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Attorneys for Plaintiff
MERCK SHARP & DOHME CORP.

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

MERCK SHARP & DOHME CORP.	)	CIVIL ACTION NO.: _____
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
WATSON LABORATORIES, INC.,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff and Merck Sharp & Dohme Corp., by way of Complaint against Watson Laboratories, Inc., alleges as follows:

THE PARTIES

1. Merck Sharp & Dohme Corp. ("Merck") is a subsidiary of Merck & Co., Inc. and is a corporation incorporated under the laws of the state of New Jersey, having its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889. Merck is a global research-driven pharmaceutical company that discovers, develops, manufactures and markets a broad range of innovative products to improve human and animal health.

2. Upon information and belief, Defendant Watson Laboratories, Inc. ("Watson") is incorporated under the laws of the State of Nevada, with its principal place of business at 311 Bonnie Circle, Corona, California 92880.

3. On information and belief, Watson is in the business of developing and manufacturing generic pharmaceutical products, which are copies of products invented and developed by innovator pharmaceutical companies.

JURISDICTION AND VENUE

4. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

5. This Court has personal jurisdiction over Watson because of its continuous and systematic contacts with the State of New Jersey.

6. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c), and/or 28 U.S.C. § 1400(b).

MERCK'S NDA AND ASSERTED PATENTS

7. Merck & Co., Inc. filed New Drug Application ("NDA") No. 020788, by which the United States Food & Drug Administration ("FDA") first granted approval for a 1 mg tablet including the active ingredient finasteride. The finasteride tablets described in NDA No. 020788 are prescribed for the treatment of male pattern baldness and sold in the United States under the tradename "PROPECIA®".

8. Merck is the owner of U.S. Patent Nos. 5,571,817 (the "'817 patent") and 5,547,957 (the "'957 patent"), which are attached as Exhibits A and B respectively.

CLAIM FOR RELIEF - COUNT I

9. Merck realleges, as if fully set forth herein, the averments contained in paragraphs 1-8.

10. Merck's '817 patent discloses and claims a method of treating androgenic alopecia which comprises orally administering to a human in need of such treatment a therapeutically effective amount of 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-l-en-3-one (i.e., finasteride).

11. Watson's ANDA No. 077335 seeks FDA approval to market 1 mg finasteride tablets for "[a]dministration ... in accordance with the PROPECIA® prescribing information ... instruct[ing] the administration of 1mg finasteride daily."

12. Watson has filed in connection with ANDA No. 077335 a certification with respect to the '817 patent under § 505(j)(2)(A)(vii)(IV) of the Federal Food Drug and Cosmetic

Act (21 U.S.C. § 355) seeking approval to sell finasteride 1 mg tablets prior to the expiration of the '817 patent.

13. On July 9, 2012, Merck received a notice in which Watson represented that it had filed an ANDA for finasteride, including the certification with respect to the '817 patent, and that it sought approval of its ANDA prior to the expiration of that patent.

14. Because Watson seeks approval of its ANDA to engage in the commercial manufacture, use or sale of a drug the use of which is claimed in the '817 patent before its expiration, Watson has infringed the '817 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

15. If Watson were to commercially market the 1 mg finasteride tablets of its ANDA No. 077335 in the United States prior to the expiration of the '817 patent, Watson would also induce infringement of the '817 patent under 35 U.S.C. § 271(b) and/or be liable as a contributory infringer under § 271(c).

16. Merck is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Watson's ANDA be a date that is not earlier than the November 5, 2013, expiration date of the '817 patent, or any later expiration of exclusivity to which Merck is or becomes entitled.

17. Upon information and belief, Watson was aware of the existence of the '817 patent and was aware that the filing of its ANDA and certification with respect to the '817 patent constituted an act of infringement of that patent.

18. This case is an exceptional one, and Merck is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

CLAIM FOR RELIEF - COUNT II

19. Merck realleges, as if fully set forth herein, the averments contained in paragraphs 1-18.

20. Merck's '957 patent discloses and claims a method of treating male pattern baldness, and a method of arresting and reversing male pattern baldness, comprising orally administering to a male person having a balding area or to a bald or balding male person, a dosage of 0.05 to 3.0 mgs/day of 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-l-en-3-one (i.e., finasteride).

21. Watson's ANDA No. 077335 seeks FDA approval to market 1 mg finasteride tablets for "[a]dministration ... in accordance with the PROPECIA® prescribing information ... instruct[ing] the administration of 1mg finasteride daily."

22. Watson has filed in connection with ANDA No. 077335 a certification with respect to the '957 patent under § 505(j)(2)(A)(vii)(IV) of the Federal Food Drug and Cosmetic Act (21 U.S.C. § 355) seeking approval to sell finasteride 1 mg tablets prior to the expiration of the '957 patent.

23. On July 9, 2012, Merck received a notice in which Watson represented that it had filed an ANDA for finasteride, including the certification with respect to the '957 patent, and that it sought approval of its ANDA prior to the expiration of that patent.

24. Because Watson seeks approval of its ANDA to engage in the commercial manufacture, use or sale of a drug the use of which is claimed in the '957 patent before its expiration, Watson has infringed the '957 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

25. If Watson were to commercially market the 1 mg finasteride tablets of its ANDA No. 077335 in the United States prior to the expiration of the '957 patent, Watson would also

induce infringement of the '957 patent under 35 U.S.C. § 271(b) and/or be liable as a contributory infringer under § 271(c).

26. Merck is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Watson's ANDA be a date that is not earlier than the October 15, 2013, expiration date of the '957 patent, or any later expiration of exclusivity to which Merck is or becomes entitled.

27. Upon information and belief, Watson was aware of the existence of the '957 patent and was aware that the filing of its ANDA and certification with respect to the '957 patent constituted an act of infringement of that patent.

28. This case is an exceptional one, and Merck is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

29. Merck requests that:

a. Judgment be entered that Watson has infringed the '817 and '957 patents by submitting the aforesaid ANDA;

b. Judgment be entered that this is an exceptional case and Merck is entitled to its reasonable attorney fees pursuant to 35 U.S.C. § 285;

c. A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Watson, its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within

the United States, or importation into the United States, of drug compounds the use of which is claimed in the '817 and '957 patents;

d. An order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 077335 be a date which is not earlier than the later of November 5, 2013, the expiration date of the '817 patent, October 15, 2013, the expiration date of the '957 patent, or any later expiration of exclusivity to which Merck is or becomes entitled; and

e. For such other and further relief as the Court may deem just and proper under the circumstances.

Dated: August 20, 2012

Respectfully submitted,

By: /s/ Sheila F. McShane

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