercially market—before the expiration date of the ’866 patent—Defendants’ generic buprenorphine buccal film, the manufacture, use, offer for sale, or sale within the United States of which would directly infringe, literally or through the doctrine of equivalents, one or more claims of the ’866 patent, and the manufacture, use, offer for sale, or sale of which would contribute to or induce the direct infringement of one or more claims of the ’866 patent by prescribers and/or users of Defendants’ generic buprenorphine buccal film.

37. On information and belief, Defendants have knowledge of the ’866 patent and have filed ANDA No. 212036 seeking authorization to commercially manufacture, use, offer for sale, and sell Defendants’ generic buprenorphine buccal film in the United States. On information and belief, if the FDA approves ANDA No. 212036, physicians, health care providers, and/or patients will prescribe and/or use Defendants’ generic buprenorphine buccal film in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the ’866 patent.

38. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will prescribe and/or use Defendants’ generic buprenorphine buccal film

in accordance with the instructions and/or label provided by Defendants and will therefore induce infringement of one or more of the claims of the ’866 patent with the requisite intent.

39. On information and belief, if the FDA approves ANDA No. 212036, Defendants will sell or offer to sell their generic buprenorphine buccal film specifically labeled for use in practicing one or more of the method claims of the ’866 patent, wherein Defendants’ generic buprenorphine buccal film is a material part of the method claimed, wherein Defendants know that physicians will prescribe and patients will use Defendants’ generic buprenorphine buccal film in practicing one or more of the methods claimed in the ’866 patent, and wherein buprenorphine buccal film is not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of the ’866 patent.

40. Plaintiffs will be substantially and irreparably harmed by Defendants’ infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

41. Plaintiffs have filed this complaint within 45 days of receiving the Notice Letter.

42. Defendants’ statements of the factual and legal bases for their opinion regarding the infringement and validity of the ’866 patent contained in the Notice Letter are devoid of any objective good-faith basis in either the facts or the law.

43. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the ’866 patent, actively inducing infringement of the ’866 patent, and/or contributing to the infringement by others of the ’866 patent. This case is therefore “exceptional,” as that term is used in 35 U.S.C. § 285.

COUNT II FOR PATENT INFRINGEMENT
(Infringement of U.S. Patent No. 9,655,843 (“the ’843 patent”) under 35 U.S.C. § 271(e)(2))

44. Plaintiffs reallege and incorporate by reference paragraphs 1-29.

45. The ’843 patent, titled “Transmucosal Delivery Devices with Enhanced Uptake,” was duly and legally issued to inventors Andrew Finn and Niraj Vasisht by the PTO on May 23, 2017. The ’843 patent is currently assigned to Plaintiff BDSI and expires on July 23, 2027. A true and correct copy of the ’843 patent is attached as Exhibit B.

46. NDA No. 207932 is directed to the use of Belbuca® in the treatment of pain by transmucosal delivery of buprenorphine. The FDA approved NDA No. 207932 on October 23, 2015. The ’843 patent is listed in the Orange Book for NDA No. 207932.

47. On information and belief, Defendants filed, or caused to be filed, ANDA No. 212036 with the FDA under 21 U.S.C. § 355(j), seeking to obtain approval for the commercial manufacture, use, and sale of Buprenorphine Buccal Film, 75 mcg, 150 mcg, 300 mcg, 450 mcg, and 900 mcg in the United States before the expiration of the ’843 patent.

48. On information and belief, ANDA No. 212036 contains a Paragraph IV certification alleging that the claims of the ’843 patent are invalid and/or not infringed.

49. Defendants sent, or caused to be sent, to Plaintiffs the Notice Letter, dated January 31, 2019, notifying Plaintiffs that Defendants had submitted ANDA No. 212036 and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). The Notice Letter alleges invalidity and noninfringement of claims 1-25 of the ’843 patent.

50. Under 35 U.S.C. § 271(e)(2)(A), Defendants infringed one or more claims of the ’843 patent, in violation of Plaintiffs’ patent rights, by submitting to the FDA ANDA No. 212036 that seeks approval to commercially market—before the expiration date of the ’843 patent—Defendants’ generic buprenorphine buccal film, the manufacture, use, offer for sale, or sale within the United States of which would directly infringe, literally or through the doctrine of equivalents, one or more claims of the ’843 patent, and the manufacture, use, offer for sale, or sale of which

would contribute to or induce the direct infringement of one or more claims of the ’843 patent by prescribers and/or users of Defendants’ generic buprenorphine buccal film.

51. On information and belief, Defendants have knowledge of the ’843 patent and have filed ANDA No. 212036 seeking authorization to commercially manufacture, use, offer for sale, and sell Defendants’ generic buprenorphine buccal film in the United States. On information and belief, if the FDA approves ANDA No. 212036, physicians, health care providers, and/or patients will prescribe and/or use Defendants’ generic buprenorphine buccal film in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the ’843 patent.

52. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will prescribe and/or use Defendants’ generic buprenorphine buccal film in accordance with the instructions and/or label provided by Defendants and will therefore induce infringement of one or more of the claims of the ’843 patent with the requisite intent.

53. On information and belief, if the FDA approves ANDA No. 212036, Defendants will sell or offer to sell their generic buprenorphine buccal film specifically labeled for use in practicing one or more of the method claims of the ’843 patent, wherein Defendants’ generic buprenorphine buccal film is a material part of the method claimed, wherein Defendants know that physicians will prescribe and patients will use Defendants’ generic buprenorphine buccal film in practicing one or more of the methods claimed in the ’843 patent, and wherein buprenorphine buccal film is not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of the ’843 patent.

54. Plaintiffs will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

55. Plaintiffs have filed this complaint within 45 days of receiving the Notice Letter.

56. Defendants' statements of the factual and legal bases for their opinion regarding the infringement and validity of the '843 patent contained in the Notice Letter are devoid of any objective good-faith basis in either the facts or the law.

57. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '843 patent, actively inducing infringement of the '843 patent, and/or contributing to the infringement by others of the '843 patent. This case is therefore "exceptional," as that term is used in 35 U.S.C. § 285.

COUNT III FOR PATENT INFRINGEMENT
(Infringement of U.S. Patent 9,901,539 ("the '539 patent")
under 35 U.S.C. § 271(e)(2))

58. Plaintiffs reallege and incorporate by reference paragraphs 1-29.

59. The '539 patent, titled "Transmucosal Delivery Devices for Use in Chronic Pain Relief," was duly and legally issued to inventors Andrew Finn and Niraj Vasisht by the PTO on February 27, 2018. The '539 patent is currently assigned to Plaintiff BDSI and expires on December 21, 2032. A true and correct copy of the '539 patent is attached as Exhibit C.

60. NDA No. 207932 is directed to the use of Belbuca® in the treatment of pain by transmucosal delivery of buprenorphine. The FDA approved NDA No. 207932 on October 23, 2015. The '539 patent is listed in the Orange Book for NDA No. 207932.

61. On information and belief, Defendants filed, or caused to be filed, ANDA No. 212036 with the FDA under 21 U.S.C. § 355(j), seeking to obtain approval for the commercial

manufacture, use, and sale of Buprenorphine Buccal Film, 75 mcg, 150 mcg, 300 mcg, 450 mcg, and 900 mcg in the United States before the expiration of the ’539 patent.

62. On information and belief, ANDA No. 212036 contains a Paragraph IV certification alleging that the claims of the ’539 patent are invalid and/or not infringed.

63. Defendants sent, or caused to be sent, to Plaintiffs the Notice Letter, dated January 31, 2019, notifying Plaintiffs that Defendants had submitted ANDA No. 212036 and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). The Notice Letter alleges invalidity and noninfringement of claims 1-22 of the ’539 patent.

64. Under 35 U.S.C. § 271(e)(2)(A), Defendants infringed one or more claims of the ’539 patent, in violation of Plaintiffs’ patent rights, by submitting to the FDA ANDA No. 212036 that seeks approval to commercially market—before the expiration date of the ’539 patent—Defendants’ generic buprenorphine buccal film, the use of which would directly infringe, literally or through the doctrine of equivalents, one or more claims of the ’539 patent, and the manufacture, use, offer for sale, or sale of which would contribute to or induce the direct infringement of one or more claims of the ’539 patent by prescribers and/or users of Defendants’ generic buprenorphine buccal film.

65. On information and belief, Defendants have knowledge of the ’539 patent and have filed ANDA No. 212036 seeking authorization to commercially manufacture, use, offer for sale, and sell Defendants’ generic buprenorphine buccal film in the United States. On information and belief, if the FDA approves ANDA No. 212036, physicians, health care providers, and/or patients will prescribe and/or use Defendants’ generic buprenorphine buccal film in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the ’539 patent.

66. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will prescribe and/or use Defendants' generic buprenorphine buccal film in accordance with the instructions and/or label provided by Defendants and will therefore induce infringement of one or more of the claims of the '539 patent with the requisite intent.

67. On information and belief, if the FDA approves ANDA No. 212036, Defendants will sell or offer to sell their generic buprenorphine buccal film specifically labeled for use in practicing one or more of the method claims of the '539 patent, wherein Defendants' generic buprenorphine buccal film is a material part of the method claimed, wherein Defendants know that physicians will prescribe and patients will use Defendants' generic buprenorphine buccal film in practicing one or more of the methods claimed in the '539 patent, and wherein buprenorphine buccal film is not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of the '539 patent.

68. Plaintiffs will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

69. Plaintiffs have filed this complaint within 45 days of receiving the Notice Letter.

70. Defendants' statements of the factual and legal bases for their opinion regarding the infringement and validity of the '539 patent contained in the Notice Letter are devoid of any objective good-faith basis in either the facts or the law.

71. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '539 patent, actively inducing infringement of the '539 patent, and/or contributing to the infringement by others of the '539 patent. This case is therefore "exceptional," as that term is used in 35 U.S.C. § 285.

COUNT IV FOR DECLARATORY JUDGMENT
(Declaratory Judgment of Patent Infringement of the '866 Patent under 35 U.S.C. §§ 271 (a), (b), and/or (c))

72. Plaintiffs reallege and incorporate by reference paragraphs 1-43.

73. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. §§ 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

74. On information and belief, and based on information provided by Defendants, if the FDA approves Defendants' generic buprenorphine buccal film for use and sale in the United States, Defendants would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '866 patent under 35 U.S.C. § 271(a), in violation of Plaintiffs' patent rights, by making, using, offering to sell, selling, and/or importing Defendants' generic buprenorphine buccal film for use and sale within the United States.

75. The manufacture, sale, offer for sale, and/or importation of Defendants' generic buprenorphine buccal film so labeled, if approved by the FDA, will induce and contribute to the infringement of one or more claims of the '866 patent under 35 U.S.C. §§ 271(b) and/or (c), in violation of Plaintiffs' patent rights.

76. On information and belief, Defendants have knowledge of the '866 patent and have filed ANDA No. 212036 seeking authorization to commercially manufacture, use, offer for sale, and sell Defendants' generic buprenorphine buccal film in the United States. On information and belief, if the FDA approves ANDA No. 212036, physicians, health care providers, and/or patients will prescribe and/or use Defendants' generic buprenorphine buccal film in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the '866 patent.

77. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will prescribe and/or use Defendants' generic buprenorphine buccal film in accordance with the instructions and/or label provided by Defendants and will therefore induce infringement of one or more of the claims of the '866 patent with the requisite intent under 35 U.S.C. § 271(b).

78. On information and belief, if the FDA approves ANDA No. 212036, Defendants will sell or offer to sell their generic buprenorphine buccal film specifically labeled for use in practicing one or more of the method claims of the '866 patent, wherein Defendants' generic buprenorphine buccal film is a material part of the method claimed in the '866 patent, wherein Defendants know that physicians will prescribe and patients will use Defendants' generic buprenorphine buccal film for one or more of the methods claimed in the '866 patent, and wherein buprenorphine buccal film is not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of the '866 patent under 35 U.S.C. § 271(c).

79. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants as to liability for the infringement of the '866 patent claims. Defendants' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

80. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '866 patent, actively inducing infringement of the '866 patent, and/or contributing to the infringement by others of the '866 patent. This case is therefore "exceptional," as that term is used in 35 U.S.C. § 285.

COUNT V FOR DECLARATORY JUDGMENT
(Declaratory Judgment of Patent Infringement of the '843 Patent under 35 U.S.C. §§ 271 (a), (b), and/or (c))

81. Plaintiffs reallege and incorporate by reference paragraphs 1-29, 44-57.

82. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. §§ 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

83. On information and belief, and based on information provided by Defendants, if the FDA approves Defendants' generic buprenorphine buccal film for use and sale in the United States, Defendants would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '843 patent under 35 U.S.C. § 271(a), in violation of Plaintiffs' patent rights, by making, using, offering to sell, selling, and/or importing Defendants' generic buprenorphine buccal film for use and sale within the United States.

84. The manufacture, sale, offer for sale, and/or importation of Defendants' generic buprenorphine buccal film so labeled, if approved by the FDA, will induce and contribute to the infringement of one or more claims of the '843 patent under 35 U.S.C. §§ 271(b) and/or (c), in violation of Plaintiffs' patent rights.

85. On information and belief, Defendants have knowledge of the '843 patent and have filed ANDA No. 212036 seeking authorization to commercially manufacture, use, offer for sale, and sell Defendants' generic buprenorphine buccal film in the United States. On information and belief, if the FDA approves ANDA No. 212036, physicians, health care providers, and/or patients will prescribe and/or use Defendants' generic buprenorphine buccal film in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the '843 patent.

86. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will prescribe and/or use Defendants' generic buprenorphine buccal film in accordance with the instructions and/or label provided by Defendants and will therefore induce infringement of one or more of the claims of the '843 patent with the requisite intent under 35 U.S.C. § 271(b).

87. On information and belief, if the FDA approves ANDA No. 212036, Defendants will sell or offer to sell their generic buprenorphine buccal film specifically labeled for use in practicing one or more of the method claims of the '843 patent, wherein Defendants' generic buprenorphine buccal film is a material part of the method claimed in the '843 patent, wherein Defendants know that physicians will prescribe and patients will use Defendants' generic buprenorphine buccal film for one or more of the methods claimed in the '843 patent, and wherein buprenorphine buccal film is not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of the '843 patent under 35 U.S.C. § 271(c).

88. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants as to liability for the infringement of the '843 patent claims. Defendants' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

89. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '843 patent, actively inducing infringement of the '843 patent, and/or contributing to the infringement by others of the '843 patent. This case is therefore "exceptional," as that term is used in 35 U.S.C. § 285.

COUNT VI FOR DECLARATORY JUDGMENT
(Declaratory Judgment of Patent Infringement of the '539 Patent under 35 U.S.C. §§ 271 (b), and/or (c))

90. Plaintiffs reallege and incorporate by reference paragraphs 1-29, 58-71.

91. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. §§ 271(b)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

92. The manufacture, sale, offer for sale, and/or importation of Defendants' generic buprenorphine buccal film so labeled, if approved by the FDA, will induce and contribute to the infringement of one or more claims of the '539 patent under 35 U.S.C. §§ 271(b) and/or (c), in violation of Plaintiffs' patent rights.

93. On information and belief, Defendants have knowledge of the '539 patent and have filed ANDA No. 212036 seeking authorization to commercially manufacture, use, offer for sale, and sell Defendants' generic buprenorphine buccal film in the United States. On information and belief, if the FDA approves ANDA No. 212036, physicians, health care providers, and/or patients will prescribe and/or use Defendants' generic buprenorphine buccal film in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the '539 patent.

94. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will prescribe and/or use Defendants' generic buprenorphine buccal film in accordance with the instructions and/or label provided by Defendants and will therefore induce infringement of one or more of the claims of the '539 patent with the requisite intent under 35 U.S.C. § 271(b).

95. On information and belief, if the FDA approves ANDA No. 212036, Defendants will sell or offer to sell their generic buprenorphine buccal film specifically labeled for use in

practicing one or more of the method claims of the ’539 patent, wherein Defendants’ generic buprenorphine buccal film is a material part of the method claimed in the ’539 patent, wherein Defendants know that physicians will prescribe and patients will use Defendants’ generic buprenorphine buccal film for one or more of the methods claimed in the ’539 patent, and wherein buprenorphine buccal film is not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of the ’539 patent under 35 U.S.C. § 271(c).

96. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants as to liability for the infringement of the ’539 patent claims. Defendants’ actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants’ threatened imminent actions.

97. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the ’539 patent, actively inducing infringement of the ’539 patent, and/or contributing to the infringement by others of the ’539 patent. This case is therefore “exceptional,” as that term is used in 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor as follows:

a) declare that United States Patent Nos. 8,147,866; 9,655,843; and 9,901,539 are valid;

b) declare that, under 35 U.S.C. § 271(e)(2)(A), Defendants infringed United States Patent Nos. 8,147,866; 9,655,843; and 9,901,539 by submitting ANDA No. 212036 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell, or import into the

United States Defendants' generic buprenorphine buccal film prior to the expiration of said patents;

c) declare that Defendants' commercial manufacture, use, sale, or offer for sale, or importation into the United States of Defendants' generic buprenorphine buccal film prior to the expiration of United States Patent Nos. 8,147,866; 9,655,843; and 9,901,539 would constitute infringement of one or more claims of said patents under 35 U.S.C. § 271 (a), (b) and/or (c);

d) order that the effective date of any FDA approval of Defendants' generic buprenorphine buccal film shall be no earlier than the expiration date of United States Patent Nos. 8,147,866; 9,655,843; and 9,901,539, including any exclusivities or extensions to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. § 271(e)(4)(A);

e) enjoin Defendants, and all persons acting in concert with Defendants, from seeking, obtaining, or maintaining final approval of ANDA No. 212036 until the expiration of United States Patent Nos. 8,147,866; 9,655,843; and 9,901,539, including any exclusivities or extensions to which Plaintiffs are or become entitled, pursuant to 35 U.S.C. § 283;

f) enjoin Defendants, and all persons acting in concert with Defendants, from commercially manufacturing, using, offering for sale, or selling Defendants' generic buprenorphine buccal film within the United States, or importing Defendants' generic buprenorphine buccal film into the United States, until the expiration of United States Patent Nos. 8,147,866; 9,655,843; and 9,901,539, including any exclusivities or extensions to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and/or 283;

g) declare this to be an exceptional case and award Plaintiffs their costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4); and

h) grant Plaintiffs such further and additional relief that this Court deems just and proper.

Dated: March 15, 2019
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

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CERTIFICATION OF NON-ARBITRABILITY PURSUANT TO LOCAL CIVIL RULE 201.1(d)

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks declaratory and injunctive relief and, therefore, is not subject to mandatory arbitration.

I certify under penalty of perjury that the foregoing is true and correct.

Dated: March 15, 2019
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.
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