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Attorneys for Plaintiff Warner Chilcott Company, Inc.

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

WARNER CHILCOTT COMPANY, INC.	)	Civil Action No. _____
	)	
Plaintiffs,	)	<b>COMPLAINT AND</b>
	)	<b>LOCAL RULE 11.2 CERTIFICATION</b>
v.	)	
BARR LABORATORIES, INC.,	)	
	)	
Defendant.	)	

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Warner Chilcott Company, Inc. by its undersigned attorneys, bring this  
action against Defendant Barr Laboratories, Inc., and hereby allege as follows:

## THE PARTIES

1. Plaintiff Warner Chilcott Company, Inc. (“Warner Chilcott”) is a corporation incorporated and existing under the laws of Puerto Rico, having its principal place of business at P.O. Box 1005, Fajardo, Puerto Rico, 00738.

2. Upon information and belief, Defendant Barr Laboratories, Inc. (“Barr”) is a corporation incorporated under the laws of the State of Delaware, having its principal place of business at Two Quaker Road, P.O. Box 2900, Pomona, New York 10970, maintains executive offices at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey, 07677, and manufacturing facilities at 265 Livingston Road, Northvale, New Jersey, 07647.

3. Upon information and belief, Barr is registered to conduct business and does business in the State of New Jersey and has a registered agent in New Jersey to accept service of process located at Corporation Service Company, 830 Bear Tavern Road, West Trenton, New Jersey 08628.

## JURISDICTION AND VENUE

4. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code. Jurisdiction is based on 28 U.S.C. §§ 1331 and 1338(a).

5. This Court has personal jurisdiction over Barr by virtue of the fact that Barr conducts business in the State of New Jersey, has availed itself of the rights and benefits of New Jersey law, and has engaged in substantial and continuing contacts with the State.

6. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (c) and 28 U.S.C 1400(b).

### CLAIM FOR PATENT INFRINGEMENT

7. Warner Chilcott is the holder of New Drug Application (“NDA”) No. 21-490, for Femcon Fe® (previously Ovcon® 35 Fe), which contains the active ingredients norethindrone and ethinyl estradiol, in a chewable, palatable tablet form. Femcon Fe® was approved by the United States Food and Drug Administration (“FDA”) on November 14, 2003 and is indicated for the prevention of pregnancy in women who elect to use it as a method of contraception. Femcon Fe® is sold as a 28-day oral contraceptive regimen that contains 21 chewable tablets comprising 0.4 mg norethindrone and 0.035 mg ethinyl estradiol followed by 7 ferrous fumarate tablets (placebo).

8. Warner Chilcott is the owner of United States Patent No. 6,667,050 (hereinafter “the ‘050 patent”). The ‘050 patent lawfully issued on December 23, 2003. A copy of the ‘050 patent is attached as Exhibit A.

9. The '050 patent claims, among other things, a chewable, palatable oral contraceptive tablet, a method of administering said tablet to a human female and a method of enhancing compliance with the oral contraception regimen.

10. The '050 patent covers Femcon Fe® and has been listed in the FDA *Approved Drug Products with Therapeutic Equivalence Evaluations* (“the Orange Book”) for that product.

11. Upon information and belief, Barr submitted to the FDA an Abbreviated New Drug Application (“ANDA”) filed under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use, or sale of a generic version of Femcon Fe® prior to the expiration of the '050 patent.

12. Upon information and belief, the composition that is the subject of Barr's ANDA contains 0.4 mg norethindrone, 0.035 mg ethinyl estradiol and ferrous fumarate in a chewable, palatable tablet form for oral contraception in a human female.

13. Upon information and belief, Barr's ANDA was submitted with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the '050 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of Barr's ANDA product.

14. Upon information and belief, Barr sent notice of that certification to Warner Chilcott on or about August 9, 2007. Warner Chilcott received Barr's notice letter on or about August 13, 2007.

15. By filing its ANDA under 21 U.S.C. § 355(j), for the purpose of obtaining approval to engage in the manufacture, use or sale of its ANDA product before the expiration of the '050 patent, Barr has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2)(A). Further, the manufacture, use or sale of Barr's proposed ANDA product will also infringe one or more claims of the '050 patent.

16. Upon approval of Barr's ANDA, Barr will actively induce and/or contribute to infringement of the '050 patent.

17. Warner Chilcott is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order from this Court that the effective date of the approval of Barr's ANDA be a date that is not earlier than the expiration date of the '050 patent, or any later expiration of exclusivity for the '050 patent to which Warner Chilcott becomes entitled.

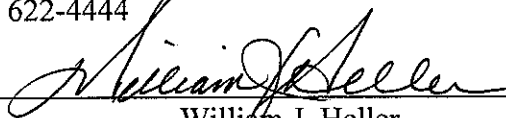
**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff respectfully requests the following relief:

- (a) Judgment that Barr infringed one or more claims of the '050 patent by submitting the aforesaid ANDA;
- (b) A permanent injunction be issued restraining and enjoining Defendant Barr Laboratories, Inc., their officers, agents, attorneys, and employees, and those acting in privity or concert with it, and their successors and assigns, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of compositions that would infringe, induce infringement and/or contribute to infringement of the '050 patent;
- (c) An order that the effective date of any approval of Barr's ANDA, be a date that is not earlier than the expiration of the '050 Patent, or any later expiration of exclusivity for the '050 patent to which Plaintiff becomes entitled;
- (d) Damages for any acts of infringement other than those expressly exempted by 35 U.S.C. § 271(e)(1); and
- (e) Such other and further relief as the Court may deem just and proper.

Dated: September 24, 2007

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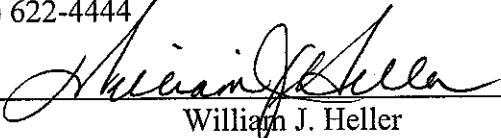
Attorneys for Plaintiff Warner Chilcott Company, Inc.

**CERTIFICATION PURSUANT TO L. CIV. R. 11.2**

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: September 24, 2007

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