IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME B.V.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff MERCK SHARP & DOHME B.V. ("Plaintiff" or "Merck B.V.") hereby asserts the following claims for patent infringement against Defendants Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Pharmaceutical Industries Ltd. ("Teva") (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 Teva USA'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 Merck B.V.'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 Merck B.V. 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. Merck B.V. 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 08889-0100.

3. On information and belief, Defendant Teva USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. On information and belief, Teva USA is in the business of, among other things, manufacturing, marketing and selling generic pharmaceutical products in the United States, including in the District of Delaware, and conducts business throughout the United States. On information and belief, Teva USA holds Pharmacy Wholesale Licenses from the State of Delaware under License Nos. A4-0001468 and A4-0001447. On information and belief, Teva USA holds Distributor/Manufacturer Licenses for Controlled Substances Registration from the State of Delaware under License Nos. DM-0007115 and DM-0006546.

4. On information and belief, Defendant Teva is an Israeli corporation having a principal place of business at 5 Basel Street, Petah Tikva 49131, Israel. On information and belief, Teva is in the business of, among other things, 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.

5. On information and belief, defendant Teva USA is a wholly-owned subsidiary of defendant Teva.

6. On information and belief, Teva USA was incorporated in Delaware and obtained licenses to distribute pharmaceuticals in Delaware with the knowledge of and at the direction of Teva. On information and belief, Teva USA is an agent of Teva and works in active concert either directly or through one or more of their wholly owned subsidiaries or agents to develop,

manufacture, distribute, market, offer to sell, and sell generic drug products for sale and use throughout the United States, including Delaware.

7. On information and belief, Teva USA has been sued for patent infringement in this District and did not contest personal jurisdiction in this District in at least the following cases: *The Medicines Co. v. Teva Parenteral Medicines, Inc.*, 1:09-cv-00750-RGA; *AstraZeneca Pharmaceuticals LP et al. v. Teva Pharmaceuticals USA*, 1:08-cv-00426-JJF; *Warner Chilcott Company et al. v. Teva Pharmaceuticals USA Inc.*, 1:08-cv-00627-LPS; *Shire LLC et al. v. Teva Pharmaceuticals USA Inc. et al.*, 1:10-cv-00329-RGA; and *Abbott Laboratories et al. v. Teva Pharmaceutical Industries Ltd. et al.*, 1:10-cv-00302-SLR-MPT. Additionally, on information and belief, Teva USA has availed itself of the benefits of this forum by bringing civil actions for patent infringement in this forum in at least the following cases: *Teva Pharmaceuticals USA Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, 1:14-cv-01278-GMS; *Teva Pharmaceuticals USA Inc. et al. v. Dr Reddy's Laboratories Ltd. et al.*, 1:14-cv-01172-GMS; *Teva Pharmaceuticals USA Inc. et al. v. Synthon Pharmaceuticals, Inc. et al.*, 1:14-cv-01419-GMS; and *In Re Copaxone 40 MG Consolidated Cases*, 1:14-cv-01171-GMS.

8. On information and belief, Teva has been sued for patent infringement in this District and did not contest personal jurisdiction in this District in at least the following cases: *The Medicines Co. v. Teva Parenteral Medicines, Inc.*, 1:09-cv-00750-RGA; *Shire LLC et al. v. Teva Pharmaceuticals USA Inc. et al.*, 1:10-cv-00329-RGA; and *Abbott Laboratories et al. v. Teva Pharmaceutical Industries Ltd. et al.*, 1:10-cv-00302-SLR-MPT. Additionally, on information and belief, Teva has availed itself of the benefits of this forum by bringing civil actions for patent infringement in this forum in at least the following cases: *Teva Pharmaceuticals USA Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, 1:14-cv-01278-GMS;

Teva Pharmaceuticals USA Inc. et al. v. Dr Reddy's Laboratories Ltd. et al. 1:14-cv-01172-GMS; *Teva Pharmaceuticals USA Inc. et al. v. Synthon Pharmaceuticals, Inc. et al*., 1:14-cv-01419-GMS; and *In Re Copaxone 40 MG Consolidated Cases*, 1:14-cv-01171-GMS.

THE PATENT-IN-SUIT

9. 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. Merck B.V. is the assignee of the '581 Patent. A copy of the '581 Patent is attached hereto as Exhibit A.

THE NUVARING® DRUG PRODUCT

10. Organon USA Inc., a company affiliated with Merck B.V., 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.

11. 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®. There is a pending Hatch-Waxman patent litigation relating to NuvaRing® and the '581 patent in the District of Delaware, *Merck Sharp & Dohme B.V. v. Warner Chilcott Company LLC et al.*, No. 13-cv-02088 (GMS).

ACTS GIVING RISE TO THIS ACTION

12. On information and belief, prior to July 23, 2013, Teva USA, as the agent of Teva and at the direction of, with the authorization of and with the cooperation, participation, and

assistance of Teva, submitted Abbreviated New Drug Application No. 207577 ("ANDA No. 207577") to the FDA under § 505(j) of the FFDCA (21 U.S.C. § 355(j)). ANDA No. 207577 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®. ANDA No. 207577 specifically seeks FDA approval to market the Proposed ANDA Product prior to the expiration of the Patent-in Suit.

13. On information and belief, following any FDA approval of ANDA No. 207577, Teva and Teva USA will work in concert with one another to make, use, offer to sell, or sell the Proposed ANDA Product throughout the United States, or import such generic products into the United States.

14. Merck B.V. received on July 27, 2015 a letter dated July 23, 2015 from Teva USA stating that ANDA No. 207577 includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Paragraph IV Certification") that the Patent-in-Suit allegedly is "not valid, unenforceable, or will not be infringed by the commercial manufacture, use or sale" of the Proposed ANDA Product.

15. On information and belief, the acts of Teva USA complained of herein were done at the direction of, with the authorization of, or with the cooperation, participation, or assistance of, and at least in part for the benefit of, Teva.

JURISDICTION AND VENUE

16. Merck B.V. incorporates by reference paragraphs 1 through 15.

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

18. This Court has personal jurisdiction over Teva USA because Teva USA is a corporation organized and existing under the laws of Delaware.

19. On information and belief, Teva conducts its North American operations in part through Teva USA. On information and belief, Teva USA is an agent of Teva and Teva USA and Teva work in active concert with respect to the development, regulatory approval, marketing, sale and distribution of pharmaceutical products, including the Proposed ANDA Product.

20. This Court has personal jurisdiction over Teva and Teva USA because, on information and belief, Teva and Teva USA manufacture pharmaceutical drugs with the knowledge and intent that their drugs will be sold in the United States, including within Delaware, through Teva and Teva USA. On information and belief, Teva and Teva USA work in concert for purposes of developing, formulating, manufacturing, marketing and selling their generic drug products throughout the United States, including Delaware. Teva and Teva USA 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.

21. This Court has personal jurisdiction over Teva because, on information and belief, Teva, either directly or through an agent, regularly does or solicits business in this jurisdiction, engages in other persistent courses of conduct in this jurisdiction, and derives substantial revenue from services or things used or consumed in this jurisdiction.

22. This Court has personal jurisdiction over Teva and Teva USA because Teva and Teva USA have directed their patent infringement at the District of Delaware. On information and belief, Teva markets and sells generic drugs manufactured by Teva throughout Delaware. On

information and belief, Teva has a distribution network in place to distribute generic drugs in Delaware. On information and belief, following any FDA approval of ANDA No. 207577, Teva and Teva USA will work in concert with one another to make, use, offer to sell, or sell the Proposed ANDA Product throughout the United States, including in Delaware.

23. On information and belief, Teva and Teva USA plan to sell the Proposed ANDA Product in Delaware and seek Medicaid reimbursements for sales of the Proposed ANDA Product in Delaware. On information and belief, Teva knows and intends that, following any FDA approval of ANDA No. 207577, its Proposed ANDA Product will be distributed and sold in Delaware and will displace sales of Merck B.V.'s NuvaRing® product, causing injury to Merck B.V. Teva also intends to take advantage of its established channels of distribution in Delaware for the sale of its Proposed Generic Product.

24. This Court has personal jurisdiction over Teva and Teva USA because, on information and belief, Teva and Teva USA acted collaboratively in the preparation and submission of ANDA No. 207577 to the FDA for the purpose of obtaining approval to distribute and sell the Proposed ANDA Product throughout the United States, including in Delaware. On information and belief, Teva developed the Proposed ANDA Product, worked on the studies submitted with ANDA No. 207577, and drafted portions of ANDA No. 207577. On information and belief, Teva directed Teva USA, as its agent, to help prepare and to file ANDA No. 207577 with the FDA. On information and belief, the preparation and submission of ANDA No. 207577 was done under the control and for the direct benefit of Teva. On information and belief, Teva knew and directed that ANDA No. 207577 be filed by a Delaware corporation, Teva USA. On information and belief, Teva and Teva USA anticipate that they may be sued for patent infringement in Delaware based on the submission of ANDA No. 207577.

25. This Court has personal jurisdiction over Teva USA and Teva because they have consented to personal jurisdiction.

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

CLAIM FOR RELIEF

COUNT I
INFRINGEMENT OF THE '581 PATENT

27. Merck B.V. incorporates by reference paragraphs 1 through 26.

28. The submission of ANDA No. 207577 to the FDA, including the 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).

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

30. Unless enjoined by this Court, upon FDA approval of ANDA No. 207577, Defendants will infringe the '581 Patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, or selling the Proposed ANDA Product in the United States.

31. Unless enjoined by this Court, upon FDA approval of ANDA No. 207577, Defendants will induce infringement of the '581 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, or selling the Proposed ANDA Product in the United States. On information and belief, upon FDA approval of ANDA No. 207577, Defendants will intentionally encourage acts of direct infringement with knowledge of the '581 Patent and knowledge that its acts are encouraging infringement.

32. Unless enjoined by this Court, upon FDA approval of ANDA No. 207577, Defendants will contributorily infringe the '581 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, or selling the Proposed ANDA Product in the United States. On information and belief, Defendants have had and continue to have knowledge that the Proposed ANDA Product is especially adapted for a use that infringes the '581 Patent and that there is no substantial non-infringing use for the Proposed ANDA Product.

33. Defendants had actual and constructive notice of the '581 Patent prior to filing ANDA No. 207577.

34. Defendants' infringing activities will substantially and irreparably harm Merck B.V. unless enjoined by this Court.

35. Merck B.V. does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Merck B.V. 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. 207577 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 ANDA No. 207577, 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 Merck B.V. 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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