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ATTORNEYS FOR PLAINTIFF
SCHERING CORPORATION

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

_____)	
SCHERING CORPORATION,)	
)	
Plaintiff,)	
)	
vs.)	Civil Action No. _____
)	
MYLAN PHARMACEUTICALS INC.,)	
)	
Defendant.)	
)	
_____)	

COMPLAINT

Plaintiff Schering Corporation ("Schering"), for its Complaint against Defendant Mylan Pharmaceuticals Inc. ("Mylan"), hereby alleges as follows.

Parties

1.A. Plaintiff Schering is a New Jersey corporation having places of business throughout New Jersey, including a place of business at 3070 Route 22 West, Branchburg, New Jersey 08876.

1.B. Upon information and belief, Defendant Mylan is a West Virginia corporation having a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26504. Upon information and belief, Defendant Mylan is registered to do business in New Jersey and has appointed Corporation Service Company of West Trenton, New Jersey as its registered agent in New Jersey for the receipt of service of process.

Nature of the Action

2. This is a civil action for the infringement of United States Patent No. 7,405,223 ("the '223 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. §1 *et seq.*

Jurisdiction and Venue

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

4. This Court has personal jurisdiction over Defendant Mylan by virtue of, *inter alia*: (1) its presence in New Jersey; (2) its systematic and continuous contacts with New Jersey; and (3) its registration to do business in New Jersey including its appointment of a registered agent in New Jersey for the receipt of service of process.

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

The Patent

6. On July 29, 2008, the '223 patent, titled "Treating Allergic And Inflammatory Conditions," was duly and legally issued to Schering as assignee. Since that time, Schering has been, and continues to be, the sole owner of the '223 patent and the sole owner of the right to sue and to recover for any infringement of that patent. A copy of the '223 patent is attached hereto as Exhibit A.

Acts Giving Rise To This Action

7. Upon information and belief, on or after June 21, 2006, Defendant Mylan submitted ANDA 78-351 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA 78-351 seeks the FDA approval necessary to engage in the commercial manufacture, use, offer for sale and sale of generic tablets containing 5 milligrams of desloratadine per tablet. Upon information and belief, ANDA 78-351 was recently amended to specifically seek FDA approval to market these proposed generic tablets as an AB-rated generic substitution for Schering's Clarinex® brand 5 milligram desloratadine tablet product prior to the expiration of the '223 patent.

8. ANDA 78-351 now alleges under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '223 patent are either invalid or not infringed by the manufacture, use or sale of its proposed generic version of Schering's Clarinex® brand 5 milligram desloratadine tablet product. Upon information and belief, Schering received written notification of ANDA 78-351 and its new § 505(j)(2)(A)(vii)(IV) allegations against the '223 patent on or about January 13, 2009.

9. Mylan's submission of ANDA 78-351 to the FDA, including its new § 505(j)(2)(A)(vii)(IV) allegation regarding the '223 patent, constitutes infringement of the '223

patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Mylan commercially uses, offers for sale or sells the proposed generic version of Schering's Clarinex® brand 5 milligram desloratadine tablet product, or induces or contributes to such conduct, it would further infringe the '223 patent under 35 U.S.C. § 271(a), (b) and/or (c).

10. Schering will be irreparably harmed by Defendant Mylan's infringing activities unless those activities are enjoined by this Court. Schering does not have an adequate remedy at law. The balance of hardships and public interest also favor an injunction.

Prayer For Relief

WHEREFORE, Schering prays for judgment as follows:

- A. That Defendant Mylan has infringed the '223 patent;
- B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA 78-351 shall not be earlier than the expiration date of the '223 patent, including any extensions;
- C. That Defendant Mylan, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from commercially using, offering for sale or selling the proposed generic product defined by ANDA 78-351, and any other product that infringes or induces or contributes to the infringement of the '223 patent, prior to the expiration of the '223 patent, including any extensions;
- D. That Schering be awarded monetary relief if Defendant Mylan commercially manufactures, uses, offers for sale or sells the proposed generic product defined by ANDA 78-351, or any other product that infringes or induces or contributes to the infringement

of the '223 patent, within the United States prior to the expiration of that patent, including any extensions, and that any such monetary relief be awarded to Schering with prejudgment interest;

E. That Schering be awarded the attorney fees, costs and expenses that it incurs prosecuting this action; and

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

Dated: February 26, 2009

Respectfully submitted,

s/ William J. O'Shaughnessy

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