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)

DEFENDANT BARR LABORATORIES' ANSWERING BRIEF IN OPPOSITION TO PLAINTIFFS' MOTION TO DISMISS COUNTERCLAIM

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INTRODUCTION

Plaintiffs base their Motion to Dismiss Barr Laboratories' ("Barr") Counterclaim on nonsensical and unsupported statutory construction. Plaintiffs contend that statutory provisions Congress enacted in 2003 divest this Court of jurisdiction over Barr's counterclaim for patent non-infringement and invalidity. They are mistaken. The statutory provisions upon which Plaintiffs rely *broaden*, rather than constrict, an ANDA applicant's right to bring claims for declaratory judgment relief. These provisions simply do not preclude an ANDA applicant from bringing a declaratory judgment counterclaim *after* the patentee has brought an infringement action. Plaintiffs' suggestion to the contrary ignores the plain language of the statute, as well as controlling case law. This Court should deny Plaintiffs' Motion to Dismiss.

NATURE AND STAGE OF PROCEEDING

This lawsuit arises from Barr's application seeking FDA approval for a generic ACTIQ® product.[1] Barr filed its Abbreviated New Drug Application ("ANDA") pursuant to the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act ("FFDCA"), which Congress designed to speed the approval process for generic drugs.

Barr's ANDA contains a so-called "paragraph IV" certification to U.S. Patent No. 4,863,737 ("the '737 patent"), which, upon information and belief, is owned by the University of Utah Research Foundation and exclusively licensed by Cephalon, Inc. By including a paragraph IV certification, Barr signaled its desire to begin marketing its generic product prior to expiration of the '737 patent because that patent is either invalid or will not be infringed by Barr's ANDA product. The filing of an ANDA containing a paragraph IV certification is a technical act of infringement sufficient to vest this Court with subject matter jurisdiction.

[1] Actiq®, an oral transmucosal fentanyl citrate product, contains a prescription opioid (narcotic) pain-relieving medicine called fentanyl.

In response to Barr's ANDA, Plaintiffs initiated this patent infringement lawsuit within forty-five days from learning of Barr's filing (D.I. #1). Barr, like virtually all defendants facing patent infringement claims, responded by asserting a declaratory judgment counterclaim seeking a declaration of non-infringement and invalidity (D.I. #9). As set forth below, nothing in Congress's recent changes to the Hatch-Waxman Amendments eliminated Barr's pre-existing right to file a declaratory judgment counterclaim for non-infringement and invalidity. And, of course, by initiating the present lawsuit, Plaintiffs have created an actual case or controversy. Without doubt, this Court has jurisdiction over Barr's counterclaim.

SUMMARY OF ARGUMENT

1. In 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA"). Various provisions of the MMA amend the 1984 Hatch-Waxman Amendments to the FFDCA and the Patent Act. The MMA provisions relevant here: (1) create an additional remedy for ANDA applicants to correct patent information that the brand-name company submits to the FDA for inclusion in the "Orange Book" and (2) set forth circumstances in which an ANDA applicant can initiate a declaratory judgment action when the patentee does not bring an infringement action.

2. The MMA provisions do not alter an ANDA applicant's right to bring a declaratory judgment counterclaim of non-infringement and invalidity *after* the patentee has brought an infringement action.

3. Plaintiffs in this case filed suit against Barr, alleging that Barr's ANDA product would infringe the patent-in-suit.

4. By initiating the present suit, Plaintiffs have created "an actual case or controversy" as mandated by Article III of the Constitution, the Declaratory Judgment Act, and U.S. Supreme Court and Federal Circuit precedent.

5. The MMA provisions upon which Plaintiffs' rely *expand* the remedies available to ANDA applicants; they do not restrict them. Nothing in the MMA divests this Court of subject matter jurisdiction over Barr's declaratory judgment counterclaim.

6. Barr's counterclaim for a declaratory judgment of non-infringement and invalidity is proper. Plaintiffs motion should be denied.

STATEMENT OF FACTS

I. THE HATCH-WAXMAN AMENDMENTS

A company seeking to sell an original new drug must file a New Drug Application ("NDA") containing, among other things, technical data establishing the safety and efficacy of the drug. *See* 21 U.S.C. § 355(b)(1). The NDA applicant also must submit to the FDA the number of any patent that "claims the drug for which the applicant submitted the application or which claims a method of using such drug . . . ." *Id.* After approving the NDA, the FDA publishes the patent information in the Orange Book. *See* 21 C.F.R. § 314.53(e).

In 1984, Congress passed the Hatch-Waxman Amendments to the FFDCA in order "to get generic drugs into the hands of patients at reasonable prices--fast." *In re Barr Laboratories, Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991). Hatch-Waxman speeds up generic approvals by, *inter alia*, permitting an ANDA applicant to rely on information from the brand-name drug. An ANDA applicant need only show that its drug product is bioequivalent to and contains the same active ingredient, dosage form, dosage strength, route of administration, and, with certain exceptions, labeling as the NDA drug. *See* 21 U.S.C. § 355(j)(2)(A). But, an ANDA must include a "certification" to each patent listed in the Orange Book. While the statute gives the applicant four certification options, only the paragraph IV certification is relevant here. A paragraph IV certification seeks immediate FDA approval because the patent is invalid or will not be infringed by the ANDA product. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Filing an ANDA

containing a paragraph IV certification is a technical act of patent infringement sufficient to vest the courts with subject matter jurisdiction. 35 U.S.C. § 271(e)(2).

Upon filing a paragraph IV certification, an applicant must give notice to the patentee and the NDA holder. 21 U.S.C. § 355(j)(2)(B). The patentee's receipt of that notice starts a forty-five day clock during which the ANDA applicant cannot initiate a declaratory judgment action on the patent-at-issue. 21 U.S.C. § 355(j)(5)(B)(iii). If the patentee files an infringement action within 45 days after receiving notice of the paragraph IV certification, it triggers an automatic stay of FDA approval for thirty months or until judicial resolution, regardless of the merit – or lack thereof – of the patentee's infringement suit. *Id.* If the patentee does not sue, the FDA can approve the application as soon as the Agency completes its substantive review of the application. *Id.*

II. PLAINTIFFS' CLAIM AND BARR'S COUNTERCLAIM

On October 1, 2004, Barr filed an ANDA seeking to market a generic ACTIQ® product. On December 7, 20, and 21, 2004, Barr sent notice letters to Plaintiffs.[2] Those letters: (1) stated that Barr filed an ANDA containing a paragraph IV certification seeking approval to launch generic ACTIQ® prior to expiration of the '737 patent; and (2) set forth Barr's basis for believing that patent to be invalid and/or not infringed. In response, Plaintiffs filed the instant action for patent infringement on January 20, 2005, within the 45-day window. On February 10, 2005, Barr answered Plaintiffs' Complaint and asserted a declaratory judgment Counterclaim for non-infringement and invalidity.

[2] Barr's December 7 notice letter involved its ANDA for 0.2 and 0.4 mg strengths of the fentanyl base. Barr's December 20 and 21 notice letters involved its ANDA amendment for the 0.6 mg. and 0.8, 1.2 and 1.6 mg strengths, respectively.

ARGUMENT

Plaintiffs ask this Court for extraordinary relief: a judicial order stripping Barr of the right to raise counterclaims for declaratory judgment of non-infringement and invalidity – claims that have been available to all patent infringement defendants for decades. Plaintiffs base their outrageous request solely on statutory provisions that, ironically, Congress expressly created to *expand*, not constrict, the rights of ANDA applicants like Barr. Indeed, as one sponsor of the provisions explained, Congress passed the MMA to "close loopholes and end the abusive practice in the pharmaceutical industry which have kept lower-priced generics off the market and cost consumers billions of dollars." 149 Cong. Rec. S15670-03 (daily ed. Nov. 24, 2003) (statement of Sen. Schumer). Congress most assuredly did *not* enact the MMA to prevent ANDA applicants from asserting declaratory judgment counterclaims of non-infringement and invalidity. Plaintiffs' argument to the contrary has no support in fact or law.

I. THE MMA DOES NOT DIVEST THIS COURT OF JURISDICTION OVER BARR'S COUNTERCLAIM

Plaintiffs' contention that the MMA divests this Court of jurisdiction over Barr's declaratory judgment counterclaim lacks merit. Congress intended these statutory sections to have one effect, and only one effect – to *expand* the counterclaims that can be asserted by an ANDA applicant. This necessarily includes an ANDA applicant's right to bring a declaratory judgment counterclaim of non-infringement and invalidity after the patentee has brought an infringement action.

A. The MMA Provides ANDA Applicants With A New Way To Fight Brand Blocking Tactics – The Right To File Declaratory Judgment Counterclaims Challenging The Listing Of Patents In The Orange Book

Title XI of the MMA, entitled "Access to Affordable Pharmaceuticals," makes several changes to the Hatch-Waxman Amendments. Before the MMA, patentees could, and

often did, list patents in the Orange Book irrespective of whether they satisfied the statutory requirements for listing. They did so because each patent provided the patentee with the opportunity to obtain another 30-month statutory stay of ANDA approval. This tactic significantly delayed the entry of less-expensive generic drugs, in contravention of Congress's express goal when passing Hatch-Waxman.

When ANDA applicants attempted to correct improper patent listings, the courts could provide no relief. Some applicants sued the FDA, seeking an order forcing the Agency to remove improperly listed patents. But the courts ruled that the FDA has no obligation to review the appropriateness of the listing. *See, e.g.*, *Apotex, Inc. v. Thompson*, 347 F.3d 1335 (Fed. Cir. 2003). Other ANDA applicants sued the brand company, seeking an order forcing the company to remove the patent from the Orange Book. But the courts ruled that there is no private right of action under the FFDCA to enforce compliance with the patent listing provisions. *See, e.g.*, *American Bioscience, Inc. v. Bristol-Myers Squibb Co.*, No. 00-8577, 2000 WL 1278348, at *1 (C.D. Cal. Sept. 7, 2000). Thus, as Congress recognized when enacting the MMA provisions, the "law provided no means for 'de-listing' a patent, although doing so can speed the marketing of generic drugs, particularly in cases involving patents that are patently frivolous and for which brand name manufacturers clearly would not win a patent infringement suit." 149 Cong. Rec. S7618-02 (July 31, 2002) (statement of Sen. McCain).

Because the courts could not provide ANDA applicants with the means needed to curb patent listing abuses, those interested in speeding generic market entry sought relief in Congress. The FTC, for example, suggested to Congress that ANDA applicants be allowed "to raise listability issues as a counterclaim in the context of a patent infringement litigation that the brand-name company already initiated in response to a paragraph IV notice from the generic applicant." *Prepared Statement of the Federal Trade Commission Before the Committee on the*

Judiciary, 107th Cong. (June 17, 2003).[3] Congress did precisely this. In the hopes of "clean[ing] up abuses of the Orange Book" by brand companies, Congress included in the MMA a provision allowing ANDA applicants to bring a counterclaim to have improperly listed patents removed from the Orange Book. As one of the MMA's sponsors explained, Congress designed the MMA to "put an end to the practice of brand companies listing frivolous patents for the sole purpose of automatically delaying generic approval." 149 Cong. Rec. S15670-03 (daily ed. Nov. 24, 2003) (statement of Sen. Schumer). In response, the FTC applauded Congress's efforts to increase the public's access to generics: "Consistent with an FTC Study recommendation, both the Senate and House bills provide generic applicants with *a new tool* to correct patent information listed in the Orange Book." *Prepared Statement of the Federal Trade Commission Before the Committee on the Judiciary*, 107th Cong. (Aug. 1, 2003)[4] (emphasis added).

Thus, Congress created the de-listing declaratory judgment counterclaim provision of the MMA, 21 U.S.C. § 355(j)(5)(C), as a means of allowing ANDA applicants to curtail patent listing abuses, thus expediting generic market entry and fostering Congress's goal of increasing the public's access to generic drugs. Congress did not add the counterclaim provision in order to eradicate an ANDA applicant's right to assert declaratory judgment counterclaims that have otherwise been available for decades, as Plaintiffs assert without citation to any authority. Indeed, the notion that the MMA's counterclaim provision narrows the rights available to ANDA applicants flies in the face of the uncontradicted legislative history, not to mention common sense.

[3] Available at http://www.ftc.gov/os/2003/06/030617pharmtestimony.htm.

[4] Available at http://www.ftc.gov/os/2003/08/030801pharmtest.htm.

B. The MMA Expands The Rights Of ANDA Holders To Bring A Civil Action For Declaratory Judgment In Those Instances Where The NDA Holder Does Not File Suit Within 45 Days

Another way that Congress sought to expedite the entry of lower-priced generic products was by giving ANDA applicants the ability to initiate a declaratory judgment action if the patentee fails to sue within the forty-five day window of § 355(j)(5)(B)(iii). *See* 21 U.S.C. § 355(j)(5)(C)(i). Under this provision, if the patentee *does not* bring an infringement action within forty-five days of receiving notice of a paragraph IV certification, the ANDA applicant may bring a civil action for a declaratory judgment that the patent-at-issue is invalid or will not be infringed by the drug for which the applicant seeks approval. *Id.* Congress correspondingly amended the Patent Act to confer district courts with subject matter jurisdiction over declaratory judgment actions brought under this provision. *See* 35 U.S.C. § 271(e)(5).

Plaintiffs assert—citing nothing—that these provisions somehow preclude Barr from bringing its declaratory judgment counterclaim of non-infringement and invalidity. Not so. The declaratory judgment action provision, in fact, has no relevance whatsoever to this case. As is clear from the title, "Declaratory judgment *absent infringement action*," this provision relates solely to instances where the NDA holder *does not* file within the 45-day window of § 355(j)(5)(B)(iii) (emphasis added). The courts agree. *See, e.g., Mylan Laboratories v. Thompson*, 332 F. Supp. 2d 106, 111 (D.D.C. 2004) ("Thus, to protect the ANDA holder's interests, if the NDA holder or patent owner does not bring suit within the 45-day window, the ANDA applicant may seek a declaratory judgment that the patent is invalid. 21 U.S.C. § 355(j)(5)(C)(ii).").

Nothing in these provisions remotely suggests that Congress enacted them for the purpose of stripping an ANDA applicant that has been sued within forty-five days of its right to

assert declaratory judgment counterclaims. Plaintiffs' arguments to the contrary have no support.

II. PLAINTIFFS' ARGUMENT CONFLICTS WITH FUNDAMENTAL PRINCIPLES OF STATUTORY CONSTRUCTION

Plaintiffs' argument runs afoul of the most basic principles of statutory construction. Plaintiffs argue that the MMA's declaratory judgment counterclaim provision implicitly abolishes an ANDA applicant's right in an infringement action to raise any counterclaim other than that challenging the Orange Book listing of the patent itself. This argument lacks any support in the law and, in fact, conflicts with fundamental principles of statutory construction.

It is well-settled that "the creation of one statutory remedy does not, in itself, abrogate a pre-existing remedy." *Figueroa v. Buccaneer Hotel, Inc.*, 188 F.3d 172, 179 (3d Cir. 1999); *see also Morton v. Mancari*, 417 U.S. 535, 548 (1974) (holding that statute codifying anti-discrimination provisions did not implicitly repeal statutory Indian preferences in the Board of Indian Affairs). Here, as discussed above, the MMA's legislative history confirms that Congress created the declaratory judgment counterclaim provision to be liberalizing, not restrictive. It would be anomalous, if not nonsensical, to conclude that Congress intended to limit the counterclaims Barr could presently raise, while at the same time expanding the rights of declaratory judgment plaintiffs. *See Morton*, 417 U.S. at 548 ("It would be anomalous to conclude that Congress intended to eliminate the longstanding statutory preferences in BIA employment . . . at the very same time it was reaffirming the right of tribal and reservation-related private employers to provide Indian preference."). No one can dispute that Congress drafted the MMA to enlarge the claims available to ANDA applicants.

III. THIS COURT HAS SUBJECT MATTER JURISDICTION OVER BARR'S DECLARATORY JUDGMENT COUNTERCLAIM BECAUSE AN ACTUAL CASE OR CONTROVERSY EXISTS

Plaintiffs' argument also runs afoul of controlling Federal Circuit case law. Without question, an actual case or controversy exists with regard to the subject matter of Barr's counterclaim.

The Federal Circuit has employed a two-part inquiry for determining whether an actual controversy sufficient to confer subject matter jurisdiction exists with respect to declaratory judgment claims of patent non-infringement or invalidity. The two-part inquiry "focuses on the conduct of both the patentee and the potential infringer...." *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 811 (Fed. Cir. 1996); *see also Gen-Probe, Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1380 (Fed. Cir. 2004). There must be both (1) an explicit threat or other action by the patentee which creates a reasonable apprehension on the part of the declaratory judgment plaintiff (or counterplaintiff) that it will face an infringement suit, and (2) present activity by the declaratory judgment plaintiff (or counterplaintiff) which could constitute infringement, or concrete steps taken with the intent to conduct such activity. *EMC Corp.*, 89 F.3d at 811. The facts of this case easily satisfy this two-part standard. Plaintiffs cannot legitimately dispute this.

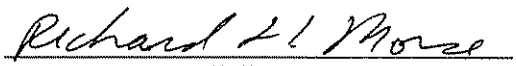
Under controlling Supreme Court case law, Plaintiffs' Complaint against Barr creates a "reasonable apprehension." *See Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 96 (1993). As for the second part of the test, the Federal Circuit has held that filing a paragraph IV ANDA satisfies the "present activity constituting infringement" part of the test. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). Because Barr filed a paragraph IV ANDA, thus providing a basis for Plaintiffs' Complaint, the second part of the test has been satisfied. Consequently, this Court has jurisdiction to consider Barr's Counterclaim, and Plaintiffs' Motion to Dismiss should be denied.

CONCLUSION

For these reasons, Plaintiffs had no reasonable basis for filing the present motion, which is erroneous on the law and wholly improper. Accordingly, Plaintiffs' Motion to Dismiss should be denied.

Dated: March 25, 2005

Respectfully submitted,



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CERTIFICATE OF SERVICE

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