IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDA PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	
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

Plaintiff Meda Pharmaceuticals Inc. ("Plaintiff" or "Meda") files this Complaint for patent infringement 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") under 35 U.S.C. §§ 271(e)(2)(A), (B), and (C). This patent action concerns the pharmaceutical drug product ASTEPRO®. Meda alleges as follows:

Nature of the Action

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*., and in particular under 35 U.S.C. § 271(a-c, e). This action relates to Abbreviated New Drug Application ("ANDA") No. 208199 filed by or for the benefit of Amneal Pharma with the United States Food and Drug Administration ("FDA") for approval to market a generic version of Plaintiff's ASTEPRO® pharmaceutical product

(azelastine hydrochloride nasal spray, 0.15%, 205.5 mcg per spray) (the "Generic Product") that is sold in the United States. ANDA No. 208199 seeks approval to market the Generic Product prior to the expiration of Meda's U.S. Patent Nos. 8,071,073 ("the '073 Patent") and 8,518,919 ("the '919 Patent"), which cover ASTEPRO® and the conditions of its use.

The Parties

2. Plaintiff Meda is a corporation organized and existing under the laws of Delaware, having its principal place of business at 265 Davidson Avenue, Suite 300, Somerset, New Jersey 08873.

3. On information and belief, Defendant Amneal Pharma is a 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.

4. 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.

5. 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.

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

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

8. 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

9. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the U.S. Code, for infringement of the ’073 Patent and the ’919 Patent.

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

11. On information and belief, Amneal Pharma is a Delaware company registered with the Delaware Department of State, Division of Corporations, under file number 3809030.

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

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

14. On information and belief and as stated in the ANDA Notice Letter, Amneal Pharma prepared and filed ANDA No. 208199 with the intention of seeking to market a generic version of Meda’s ASTEPRO® product throughout the United States, including in Delaware.

15. On information and belief, Amneal Pharma holds a Delaware pharmacy wholesale license (No. A4-0001536) and a Delaware controlled substances distributor/manufacturer license (No. DM 0006588).

16. On information and belief, Amneal Pharma 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 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.); *Forest Laboratories, Inc. v. Amneal Pharmaceuticals* LLC, 1:14-cv-508-LPS (D. Del.); *Abbott Laboratories v. Amneal Pharmaceuticals, LLC*, 1:12-cv-235- SLR (D. Del.).

17. This Court has personal jurisdiction over Amneal Pharma 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 Plaintiff Meda, which is a Delaware corporation; 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 Plaintiff Meda, which is a Delaware corporation; 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. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

Regulatory Requirements for New and Generic Drugs

31. A person wishing to market a new drug that has not previously been approved by FDA (a "pioneering" drug) must file a New Drug Application ("NDA") with FDA demonstrating that the drug is safe and effective for its intended use. 21 U.S.C. § 355(b).

32. A person wishing to market a generic copy of a drug that previously has been approved by FDA may follow a truncated approval process by filing an ANDA for a generic version of that drug. In the ANDA, the applicant must demonstrate, among other things, bioequivalence of the generic copy with the pioneering drug. 21 U.S.C. § 355(j)(2)(A)(iv).

33. Unlike an NDA applicant, an ANDA applicant is not required to include safety and effectiveness data. Instead, the ANDA applicant is permitted to rely on the approval of the NDA applicant's drug—in essence, piggybacking on the NDA application and safety and effectiveness conclusions. 21 U.S.C. § 355(j).

34. Nor does an ANDA applicant establish any new conditions of use for the proposed drug product. Instead, an ANDA applicant may seek approval only for conditions of use that previously have been approved in connection with an approved NDA. 21 U.S.C. § 355(j)(2)(A)(i).

The Patents-in-Suit

35. On December 6, 2011, the U.S. Patent and Trademark Office duly and legally issued the '073 Patent, titled "Compositions Comprising Azelastine and Methods of Use Thereof." The Orange Book presently shows that the '073 Patent's term ends on June 4, 2028. A true and correct copy of the '073 Patent is attached hereto as **Exhibit A**.

36. On August 27, 2013, the U.S. Patent and Trademark Office duly and legally issued the '919 Patent, also titled "Compositions Comprising Azelastine and Methods of Use

Thereof." The Orange Book shows that the '919 Patent's term ends on November 22, 2025. A true and correct copy of the '919 Patent is attached hereto as **Exhibit B**.

The Approved Drug Product

37. Meda is the current holder of NDA No. 22-371, ASTEPRO® (205.5 mcg azelastine hydrochloride nasal spray), which was approved by FDA on August 31, 2009.

38. ASTEPRO® is indicated for the treatment of the symptoms of seasonal and perennial allergic rhinitis. A true and correct copy of the ASTEPRO® Prescribing Information is attached hereto as **Exhibit C**.

39. FDA has listed the '073 Patent and the '919 Patent in the Orange Book—formally known as *Approved Drug Products With Therapeutic Equivalence Evaluations*—in connection with NDA No. 22-371.

40. Meda is the owner of the '073 Patent and the '919 Patent and has the right to make, use, and sell certain pharmaceutical preparations containing azelastine hydrochloride to treat the symptoms of allergic and non-allergic vasomotor rhinitis. Meda currently markets an azelastine hydrochloride nasal spray in the United States under the trademark ASTEPRO®. The ASTEPRO® product and the conditions of use for which ASTEPRO® is approved fall within the claims of the '073 Patent and the '919 Patent.

ANDA No. 208199

41. On information and belief, Amneal Pharma, on or before June 4, 2015, submitted to FDA an ANDA (ANDA No. 208199) with paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), for the Generic Product. The purpose of the ANDA is to obtain approval

under section 505(j) of the FDCA to engage in the commercial manufacture and sale of the Generic Product.

42. On information and belief, Amneal NY and Amneal Ltd. participated in and/or directed activities related to the submission of ANDA No. 208199 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.

43. On information and belief, the indication set forth in the proposed labeling submitted in ANDA No. 208199 for the Generic Product is for the relief of the symptoms of seasonal and perennial allergic rhinitis, *i.e.*, the same indication as set forth in the approved labeling for ASTEPRO®.

44. On information and belief, Amneal Pharma sent Meda a letter dated June 4, 2015, which was received by Meda on or about June 5, 2015 (the "Notice Letter"). The Notice Letter represented that Amneal had submitted to FDA an ANDA, No. 208199, with a paragraph IV certification for the '073 Patent and the '919 Patent.

45. On information and belief, the purpose of the ANDA and paragraph IV certifications are to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of a generic version of ASTEPRO® before the expiration of the patents listed in the Orange Book for NDA No. 22-371. Hence, Amneal Pharma's purpose in submitting ANDA No. 208199 is to market products described therein before expiration of the '073 Patent and '919 Patent.

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

Count I: Patent Infringement of the ’073 Patent

47. Plaintiff incorporates by reference the allegations contained in paragraphs 1 to 46 above.

48. On information and belief, Amneal Pharma submitted ANDA No. 208199 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of ASTEPRO® before the expiration of the ’073 Patent.

49. Defendants’ manufacture, use, offer for sale, or sale of such product would infringe the claims of the ’073 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

50. On information and belief, as part of the ANDA filing, Amneal Pharma purportedly provided written certification to FDA that the claims of the ’073 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of Defendants’ generic version of ASTEPRO®.

51. Amneal Pharma gave written notice of its certification of invalidity and/or non-infringement of the ’073 Patent, alleging that certain claims of the ’073 Patent are invalid and that certain claims would not be infringed by Defendants’ generic version of ASTEPRO®, and informing Plaintiff that Amneal Pharma seeks approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to ASTEPRO® prior to the expiration of the ’073 Patent.

52. Defendants have infringed the ’073 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 208199 with a paragraph IV certification and seeking FDA approval of ANDA No. 208199 to market a generic version of ASTEPRO® prior to the expiration of the ’073 Patent.

53. On information and belief, if the FDA approves ANDA No. 208199, Defendants will further infringe one or more claims of the ’073 Patent by manufacturing, using, offering to sell, and selling the Generic Product in the United States and/or importing the Generic Product into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c), unless enjoined by the Court.

54. Unless Defendants’ manufacture, marketing, and sale of the Generic Product before the expiration of the ’073 Patent is enjoined, Meda will suffer substantial and irreparable harm for which there is no adequate remedy at law.

Count II: Patent Infringement of the ’919 Patent

55. Plaintiff incorporates by reference the allegations contained in paragraphs 1 to 54 above.

56. On information and belief, Amneal Pharma submitted ANDA No. 208199 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of ASTEPRO® before the expiration of the ’919 Patent.

57. Defendants’ manufacture, use, offer for sale, or sale of such product would infringe the claims of the ’919 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

58. On information and belief, if approved, the generic ASTEPRO® product for which approval is sought in Amneal Pharma’s ANDA No. 208199 will be administered to human patients to treat the symptoms of seasonal and perennial allergic rhinitis. This administration, in turn, would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the ’919 Patent. On information and belief, this infringement will occur at Defendants’ behest, with their intent, knowledge, and encouragement,

and Defendants will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiff's rights under the '919 Patent.

59. Defendants' manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic ASTEPRO® product for which approval is sought in ANDA No. 208199 would actively induce and contribute to infringement of the '919 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

60. On information and belief, as part of the ANDA filing, Amneal Pharma purportedly provided written certification to FDA that the claims of the '919 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of Defendants' generic version of ASTEPRO®.

61. Amneal Pharma gave written notice of its certification of invalidity and/or non-infringement of the '919 Patent, alleging that certain claims of the '919 Patent are invalid and that certain claims would not be infringed by Defendants' generic version of ASTEPRO®, and informing Plaintiff that Amneal Pharma seeks approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to ASTEPRO® prior to the expiration of the '919 Patent.

62. Defendants have infringed the '919 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 208199 with a paragraph IV certification and seeking FDA approval of ANDA No. 208199 to market a generic version of ASTEPRO® prior to the expiration of the '919 Patent.

63. On information and belief, if the FDA approves ANDA No. 208199, Defendants will further infringe one or more claims of the '919 Patent by manufacturing, using, offering to sell, and selling the Generic Product in the United States and/or importing the Generic Product

into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c), unless enjoined by the Court.

64. Unless Defendants' manufacture, marketing, and sale of the Generic Product before the expiration of the '919 Patent is enjoined, Meda will suffer substantial and irreparable harm for which there is no adequate remedy at law.

Request for Relief

WHEREFORE, Plaintiff respectfully seeks the following relief:

A. A judgment that Defendants have infringed valid and enforceable claims of the '073 Patent and the '919 Patent under 35 U.S.C. § 271(e)(2)(A);

B. A judgment and order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 208199 shall not be earlier than the latest of the expiration dates of the '073 Patent and the '919 Patent, including any extension(s) or additional period(s) of exclusivity for the '073 Patent and the '919 Patent to which Plaintiff is or becomes entitled;

C. A judgment declaring that making, using, selling, offering to sell, or importing the Generic Product, or inducing or contributing to such conduct, would constitute infringement of the'073 Patent and the '919 Patent by Defendants pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

D. A permanent injunction restraining and enjoining Defendants and their officers, agents, servants, employees, parents, subsidiaries, divisions, affiliates, and those persons in active concert or participation with any of them, from making, using, selling, offering to sell, or importing any product that infringes the '073 Patent and the '919 Patent, including the Generic Product;

E. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

F. An award of costs and expenses in this action; and

G. Such further and other relief as this Court determines to be just and proper.

ASHBY & GEDDES

/s/ Steven J. Balick

Steven J. Balick (#2114)
John G. Day (#2403)
Andrew C. Mayo (#5207)
500 Delaware Ave., 8th Floor
P.O. Box 1150
Wilmington, DE 19899
(302) 654-1888
sbalick@ashby-geddes.com
jday@ashby-geddes.com
amayo@ashby-geddes.com

Attorneys for Plaintiff
Meda Pharmaceuticals Inc.

Of Counsel:

Jeffrey B. Elikan
Ahmed S. Mousa
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street, NW
Washington, D.C. 20001
Tel: (202) 662-6000

Dated: July 17, 2015