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Attorneys for Plaintiffs
MERCK FROSST CANADA & CO.,
MERCK CANADA INC., and
MERCK SHARP & DOHME PHARMACEUTICALS

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

MERCK FROSST CANADA & CO., MERCK CANADA INC., and MERCK SHARP & DOHME PHARMACEUTICALS, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. Defendant.	CIVIL ACTION NO.:____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Merck Frosst Canada & Co., Merck Canada Inc., and Merck Sharp & Dohme Pharmaceuticals (collectively, "Plaintiffs") by way of Complaint against Teva Pharmaceuticals USA, Inc., allege as follows:

THE PARTIES

1. Plaintiff Merck Frosst Canada & Co. is a corporation organized and existing under the laws of Canada, having a principal place of business at 16711 TransCanada Highway, Kirkland, Quebec H9H 3L1.

2. Plaintiff Merck Canada Inc., formerly Merck Frosst Canada Ltd., is a corporation organized and existing under the laws of Canada, having a principal place of business at 16711 TransCanada Highway, Kirkland, Quebec H9H 3L1.

3. Plaintiff Merck Sharp & Dohme Pharmaceuticals, formerly Merck Sharp & Dohme Pharmaceuticals SRL (Barbados), is a restricted liability company organized under the laws of Bermuda, with offices at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda.

4. On information and belief, Teva Pharmaceuticals USA, Inc. ("Teva") is a corporation organized and existing under the laws of the state of Delaware, having an office and place of business at 1090 Horsham Road, North Wales, Pennsylvania, 19454.

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

6. On information and belief, Teva has engaged in continuous and systematic contacts with New Jersey, and purposefully availed itself of this forum by, among other things, shipping, using, offering to sell, selling, or causing others to use, offer to sell, or sell pharmaceutical products in New Jersey and deriving substantial revenue from such activities.

JURISDICTION AND VENUE

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

8. This Court has personal jurisdiction over Teva because of its continuous and systematic contacts with the state of New Jersey.

9. 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 PATENT

10. Merck Research Laboratories, a division of Merck & Co., Inc. ("Merck"), filed New Drug Application ("NDA") No. 021409, by which the U.S. Food and Drug Administration ("FDA") granted approval for Montelukast Sodium Oral Granules Eq. to 4 mg Base/Packet. The montelukast sodium formulation described in NDA No. 021409 is approved for the treatment of asthma in pediatric patients. Montelukast Sodium Oral Granules Eq. to 4 mg Base/Packet is sold by Merck under the tradename "SINGULAIR®".

11. Plaintiffs own all right, title, and interest in U.S. Patent No. 8,007,830 (the "'830 patent"), which is attached as Exhibit A.

12. Pursuant to 21 U.S.C. § 355(b)(1), Merck has submitted information concerning the '830 patent to the FDA in connection with its NDA No. 021409, identifying it as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug."

TEVA'S ANDA AND NOTICE LETTER

13. By letter ("Notice Letter") dated November 29, 2011, Teva gave notice that it had submitted Abbreviated New Drug Application ("ANDA") No. 090955 to the FDA

under 21 U.S.C. § 355(j) seeking approval to manufacture, use and sell generic Montelukast Sodium Oral Granules, Eq. to 4 mg Base/Packet, (the "Teva Generic Product"), prior to the expiration of the '830 patent.

14. In the Notice Letter, Teva informed Merck Canada Inc. and Merck that its ANDA contained a "Paragraph IV Certification" that the '830 patent will not be infringed by the manufacture, use, offer for sale and sale of the Teva Generic Product.

15. This complaint for patent infringement is being filed before the expiration of forty-five days from the date Merck Canada Inc. and Merck received the Teva Notice Letter.

INFRINGEMENT OF THE '830 PATENT

16. Plaintiffs reallege, as if fully set forth herein, the averments contained in paragraphs 1-15.

17. Claims 1-5 of the '830 patent claim a pharmaceutical composition comprising granules having a substrate agglomerated with a binder and coated with an aqueous solution of montelukast sodium.

18. Teva's Notice Letter states, *inter alia*, that the Teva Generic Product "will not infringe any claim of the '830 patent, either literally or under the doctrine of equivalents."

19. As set forth below, Teva has prevented Plaintiffs from evaluating the accuracy of Teva's assertion that its Generic Product "will not infringe any claim of the '830 patent, either literally or under the doctrine of equivalents." Accordingly, Plaintiffs herein allege that the filing of Teva's ANDA infringed the '830 patent under 35 U.S.C. § 271(e)(2)(A), and that the commercial manufacture, use, offer for sale, and sale of the Teva Generic Product prior to the expiration of the '830 patent would infringe the '830 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

20. The Offer of Confidential Access included with Teva's Notice Letter was unreasonable on its face because it contained far stricter restrictions as to persons entitled to access than would apply had a protective order been entered by this Court for the purpose of protecting trade secrets and other confidential business information. For example, it prohibited outside experts and in-house counsel not directly or indirectly involved in patent prosecution duties relating to montelukast sodium from having access to Teva's confidential materials. Teva further refused to provide samples of Teva's Generic Product. Finally, Teva agreed to produce only portions of the ANDA selected by Teva, and refused to produce any DMF incorporated by reference into the ANDA. Negotiations to remove these inappropriate restrictions have been unsuccessful. As a result, Plaintiffs have not received any part of Teva's ANDA or samples of Teva's Generic Product.

21. Plaintiffs are not aware of any other means of obtaining information regarding Teva's Generic Product within the 45-day statutory period. In the absence of such information, Plaintiffs resort to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm their allegations of infringement and to present the Court evidence that Teva's Generic Product, or the use or manufacture of that product, falls within the scope of one or more of Claims 1-5 of the '830 patent.

22. Plaintiffs will be substantially and irreparably harmed if Teva's infringement of the '830 patent is not enjoined. Plaintiffs do not have an adequate remedy at law.

23. Plaintiffs are 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 Teva's ANDA be a date

that is not earlier than the October 24, 2022, expiration date of the '830 patent, or the date of any later expiration of exclusivity to which Plaintiffs are or become entitled.

24. Upon information and belief, Teva was aware of the existence of the '830 patent and was aware that the filing of its ANDA and certification with respect to the '830 patent constituted an act of infringement of that patent.

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

PRAYER FOR RELIEF

26. Plaintiffs request that:

a. Judgment be entered that Teva has infringed the '830 patents by submitting ANDA No. 090955;

b. Judgment be entered that this is an exceptional case, and that Plaintiffs are entitled to their 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 Teva, its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of drug compositions claimed in the '830 patent;

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. 090955 be a date which is not earlier than the later of October 24, 2022, the expiration date of the '830 patent, or the date of any later expiration of exclusivity to which Plaintiffs are or become entitled; and

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

Dated: January 11, 2012

Respectfully submitted,

By: s/ Sheila F. McShane

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