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. COBALT PHARMACEUTICALS INC., and COBALT LABORATORIES INC., Defendants.	Civil Action No.: 07-811-JJF-LPS **REDACTED VERSION DI 25**

PLAINTIFFS' BRIEF IN SUPPORT OF MOTION TO DISMISS
COBALT'S FOURTH CLAIM FOR RELIEF

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Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha (collectively "AstraZeneca") move to dismiss Defendants' Fourth Claim for Relief: Declaratory Judgment of Noninfringement or Invalidity of the '460 Patent (D.I. 16) 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 Cobalt Pharmaceuticals Inc. and Cobalt Laboratories Inc. (collectively "Cobalt") 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 Cobalt filing Abbreviated New Drug Application ("ANDA") No. 79-167 with the United States Food and Drug Administration ("FDA"), and Cobalt's certification to the FDA that it intends to market generic versions of AstraZeneca's highly successful drug CRESTOR® before the '314 patent expires.

Cobalt 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, Defenses, and Counterclaims (D.I. 16), Cobalt raised a counterclaim requesting declaratory judgment of invalidity or noninfringement of a patent not asserted by AstraZeneca–U.S. Patent No. 6,316,460 ("the '460 patent"). This motion seeks to dismiss that counterclaim.

II. SUMMARY OF ARGUMENT

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III. STATEMENT OF FACTS

This case relates to AstraZeneca's CRESTOR® pharmaceutical product, and Cobalt's efforts to sell a generic version of CRESTOR® before expiration of the pioneer patent on the active ingredient, rosuvastatin calcium. On October 29, 2007, Cobalt 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 Cobalt.

In its Complaint, AstraZeneca only asserted infringement of the '314 patent. (D.I. 1.) In its Answer, Defenses, and Counterclaims, however, Cobalt counterclaimed for declaratory judgment of non-infringement or invalidity of the unasserted '460 patent. (D.I. 16 ¶¶ 41-43.)

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AstraZeneca now moves to dismiss Cobalt's Fourth Claim for Relief 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, Cobalt 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.

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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,

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[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.

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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").

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V. CONCLUSION

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

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REDACTED VERSION: March 28, 2008
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Respectfully Submitted:

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CERTIFICATE OF SERVICE

I hereby certify on this 28th day of March, 2008 I electronically filed the foregoing Redacted Version DI 25 PLAINTIFFS' BRIEF IN SUPPORT OF MOTION TO DISMISS COBALT'S FOURTH CLAIM FOR RELIEF with the Clerk of Court using CM/ECF which will send notification of such filing to the following:

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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:

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EXHIBIT 1
FULLY REDACTED