IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDA PHARMACEUTICALS INC. and CIPLA LTD.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. _____
TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	)	
Defendants.	)	

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 defendants Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") (collectively, "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 the expiration of Plaintiff Cipla's U.S. Patent Nos. 8,163,723 ("the '723 patent") and 8,168,620 ("the '620 patent"), both of which cover the DYMISTA® drug product, and for both 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.

5. Upon information and belief, Teva Ltd. is a corporation organized and existing under the laws of Israel, having its principal place of business at 5 Basel Street, Petach Tikva 49131, Israel.

6. Upon information and belief, Teva USA is a wholly-owned subsidiary and agent of Teva Ltd. Teva USA acts at the direction, under the control, and for the benefit of Teva Ltd.

JURISDICTION AND VENUE

7. 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.

8. 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.

9. This Court also has personal jurisdiction over Teva USA because, *inter alia*,: (a) Teva USA is a Delaware corporation that knew it could be haled into court 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.

10. Upon information and belief, Teva Ltd. and Teva USA are agents of each other and/or work in concert with each other with respect to the development, regulatory approval, marketing, sale, and distribution of generic drug products throughout the United States, including into the State of Delaware.

11. Upon information and belief, Teva USA's tortious acts of preparing and filing ANDA No. 208436 and directing notice of its ANDA submission and Paragraph IV certification to Plaintiffs Meda and Cipla ("the Notice Letter") were performed at the direction of, with the authorization of and with the cooperation, participation, assistance and at least in part the benefit of Teva Ltd. These are acts with real and injurious consequences giving rise to this infringement action. And because Plaintiff Meda is a Delaware corporation, these injuries and consequences are suffered in Delaware. Therefore, Teva Ltd. and Teva USA together purposefully directed their activities towards the State of Delaware, where Meda is incorporated. And because defending against an infringement lawsuit such as this one is an inherent and expected part of a generic ANDA filer's business, they reasonably anticipated being haled into court in Delaware.

Furthermore, Teva knew or should have known that Plaintiffs had already begun related litigation in this Court to enforce the DYMISTA® patents against another ANDA filer and that Plaintiffs would almost certainly file an action against Teva in the same Court.

12. This Court has personal jurisdiction over Teva Ltd. and Teva USA because, *inter alia*, they waived any objection and consented to suit in the U.S. District Court for the District of Delaware. They purposefully availed themselves of the benefits and protections of this Court when they brought patent infringement actions in this Court. *See, e.g., Teva Pharmaceuticals USA, Inc. et al. v. Synthon Pharmaceuticals, Inc. et al.*, No. 1:14-cv-01419-GMS (D. Del.) and *Teva Pharmaceuticals USA, Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, No. 1:14-cv-01278-GMS (D. Del.). Teva Ltd. and Teva USA have also been sued in this judicial district without objecting on the basis of lack of personal jurisdiction. *See, e.g., UCB, Inc. et al. v. Teva Pharmaceuticals USA, Inc. et al.*, No. 1:13-cv-01148-LPS (D. Del.) and *Millennium Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc. et al.*, No. 1:14-cv-00093-GMS (D. Del.).

13. Therefore, this Court has personal jurisdiction over Teva Ltd. because, *inter alia*,: (a) Teva Ltd. has purposefully directed its activities and the activities of Teva USA, its wholly-owned subsidiary and a Delaware corporation, at residents and corporate entities within the State of Delaware; (b) the claims set forth herein as to Teva Ltd. arise out of or relate to those activities; (c) Teva Ltd.'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 Ltd.

14. Should Teva Ltd. deny all bases for personal jurisdiction alleged in Paragraphs 7 to 13, this Court has personal jurisdiction over Teva Ltd. under: (a) Fed. R. Civ. P. 4(k)(1); and/or (b) Fed. R. Civ. P. 4(k)(2).

15. 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 Ltd. and Teva USA.

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

REGULATORY REQUIREMENTS FOR APPROVAL OF NEW AND GENERIC DRUGS

17. 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.

18. 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").

19. 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.

20. 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

21. 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**.

22. 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**.

23. Plaintiff Cipla is the owner of the '723 and '620 patents.

24. Plaintiff Meda is the exclusive licensee of the '723 and '620 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 and '620 patents.

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

MEDA'S APPROVED DRUG PRODUCT: DYMISTA®

26. 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").

27. 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).

TEVA'S ANDA

28. 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.

29. 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.

30. 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®.

31. 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 and ’620 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 and ’620 patents.

32. The filing 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.

33. This Complaint is being filed within 45 days from the date Meda and Cipla received the Notice Letter. 35 U.S.C. § 355(j)(5)(B)(iii).

COUNT I: INFRINGEMENT OF THE ’723 PATENT

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

35. 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).

36. 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.

37. 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

38. Meda and Cipla reallege paragraphs 1 to 37 above as if fully set forth herein.

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

40. 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.

41. 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.

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

43. 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.

44. 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

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

46. 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).

47. 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.

48. 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

49. Meda and Cipla reallege paragraphs 1 to 48 above as if fully set forth herein.

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

51. 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.

52. 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.

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

54. 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.

55. 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.

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 and '620 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 and '620 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 and '620 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 and '620 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 and '620 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: September 8, 2015