IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME B.V.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
WARNER CHILCOTT COMPANY, LLC and WARNER CHILCOTT (US), LLC,	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff MERCK SHARP & DOHME B.V. ("Plaintiff" or "MSD") hereby asserts the following claims for patent infringement against Defendants Warner Chilcott Company, LLC ("Warner Chilcott") and Warner Chilcott (US), LLC ("Warner Chilcott (US)") (collectively "Defendants"), and alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, arising from Warner Chilcott's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of MSD's NuvaRing® drug product prior to the expiration of United States Patent No. 5,989,581 ("the Patent-in-Suit" or "the '581 Patent").

THE PARTIES

2. Plaintiff MSD is a corporation organized and existing under the laws of the Netherlands with its principal place of business at Waarderweg 39, Haarlem, Netherlands 2031 BN. MSD is a wholly owned subsidiary, through intervening affiliated companies, of Merck &

Co., Inc., a Delaware corporation which has its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

3. On information and belief, Defendant Warner Chilcott is a limited liability company organized and existing under the laws of Puerto Rico, having a principal place of business at Union Street, Road 195, Km 1.1, Fajardo, Puerto Rico 00738-1005. On information and belief, Warner Chilcott is in the business of, among other things, developing, manufacturing, marketing and selling branded prescription pharmaceutical products in the United States, including in the District of Delaware, and conducts business throughout the United States.

4. On information and belief, Defendant Warner Chilcott (US) is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 100 Enterprise Drive, Suite 280, Rockaway, NJ 07866. On information and belief, Warner Chilcott (US) is in the business of, among other things, developing, manufacturing, marketing and selling branded prescription pharmaceutical products in the United States, including in the District of Delaware, and conducts business throughout the United States. Further, on information and belief, Warner Chilcott (US) conducts activities as the agent of Warner Chilcott in the District of Delaware.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over the matters asserted herein under 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Warner Chilcott and Warner Chilcott (US) because, on information and belief, Warner Chilcott manufactures pharmaceutical drugs with the knowledge and intent that Warner Chilcott's drugs will be sold in the United States, including within Delaware, through Warner Chilcott and Warner Chilcott (US). Warner Chilcott

and Warner Chilcott (US) have thus engaged in systematic and continuous business contacts within Delaware, and have therefore purposefully availed themselves of the benefits and protections of Delaware's laws such that they should reasonably anticipate being sued in this jurisdiction. In addition, this Court has personal jurisdiction over Warner Chilcott (US) because Warner Chilcott (US) is a limited liability corporation organized and existing under the laws of Delaware.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

THE PATENT-IN-SUIT

8. On November 23, 1999, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 5,989,581, entitled "Drug Delivery System for Two or More Active Substances" to inventor Rudolf Johannes Joseph Groenewegen. MSD is the assignee of the '581 Patent. A copy of the '581 Patent is attached hereto as Exhibit A.

THE NUVARING® DRUG PRODUCT

9. Organon USA Inc., a company affiliated with MSD, holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for ethinyl estradiol and etonogestrel vaginal ring, 0.015 mg/24 hour and 0.12 mg/24 hour (NDA No. 21-187), which is sold under the trade name NuvaRing®. The claims of the Patent-in-Suit cover, *inter alia*, the drug delivery system containing ethinyl estradiol and etonogestrel vaginal ring, 0.015 mg/24 hour and 0.12 mg/24 hour.

10. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the Patent-in-Suit is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), in connection with NuvaRing®.

ACTS GIVING RISE TO THIS ACTION

11. On information and belief, prior to November 6, 2013, Warner Chilcott submitted Abbreviated New Drug Application No. 204305 ("Warner Chilcott's ANDA") to the FDA under § 505(j) of the FFDCA (21 U.S.C. § 355(j)). Warner Chilcott's ANDA seeks approval to engage in the commercial manufacture, use, offer for sale, and/or sale of a generic ethinyl estradiol and etonogestrel vaginal ring, 0.015 mg/24 hour and 0.12 mg/24 hour (the "Proposed ANDA Product"), a generic version of NuvaRing®. Warner Chilcott's ANDA specifically seeks FDA approval to market the Proposed ANDA Product prior to the expiration of the Patent-in Suit.

12. On information and belief, Warner Chilcott and Warner Chilcott (US) acted collaboratively in the preparation and submission of ANDA No. 204305 to the FDA. On information and belief, Warner Chilcott's preparation and submission of ANDA No. 204305 to the FDA was done at the direction, under the control, and for the direct benefit of Warner Chilcott (US).

13. On information and belief, following any FDA approval of ANDA No. 204305, Warner Chilcott and Warner Chilcott US will work in concert with one another to make, use, offer to sell, and/or sell the Proposed ANDA Product throughout the United States, and/or import such generic products into the United States.

14. MSD received on November 8, 2013 a letter dated November 6, 2013 from Warner Chilcott notifying them that Warner Chilcott's ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Warner Chilcott Paragraph IV Certification") that, in

Warner Chilcott's opinion, the Patent-in-Suit is invalid, unenforceable or will not be infringed by the commercial manufacture, use or sale of the Proposed ANDA Product.

CLAIM FOR RELIEF

COUNT I: INFRINGEMENT OF THE '581 PATENT

15. MSD incorporates by reference paragraphs 1 through 14.

16. The submission of Warner Chilcott's ANDA to the FDA, including the Warner Chilcott Paragraph IV Certification, to obtain approval to engage in the commercial use, manufacture, sale, offer for sale or importation of a generic ethinyl estradiol and etonogestrel vaginal ring, 0.015 mg/24 hour and 0.12 mg/24 hour, prior to the expiration of the '581 Patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

17. There is a justiciable controversy between the parties hereto as to the infringement of the '581 Patent.

18. Unless enjoined by this Court, upon FDA approval of Warner Chilcott's ANDA, Defendants will infringe the '581 Patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, or selling Warner Chilcott's Proposed ANDA Product in the United States.

19. Unless enjoined by this Court, upon FDA approval of Warner Chilcott's ANDA, Defendants will induce infringement of the '581 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, or selling Warner Chilcott's Proposed ANDA Product in the United States. On information and belief, upon FDA approval of Warner Chilcott's ANDA, Warner Chilcott will intentionally encourage acts of direct infringement with knowledge of the '581 Patent and knowledge that its acts are encouraging infringement.

20. Unless enjoined by this Court, upon FDA approval of Warner Chilcott's ANDA, Defendants will contributorily infringe the '581 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, or selling Warner Chilcott's Proposed ANDA Product in the United States. On information and belief, Defendants have had and continue to have knowledge that Warner Chilcott's Proposed ANDA Product is especially adapted for a use that infringes the '581 Patent and that there is no substantial non-infringing use for Warner Chilcott's Proposed ANDA Product.

21. Defendants had actual and constructive notice of the '581 Patent prior to filing Warner Chilcott's ANDA.

22. Defendants' infringing activities will substantially and irreparably harm Plaintiff unless enjoined by this Court.

23. MSD does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, MSD respectfully requests:

1. Judgment be entered that Defendants have infringed the Patent-in-Suit;

2. Judgment be entered that the commercial use, sale, offer for sale, manufacture, or importation by Defendants of the Proposed ANDA Product would infringe the Patent-in-Suit;

3. Judgment be entered that Defendants have infringed the Patent-in-Suit by submitting ANDA No. 204305 to the FDA;

4. An order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Warner Chilcott's ANDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), be a date which is not earlier than the expiration date of the Patent-in-Suit, including any extensions;

5. That Defendants, their officers, agents, servants, and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from commercially manufacturing, using, offering to sell, or selling the Proposed ANDA Product within the United States, or importing the Proposed ANDA Product into the United States, prior to the expiration of the Patent-in-Suit, including any extensions;

6. That the case be found exceptional under 35 U.S.C. § 285 and that MSD be awarded its attorneys' fees;

7. Costs and expenses in this action; and

8. Such other and further relief as the Court may deem just and proper under the circumstances.

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/s/ Mary B. Graham

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