IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS, INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA, Plaintiffs, v. PAR PHARMACEUTICAL, INC., Defendant.	Civil Action No.: 07-808-JJF-LPS **REDACTED VERSION DI 18**

PLAINTIFFS' BRIEF IN SUPPORT OF MOTION TO DISMISS
PAR PHARMACEUTICAL'S COUNTERCLAIM COUNTS IV AND V

Ford F. Farabow Charlie E. Lipsey York M. Faulkner FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P. 901 New York Avenue, N.W. Washington, D.C. 20001 Telephone: (202) 408-4000 Facsimile: (202) 408-4400 Henry J. Renk FITPATRICK, CELLA, HARPER & SCINTO 30 Rockefeller Plaza New York, NY 10112 Telephone: (212) 218-2100 Facsimile: (212) 218-2200 *Of Counsel for Plaintiffs,* AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha	Mary W. Bourke (#2356) CONNOLLY BOVE LODGE & HUTZ LLP 1007 N. Orange Street Wilmington, DE 19899 Telephone: (302) 658-9141 Facsimile: (302) 658-5614 mbourke@cblh.com *Attorneys for Plaintiffs*

Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha (collectively "AstraZeneca") move to dismiss Par Pharmaceutical, Inc.'s Counterclaim Counts IV (Declaration of Noninfringement of the '460 Patent) and V (Declaration of Invalidity of the '460 Patent) (D.I. 11) for lack of subject matter jurisdiction pursuant to Fed. R. Civ. P. 12(b)(1).

I. THE NATURE AND STAGE OF THE PROCEEDING

AstraZeneca has sued Par Pharmaceutical, Inc. ("Par") for infringement of U.S. Reissue Patent RE37,314 ("the '314 patent") under 35 U.S.C. § 271(e)(2)(A) and for a declaratory judgment under 35 U.S.C. § 271(a) based on threatened infringement. The action results from Par filing Abbreviated New Drug Application ("ANDA") No. 79-168 with the United States Food and Drug Administration ("FDA") and Par's certification to the FDA that it intends to market generic versions of AstraZeneca's highly successful drug CRESTOR® before the '314 patent expires.

Par is one of seven generic pharmaceutical companies to so challenge the '314 patent. In an effort to resolve the multiple challenges to its patent rights, AstraZeneca filed seven related patent infringement actions, including this one, in the District of Delaware on December 11, 2007 (C.A. Nos. 07-805, 07-806, 07-807, 07-808, 07-809, 07-810, and 07-811). The Complaint in each action alleges infringement of the '314 patent as noted above. In its Answer and Counterclaims (D.I. 11), Par raised two counterclaims requesting declaratory judgment of invalidity and noninfringement of a patent not asserted by AstraZeneca–U.S. Patent No. 6,316,460 ("the '460 patent"). This motion seeks the dismissal of those counterclaims.

II. SUMMARY OF ARGUMENT

REDACTED

REDACTED

III. STATEMENT OF FACTS

This case relates to AstraZeneca's CRESTOR® pharmaceutical product, and Par's efforts to sell a generic version of CRESTOR® before expiration of the pioneer patent on the active ingredient, rosuvastatin calcium. On November 5, 2007, Par notified AstraZeneca of its ANDA and intentions to obtain FDA approval to engage in the manufacture, importation, use, or sale of rosuvastatin calcium before the '314 patent (covering the active ingredient in CRESTOR®) and the '460 patent (covering certain drug formulations containing that active ingredient) expire, alleging that these patents are invalid, unenforceable, and/or will not be infringed. In response to this notification, AstraZeneca filed suit against Par.

In its Complaint, AstraZeneca only asserted infringement of the '314 patent. (D.I. 1.) In its Answer and Counterclaims, however, Par counterclaimed for declaratory judgment of non-infringement and invalidity of the unasserted '460 patent. (D.I. 11 ¶¶ 64-71.)

REDACTED

AstraZeneca now moves to dismiss Par's Counterclaim Counts IV and V, regarding the validity and infringement of the '460 patent, for lack of subject matter jurisdiction pursuant to Fed. R. Civ. P. 12(b)(1).

IV. ARGUMENT

> Pursuant to Federal Rule of Civil Procedure 12(b)(1), the Court is authorized to dismiss a complaint, or in this case, a counterclaim, if the Court lacks subject matter jurisdiction over the claims alleged.... Once the Court's subject matter jurisdiction over a counterclaim is challenged, the counterclaim plaintiff bears the burden of proving that jurisdiction exists.

Pfizer, Inc. v. Ranbaxy Labs. Ltd, 525 F. Supp. 2d 680, 684 (D. Del. 2007) (citations omitted). To establish jurisdiction under the Declaratory Judgment Act, Par bears the burden of proving that the facts alleged "under all the circumstances show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 771 (2007); *see also Pfizer*, 525 F. Supp. 2d at 684.

REDACTED

In *Pfizer*, Pfizer brought suit against Ranbaxy on two Orange Book-listed patents. 525 F. Supp. 2d at 683-84. In response, Ranbaxy raised, *inter alia*, counterclaims of invalidity, noninfringement, and unenforceability of an unasserted patent,

REDACTED

[1] The Federal Circuit had declared a claim of the unasserted patent invalid in previous litigation between the parties, and Pfizer sought reissue of that patent to correct errors in the claims. *Pfizer*, 525 F. Supp. 2d at 683-84.

REDACTED

Ranbaxy's counterarguments regarding the prospect of future litigation related to the potential reissue patent were unavailing, as the Court found those claims "speculative, purely hypothetical and unripe for judicial determination." *Id.* at 686-87; *see also id.* at 687 (advisory opinions are "wholly inconsistent with the most basic precepts of jurisdictional jurisprudence").

REDACTED

REDACTED

V. CONCLUSION

For the forgoing reasons, AstraZeneca respectfully requests that this Court follow its recent decisions in similar disputes, and dismiss Par's Counterclaim Counts IV and V for lack of subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1).

Ford F. Farabow
Charlie E. Lipsey
York M. Faulkner
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.
901 New York Avenue, N.W.
Washington, D.C. 20001
Telephone: (202) 408-4000
Facsimile: (202) 408-4400

Henry J. Renk
FITPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, NY 10112
Telephone: (212) 218-2100
Facsimile: (212) 218-2200

Of Counsel for Plaintiffs,
AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha

REDACTED VERSION: March 28, 2008
Dated: March 21, 2008

Respectfully Submitted:

/s/ Mary W. Bourke

Mary W. Bourke (#2356)
CONNOLLY BOVE LODGE & HUTZ LLP
1007 N. Orange Street
Wilmington, DE 19899
Telephone: (302) 658-9141
Facsimile: (302) 658-5614
mbourke@cblh.com
Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify on this 28th day of March, 2008 I electronically filed the foregoing Redacted Version DI 18 **PLAINTIFFS' BRIEF IN SUPPORT OF MOTION TO DISMISS PAR PHARMACEUTICAL'S COUNTERCLAIM COUNTS IV AND V** with the Clerk of Court using CM/ECF which will send notification of such filing to the following:

Steven J. Fineman
RICHARDS, LAYTON & FINGER P.A.
One Rodney Square
920 N. King Street
Wilmington, DE 19801
Telephone: 302-651-7700
Fax: 302-651-7701
Fineman@rlf.com

The undersigned counsel further certifies that, on March 28, 2008, copies of the foregoing document were also served upon the following individuals in the manner indicated:

Via Email:
Frederick L. Cottrell, III
Steven J. Fineman
RICHARDS, LAYTON & FINGER P.A.
One Rodney Square
920 N. King Street
Wilmington, DE 19801
Telephone: 302-651-7700
Fax: 302-651-7701
Cottrell@rlf.com
Fineman@rlf.com

Via Email:
Edgar H. Haug
Daniel G. Brown
FROMMER LAWRENCE & HAUG LLP
745 Fifth Avenue
New York, NY 10151
Phone: 212-588-0800
Phone: 212-558-0500
ehaug@flhlaw.com
dbrown@flhlaw.com

CONNOLLY BOVE LODGE & HUTZ LLP

By: */s/ Mary W. Bourke*
Mary W. Bourke (#2356)
1007 N. Orange Street
Wilmington, DE 19899
Telephone: (302) 658-9141
Facsimile: (302) 658-5614
mbourke@cblh.com

601378

EXHIBIT 1
FULLY REDACTED