IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

CEPHALON, INC. and UNIVERSITY OF UTAH RESEARCH FOUNDATION, Plaintiffs, v BARR LABORATORIES, INC., Defendant.	Civil Action No. 05-29-JJF

PLAINTIFFS' MOTION TO DISMISS COUNTERCLAIM

Plaintiffs and counterclaim-defendants Cephalon, Inc. ("Cephalon") and the University of Utah Research Foundation (the "Foundation") (collectively, the "Plaintiffs"), hereby move to dismiss the Counterclaim of defendant and counterclaim-plaintiff Barr Laboratories, Inc. ("Barr") ("Motion") As set forth below, under the recent amendments to the applicable statutory framework which governs Abbreviated New Drug Application ("ANDA") patent infringement litigation of this type, because the Plaintiffs commenced suit against Barr within the forty-five day period set forth in the relevant statutes, Barr has not met the statutory prerequisites for pursuing its declaratory judgment claims against the Plaintiffs and, pursuant to Fed. R. Civ. P. 12(b)(1), the Court lacks subject matter jurisdiction to hear Barr's Counterclaim.

As grounds for this Motion, the Plaintiffs state as follows:

1. As set forth in the Plaintiffs' Complaint, U.S. Patent No. 4,863,737 (the "'737 Patent"), entitled "Compositions and Methods of Manufacture of Compressed Powder Medicaments," was issued on September 5, 1989 by the United States Patent and Trademark

Office to Theodore H. Stanley and Brian Hague. The '737 Patent was assigned to the University of Utah, and subsequently assigned to the Foundation. The '737 Patent expires on September 5, 2006. Cephalon is the exclusive licensee under the '737 Patent. In the United States, Cephalon sells drug products under the trademark ACTIQ®, an oral transmucosal fentanyl citrate which is a solid drug matrix on a handle. ACTIQ® is covered by the claims of the '737 Patent.

2. By letters dated December 7, 2004, December 20, 2004, and December 21, 2004 (the "Barr Notice Letters"), Barr notified Cephalon that Barr had submitted ANDA No. 77-312 (the "Barr ANDA") to the U.S. Food and Drug Administration under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, and sale of a generic version of ACTIQ® before the expiration date of the '737 Patent. In the Barr Notice Letters, Barr notified Cephalon that its ANDA contained a "paragraph IV certification" asserting that, in Barr's opinion, the commercial manufacture, use or sale of the products described in the Barr ANDA will not infringe any valid or enforceable claim of the '737 Patent.

3. On January 20, 2005, the Plaintiffs filed the present action against Barr, alleging, inter alia, that Barr's submission of its ANDA constitutes infringement of one or more of the valid claims of the '737 Patent under 35 U.S.C. § 271(e)(2)(A). This action was filed within forty-five days of Plaintiffs' receipt of the Barr Notice Letters.

4. On February 10, 2005, Barr filed its Answer, Affirmative Defenses and Counterclaim. Barr's Counterclaim seeks a declaratory judgment that: (1) the '737 Patent will not be infringed by the manufacture, use or sale of the products described in the Barr ANDA; and (2) one or more claims of the '737 Patent are invalid.

5 On December 8, 2003, Congress enacted several changes to Section 505(j) of the Federal Food, Drug and Cosmetic Act, which provides the statutory framework for ANDA patent infringement litigation such as the present case. Congress enacted these changes as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "Medicare Act"), Pub. L. No. 108-173, 117 Stat. 2066. One of these revised sections, codified at 21 U.S.C. § 355(j)(5)(C), provides that an ANDA applicant may not seek a declaratory judgment for invalidity or non-infringement unless three conditions are met. The statute provides, in relevant part:

> (C) Civil action to obtain patent certainty. –
> (i) Declaratory judgment absent infringement action –
> (I) In general. – No action may be brought under section 2201 of Title 28 [United States Code], by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless--
> (aa) the 45-day period referred to in such subparagraph has expired;
> (bb) neither the owner of such patent nor the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; **and**
> (cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

21 U.S.C. § 355(j)(5)(C) (emphasis added). Here, the Plaintiffs filed an infringement action within the forty-five day period identified in the statute. Accordingly, under the plain language of 21 U.S.C. § 355(j)(5)(C)(i), Barr has not met the statutory prerequisites for pursuing the declaratory judgment claims it has filed by counterclaim in this action.

6. Further, the Medicare Act added a new provision to 35 U.S.C. § 271(e), the section of the patent code relevant to infringement actions. The amended statute gives the

federal courts subject matter jurisdiction over actions for declaratory judgments brought by ANDA applicants when the patentee has failed to bring an infringement action within forty-five days after receiving notice of a paragraph IV certification:

> Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

35 U.S.C. § 271(e)(5). Thus, where, as here, the patentee has brought an infringement action within the forty-five day period, there is no subject matter jurisdiction for a declaratory judgment claim such as that asserted by Barr in its Counterclaim.

7. Finally, where an ANDA applicant such as Barr has been sued for patent infringement, 21 U.S.C. § 355(j)(5)(C) has defined a narrow exception to the preconditions described above in Paragraph 5. This exception permits the ANDA applicant to bring a counterclaim to an infringement action under limited circumstances. However, this narrow exception does not apply to Barr's proffered Counterclaim.

> (ii) Counterclaim to infringement action. –
>
> (I) In general. – If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this Section on the ground that the patent does not claim either–

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

21 U.S.C. § 355(j)(5)(C)(ii). As Barr's declaratory judgment Counterclaim for non-infringement and patent invalidity does not fall within the narrow parameters outlined above, it is not permitted under the statute.

8. Accordingly, in light of the recent changes to the statutory framework governing ANDA litigation, Barr has not met the statutory prerequisites for pursuing a declaratory judgment claim against the Plaintiffs, and this Court lacks subject matter jurisdiction over Barr's Counterclaim.

WHEREFORE, Cephalon and the Foundation respectfully request that the Court dismiss the Counterclaim in its entirety. A form of order is attached hereto.

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CERTIFICATE OF SERVICE

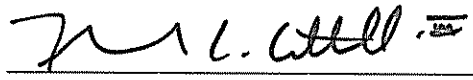
I hereby certify that on March 9, 2005, I electronically filed the foregoing document with the Clerk of Court using CM/ECF which will send notification of such filing and Hand Delivered to the following:

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