

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

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RELIANT PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
PAR PHARMACEUTICAL, INC.	)	
	)	
Defendant.	)	

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Civil Action No.

**COMPLAINT**

Plaintiff Reliant Pharmaceuticals, Inc., for its Complaint against Defendant Par Pharmaceutical, Inc., hereby alleges as follows:

**PARTIES**

1. Plaintiff Reliant Pharmaceuticals, Inc. (“Reliant”) is a Delaware corporation having a principal place of business at 110 Allen Road, Liberty Corner, New Jersey 07938.
2. Upon information and belief, Defendant Par Pharmaceutical, Inc. (“Par”) is a Delaware Corporation having a principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

**NATURE OF ACTION**

3. This is a civil action for infringement of United States Patent No. 5,681,588 (“the ‘588 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 Par because Par is a Delaware corporation, and because Par has had consistent and continuous contacts within this judicial district.

6. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b), as Par resides in this judicial district.

## THE PATENT

7. On October 28, 1997, the '588 patent, entitled "Delayed Release Microtablet of  $\beta$ -phenylpropiophenone Derivatives" was duly and legally issued to Knoll Aktiengesellschaft as assignee. Plaintiff Reliant is the current assignee of the '588 patent. Reliant holds New Drug Application ("NDA") No. 21-416 on Rythmol<sup>®</sup> SR brand propafenone HCl extended release capsules, and is the exclusive distributor of Rythmol<sup>®</sup> SR in the United States. Reliant has the right to sue and recover for any infringement of the '588 patent. A copy of the '588 patent is attached hereto as Exhibit A.

## ACTS GIVING RISE TO THIS ACTION

8. Upon information and belief, before November 7, 2006, Par submitted an Abbreviated New Drug Application ("Par's ANDA") 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)). Upon information and belief, Par's ANDA seeks the FDA approval necessary for Par to engage in the commercial manufacture, use and sale of generic Propafenone HCl SR capsules, including generic 325 mg Propafenone HCl SR capsules ("the Generic Products"). Upon

information and belief, Par's ANDA specifically seeks FDA approval to market the Generic Products prior to the expiration of the '588 patent.

9. Upon information and belief, Par alleged, under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, that the claims of the '588 patent are invalid, unenforceable and/or not infringed by the manufacture, use or sale of the Generic Products. Reliant received written notification of Par's ANDA and its § 505(j)(2)(A)(vii)(IV) allegations on November 8, 2006.

10. The submission of Par's ANDA to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegation, constitutes infringement of the '588 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, any commercial manufacture, use, offer to sell, sale or import of the Generic Products would further infringe the '588 patent under 35 U.S.C. § 271(a), (b) and/or (c).

11. Reliant will be irreparably harmed by Par's infringing activities unless those activities are enjoined by this Court. Reliant does not have an adequate remedy at law.

#### PRAYER FOR RELIEF

WHEREFORE, Reliant prays for judgment as follows:

A. That Par has infringed the '588 patent;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Par's ANDA 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 '588 patent, including any extensions;

C. That Par, its 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 to sell, selling or importing any Generic

Products, and any other product that infringes or induces or contributes to the infringement of the '588 patent, prior to the expiration of the '588 patent, including any extensions;


D. That Reliant be awarded monetary relief if Par commercially manufactures, uses, offers to sell, sells or imports any Generic Products, or any other product that infringes or induces or contributes to the infringement of the '588 patent, within the United States prior to the expiration of the '588 patent;

E. That, based on Par's conduct, this be declared an exceptional case pursuant to 35 U.S.C. § 285;

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

G That Reliant be awarded such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

  
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