IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA AB, and AMYLIN PHARMACEUTICALS, LLC	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC and AMNEAL PHARMACEUTICALS CO. INDIA PRIVATE LIMITED,	)	
Defendants.		

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca Pharmaceuticals LP and AstraZeneca AB (collectively, "AstraZeneca"), and Amylin Pharmaceuticals, LLC ("Amylin") (collectively "Plaintiffs"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This action is for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, against Defendants Amneal Pharmaceuticals LLC ("Amneal Pharma"), Amneal Pharmaceuticals of New York, LLC ("Amneal NY") and Amneal Pharmaceuticals Co. India Private Limited ("Amneal Ltd."), (collectively "Defendants" or "Amneal"). This action relates to Abbreviated New Drug Application ("ANDA") No. 206697 filed by Amneal Pharma with the U.S. Food and Drug Administration ("FDA") for approval to market exenatide injection, 250 mcg/mL, 1.2 mL and 2.4 mL prefilled syringe, generic versions

of AstraZeneca's Byetta® drug product, prior to expiration of U.S. Patent Nos. 6,872,700 (the "'700 patent") and 6,902,744 (the "'744 patent").

THE PARTIES

2. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19850.

3. Plaintiff AstraZeneca AB is a public, limited-liability company organized under the laws of Sweden with its principal place of business at Karlebyhus, Astraallén, Södertälje, S-151 85, Sweden.

4. Plaintiff Amylin Pharmaceuticals, LLC is an indirect, wholly-owned subsidiary of AstraZeneca PLC. Amylin Pharmaceuticals, LLC is organized under the laws of the State of Delaware, with its principal place of business at 9625 Towne Centre Drive, San Diego, California 92121.

5. AstraZeneca is engaged in the business of creating, developing, and bringing to market revolutionary biopharmaceutical products to help patients prevail against serious diseases, including treatments for Type II diabetes. Through its subsidiary, AstraZeneca Pharmaceuticals LP, AstraZeneca markets and sells Byetta® in this judicial district and throughout the United States.

6. On information and belief, Amneal Pharma is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey 08807-2863.

7. On information and belief, Defendant Amneal NY is a company organized and existing under the laws of the State of Delaware, having its principal place of business at 85 Adams Avenue, Hauppauge, NY 11788.

8. On information and belief, Defendant Amneal Ltd. is an Indian corporation, having its principal place of business at 882/1-871, Village Rajoda, Near Hotel Kankavati, Bavla Taluka, Ahmedabad-382220, Gujarat, India.

9. On information and belief, Amneal NY is a wholly owned subsidiary of Amneal Pharma.

10. On information and belief, Amneal Ltd. is a wholly owned subsidiary of Amneal Pharma.

11. On information and belief, Amneal, either directly or through one or more of its wholly owned subsidiaries and/or agents, develops, manufactures, distributes, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including in Delaware.

JURISDICTION AND VENUE

12. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271, and alleges infringement of the ’700 patent and the ’744 patent (collectively, “the asserted patents”). This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

13. This Court has jurisdiction over Amneal because it is a pharmaceutical company that, directly and through its affiliates, formulates, manufactures, packages, and/or markets generic drug products for distribution in the State of Delaware and throughout the United States.

14. On information and belief, Amneal Pharma, a Delaware Corporation, is qualified to do business in Delaware and appointed a registered agent for service of process, by filing with the Secretary of State on June 15, 2004 pursuant to sections 371 and 376 of title 8 of the Delaware Code: (1) a certificate of incorporation, representing its business as "[p]harmaceutical manufacturing, distribution and sales" under file number 3809030; and (2) a statement naming "The Corporation Trust Company" located at Corporation Trust Center, 1209 Orange St., Wilmington, Delaware 19801, as its registered agent to accept service of process in the State of Delaware.

15. On information and belief, Amneal Pharma is also actively registered with the Delaware Board of Pharmacy, pursuant to 24 *Del. C.* § 2540, as a licensed "Pharmacy-Wholesale" for both its Glasgow, Kentucky (License No. A4-0001536) and Florida, New York (License No. A4-0002253) facilities, and as a "Distributor/Manufacturer CSR" (License No. DM-00006588) for its Florida, New York facility.

16. On information and belief, Amneal Pharma has availed itself of this Court's jurisdiction by filing counterclaims in this District, and it has previously been sued in this district and has not challenged personal jurisdiction. *See*, *e.g.*, *Forest Laboratories, Inc. v. Amneal Pharmaceuticals, LLC*, 1:13-cv-01737-SLR (D. Del.) (consolidated with 1:13-cv-1602-SLR); *Endo Pharmaceuticals Inc. v. Amneal Pharmaceuticals, LLC*, 1:14-cv- 1382-RGA (D. Del.); *UCB, Inc. v. Amneal Pharmaceuticals, LLC*, 1:13-cv-1208-LPS (D. Del.); and *Forest Laboratories, Inc. v. Amneal Pharmaceuticals, LLC,* 1:14-cv-508-LPS (D. Del.).

17. This Court has personal jurisdiction over Amneal Pharma by virtue of, among other things: its formation under Delaware law; its registration to do business in Delaware, including appointment of a registered agent for service of process; its sale and distribution of

generic drugs in Delaware; 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; its purposeful availment of this forum previously; and its consent to the Court's jurisdiction in other patent litigations.

18. On information and belief, Amneal NY is a Delaware company registered with the Delaware Department of State, Division of Corporations, under file number 4533207.

19. On information and belief, Amneal NY maintains a registered agent for service of process in Delaware, the Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware, 19801.

20. On information and belief, Amneal NY is a generic pharmaceutical company in the business of marketing and distributing generic drug products. On information and belief, Amneal NY, directly and through its affiliates, markets and sells drug products in Delaware and throughout the United States.

21. On information and belief, Amneal NY holds a Delaware pharmacy wholesale license (Nos. A4-0001538 and A4-0001537) and a Delaware controlled substances distributor/manufacturer license (Nos. DM-0006604 and DM-0006605).

22. On information and belief, Amneal NY has availed itself of this Court's jurisdiction by filing counterclaims in this district, and has previously been sued in this district and has not challenged personal jurisdiction. *Forest Labs., Inc. v. Amneal Pharms. LLC*, et al., 14-cv-00508-LPS (D. Del.).

23. On information and belief, Amneal Pharma and Amneal NY collaborate to develop, manufacture, import, market, distribute, and/or sell pharmaceutical products (including

generic drug products manufactured and sold pursuant to ANDAs) throughout the United States, including the State of Delaware.

24. This Court has personal jurisdiction over Amneal NY by virtue of, among other things: its formation in Delaware; its registration to do business in Delaware, including appointment of a registered agent; its sale and distribution of generic drugs in Delaware; 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 AstraZeneca and Amylin which are Delaware corporations; its purposeful availment of this forum previously; and its consent to the Court's jurisdiction in other patent litigations.

25. On information and belief, Amneal Ltd. is a generic pharmaceutical company in the business of researching, developing, marketing and/or distributing generic drug products. On information and belief, Amneal Ltd., directly and through its affiliates, markets and sells drug products in Delaware and throughout the United States.

26. On information and belief, Amneal Ltd. 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, demonstrating that Amneal Ltd. has continuous and systematic contacts with Delaware.

27. On information and belief, Amneal Ltd. has availed itself of this Court's jurisdiction by filing counterclaims in this district, and has previously been sued in this district and has not challenged personal jurisdiction. *Forest Labs., Inc. v. Amneal Pharms. LLC*, et al., 14-cv-00508-LPS (D. Del.).

28. On information and belief, Amneal Pharma and Amneal Ltd. collaborate to develop, manufacture, import, market, distribute, and/or sell pharmaceutical products (including

generic drug products manufactured and sold pursuant to ANDAs) throughout the United States, including the State of Delaware.

29. This Court has personal jurisdiction over Amneal Ltd. by virtue of, among other things: its participation in the research, development, marketing, sale and/or distribution of generic drugs in Delaware; its purposeful availment of this forum previously; and its consent to the Court's jurisdiction in other patent litigations.

30. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Amneal.

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

PLAINTIFFS' PATENTS AND APPROVED BYETTA® DRUG PRODUCT

32. Plaintiffs make and sell Byetta® (exenatide injection), a prescription medicine that may improve blood sugar (glucose) control in adults with Type II diabetes, when used with diet and exercise. Type II diabetes is a condition characterized by high blood sugar (glucose) levels caused by either a lack of insulin or the body's inability to use insulin efficiently. Type II diabetes develops most often in middle-aged and older adults but can appear in younger adults, and it is the most common form of diabetes.

33. Byetta® is a GLP-1 receptor agonist that enhances glucose-dependent insulin secretion by the pancreatic beta-cell, suppresses inappropriately elevated glucagon secretion, and slows gastric emptying.

34. Plaintiff AstraZeneca AB is the holder of New Drug Application ("NDA") No. 021773 for Byetta® (300 mcg/1.2 mL and 600 mcg/2.4 mL (250 mcg/mL)). FDA initially approved NDA No. 021773 in April 2005 to improve glycemic control in patients with Type II diabetes mellitus who have not achieved adequate glycemic control on metformin, a

sulfonylurea, or a combination of metformin and a sulfonylurea. On October 30, 2009, FDA approved the use of Byetta® (exenatide) as an adjunct to diet and exercise to improve glycemic control in adults with Type II diabetes mellitus.

35. The following patents are listed in the FDA's Orange Book Byetta®: U.S. Patent Nos. 5,424,286, 6,858,576, 6,956,026, 7,297,761, 7,521,423, 7,741,269, 6,872,700 (the "'700 patent"), and 6,902,744 (the "'744 patent").

36. On March 29, 2005, the USPTO duly and lawfully issued the '700 patent, entitled "Methods for glucagon suppression." The expiration date for the '700 patent, as listed in the Orange Book, is January 14, 2020. A true and correct copy of the '700 patent is attached as Exhibit A.

37. On June 7, 2005, the USPTO duly and lawfully issued the '744 patent, entitled "Exendin agonist formulations and methods of administration thereof." The expiration date for the '744 patent, as listed in the Orange Book, is January 14, 2020. A true and correct copy of the '744 patent is attached as Exhibit B.

38. Each of the '700 and '744 patents is jointly owned by Plaintiffs AstraZeneca Pharmaceuticals LP and Amylin Pharmaceuticals, LLC. Plaintiffs have all right, title, and interest to the '700 and '744 patents, and are authorized to enforce them.

DEFENDANTS' ANDA

39. On information and belief, on or before October 26, 2015, Amneal Pharma submitted or caused to be submitted to FDA ANDA No. 206697 ("Amneal's ANDA") and a paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), seeking approval to engage in the commercial manufacture, use or sale of Exenatide Injection, 250 mcg/mL, 1.2 mL and 2.4mL

prefilled syringe ("Amneal ANDA Products"), as purported generic versions of Byetta®, prior to the expiration of the '700 and '744 patents.

40. In the past, Amneal has admitted that Amneal NY and Amneal Ltd. performed activities associated with the preparation and submission of Abbreviated New Drug Applications to FDA.

41. On information and belief, Amneal NY and Amneal Ltd. participated in and/or directed activities related to the submission of ANDA No. 206697 and the development of the Generic Product, were actively involved in preparing the ANDA, and/or intend to directly benefit from and have a financial stake in the approval of the ANDA.

42. Amneal Pharma sent Plaintiffs a letter entitled "Notice of Paragraph IV Certification of U.S. Patent Nos. 6,872,700 and 6,902,744, Concerning ANDA 206697 for Exenatide Injection, 250 mcg/mL, 1.2 mL and 2.4 mL prefilled syringe" (the "Amneal Notice Letter") and dated October 26, 2015. The Amneal Notice Letter represented that Amneal Pharma had submitted to FDA ANDA No. 206697 and a purported Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the products described in the Amneal ANDA before the expiration of the '700 and '744 patents listed in the Orange Book for NDA No. 021773. Hence, Amneal Pharma's purpose in submitting the Amneal ANDA is to manufacture and market the ANDA Products before the expiration of the '700 and '744 patents.

43. The Amneal Notice Letter stated that the Paragraph IV certification it submitted to FDA relates to the '700 and '744 patents.

44. The Amneal Notice Letter did not assert that Amneal submitted a Paragraph IV certification for any patent listed in FDA's Orange Book for Byetta® other than the '700 and '744

patents. The Amneal Notice Letter did not assert non-infringement or invalidity of any patent listed in FDA's Orange Book for Byetta® other than the '700 and '744 patents.

45. The Amneal Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding all defenses, does not allege invalidity or unenforceability of any claims of the '700 patent.

46. The Amneal Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding all defenses, does not allege unenforceability for any claims of the '744 patent and does not allege non-infringement for certain claims of the '744 patent.

47. Amneal Pharma has committed acts of infringement of the '700 and '744 patents under 35 U.S.C. § 271(e)(2)(A) by virtue of filing ANDA No. 206697 with a Paragraph IV certification seeking FDA approval of ANDA No. 206697 prior to expiration of the '700 and '744 patents.

48. On information and belief, if FDA approves the Amneal ANDA, Defendants will manufacture, offer for sale, or sell the Amneal ANDA Products within the United States, or will import the Amneal ANDA Products into the United States.

49. The conditions for use of the product(s) for which Amneal seeks approval in ANDA No. 206697 fall within one or more of the claims of the asserted patents. If approved, use of the Amneal ANDA product(s) in accordance with the labeling required by 21 U.S.C. § 505(j)(2)(A)(v) would infringe one or more of the claims of the '700 or '744 patents.

50. On information and belief, if FDA approves Amneal's ANDA, the importation, manufacture, sale, offer for sale, or use of the product(s) that are the subject of ANDA No. 206697 would infringe one or more claims of the '700 and '744 patents.

51. This action is being brought pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) within forty-five days of Plaintiffs' receipt of the Amneal Notice Letter.

COUNT I: CLAIM FOR INFRINGEMENT OF THE '700 PATENT

52. Plaintiffs restate, re-allege, and incorporate by reference the foregoing paragraphs as if fully set forth herein.

53. On information and belief, Amneal Pharma has submitted or caused the submission of ANDA No. 206697 to FDA, and continues to seek FDA approval of ANDA No. 206697.

54. Amneal has infringed the '700 patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Amneal ANDA with a Paragraph IV certification and seeking FDA approval of the Amenal ANDA prior to the expiration of the '700 patent.

55. If approved the product(s) for which approval is sought in Amneal's ANDA will be administered to human patients to improve glycemic control in adults with Type 2 diabetes mellitus, reduce gastric motility, delay gastric emptying, reduce food intake, reduce appetite, or lower plasma glucagon, which administration would constitute direct infringement of one or more claims of the '700 patent. Upon information and belief, this infringement will occur at Defendants' behest, with its intent, knowledge, and encouragement, and Defendants will actively induce, encourage, aid, and abet this administration with knowledge that is in contravention of Plaintiffs' rights under the '700 patent.

56. Amneal's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Products would directly infringe under 35 U.S.C. § 271(a), and would actively induce and contribute to infringement of the '700 patent, such that Amneal would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or 271(c). Accordingly, unless enjoined

by this Court, upon FDA approval of ANDA No. 206697, Amneal will make, use, offer to sell, or sell the Amneal ANDA Products within the United States, or will import the Amneal ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '700 patent.

57. On information and belief, upon FDA approval of ANDA No. 206697, Amneal will market and distribute the ANDA Products to resellers, pharmacies, health care professionals and end users of the Amneal ANDA Products. Amneal will also knowingly and intentionally accompany the Amneal ANDA Products with a product label and product insert that will include instructions for using the Amneal ANDA Products. Accordingly, Amneal will induce physicians and other health care professionals, resellers, pharmacies, and end users of the Amneal ANDA Products to directly infringe one or more claims of the '700 patent. In addition, on information and belief, Amneal will encourage acts of direct infringement with knowledge of the '700 patent and knowledge that it is encouraging infringement.

58. Amneal had actual and constructive notice of the '700 patent prior to filing the Amneal ANDA, and was aware that the filing of the ANDA with the request for FDA approval prior to the expiration of the '700 patent would constitute an act of infringement of the '700 patent. Amneal has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Products will not infringe, contribute to the infringement of, or induce the infringement of the '700 patent. In addition, Amneal filed the Amneal ANDA without adequate justification for asserting the '700 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the Amneal ANDA Products. Amneal's conduct in certifying invalidity and non-infringement with respect to the '700 patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

59. Plaintiffs will be irreparably harmed if Amneal is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '700 patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendant, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT II: CLAIM FOR INFRINGEMENT OF THE '744 PATENT

60. Plaintiffs restate, re-allege, and incorporate by reference the foregoing paragraphs as if fully set forth herein.

61. On information and belief, Amneal Pharma has submitted or caused the submission of ANDA No. 206697 to FDA, and continues to seek FDA approval of ANDA No. 206697.

62. Amneal has infringed the '744 patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Amneal ANDA with a Paragraph IV certification and seeking FDA approval of the Amneal ANDA prior to the expiration of the '744 patent.

63. Amneal's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Products would directly infringe under 35 U.S.C. § 271(a), and would actively induce and contribute to infringement of the '744 patent, such that Amneal would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or 271(c). Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 206697, Amneal will make, use, offer to sell, or sell the Amneal ANDA Products within the United States, or will import the Amneal ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '744 patent.

64. On information and belief, upon FDA approval of ANDA No. 206697, Amneal will market and distribute the ANDA Products to resellers, pharmacies, health care professionals and end users of the Amneal ANDA Products. Amneal will also knowingly and intentionally accompany the Amneal ANDA Products with a product label and product insert that will include instructions for using the Amneal ANDA Products. Accordingly, Amneal will induce physicians and other health care professionals, resellers, pharmacies, and end users of the Amneal ANDA Products to directly infringe one or more claims of the '744 patent. In addition, on information and belief, Amneal will encourage acts of direct infringement with knowledge of the '744 patent and knowledge that it is encouraging infringement.

65. Amneal had actual and constructive notice of the '744 patent prior to filing the Amneal ANDA, and was aware that the filing of the ANDA with the request for FDA approval prior to the expiration of the '744 patent would constitute an act of infringement of the '744 patent. Amneal has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the Amneal ANDA Products will not infringe, contribute to the infringement of, or induce the infringement of the '744 patent. In addition, Amneal filed the Amneal ANDA without adequate justification for asserting the '744 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Amneal's conduct in certifying invalidity and non-infringement with respect to the '744 patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

66. Plaintiffs will be irreparably harmed if Amneal is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '744 patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs

and Defendant, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A judgment that Defendants have infringed the '700 and '744 patents under 35 U.S.C. § 271(e)(2)(A);

(B) A judgment declaring that the making, using, selling, offering to sell, or importing of the products for which approval is sought in Amneal's ANDA, or inducing or contributing to such conduct, would constitute infringement of the '700 and '744 patents by Defendants pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c);

(C) A judgment that the claims of the '700 and '744 patents are valid and enforceable;

(D) A permanent injunction enjoining Defendants and their officers, directors, agents, servants, employees, parents, subsidiaries, affiliate companies, other related business entities, and all other persons acting in concert, participation, or in privity with Defendants, and its successors or assigns, from making, using, selling, offering for sale, or importing the ANDA Products in the United States until expiration of the last of the asserted patents and associated regulatory exclusivities extending that date;

(E) The entry of an order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of ANDA No. 206697 shall be a date that is not earlier than the last expiration date of any of the '700 and '744 patents, or any later expiration of exclusivity for any of the patents, including any extensions or regulatory exclusivities;

(F) A finding that this is an exceptional case, and an award of Plaintiffs' attorneys' fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

(G) An award to Plaintiffs of their costs and expenses in this action; and

(H) Such other and further relief as the Court deems just and proper.

DATED: December 9, 2015

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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