

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MEDA PHARMACEUTICALS INC.,)	
)	
Plaintiff,)	
)	
vs.)	Civil Action No. _____
)	
SUN PHARMACEUTICAL INDUSTRIES)	
LTD.,)	
)	
Defendant.)	
)	

COMPLAINT

Plaintiff Meda Pharmaceuticals Inc. ("Meda"), for its Complaint against Defendant Sun Pharmaceutical Industries Ltd. ("Sun"), hereby alleges as follows:

PARTIES

1. Plaintiff Meda is a Delaware corporation having a place of business at 265 Davidson Avenue, Somerset, New Jersey 08873.
2. Upon information and belief, Defendant Sun is an Indian corporation having a place of business at Acme Plaza, Andheri - Kurla Rd, Andheri (E), Mumbai - 400 059. Upon information and belief, Defendant Sun manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district. Sun has appointed an agent authorized to accept service of process in New Jersey.

NATURE OF THE ACTION

3. This is a civil action for the infringement of United States Patent No. 5,164,194 ("the '194 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

JURISDICTION AND VENUE

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

5. This Court has personal jurisdiction over Defendant Sun by virtue of, *inter alia*: (1) its consent to personal jurisdiction in Delaware in the related action *Meda Pharmaceuticals Inc. v. Sun Pharmaceutical Industries Ltd.*, No. 1:07-cv-00407-SLR; (2) its systematic and continuous contacts with Delaware; (3) its placement of goods into the stream of commerce for distribution throughout the United States, including Delaware; and (4) the fact that Sun has committed, and/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 a Delaware corporation, Plaintiff Meda, in Delaware.

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

THE PATENT

7. On November 17, 1992, the '194 patent, titled "AzelaStine Containing Medicaments," was duly and legally issued to Asta Pharma AG as assignee. Since August 16, 2002, Meda has been, and continues to be, the sole owner of the '194 patent and the sole owner of the right to sue and to recover for any infringement of that patent. A copy of the '194 patent is attached hereto as Exhibit A.

ACTS GIVING RISE TO THIS ACTION

COUNT I – INFRINGEMENT OF THE '194 PATENT BY DEFENDANT SUN

8. Upon information and belief, on or after November 14, 2005, Defendant Sun submitted ANDA 90-423 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)).

9. ANDA 90-423 seeks the FDA approval necessary to engage in the commercial manufacture, use, offer for sale and sale of a generic nasal spray product containing 0.1% azelastine hydrochloride in an aqueous solution for use in treating, *inter alia*, seasonal allergic rhinitis ("the Generic Product"). ANDA 90-423 specifically seeks FDA approval to market the Generic Product prior to the expiration of the '194 patent.

10. ANDA 90-423 contains an allegation under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '194 patent are either invalid or not infringed by the manufacture, use or sale of the Generic Product. Upon information and belief, Meda received written notification of ANDA 90-423 and its § 505(j)(2)(A)(vii)(IV) allegation on February 26, 2009.

11. Sun's submission of ANDA 90-423 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegation, constitutes infringement of the '194 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Sun commercially makes, uses, offers to sell or sells the Generic Product within the United States, or imports the Generic Product into the United States, or induces or contributes to any such conduct during the term of the '194 patent, it would further infringe the '194 patent under 35 U.S.C. § 271 (a), (b) and/or (c).

12. Sun had actual and constructive notice of the '194 patent prior to filing ANDA 90-423.

13. Meda will be irreparably harmed by Defendant Sun's infringing activities unless those activities are enjoined by this Court. Meda does not have an adequate remedy at law. Both the balance of the hardships as between Meda and Sun and the public interest further support this Court enjoining Sun's infringing activities.

PRAYER FOR RELIEF

WHEREFORE, Meda prays for judgment as follows:


- A. That Defendant Sun has infringed the '194 patent;
- B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA 90-423 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration date of the '194 patent, including any extensions;
- C. That Defendant Sun, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from making, using, offering for sale or selling the Generic Product within the United States, or importing the Generic Product into the United States, prior to the expiration of the '194 patent, including any extensions;
- D. That Meda be awarded monetary relief if Defendant Sun commercially makes, uses, offers for sale or sells the Generic Product within the United States, or imports the Generic Product into the United States, prior to the expiration of the '194 patent, including any extensions, and that any 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.

Of Counsel:

John M. Desmarais
Peter J. Armenio
Anne S. Toker
KIRKLAND & ELLIS LLP
Citigroup Center
153 East 53rd Street
New York, New York 10022
(212) 446-4800

Dated: April 9, 2009



Frederick D. Cottrell, III (#2555)
Kelly E. Farnan (#4395)
Richards, Layton & Finger, P.A.
One Rodney Square
920 North King Street
Wilmington, Delaware 19801
(302) 651-7700
cottrell@rlf.com
farnan@rlf.com

*Attorneys for Plaintiff
Meda Pharmaceuticals Inc*