IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDA PHARMACEUTICALS INC. Plaintiff, v. AKORN, INC. and HI-TECH PHARMACAL CO., INC. Defendants.	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Meda Pharmaceuticals Inc. ("Meda" or "Plaintiff") files this Complaint for patent infringement against Defendants Akorn, Inc. ("Akorn") and Hi-Tech Pharmacal Co., Inc. ("Hi-Tech") (collectively "Defendants") under 35 §§ 271(e)(2)(A), (B), and (C). This patent action concerns the pharmaceutical drug product ASTEPRO®. Plaintiff 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. 210032 filed by or for the benefit of Defendants 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. 210032 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 1000 Mylan Boulevard, Canonsburg, PA 15317.

3. On information and belief, Defendant Akorn is a company organized and existing under the laws of the State of Louisiana, having its principal place of business at 1925 West Field Court, Suite 300, Lake Forest, IL 60045.

4. On information and belief, Defendant Hi-Tech is a company organized and existing under the laws of the State of Delaware, having its principal place of business at 369 Bayview Ave., Amityville, NY 11701.

5. On information and belief, Hi-Tech is a wholly owned subsidiary of Akorn.

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

JURISDICTION AND VENUE

7. 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.

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

9. On information and belief, Akorn is a company registered with the Delaware Department of State, Division of Corporations, under file number 4333511.

10. On information and belief, Akorn maintains a registered agent for service of process in Delaware, the Corporation Service Company, 2711 Centerville Rd., Suite 400,

Wilmington, Delaware, 19808.

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

12. On information and belief, Akorn holds Delaware pharmacy wholesale licenses (Nos. A4-0000573 and A4-0000687) and a Delaware controlled substances distributor/manufacturer license (No. DS0270).

13. On information and belief, Akorn 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 this Court's exercise of personal jurisdiction over Akorn. *Mallinckrodt LLC v. Hi-Tech Pharmacal Co., Inc.*, 1:14-cv-01084-RGA (D. Del.); *Astellas US LLC v. Akorn, Inc.*, 1:12-cv-01489-SLR (D. Del.); *Allegran, Inc. v. Akorn, Inc.*, 1:11-cv-01270-LPS-CJB (D. Del.).

14. This Court has personal jurisdiction over Akorn by virtue of, among other things: its registration to do business in Delaware, including appointment of a registered agent; its sale and distribution of generic and branded pharmaceutical 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; its purposeful availment of this forum previously; and its consent to the Court's jurisdiction in other patent litigations.

15. On information and belief, Hi-Tech is a Delaware company registered with the Delaware Department of State, Division of Corporations, under file number 2649635.

16. On information and belief, Hi-Tech maintains a registered agent for service of process in Delaware, the Corporation Service Company, 2711 Centerville Rd., Suite 400,

Wilmington, Delaware, 19808.

17. On information and belief, Hi-Tech is a pharmaceutical company in the business of marketing and distributing generic and branded prescription drug products. On information and belief, Hi-Tech, directly and through its affiliates, markets and sells drug products in Delaware and throughout the United States.

18. On information and belief, Hi-Tech holds a Delaware pharmacy wholesale license (No. A4-0002139) and a Delaware controlled substances distributor/manufacturer license (No. DM-0010486).

19. On information and belief, Hi-Tech 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 this Court's exercise of personal jurisdiction over Hi-Tech. *Shinogi Inc. v. Hi-Tech Pharmacal Co., Inc.*, 1:16-cv-00676-LPS (D. Del.); *Mallinckrodt LLC v. Hi-Tech Pharmacal Co., Inc.*, 1:14-cv-01084-RGA (D. Del.).

20. On information and belief, and as stated in the ANDA Notice Letter, Hi-Tech prepared and filed ANDA No. 210032 with the intention of seeking to market a generic version of Plaintiff's ASTEPRO® product throughout the United States, including in Delaware.

21. On information and belief, Akorn and Hi-Tech 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 in the State of Delaware.

22. This Court has personal jurisdiction over Hi-Tech 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 and branded pharmaceutical

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

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

REGULATORY REQUIREMENTS FOR APPROVAL OF NEW AND GENERIC DRUGS

24. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq*., as amended by the Hatch-Waxman Amendments, sets forth the rules FDA follows when considering whether to approve the marketing of pharmaceutical drugs.

25. With the passage of the Hatch-Waxman Act in 1984, the FFDCA provisions with respect to the generic drug approval process were amended in several aspects. One provision requires innovator drug companies to submit patent information to the FDA "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). FDA publishes the submitted patent information in a publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book").

26. The Hatch-Waxman Act further amended the FFDCA to permit generic drug companies to follow a truncated approval process by filing an ANDA for a generic version of an innovator drug (also called "reference drugs" or "pioneer drugs"). In the ANDA, the applicant must demonstrate, among other things, bioequivalence of the generic copy with the pioneer drug. 21 U.S.C. § 355(j)(2)(A)(iv).

27. A person wishing to market a new drug that has not previously been approved by

FDA (a "pioneer" 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).

28. 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 pioneer drug. 21 U.S.C. § 355(j)(2)(A)(iv).

29. 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 and the safety and effectiveness conclusions in that NDA. 21 U.S.C. § 355(j).

30. 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).

31. ANDA applicants are also required to review the patent information that the FDA lists in the Orange Book and make a statutory certification (commonly referred to as a "patent certification") with respect to the pioneer drug. One such certification is the paragraph IV certification, wherein the ANDA applicant seeks FDA approval to market its generic drug products prior to patent expiration by stating in its ANDA that the Orange Book-listed patents are purportedly "invalid or will not be infringed." 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

PATENTS-IN-SUIT

32. 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**.

33. 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

34. Meda is the current holder of NDA No. 22-203, ASTEPRO® (205.5 mcg azelastine hydrochloride nasal spray), which was approved by FDA on August 31, 2009.

35. 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**.

36. The FDA has listed the '073 Patent and the '919 Patent in the Orange Book in connection with NDA No. 22-203 because each patent individually claims the drug composition or methods for using the approved drug product. 21 U.S.C. § 355(b)(1).

37. 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. 210032

38. On information and belief, Hi-Tech, on or before March 7, 2017, submitted to

the FDA an ANDA (ANDA No. 210032) with paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the FFDCA, 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 FFDCA to engage in the commercial manufacture, use, offer for sale, and sale of the Generic Product.

39. On information and belief, Akorn participated in and/or directed activities related to the submission of ANDA No. 210032 and the development of the Generic Product, was actively involved in preparing the ANDA, and/or intends to directly benefit from and has a financial stake in the approval of the ANDA.

40. In submitting its ANDA No. 210032 to the FDA, Hi-Tech has represented that its Generic Product has the same active ingredient and dosage form as Plaintiff's ASTEPRO® and is bioequivalent to ASTEPRO®.

41. On or about March 7, 2017 Defendants sent Plaintiff a letter (the "Notice Letter") stating that Hi-Tech had submitted to the FDA an ANDA, No. 210032, with a paragraph IV certification asserting that the '073 Patent and '919 Patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, and sale of the Generic Product.

42. On information and belief, the indication in the proposed labeling submitted with ANDA No. 210032 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®.

43. The Generic Product and the conditions of use for which Hi-Tech seeks approval in ANDA No. 210032 fall within one or more of the claims of the'073 Patent and '919 Patent. If approved, the importation, manufacture, sale, offer for sale, and/or use of the

Generic Product would infringe one or more claims of the ’073 Patent and ’919 Patent.

44. On information and belief, the purpose of the ANDA and paragraph IV certifications are to obtain approval under section 505(j) of the FFDCA 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. 22-203. Hence, Hi-Tech’s purpose in submitting ANDA No. 210032 is to market products described therein before expiration of the ’073 Patent and ’919 Patent.

45. This Complaint is being filed within 45 days from the date Plaintiff received the Notice Letter. 21 U.S.C. § 355(j)(B)(iii).

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. Defendants have infringed the ’073 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 210032 with a paragraph IV certification and seeking FDA approval of ANDA No. 210032 to market a generic version of ASTEPRO® prior to the expiration of the ’073 Patent.

49. On information and belief, if the FDA approves ANDA No. 210032, 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.

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

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '073 PATENT

51. Plaintiff incorporates by reference the allegations contained in paragraphs 1 to 50 above.

52. Plaintiff's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

53. There is an actual case and controversy between Plaintiff on the one side, and the Defendants on the other, creating a justiciable case and controversy for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

54. The Defendants have made, and will continue to make substantial preparations in the United States, including Delaware, to manufacture, sell, offer to sell, and/or import the Generic Product.

55. The Defendants' actions indicate a refusal to change the course of their actions in the face of acts by Plaintiff.

56. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Generic Product before the '073 Patent expires will constitute direct infringement and/or contribute to and/or actively induce the infringement by others of the '073 Patent.

57. On information and belief, Akorn actively and knowingly caused to be submitted and/or assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 210032 to the FDA, while knowing of the '073 Patent.

58. The submission of ANDA No. 210032 by the Defendants through Hi-Tech

constituted direct infringement of the ’073 Patent under 35 U.S.C. § 271(e). Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), Akorn induced the infringement of the ’073 Patent by actively and knowingly causing to be submitted and/or assisting with, participating in, contributing to, and/or directing the submission of ANDA No. 210032 to the FDA and knowing that the submission of ANDA No. 210032 would constitute direct infringement of the ’073 Patent. Akorn knowing and purposeful activities of causing to be submitted and/or assisting with, participating in, contributing to, and/or directing the filing of ANDA No. 210032 while knowing that its submission would constitute direct infringement, constitute induced infringement of the ’073 Patent.

59. Unless the Defendants are enjoined from directly and indirectly infringing the ’073 Patent, Plaintiff will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT III: PATENT INFRINGEMENT OF THE ’919 PATENT

60. Plaintiff incorporates by reference the allegations contained in paragraphs 1 to 59 above.

61. Defendants have infringed the ’919 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 210032 with a paragraph IV certification and seeking FDA approval of ANDA No. 210032 to market a generic version of ASTEPRO® prior to the expiration of the ’919 Patent.

62. On information and belief, if the FDA approves ANDA No. 210032, 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.

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

COUNT IV: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '919 PATENT

64. Plaintiff incorporates by reference the allegations contained in paragraphs 1 to 63 above.

65. Plaintiff's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

66. There is an actual case and controversy between Plaintiff on the one side, and the Defendants on the other, creating a justiciable case and controversy for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

67. The Defendants have made, and will continue to make substantial preparations in the United States, including Delaware, to manufacture, sell, offer to sell, and/or import the Generic Product.

68. The Defendants' actions indicate a refusal to change the course of their actions in the face of acts by Plaintiff.

69. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Generic Product before the '919 Patent expires will constitute direct infringement and/or contribute to and/or actively induce the infringement by others of the '919 Patent.

70. On information and belief, Akorn actively and knowingly caused to be submitted and/or assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 210032 to the FDA, while knowing of the '919 Patent.

71. The submission of ANDA No. 210032 by the Defendants through Hi-Tech constituted direct infringement of the '919 Patent under 35 U.S.C. § 271(e). Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), Akorn induced the infringement of the '919 Patent by actively and knowingly causing to be submitted and/or assisting with, participating in, contributing to, and/or directing the submission of ANDA No. 210032 to the FDA and knowing that the submission of ANDA No. 210032 would constitute direct infringement of the '919 Patent. Akorn knowing and purposeful activities of causing to be submitted and/or assisting with, participating in, contributing to, and/or directing the filing of ANDA No. 210032 while knowing that its submission would constitute direct infringement, constitute induced infringement of the '919 Patent.

72. Unless the Defendants are enjoined from directly and indirectly infringing the '919 Patent, Plaintiff 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. 210032 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, regulatory or otherwise, for the '073 Patent and the '919 Patent to which Plaintiff is or becomes entitled;

C. A judgment declaring that Defendants' manufacture, use, sale, offer for sale, or

importation into the United States of the Generic Product for which approval is sought in ANDA No. 210032 would constitute infringement of the'073 Patent and the '919 Patent, or would induce or contribute to such infringement, 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 in the United States, or importing into the United States any product that infringes the '073 Patent and the '919 Patent, including the Generic Product;

E. A declaration under 28 U.S.C. § 2201 that if the Defendants, their officers, agents, servants, employees, licensees, representatives, and attorneys, and any other persons acting or attempting to act in active concert or participation with them or acting on their behalf, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Generic product prior to patent expiry, it will constitute an act of direct and/or indirect infringement of the 073 Patent and the '919 Patent;

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

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

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

Dated: April 19, 2017

STAMOULIS & WEINBLATT LLC

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