IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDA PHARMACEUTICALS INC. and CIPLA LTD.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 15-785-LPS
TEVA PHARMACEUTICALS USA, INC.,	)	
Defendant.	)	

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Meda Pharmaceuticals Inc. ("Meda") and Cipla Ltd. ("Cipla") (collectively, "Plaintiffs"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, against defendant Teva Pharmaceuticals USA, Inc. ("Teva"). Teva filed or caused to be filed Abbreviated New Drug Application ("ANDA") No. 208436 with the U.S. Food and Drug Administration ("FDA"). ANDA No. 208436 seeks approval to market a 137 mcg strength azelastine hydrochloride and 50 mcg strength fluticasone propionate combination nasal spray ("Generic Product")—a generic version of Plaintiff Meda's proprietary DYMISTA® drug product—before expiration of Plaintiff Cipla's U.S. Patent Nos. 8,163,723 ("the '723 patent"), 8,168,620 ("the '620 patent"), and 9,259,428 ("the '428 patent"), all of which cover the DYMISTA® drug product, and for all of which Meda is the exclusive licensee in the United States.

PARTIES

2. Meda is a corporation organized and existing under the laws of Delaware, and having its principal place of business at 265 Davidson Avenue, Suite 300, Somerset, New Jersey 08873-4120.

3. Cipla is a publicly held company organized and existing under the laws of India, and having a registered office at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400 013, Maharashtra, India.

4. Upon information and belief, Teva USA is a corporation organized and existing under the laws of Delaware, and having its principal place of business at 1090 Horsham Road, North Wales, PA 19454.

JURISDICTION AND VENUE

5. This action arises under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. This Court has personal jurisdiction over Teva USA because, upon information and belief, Teva USA is a Delaware corporation with a registered agent in Delaware: Corporate Creations Network, Inc., 3411 Silverside Road #104, Rodney Building, Wilmington, Delaware 19810. Teva USA has therefore availed itself of the rights, benefits, and privileges of Delaware's laws.

7. This Court also has personal jurisdiction over Teva USA because, *inter alia*,: (a) Teva USA is a Delaware corporation that knew it could be sued in Delaware and purposefully directed its activities at residents and corporate entities within the State of Delaware; (b) the claims set forth herein as to Teva USA arise out of, or relate to, those activities; (c) Teva USA's

contacts with the State of Delaware (direct and/or indirect) are continuous and systematic; and (d) it is reasonable and fair for this Court to exercise personal jurisdiction over Teva USA.

8. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, this Court has personal jurisdiction over Teva USA.

9. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

REGULATORY REQUIREMENTS FOR APPROVAL OF NEW AND GENERIC DRUGS

10. 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.

11. 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 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 entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book").

12. The Hatch-Waxman Act further amended the FFDCA to permit generic drug companies to gain approval of generic copies of innovator drugs (also called "reference drugs") by referencing studies performed by the innovator, without having to expend the same considerable investment in time and resources. Thus, generic drug companies are permitted to file what is referred to as an ANDA under 21 U.S.C. § 355(j). When filing an ANDA, generic drug companies are required to review the patent information that FDA lists in the Orange Book

for the reference drug and make a statutory certification (commonly called "patent certification") with respect to the same.

13. One such certification is the Paragraph IV certification, where the generic drug company 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

14. On April 24, 2012, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,163,723, titled "Combination of Azelastine and Steroids." The Orange Book presently shows that the '723 patent's term ends on August 29, 2023. A true and correct copy of the '723 patent is attached hereto as **Exhibit A**.

15. On May 1, 2012, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,168,620, also titled "Combination of Azelastine and Steroids." The Orange Book shows that the '620 patent's term ends on February 24, 2026. A true and correct copy of the '620 patent is attached hereto as **Exhibit B**.

16. On February 16, 2016, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 9,259,428, titled "Combination of Azelastine and Fluticasone for Nasal Administration." The '428 patent's term ends on June 13, 2023. A true and correct copy of the '428 patent is attached hereto as **Exhibit C**.

17. Plaintiff Cipla is the owner of the '723, '620, and '428 patents.

18. Plaintiff Meda is the exclusive licensee of the '723, '620, and '428 patents in the United States, pursuant to an exclusive license agreement between Meda and Cipla, of the right to make, use, and sell certain pharmaceutical preparations containing azelastine hydrochloride

and fluticasone propionate to treat seasonal allergic rhinitis. Pursuant to that exclusive license, Meda currently markets an azelastine hydrochloride and fluticasone propionate combination nasal spray in the United States under the trademark DYMISTA®. The DYMISTA® product and the conditions of use for which DYMISTA® is approved fall within the claims of the '723, '620, and '428 patents.

19. As exclusive licensee, Meda has the right to enforce the '723, '620, and '428 patents.

MEDA'S APPROVED DRUG PRODUCT: DYMISTA®

20. Meda holds NDA No. 202236, which covers the DYMISTA® (137 mcg azelastine hydrochloride and 50 mcg fluticasone propionate) nasal spray. The FDA approved NDA No. 202236 on May 1, 2012, allowing Meda to market DYMISTA® throughout the United States for the treatment of seasonal allergic rhinitis ("SAR").

21. The FDA lists the '723 and '620 patents in the Orange Book in connection with NDA No. 202236 because each individually claims the drug composition or methods for using the approved drug product. 21 U.S.C. § 355(b)(1). The '428 patent will be added to the Orange Book in connection with NDA No. 202236 within 30 days of issuance. 21 U.S.C. § 314.53(d)(3).

TEVA'S ANDA

22. By Notice Letter dated July 27, 2015, Teva USA notified Meda and Cipla that it had submitted or caused to be submitted ANDA No. 208436 and a Paragraph IV certification under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) for a Generic Product purportedly bioequivalent to Meda's DYMISTA® product.

23. The Notice Letter states that Teva seeks approval from the FDA to engage in the commercial manufacture, use, and sale of the Generic Product before the expiration of the '723 and '620 patents.

24. By filing ANDA No. 208436, Teva has necessarily represented to the FDA that its Generic Product has the same active ingredients as Meda's DYMISTA®, and is bioequivalent to DYMISTA®.

25. The product and the conditions of use for which Teva seeks approval in ANDA No. 208436 fall within one or more of the claims of the '723, '620, and '428 patents. If approved, the importation, manufacture, sale, offer for sale and/or use of Teva's Generic Product would infringe one or more claims of the '723, '620, and '428 patents.

26. The filing of ANDA No. 208436 evidences Teva's intent to compete with Meda and place Teva's Generic Product into the State of Delaware where Meda's DYMISTA® product is currently found.

27. The original Complaint was initially filed on September 8, 2015, within 45 days from the date Meda and Cipla received the Notice Letter. 35 U.S.C. § 355(j)(5)(B)(iii).

28. Upon review of ANDA No. 208436, Meda and Cipla allege that Teva's Generic Product as described in ANDA No. 208436 would infringe one or more claims of the '428 patent.

COUNT I: INFRINGEMENT OF THE '723 PATENT

29. Meda and Cipla reallege paragraphs 1 to 28 above as if fully set forth herein.

30. Teva's submission of ANDA No. 208436 infringes one or more claims of the '723 patent under 35 U.S.C. § 271(e)(2)(A).

31. Upon information and belief, if the FDA approves Teva's ANDA No. 208436, Teva will further infringe one or more claims of the '723 patent by making, using, offering to

sell, and selling its Generic Product in the United States and/or importing such sprays 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.

32. If Teva's marketing and sale of its Generic Product before the expiration of the '723 patent is not enjoined, Meda and Cipla will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '723 PATENT

33. Meda and Cipla reallege paragraphs 1 to 32 above as if fully set forth herein.

34. These claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

35. There is an actual case and controversy between Meda and Cipla on the one side, and Teva 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.

36. Teva has 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 Products.

37. Teva's actions indicate a refusal to change the course of its action in the face of acts by Meda and Cipla.

38. Any commercial manufacture, use, offer for sale, sale and/or importation of the Generic Products prior to patent expiry will constitute direct and/or contributory and/or active inducement of the '723 patent.

39. Unless Teva is enjoined from infringing, inducing infringement and contributing to the infringement of, the '723 patent, Meda and Cipla will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT III: INFRINGEMENT OF THE ’620 PATENT

40. Meda and Cipla reallege paragraphs 1 to 39 above as if fully set forth herein.

41. Teva’s submission of ANDA No. 208436 infringes one or more claims of the ’620 patent under 35 U.S.C. § 271(e)(2)(A).

42. Upon information and belief, if the FDA approves Teva’s ANDA No. 208436, Teva will further infringe one or more claims of the ’620 patent by making, using, offering to sell, and selling its Generic Product in the United States and/or importing such sprays 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.

43. If Teva’s marketing and sale of its Generic Product before the expiration of the ’620 patent is not enjoined, Meda and Cipla will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT IV: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’620 PATENT

44. Meda and Cipla reallege paragraphs 1 to 43 above as if fully set forth herein.

45. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

46. There is an actual case and controversy between Meda and Cipla on the one side, and Teva 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.

47. Teva has 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 Products.

48. Teva’s actions indicate a refusal to change the course of its action in the face of acts by Meda and Cipla.

49. Any commercial manufacture, use, offer for sale, sale and/or importation of the Generic Products prior to patent expiry will constitute direct and/or contributory and/or active inducement of the ’620 patent.

50. Unless Teva is enjoined from infringing, inducing infringement and contributing to the infringement of, the ’620 patent, Meda and Cipla will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT V: INFRINGEMENT OF THE ’428 PATENT

51. Meda and Cipla reallege paragraphs 1 to 50 above as if fully set forth herein.

52. Teva’s submission of ANDA No. 208436 infringes one or more claims of the ’428 patent under 35 U.S.C. § 271(e)(2)(A).

53. Upon information and belief, if the FDA approves Teva’s ANDA No. 208436, Teva will further infringe one or more claims of the ’428 patent by making, using, offering to sell, and selling its Generic Product in the United States and/or importing such sprays 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. If Teva’s marketing and sale of its Generic Product before the expiration of the ’428 patent is not enjoined, Meda and Cipla will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT VI: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’428 PATENT

55. Meda and Cipla reallege paragraphs 1 to 54 above as if fully set forth herein.

56. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

57. There is an actual case and controversy between Meda and Cipla on the one side, and Teva 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.

58. Teva has 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 Products.

59. Teva's actions indicate a refusal to change the course of its action in the face of acts by Meda and Cipla.

60. Any commercial manufacture, use, offer for sale, sale and/or importation of the Generic Products prior to patent expiry will constitute direct and/or contributory and/or active inducement of the '428 patent.

61. Unless Teva is enjoined from infringing, inducing infringement and contributing to the infringement of, the '428 patent, Meda and Cipla will suffer substantial and irreparable harm for which there is no adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Meda and Cipla respectfully request that this Court grant the following relief:

A. A judgment that Teva has infringed valid and enforceable claims of the '723, '620, and '428 patents 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. 208436 not be earlier than the latest of the expiration dates of the '723, '620, and '428 patents, inclusive of any extension(s) and additional period(s) of exclusivity;

C. A judgment declaring that Teva's manufacture, use, sale, offer for sale, or importation into the United States of the Generic Product for which approval is sought in ANDA No. 208436 would constitute infringement of the '723, '620, and '428 patents, or would induce or contribute to such infringement, pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

D. A permanent injunction enjoining Teva and its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making, using, selling, or offering to sell in the United States, or importing into the United States, the Generic Product for which approval is sought in ANDA No. 208436, or any generic azelastine hydrochloride and fluticasone propionate combination nasal spray product that infringes or induces or contributes to the infringement of the '723, '620, and '428 patents, until expiration of those patents;

E. A declaration under 28 U.S.C. § 2201 that if Teva, their officers, agents, servants, employees, licensees, representatives, and attorneys, and all 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 Products prior to patent expiry, it will constitute an act of direct and/or indirect infringement of the '723, '620, and '428 patents;

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.

ASHBY & GEDDES

/s/ Andrew C. Mayo

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 Plaintiffs
Meda Pharmaceuticals Inc. and Cipla Ltd.

Of Counsel:

H. Keeto Sabharwal
Dennies Varughese
Uma N. Everett
STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 New York Ave., N.W., Suite 800
Washington, DC 20005-3934
(202) 371-2600

Dated: February 29, 2016