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

_____	)	
	)	
MERCK SHARP & DOHME	)	
PHARMACEUTICALS SRL,	)	
	)	
Plaintiff,	)	
	)	Civil Action No. _____
v.	)	
	)	
TEVA PHARMACEUTICALS USA, INC., AND	)	
TEVA PHARMACEUTICAL INDUSTRIES, LTD.,	)	
	)	
Defendants.	)	
	)	
_____	)	

**COMPLAINT FOR PATENT INFRINGEMENT**

For its Complaint, Plaintiff Merck Sharp & Dohme Pharmaceuticals SRL alleges as follows:

**PARTIES**

1. Merck Sharp & Dohme Pharmaceuticals SRL (“MSD”), formerly Tradewinds Manufacturing SRL, is a restricted liability society organized under the laws of Barbados, with offices at Chancery House, High Street, Bridgetown, Barbados.

2. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. (“Teva USA”) regularly transacts business in the State of New Jersey, has multiple offices in the State of New Jersey, and is a Delaware corporation with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

3. On information and belief, Defendant Teva Pharmaceutical Industries Ltd. (“Teva Ltd.”) is a company organized and existing under the laws of Israel having its principal place of business at 5 Basel St., Petach Tikva 49131, Israel.

4. On information and belief, Teva USA is a wholly owned subsidiary of Teva Ltd.

5. On information and belief, Teva USA is controlled and/or dominated by Teva Ltd.

6. On information and belief, Teva Ltd. conducts its operations through subsidiaries in the United States, including New Jersey, through Teva USA.

**JURISDICTION AND VENUE**

7. This action arises under the patent laws of the United States of America, Title 35, United States Code and jurisdiction is founded on Title 28, United States Code §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Teva USA because Teva USA resides in this judicial district and engages in continuous and systematic contacts with the State of New Jersey.

9. On information and belief, Teva USA acts under the direction, control and influence of Teva Ltd. with respect to the acts and conduct alleged in this Complaint.

10. Teva USA's acts and continuous and systematic contacts with the State of New Jersey, as an agent of Teva Ltd., are also attributable to Teva Ltd. for jurisdictional purposes.

11. Teva USA and Teva Ltd. have jointly filed at least ten complaints for patent infringement in this judicial district in 2007, and therefore, have submitted themselves to the jurisdiction of this Court.

12. For all of the reasons set forth above, this Court has personal jurisdiction over Teva Ltd.

13. Venue is proper in this Court under Title 28, United States Code §§ 1391(c) and 1400(b), because Teva USA and Teva Ltd., acting in concert, employ individuals in this judicial district and have offices and manufacturing facilities in this judicial district, and thus purposefully avail themselves of the privilege of conducting activities within New Jersey.

### **BACKGROUND**

14. On October 15, 1996, United States Letters Patent No. 5,565,473 (the "473 patent") duly and legally issued to inventors Michel L. Belley, Serge Leger, Marc Labelle, Patrick Roy, Yi B. Xiang, and Daniel Guay, entitled "UNSATURATED HYDROXYALKYLQUINOLINE ACIDS AS LEUKOTRIENE ANTAGONISTS." A copy of the '473 patent is attached as Exhibit 1.

15. MSD owns the '473 patent.

16. Merck & Co., Inc. ("Merck") has an approved New Drug Application ("NDA") No. 20-829 for montelukast sodium pharmaceutical products that are sold under Merck's trademark SINGULAIR®.

17. Merck purchases montelukast sodium used in SINGULAIR® pharmaceutical products from MSD according to a supply and distributorship agreement.

18. Merck's SINGULAIR® pharmaceutical products are extremely successful and are widely used in New Jersey, the United States, and throughout the world to treat asthma and allergic rhinitis.

19. On information and belief, Teva USA has filed Abbreviated New Drug Application ("ANDA") No. 78-723 with the Food and Drug Administration ("FDA"), for generic tablets containing 4 milligrams and 5 milligrams of montelukast sodium. Teva USA's ANDA contains a certification of invalidity, unenforceability, and/or noninfringement of the '473 patent. Notice of that certification, but not the certification itself, was transmitted to MSD and Merck on or after April 2, 2007, and was received by them on April 4, 2007.

20. Teva USA had no adequate good faith basis for filing its ANDA containing a certification of the alleged invalidity, unenforceability, and/or noninfringement of the claims of the '473 patent.

21. On information and belief, Teva USA and Teva Ltd. were aware of the '473 patent.

22. Teva USA filed its ANDA for generic montelukast sodium tablets because both Teva USA and Teva Ltd., through its subsidiary, seek to enter the lucrative montelukast sodium

market that SINGULAIR® pharmaceutical products have created by providing very beneficial and advantageous treatments for asthma and allergic rhinitis.

23. Teva Ltd. actively and knowingly aided and abetted Teva USA's filing of its ANDA seeking approval to market generic copies of Merck's SINGULAIR® pharmaceutical products.

### COUNT I

24. Each of the preceding paragraphs 1-23 is incorporated as if fully set forth herein.

25. Teva USA filed its ANDA to obtain approval under the Federal Food, Drug, and Cosmetic Act to market a pharmaceutical drug product as claimed in the '473 patent before the expiration of the '473 patent. On information and belief, Teva USA has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

26. When Teva USA filed its ANDA seeking approval to market generic montelukast sodium tablets before the expiration of the '473 patent, Teva USA was aware of the existence of the '473 patent and that the filing of the ANDA constituted an act of infringement.

27. Teva USA acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '473 patent.

28. Teva USA's infringement of the '473 patent was and is willful.

29. As to the extent Teva USA has committed any infringing act with respect to montelukast sodium other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

**COUNT II**

30. Each of the preceding paragraphs 1-29 is incorporated as if fully set forth herein.

31. When Teva Ltd. actively and knowingly aided and abetted Teva USA with the filing of its ANDA seeking approval to market generic montelukast sodium tablets, Teva Ltd. was aware of the '473 patent and knew that Teva USA's filing of its ANDA constituted an act of infringement. On information and belief, Teva Ltd. has committed an act of infringement under 35 U.S.C. § 271(b).

32. Teva Ltd. acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '473 patent.

33. Teva Ltd.'s infringement of the '473 patent was and is willful.

34. As to the extent Teva Ltd. has committed any infringing act with respect to montelukast sodium other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

**REQUESTED RELIEF**

WHEREFORE, Plaintiff Merck respectfully seeks the following relief:

a. That judgment be entered that Defendant Teva USA has infringed the '473 patent by submitting its ANDA;

b. That judgment be entered that Defendant Teva Ltd. has infringed the '473 patent by inducing Teva USA's infringement of the '473 patent through actively and knowingly aiding and abetting Teva USA's filing of its ANDA;

c. That a permanent injunction be issued under 35 U.S.C. § 271(e) restraining or enjoining Defendants Teva USA and Teva Ltd., their officers, agents or 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 any therapeutic composition, or method of use covered by the '473 patent for the full term thereof, and from inducing or contributing to such activities;

d. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of the ANDA be a date which is not earlier than the expiration of the '473 patent;

e. That judgment be entered that Defendants Teva USA and Teva Ltd. willfully and deliberately infringed the claims of the '473 patent;

f. That this is an exceptional case under 35 U.S.C. § 285, and that judgment be entered for costs and reasonable attorneys fees to be awarded to MSD; and

g. That this Court award such other and further relief as the Court may deem proper and just under the circumstances.

Dated: May 14, 2007  
Newark, New Jersey

Respectfully submitted,

**GIBBONS P.C.**

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