

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

MEDPOINTE HEALTHCARE INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. _____
)	
SUN PHARMACEUTICAL INDUSTRIES)	
LTD.,)	
)	
Defendant.)	

COMPLAINT

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

PARTIES

1. Plaintiff MedPointe Healthcare Inc. ("MedPointe") 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.

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. §100 *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 Sun by virtue of, *inter alia*, its consent to personal jurisdiction in this judicial district for purposes of this action.

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

8. Upon information and belief, on or after December 13, 2006, Sun submitted ANDA 78-738 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)).

9. A under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)).

10. ANDA 78-738 seeks the FDA approval necessary to engage in the commercial manufacture, use, offer for sale and sale of a generic ophthalmic solution product containing 0.05% azelastine hydrochloride in an aqueous solution for use in treating, *inter alia*,

seasonal allergic rhinitis ("the Generic Product"). ANDA 78-738 specifically seeks FDA approval to market the Generic Product prior to the expiration of the '194 patent.

11. ANDA 78-738 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, unenforceable and/or not infringed by the manufacture, use or sale of the Generic Product. MedPointe received written notification of ANDA 78-738 and its § 505(j)(2)(A)(vii)(IV) allegation on May 14, 2007.

12. Sun's submission of ANDA 78-738 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).

13. Sun had actual and constructive notice of the '194 patent prior to filing ANDA 78-738.

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

PRAYER FOR RELIEF

WHEREFORE, MedPointe prays for judgment as follows:

- A. That 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 78-738 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 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 to sell 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 MedPointe be awarded monetary relief 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, prior to the expiration of the '194 patent, including any extensions, and that any such monetary relief be awarded to MedPointe with prejudgment interest;
- E. That MedPointe be awarded the attorney fees, costs and expenses that it incurs prosecuting this action under 35 U.S.C. §285; and
- F. That MedPointe be awarded such other and further relief as this Court deems just and proper.



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