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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. \_\_\_\_\_

DR. REDDY'S LABORATORIES, INC. and )

DR. REDDY'S LABORATORIES, LTD., )

Defendants. )  
\_\_\_\_\_

**COMPLAINT**

Plaintiff Schering Corporation ("Schering"), for its Complaint against Defendants  
Dr. Reddy's Laboratories, Inc. ("DRLI") and Dr. Reddy's Laboratories, Ltd. ("DRLL"),  
(collectively, "DRL"), 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 DRLI is a New Jersey corporation and wholly-owned subsidiary, agent and alter-ego of DRLL having a place of business at 200 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807.

1.C. Upon information and belief, Defendant DRLL is an Indian corporation having a place of business at 7-1-27 Ameerpet, Hyderabad 500 016, Andhra Pradesh, India. Upon information and belief, Defendant DRLL manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district, through its wholly owned subsidiary, agent and alter-ego Defendant DRLI.

1.D. Upon information and belief, Defendants DRLI and DRLL have appointed Lee C. Banks, Esq. of Defendant DRLI, which is located at 200 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807, as their agent in New Jersey for the receipt of any service of process in this action.

**Nature of the Action**

2. This is a civil action for the infringement of United States Patent No. 6,100,274 ("the '274 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 Defendants DRLI and DRLL 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 a New Jersey corporation, Plaintiff Schering, in New Jersey. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

5. This Court has personal jurisdiction over Defendant DRLI by virtue of, *inter alia*: (1) the fact that DRLI is a New Jersey corporation; (2) its appointment of an agent to receive service of process in New Jersey; and (3) its admission that this Court has personal jurisdiction over it in *Schering Corp. v. Zydus Pharmaceuticals, USA, Inc. et al.*, 3:06-cv-04715-MLC-TJB, in which DRL stated in its January 10, 2007 Answer To Amended Complaint And Counterclaims that "DRL admits that DRL, Inc. is subject to personal jurisdiction within this judicial district."

6. This Court has personal jurisdiction over Defendant DRLL by virtue of, *inter alia*: (1) its appointment of an agent to receive service of process in New Jersey; (2) its presence in New Jersey, including through its subsidiary, agent, and alter ego; (3) its systematic and continuous contacts with New Jersey, including through its subsidiary, agent and alter ego; and (4) its admission that this Court has personal jurisdiction over it in *Schering Corp. v. Zydus Pharmaceuticals, USA, Inc. et al.*, 3:06-cv-04715-MLC-TJB, in which DRL stated in its January

10, 2007 Answer To Amended Complaint And Counterclaims that "DRL admits that DRL, Ltd. is subject to personal jurisdiction within this judicial district."

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

#### **The Patents**

8. On August 8, 2000, the '274 patent, titled "8-Chloro-6,11-Dihydro-11-(4-Piperidylidene)-5H-Benzo[5,6]Cyclohepta[1,2-b]Pyridine Oral Compositions," was duly and legally issued to Schering as assignee. Since that time, Schering has been, and continues to be, the sole owner of the '274 patent and the sole owner of the right to sue and to recover for any infringement of that patent. A copy of the '274 patent is attached hereto as Exhibit A.

#### **Acts Giving Rise to this Action**

9. Upon information and belief, on or after June 21, 2006, Defendant DRLL, through its subsidiary, agent and alter-ego Defendant DRLI, submitted Abbreviated New Drug Application ("ANDA") 78-365 to the United States Food and Drug Administration ("FDA") under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA 78-365 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. ANDA 78-365 specifically seeks FDA approval to market a proposed generic version of Schering's Clarinex<sup>®</sup> brand desloratadine 5 milligram tablet product prior to the expiration of the '274 patent.

10. ANDA 78-365 alleges under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '274 patent are either invalid, unenforceable, or not infringed by the manufacture, use or sale of the proposed generic version of Schering's Clarinex<sup>®</sup>

brand desloratadine 5 milligram tablet product. Schering received written notification of ANDA 78-365 and its § 505(j)(2)(A)(vii)(IV) allegation on September 7, 2007.

11. DRLL's submission of ANDA 78-365 to the FDA, through DRLI, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '274 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if DRLL commercially uses, offers for sale or sells the proposed generic version of Schering's Clarinex<sup>®</sup> brand desloratadine 5 milligram tablet product, or induces or contributes to such conduct, it would further infringe the '274 patent under 35 U.S.C. § 271(a), (b) and/or (c).

12. DRLI is jointly and severally liable for any infringement of the '274 patent. This is so because, upon information and belief, DRLI participated in, contributed to, aided, abetted and/or induced the submission of ANDA 78-365 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

13. DRLI's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 78-365 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '274 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if DRLI commercially manufactures, uses, offers for sale or sells the proposed generic version of Schering's Clarinex<sup>®</sup> brand desloratadine 5 milligram tablet product within the United States, or induces or contributes to any such conduct, it would further infringe the '274 patent under 35 U.S.C. § 271(a), (b) and/or (c).

14. Schering will be irreparably harmed by Defendant DRLL's and Defendant DRLI's infringing activities unless those activities are enjoined by this Court. Schering does not have an adequate remedy at law.

**Prayer for Relief**

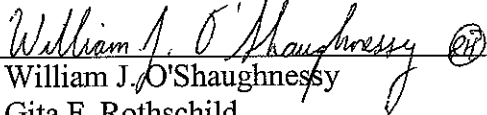
**WHEREFORE**, Schering prays for judgment as follows:

- A. That Defendants DRLI and DRLL have infringed the '274 patent;
- B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA 78-365 shall not be earlier than the expiration date of the '274 patent, including any extensions;
- C. That Defendants DRLI and DRLL, 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 the proposed generic product defined by ANDA 78-365, and any other product that infringes or induces or contributes to the infringement of the '274 patent, prior to the expiration of the '274 patent, including any extensions;
- D. That Schering be awarded monetary relief if Defendant DRLI and/or Defendant DRLL commercially manufactures, uses, offers for sale or sells the proposed generic product defined by ANDA 78-365, or any other product that infringes or induces or contributes to the infringement of the '274 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: October 19, 2007

Respectfully submitted,

  
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