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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MEDA PHARMACEUTICALS INC., Plaintiff, v. CADILA HEALTHCARE LTD. (d/b/a ZYDUS CADILA) and ZYDUS PHARMACEUTICALS USA, INC., Defendants.	Civil Action No. _____

COMPLAINT

Plaintiff Meda Pharmaceuticals Inc. ("Meda"), for its Complaint against Defendants Cadila Healthcare Ltd. (d/b/a Zydus Cadila) ("Zydus Cadila") and Zydus Pharmaceuticals USA, Inc. ("Zydus USA"), hereby alleges as follows.

PARTIES

1. Plaintiff Meda is a Delaware corporation having a principal place of business at 265 Davidson Avenue, Somerset, New Jersey 08873.

2. Upon information and belief, Zydus Cadila is a company organized and existing under the laws of India, having a place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad-380015 Gujarat, India, and is the parent corporation of Zydus USA.

3. Upon information and belief, Zydus Cadila develops and manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

4. Upon information and belief, Defendant Zydus USA is a corporation organized and existing under the laws of New Jersey, having a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

5. Upon information and belief, Zydus USA is a wholly owned subsidiary of Zydus Cadila and the United States agent for Zydus Cadila for purposes including, but not limited to, making regulatory submissions to the United States Food and Drug Administration ("FDA").

6. Upon information and belief, Zydus USA is the United States marketing and sales agent for Zydus Cadila wherein, following FDA approval of an Abbreviated New Drug Application ("ANDA"), Zydus Cadila manufactures and supplies the approved generic drug products to Zydus USA, which then markets and sells those products throughout the United States, including in this judicial district.

7. Upon information and belief, and consistent with its practice with respect to other generic products, Zydus Cadila will sell the proposed generic product accused of infringement in this Complaint through Zydus USA throughout the United States, including in this judicial district, following any FDA approval.

8. Upon information and belief, Zydus USA is the United States subsidiary, agent, and alter-ego of Zydus Cadila. Upon information and belief, for all purposes relevant to this action, Zydus USA and Zydus Cadila are effectively the same entity and are referred to collectively hereinafter as Zydus.

NATURE OF THE ACTION

9. This is a civil action for the infringement of United States Patent No. 8,071,073 ("the '073 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.

JURISDICTION AND VENUE

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

11. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to, and/or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to Meda in New Jersey. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for additional reasons that will be presented to the Court if such jurisdiction is challenged.

12. This Court has personal jurisdiction over Zydus Cadila by virtue of, *inter alia*: (1) its presence in New Jersey through its United States subsidiary, agent, and alter-ego, Zydus USA; and (2) its systematic and continuous contacts with New Jersey, including such contacts with New Jersey corporation Zydus USA; and (3) its specific contacts with New Jersey regarding the proposed generic product accused of infringement in this action, including such contacts with New Jersey corporation Zydus USA.

13. Upon information and belief, Zydus Cadila develops and manufactures generic drugs for sale and use throughout the United States, including this judicial district. Upon information and belief, Zydus Cadila derives substantial revenue from the sale of its products to customers in New Jersey.

14. As further evidence of personal jurisdiction, Zydus Cadila has previously been sued for patent infringement, and has consented to personal jurisdiction, in this judicial district. (*See*, *e.g.*, Civil Action Nos. 3:10-cv-1723, 3:07-cv-4942, and 3:12-cv-2813.)

15. This Court has personal jurisdiction over Zydus USA by virtue of, *inter alia*: (1) its presence in New Jersey, including its status as a New Jersey corporation; and (2) its systematic and continuous contacts with New Jersey.

16. Upon information and belief, Zydus USA sells numerous generic drugs manufactured and supplied by Zydus Cadila throughout the United States, including this judicial district.

17. Upon information and belief, Zydus USA is registered with the New Jersey Department of Health and Senior Services as a "Drug or Medical Device Manufacturing or Wholesale Drug or Medical Device Business" pursuant to N.J.S.A. 24:6B.

18. As further evidence of personal jurisdiction, Zydus USA has been sued for patent infringement, and has consented to personal jurisdiction, in this judicial district. (*See*, *e.g.*, Civil Action Nos. 3:10-cv-1723, 3:07-cv-4942, and 3:12-cv-2813.)

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

THE PATENT

20. On December 6, 2011, U.S. Patent No. 8,071,073 ("the '073 patent"), titled "Compositions Comprising Azelastine and Methods of Use Thereof," was duly and legally

issued to Meda Pharmaceuticals Inc. as assignee. Since the patent issued, Meda Pharmaceuticals Inc. has been, and continues to be, the sole owner of the '073 patent and the sole owner of the right to sue and to recover for any infringement of that patent. A copy of the '073 patent is attached hereto as Exhibit A.

21. The '073 patent is listed in the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") in connection with certain Meda Astepro® brand azelastine nasal spray products, including Meda's Astepro® brand azelastine 0.15% nasal spray product that delivers the equivalent of 0.1876 milligrams of base per spray ("the Meda Reference Product"), and has been so listed since no later than December 21, 2011.

ACTS GIVING RISE TO THIS ACTION

Count I – Infringement Of The '073 Patent

22. Upon information and belief, on or before June 18, 2012, but after the listing of the '073 patent in the Orange Book, Defendants submitted ANDA No. 20-3926 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). This ANDA seeks the FDA approval necessary to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of the Meda Reference Product. ANDA No. 20-3926 specifically seeks FDA approval to market a proposed generic version of the Meda Reference Product prior to the expiration of the '073 patent.

23. ANDA No. 20-3926 alleges under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '073 patent are either invalid or not infringed by the manufacture, use, or sale of the proposed generic version of the Meda Reference Product. Meda received written notification of ANDA No. 20-3926 and its § 505(j)(2)(A)(vii)(IV) allegation on or about June 19, 2012.

24. Defendants' submission of ANDA No. 20-3926 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegation, constitutes infringement of the '073 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if either of the Defendants commercially makes, uses, offers to sell, or sells in the United States, or imports into the United States, the proposed generic version of the Meda Reference Product, or induces or contributes to such conduct, it would further infringe the '073 patent under 35 U.S.C. § 271(a), (b), and/or (c).

25. Meda will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Meda does not have an adequate remedy at law.

26. Even if Zydus Cadila and Zydus USA are not treated as a single entity for the purposes of this action, which they should be, each of them is nonetheless jointly and severally liable for the infringement of the '073 patent.

27. Zydus USA is jointly and severally liable for infringement of the '073 patent. That is so because, upon information and belief, Zydus USA submitted ANDA No. 20-3926 to the FDA under § 505(j) and will, *inter alia*, offer to sell and sell the proposed generic version of the Meda Reference Product upon receipt of FDA approval.

28. Zydus USA's submission of ANDA No. 20-3926 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegation, constitutes infringement of the '073 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Zydus USA commercially makes, uses, offers to sell, or sells in the United States, or imports into the United States, the proposed generic version of the Meda Reference Product, or induces or contributes to any such conduct during the term of the '073 patent, it would further infringe the '073 patent under 35 U.S.C. § 271(a), (b), and/or (c).

29. Meda will be irreparably harmed by Zydus USA's infringing activities unless those actions are enjoined by this Court. Meda does not have an adequate remedy at law.

30. Zydus Cadila is jointly and severally liable for infringement of the '073 patent, regardless of which Zydus entity actually filed ANDA No. 20-3926 and regardless of whether Zydus USA is treated as an agent or alter-ego of Zydus Cadila for purposes of this action. This is so because, upon information and belief, Zydus Cadila participated in, contributed to, aided, abetted, and/or induced the submission of ANDA No. 20-3926 and its § 505(j)(2)(A)(vii)(IV) allegation to the FDA and will, *inter alia*, import the proposed generic version of the Meda Reference Product into the United States and this judicial district upon receipt of any FDA approval of ANDA No. 20-3926.

31. Zydus Cadila's participation in, contribution to, aiding, abetting, and/or inducement of the submission of ANDA No. 20-3926 and its §505(j)(2)(A)(vii)(IV) allegation to the FDA constitutes infringement of the '073 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Zydus Cadila commercially makes, uses, offers to sell, or sells in the United States, or imports into the United States, the proposed generic version of the Meda Reference Product, or induces or contributes to any such conduct during the term of the '073 patent, it would further infringe the '073 patent under 35 U.S.C. § 271(a), (b), and/or (c).

32. Meda will be irreparably harmed by Zydus Cadila's infringing activities unless those actions are enjoined by this Court. Meda does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Meda prays for judgment as follows:

A. That Defendants have infringed the '073 patent;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 20-3926 shall not be earlier than the expiration date of the '073 patent, including any extensions and exclusivities;

C. That Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling in the United States, or importing into the United States, the proposed generic version of the Meda Reference Product, and any other product that infringes or induces or contributes to the infringement of the '073 patent, prior to the expiration of the '073 patent, including any extensions and exclusivities;

D. That Meda be awarded monetary relief if any Defendant commercially makes, uses, offers for sale, or sells in the United States, or imports into the United States, the proposed generic version of the Meda Reference Product, or any other product that infringes or induces or contributes to the infringement of the '073 patent, prior to the expiration of that patent, including any extensions and exclusivities, and that such monetary relief be awarded to Meda with prejudgment interest;

E. That Meda be awarded the attorney fees, costs, and expenses that it incurs prosecuting this action under 35 U.S.C. §285; and

F. That Meda be awarded such other and further relief as this Court deems just and proper.

CERTIFICATION PURSUANT TO L.CIV.R. 11.2

Meda, by its undersigned counsel, hereby certifies pursuant to L.CIV.R. 11.2 that the patent at issue in this action is also the subject of the following action pending in this Court: *Meda Pharmaceuticals Inc. v. Apotex Inc., Apotex Corp., Perrigo Israel Pharmaceuticals Ltd., Perrigo Company, and L. Perrigo Company*, Civil Action No. 3:12-361 (JAP) (TJB). Except as so stated, the matters in controversy are not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: July 27, 2012

Respectfully submitted,

/s/ Thomas R. Curtin

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