IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIODELIVERY SCIENCES INTERNATIONAL, INC. and ARIUS TWO, INC.,	)	
Plaintiffs,	)	
v.	)	
	)	C.A. No. _____
CHEMO RESEARCH, S.L., INSUD PHARMA S.L.U., INTELGENX CORP., INTELGENX TECHNOLOGIES CORP., and XIROMED, LLC	)	ANDA case
Defendants.	)	

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.U, IntelGenx Corp., IntelGenx Technologies Corp., and Xiromed, LLC (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. As discussed below, this case involves the same ANDA No. 212036 and thus is a related case to *BioDelivery Sciences Int'l Inc., et al. v. Chemo Research, S.L. et al.*, C.A. No. 19-444-CFC (D. Del.). 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.U.

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 Delaware and throughout the United States.

6. This Court has personal jurisdiction over Defendant Chemo Research by virtue of, among other things: (1) its sale and distribution of generic drugs in Delaware; (2) its course of conduct that is designed to cause the performance of the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, which are Delaware corporations; and (3) its capacity as a party in pending litigations within this District (*see, e.g.*, *Chemo Research, S.L. et al. v. Encube Ethicals Private, Ltd.*, C.A. No. 22-854-CFC (D. Del. 2022)).

7. Further, this Court has personal jurisdiction over Defendant Chemo Research as it consented to personal jurisdiction for the related matter *BioDelivery Sciences Int'l Inc., et al. v. Chemo Research, S.L. et al.*, C.A. No. 19-444-CFC, concerning the same ANDA No. 212036, and

the same parties, and has been actively litigating that matter in this Court since 2019. (C.A. No. 19-444-CFC at D.I. 11, at ¶¶ 5-7.)

8. This Court further has personal jurisdiction over Defendant Chemo Research because at least one provision of the Delaware long-arm statute, 10 Del. C. § 3104(c), is satisfied. On information and belief, Defendant Chemo Research satisfies at least § 3104(c)(1) ("[t]ransacts any business or performs any character of work or service in the State"), § 3104(c)(2) ("[c]ontracts to supply services or things in this State"), § 3104(c)(3) ("[c]auses tortious injury in the State by an act or omission in this State"), § 3104(c)(4) ("[c]auses tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State"), and § 3104(c)(5) ("[h]as an interest in, uses or possesses real property in the State").

9. In addition, in the Notice Letter, dated July 29, 2022, Defendant Chemo Research did not identify a U.S. agent as required under 21 C.F.R. § 314.95(c)(9). Upon information and belief, Xiromed, LLC is the designated U.S. agent for Defendant Chemo Research.

10. 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.

11. On information and belief, Defendant Insud Pharma S.L.U. ("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.

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

13. This Court has personal jurisdiction over Defendant Insud by virtue of, among other things: (1) its sale and distribution of generic drugs in Delaware; (2) its course of conduct that is designed to cause the performance of the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, which are Delaware corporations; and (3) its capacity as a party in pending litigations within this District (*see, e.g., BioDelivery Sciences Int'l Inc., et al. v. Chemo Research, S.L. et al.*, C.A. No. 19-444-CFC (D. Del. 2019)).

14. Further, this Court has personal jurisdiction over Defendant Insud as it consented to personal jurisdiction for the related matter *BioDelivery Sciences Int'l Inc., et al. v. Chemo Research, S.L. et al.*, C.A. No. 19-444-CFC, concerning the same ANDA No. 212036, and the same parties, and has been actively litigating that matter in this Court since 2019. (C.A. No. 19-444-CFC at D.I. 11, at ¶¶ 11-13.)

15. This Court further has personal jurisdiction over Defendant Insud because at least one provision of the Delaware long-arm statute, 10 Del. C. § 3104(c), is satisfied. On information

and belief, Defendant Insud satisfies at least § 3104(c)(1) ("[t]ransacts any business or performs any character of work or service in the State"), § 3104(c)(2) ("[c]ontracts to supply services or things in this State"), § 3104(c)(3) ("[c]auses tortious injury in the State by an act or omission in this State"), § 3104(c)(4) ("[c]auses tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State"), and § 3104(c)(5) ("[h]as an interest in, uses or possesses real property in the State").

16. 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.

17. 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.

18. 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.

19. 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 Delaware and throughout the United States.

20. On information and belief, Defendant IntelGenx Corp. is amenable to litigating in this forum based on its conduct in other litigations in this District. *See, e.g., Biovail Labs. Int'l SRL v. IntelGenx Corp.*, C.A. No. 09-605-LPS (D. Del. 2010).

21. Further, this Court has personal jurisdiction over Defendant IntelGenx Corp. as it consented to personal jurisdiction for the related matter *BioDelivery Sciences Int'l Inc., et al. v. Chemo Research, S.L. et al.*, C.A. No. 19-444-CFC, concerning the same ANDA No. 212036, and the same parties, and has been actively litigating that matter in this Court since 2019. (C.A. No. 19-444-CFC at D.I. 11, at ¶¶ 18-20.)

22. This Court has personal jurisdiction over Defendant IntelGenx Corp. by virtue of, among other things: (1) its sale and distribution of generic drugs in Delaware; (2) its course of conduct that is designed to cause the performance of the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, which are Delaware corporations; and (3) its admission that it is subject to the Court's jurisdiction in other patent litigations.

23. This Court further has personal jurisdiction over Defendant IntelGenx Corp. because at least one provision of the Delaware long-arm statute, 10 Del. C. § 3104(c), is satisfied. On information and belief, Defendant IntelGenx Corp. satisfies at least § 3104(c)(1) ("[t]ransacts any business or performs any character of work or service in the State"), § 3104(c)(2) ("[c]ontracts to supply services or things in this State"), § 3104(c)(3) ("[c]auses tortious injury in the State by

an act or omission in this State"), § 3104(c)(4) ("[c]auses tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State"), and § 3104(c)(5) ("[h]as an interest in, uses or possesses real property in the State").

24. 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.

25. 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. On information and belief, Defendant IntelGenx Tech. maintains a registered agent in Delaware, the Corporation Service Company.

26. 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 Delaware and throughout the United States.

27. On information and belief, Defendant IntelGenx Tech. derives substantial revenue from the sale of its products in Delaware and throughout the United States.

28. On information and belief, Defendant IntelGenx Tech. is amenable to litigating in this forum based on its conduct in numerous other litigations in this District. In particular, Defendant IntelGenx Tech. has previously availed itself of the rights and privileges of this forum for the purpose of litigating patent disputes. Additionally, Defendant IntelGenx Tech. has submitted to this Court's jurisdiction by consenting to personal jurisdiction and asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g., Reckitt Benckiser Pharm. Inc. et al. v. Par Pharm., Inc., IntelGenx Techs. Corp., and LTS Lohmann Therapy Sys. Corp.*, C.A. No. 13-1461-RGA (D. Del. 2013); *Reckitt Benckiser Pharm. Inc. et al. v. Par Pharm., Inc. and IntelGenx Techs. Corp.*, C.A. No. 14-422-RGA (D. Del. 2014); *Reckitt Benckiser Pharm. Inc. et al. v. Par Pharm., Inc. and IntelGenx Techs. Corp.*, C.A. No. 14-1573-RGA (D. Del. 2014).

29. Further, this Court has personal jurisdiction over Defendant IntelGenx Tech. as it consented to personal jurisdiction for the related matter *BioDelivery Sciences Int'l Inc., et al. v. Chemo Research, S.L. et al.*, C.A. No. 19-444-CFC, concerning the same ANDA No. 212036, and the same parties, and has been actively litigating that matter in this Court since 2019. (C.A. No. 19-444-CFC at D.I. 11, at ¶¶ 26-28.)

30. This Court has personal jurisdiction over Defendant IntelGenx Tech. by virtue of, among other things: (1) its incorporation in Delaware; (2) its registration to do business in Delaware, including appointment of a registered agent; (3) its sale and distribution of generic drugs in Delaware; (4) its course of conduct that is designed to cause the performance of the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, which are Delaware corporations; (5) its purposeful availment of this forum previously for the purpose of litigating a patent dispute; and (6) its admission that it is subject to the Court's jurisdiction in other patent litigations.

31. 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.

32. 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.

33. On information and belief, Defendant Xiromed, LLC ("Xiromed") is a corporation organized and existing under the laws of New Jersey, having a principal place of business at 180 Park Ave., Suite 101, Florham Park, NJ 07932. On information and belief, Defendant Xiromed is the designated U.S. agent of Chemo Research and is the wholly owned subsidiary of Chemo Research. As stated above, Defendant Chemo Research did not identify its U.S. agent as required under 21 C.F.R. § 314.95(c)(9) in its Notice Letter.

34. On information and belief, Defendant Xiromed is a pharmaceutical company and the United States agent for Chemo Research which, in conjunction with the other Defendants, formulates, manufactures, packages, and markets generic drug products for distribution in the District of Delaware and throughout the United States.

35. This Court has personal jurisdiction over Defendant Xiromed by virtue of, among other things: (1) its sale and distribution of generic drugs in Delaware; and (2) its course of conduct that is designed to cause the performance of the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, which are Delaware corporations.

36. This Court further has personal jurisdiction over Defendant Xiromed because at least one provision of the Delaware long-arm statute, 10 Del. C. § 3104(c), is satisfied. On

information and belief, Defendant Xiromed satisfies at least § 3104(c)(1) ("[t]ransacts any business or performs any character of work or service in the State"), § 3104(c)(2) ("[c]ontracts to supply services or things in this State"), § 3104(c)(3) ("[c]auses tortious injury in the State by an act or omission in this State"), § 3104(c)(4) ("[c]auses tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State"), and § 3104(c)(5) ("[h]as an interest in, uses or possesses real property in the State").

37. On information and belief, the acts of Defendant Xiromed 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.

38. 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 Delaware.

39. 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).

40. Defendants Chemo Research, Insud, IntelGenx Corp., and IntelGenx Tech. have agreed that this Court has subject matter jurisdiction over ANDA No. 212036 in the related matter

BioDelivery Sciences Int'l Inc., et al. v. Chemo Research, S.L. et al., C.A. No. 19-444-CFC. (C.A. No. 19-444-CFC at D.I. 11, at ¶ 30.)

41. Venue is further proper in this district as Defendants Chemo Research, Insud, IntelGenx Corp., and IntelGenx Tech. have consented to venue in the related matter *BioDelivery Sciences Int'l Inc., et al. v. Chemo Research, S.L. et al.*, C.A. No. 19-444-CFC, concerning the same ANDA No. 212036, the same parties, and similar acts of infringement. (C.A. No. 19-444-CFC at D.I. 11, at ¶ 30.) Chemo Research's consent to venue in this district concerning patent litigation involving ANDA No. 212036 and similar acts of infringement also applies to defendant Xiromed, Chemo Research's subsidiary and U.S. agent concerning ANDA No. 212036.

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))

42. Plaintiffs reallege and incorporate by reference paragraphs 1-41.

43. 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.

44. 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.

45. Defendants filed, or caused to be filed, in 2018, 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.

46. Defendants filed, or caused to be filed, an amendment to ANDA No. 212036 ("amended ANDA") with the FDA under 21 U.S.C. § 355(j) and 21 C.F.R. § 314.95, seeking for the first time to obtain approval for the commercial manufacture, use, and sale of Buprenorphine Buccal Film, 600 mcg and 750 mcg ("generic buprenorphine buccal film (600 mcg and 750 mcg)"), in the United States before the expiration of the '866 patent. Defendants' original ANDA No. 212036, before this amendment, did not seek approval for these two doses. On information and belief, amended ANDA No. 212036 contains a Paragraph IV certification alleging that the claims of the '866 patent are not infringed by the commercial manufacture, use, and sale of Buprenorphine Buccal Film, 600 mcg and 750 mcg, by Defendants.

47. Defendants sent, or caused to be sent, to Plaintiffs a letter dated July 29, 2022 (the "Notice Letter") notifying Plaintiffs that Defendants had submitted an amendment to ANDA No. 212036 and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). The "Factual and Legal Bases for Chemo's Research's Certification" set forth in the Notice Letter alleges solely that Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) does not infringe claims 1-12 of the '866 patent.

48. By stipulation dated February 26, 2021, the Defendants are precluded from asserting any validity challenges to the '866 patent in this action or in any subsequent trial between the parties concerning ANDA No. 212036. (C.A. No. 19-444-CFC at D.I. 338 at ¶2.)

49. 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 (as amended) that seeks approval to commercially market—before the expiration date of the '866

patent—Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg), 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 (600 mcg and 750 mcg).

50. On information and belief, Defendants have knowledge of the '866 patent and have filed ANDA No. 212036 (as amended) seeking authorization to commercially manufacture, use, offer for sale, and sell Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) in the United States. On information and belief, if the FDA approves ANDA No. 212036 (as amended), physicians, health care providers, and/or patients will prescribe and/or use Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the '866 patent.

51. 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 (600 mcg and 750 mcg) 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.

52. On information and belief, if the FDA approves ANDA No. 212036 (as amended), Defendants will sell or offer to sell their generic buprenorphine buccal film (600 mcg and 750 mcg) specifically labeled for use in practicing one or more of the method claims of the '866 patent, wherein Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) is a

material part of the method claimed, wherein Defendants know that physicians will prescribe and patients will use Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) 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.

53. 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.

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

55. 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))

56. Plaintiffs reallege and incorporate by reference paragraphs 1-41.

57. 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.

58. 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.

59. Defendants filed, or caused to be filed, in 2018, 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.

60. Defendants filed, or caused to be filed, an amendment to ANDA No. 212036 ("amended ANDA") with the FDA under 21 U.S.C. § 355(j) and 21 C.F.R. § 314.95, seeking for the first time to obtain approval for the commercial manufacture, use, and sale of Buprenorphine Buccal Film, 600 mcg and 750 mcg ("generic buprenorphine buccal film (600 mcg and 750 mcg)"), in the United States before the expiration of the '843 patent. Defendants' original ANDA No. 212036, before this amendment, did not seek approval for these two doses. On information and belief, amended ANDA No. 212036 contains a Paragraph IV certification alleging that the claims of the '843 patent are not infringed by the commercial manufacture, use, and sale of Buprenorphine Buccal Film, 600 mcg and 750 mcg, by Defendants.

61. Defendants sent, or caused to be sent, to Plaintiffs the Notice Letter, dated July 29, 2022, notifying Plaintiffs that Defendants had submitted an amendment to ANDA No. 212036 and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). The "Factual and Legal Bases for Chemo's Research's Certification" set forth in the Notice Letter alleges solely that Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) does not infringe claims 1-25 of the '843 patent.

62. By stipulation dated February 26, 2021, the Defendants are precluded from asserting any validity challenges to the '843 patent in this action or in any subsequent trial between the parties concerning ANDA No. 212036.

63. 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 (as amended) that seeks approval to commercially market—before the expiration date of the '843 patent—Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg), 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 (600 mcg and 750 mcg).

64. On information and belief, Defendants have knowledge of the '843 patent and have filed ANDA No. 212036 (as amended) seeking authorization to commercially manufacture, use, offer for sale, and sell Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) in the United States. On information and belief, if the FDA approves ANDA No. 212036 (as amended), physicians, health care providers, and/or patients will prescribe and/or use Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the '843 patent.

65. On information and belief, Defendants have knowledge of the '843 patent and have filed ANDA No. 212036 (as amended) seeking authorization to commercially manufacture, use, offer for sale, and sell Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) in the United States. On information and belief, if the FDA approves ANDA No. 212036 (as amended), physicians, health care providers, and/or patients will prescribe and/or use Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) in accordance with the instructions

and/or label provided by Defendants and will directly infringe one or more claims of the '843 patent.

66. On information and belief, if the FDA approves ANDA No. 212036 (as amended), Defendants will sell or offer to sell their generic buprenorphine buccal film (600 mcg and 750 mcg) specifically labeled for use in practicing one or more of the method claims of the '843 patent, wherein Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) is a material part of the method claimed, wherein Defendants know that physicians will prescribe and patients will use Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) 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.

67. 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.

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

69. 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))

70. Plaintiffs reallege and incorporate by reference paragraphs 1-41.

71. The '539 patent, titled "Transmucosal Drug 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.

72. 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.

73. Defendants filed, or caused to be filed, in 2018, 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.

74. Defendants filed, or caused to be filed, an amendment to ANDA No. 212036 ("amended ANDA") with the FDA under 21 U.S.C. § 355(j) and 21 C.F.R. § 314.95, seeking for the first time to obtain approval for the commercial manufacture, use, and sale of Buprenorphine Buccal Film, 600 mcg and 750 mcg ("generic buprenorphine buccal film (600 mcg and 750 mcg)"), in the United States before the expiration of the '539 patent. Defendants' original ANDA No. 212036, before this amendment, did not seek approval for these two doses. On information and belief, amended ANDA No. 212036 contains a Paragraph IV certification alleging that the claims of the '539 patent are not infringed by the commercial manufacture, use, and sale of Buprenorphine Buccal Film, 600 mcg and 750 mcg, by Defendants.

75. Defendants sent, or caused to be sent, to Plaintiffs a letter dated July 29, 2022, notifying Plaintiffs that Defendants had submitted an amendment to ANDA No. 212036 and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). The "Factual and Legal Bases for

Chemo's Research's Certification" set forth in the Notice Letter alleges solely that Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) does not infringe claims 1-22 of the '539 patent.

76. By stipulation dated February 26, 2021, the Defendants are precluded from asserting any validity challenges to the '539 patent in this action or in any subsequent trial between the parties concerning ANDA No. 212036.

77. 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 (as amended) that seeks approval to commercially market—before the expiration date of the '539 patent—Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg), 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 (600 mcg and 750 mcg).

78. On information and belief, Defendants have knowledge of the '539 patent and have filed ANDA No. 212036 (as amended) seeking authorization to commercially manufacture, use, offer for sale, and sell Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) in the United States. On information and belief, if the FDA approves ANDA No. 212036 (as amended), physicians, health care providers, and/or patients will prescribe and/or use Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the '539 patent.

79. 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 (600 mcg and 750 mcg) 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.

80. On information and belief, if the FDA approves ANDA No. 212036 (as amended), Defendants will sell or offer to sell their generic buprenorphine buccal film (600 mcg and 750 mcg) specifically labeled for use in practicing one or more of the method claims of the '539 patent, wherein Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) is a material part of the method claimed, wherein Defendants know that physicians will prescribe and patients will use Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) 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.

81. 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.

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

83. 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))

84. Plaintiffs reallege and incorporate by reference paragraphs 1-55.

85. 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.

86. On information and belief, and based on information provided by Defendants, if the FDA approves Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) 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 (600 mcg and 750 mcg) for use and sale within the United States.

87. The manufacture, sale, offer for sale, and/or importation of Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) 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.

88. On information and belief, Defendants have knowledge of the '866 patent and have filed ANDA No. 212036 (as amended) seeking authorization to commercially manufacture, use, offer for sale, and sell Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) in the United States. On information and belief, if the FDA approves ANDA No. 212036 (as amended), physicians, health care providers, and/or patients will prescribe and/or use Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) in accordance with the instructions

and/or label provided by Defendants and will directly infringe one or more claims of the '866 patent.

89. 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 (600 mcg and 750 mcg) 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).

90. On information and belief, if the FDA approves ANDA No. 212036 (as amended), Defendants will sell or offer to sell their generic buprenorphine buccal film (600 mcg and 750 mcg) specifically labeled for use in practicing one or more of the method claims of the '866 patent, wherein Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) 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 (600 mcg and 750 mcg) 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).

91. 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.

92. 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))

93. Plaintiffs reallege and incorporate by reference paragraphs 1-41, 56-69.

94. 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.

95. On information and belief, and based on information provided by Defendants, if the FDA approves Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) 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 (600 mcg and 750 mcg) for use and sale within the United States.

96. The manufacture, sale, offer for sale, and/or importation of Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) 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.

97. On information and belief, Defendants have knowledge of the '843 patent and have filed ANDA No. 212036 (as amended) seeking authorization to commercially manufacture, use, offer for sale, and sell Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) in the United States. On information and belief, if the FDA approves ANDA No. 212036 (as amended), physicians, health care providers, and/or patients will prescribe and/or use Defendants'

generic buprenorphine buccal film (600 mcg and 750 mcg) in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the '843 patent.

98. 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 (600 mcg and 750 mcg) 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).

99. On information and belief, if the FDA approves ANDA No. 212036 (as amended), Defendants will sell or offer to sell their generic buprenorphine buccal film (600 mcg and 750 mcg) specifically labeled for use in practicing one or more of the method claims of the '843 patent, wherein Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) 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 (600 mcg and 750 mcg) 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).

100. 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.

101. 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))

102. Plaintiffs reallege and incorporate by reference paragraphs 1-41, 70-83.

103. 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.

104. The manufacture, sale, offer for sale, and/or importation of Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) 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.

105. On information and belief, Defendants have knowledge of the '539 patent and have filed ANDA No. 212036 (as amended) seeking authorization to commercially manufacture, use, offer for sale, and sell Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) in the United States. On information and belief, if the FDA approves ANDA No. 212036 (as amended), physicians, health care providers, and/or patients will prescribe and/or use Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the '539 patent.

106. 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 (600 mcg and 750 mcg) 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).

107. On information and belief, if the FDA approves ANDA No. 212036 (as amended), Defendants will sell or offer to sell their generic buprenorphine buccal film (600 mcg and 750 mcg) specifically labeled for use in practicing one or more of the method claims of the '539 patent, wherein Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) 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 (600 mcg and 750 mcg) 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).

108. 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.

109. 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, 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 (as amended) 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 (600 mcg and 750 mcg) prior to the expiration of said patents;

b) declare that Defendants' commercial manufacture, use, sale, or offer for sale, or importation into the United States of Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) 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);

c) order that the effective date of any FDA approval of Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) 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);

d) enjoin Defendants, and all persons acting in concert with Defendants, from seeking, obtaining, or maintaining final approval of ANDA No. 212036 (as amended) 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;

e) enjoin Defendants, and all persons acting in concert with Defendants, from commercially manufacturing, using, offering for sale, or selling Defendants' generic

buprenorphine buccal film (600 mcg and 750 mcg) within the United States, or importing Defendants' generic buprenorphine buccal film (600 mcg and 750 mcg) 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 becomes entitled, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and/or 283;

f) 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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

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September 12, 2022