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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

LUPIN LTD. and LUPIN
PHARMACEUTICALS, INC.

Plaintiffs,

v.

MERCK, SHARP & DOHME CORP.,

Defendant.

Civil Action No.

COMPLAINT OF LUPIN LTD., ET AL.

DOCUMENT FILED ELECTRONICALLY

Plaintiffs Lupin Ltd. and Lupin Pharmaceuticals, Inc. (“Lupin Pharma”) (collectively “Plaintiffs” or “Lupin”), by their undersigned counsel, for their Complaint against Merck, Sharp & Dohme Corp. (hereafter “Defendant” or “Merck”) state as follows:

THE PARTIES

1. Lupin Ltd. is a corporation organized and existing under the laws of India, with a place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (W), Mumbai, Maharashtra 400 051, India, and with its only places of business located in India.
2. Lupin Pharmaceuticals is a Virginia corporation and a wholly-owned subsidiary of Lupin Ltd. having a place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland, 21202.
3. On information and belief, Merck is a company organized and existing under the laws of

New Jersey, having its principal place of business at 126 E. Lincoln Avenue, Rahway, New Jersey. On information and belief, Merck, Sharp & Dohme Corp. was a corporate name change from Merck & Co.

JURISDICTION AND VENUE

4. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), in that it involves substantial claims arising under the United States Patent Act, 35 U.S.C. § 1 et seq.

5. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because this is a case of actual controversy within the Court's jurisdiction seeking a declaratory judgment that the patents are not infringed and are invalid.

6. Venue is proper pursuant to 28 U.S.C. §§ 1391(b) and (c).

THE CONTROVERSY

7. Lupin holds Abbreviated New Drug Application (“ANDA”) No. 91-324 for “Esomeprazole Magnesium Delayed Release Capsules (20 mg Base and 40 mg)” (hereinafter referred to as “Esomeprazole Magnesium Capsules”) containing the active ingredient esomeprazole magnesium.

8. On information and belief based on assignment records available at the website of the United States Patent and Trademark Office, upon issuance, U.S. Patent No. 6,147,103 (“the ’103 patent”), 6,166,213 (“the ’213 patent”), and 6,191,148 (“the ’148 patent”) were assigned to Merck & Co.

9. On information and belief based on similar assignment records, Merck & Co. assigned the the ’103 patent, the ’213 patent, and the ’148 patent to Merck, and Merck owns the ’103 patent, the ’213 patent, and the ’148 patent.

10. On information and belief, AstraZeneca LP (hereafter “Astra”) holds an approved New Drug Application, 21-153, from the United States Food and Drug Administration (“FDA”) for an esomeprazole magnesium formulation which it sells under the name NEXIUM®.

11. Astra has informed the FDA of the following unexpired patents “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 esomeprazole magnesium capsules: eleven patents, including the ’103 patent, the ’213 patent, and the ’148 patent. *See* 21 U.S.C. § 355(b)(1), (c)(2). The FDA listed these eleven patents, *inter alia*, in a publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly known as the Orange Book,” in connection with NDA No. 21-153. *See* 21 U.S.C. § 355(j)(2)(A)(i). (The eleven patents are collectively “the Orange Book patents.”)

12. On or about October 21, 2009, Astra, AstraZeneca AB, Aktiebolaget Hassle, KBI Inc. and KBI-E Inc. (collectively “Astra Plaintiffs”) filed in this district Action No. 3:09-cv-05404-JAP-TJB against Lupin in this district alleging infringement of five of the Orange Book patents, not including the ’103 patent, the ’213 patent, and the ’148 patent.

13. On or about December 11, 2009, Lupin answered in 3:09-cv-05404, and counterclaimed for a declaratory judgment of invalidity and/or non-infringement of all of the unexpired Orange Book patents, including the ’103 patent, the ’213 patent, and the ’148 patent in Counterclaims 8, 9, and 10.

14. On or about January 19, 2010, the Astra Plaintiffs moved to dismiss Lupin’s declaratory judgment counterclaims 8-10 on the basis that Lupin failed to join a necessary and indispensable party, namely the owner of the ’103, ’213 and ’148 patents, and therefore, the Court lacked jurisdiction over those counterclaims. 3:09-cv-05404 Document No. 23-1.

COUNT 1

DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF

U.S. PATENT NO. 6,147,103

15. Plaintiffs repeat and incorporate by reference paragraphs 1-14.

16. The manufacture, use, offer for sale, sale or importation of the esomeprazole magnesium products that are the subject of Lupin's ANDA 91-324 will not infringe any valid claim of the '103 patent.

17. The filing of ANDA 91-324 did not infringe the '103 patent because the manufacture, use, offer for sale, sale, or importation of the esomeprazole magnesium products that are the subject of ANDA 91-324 will not infringe any valid claim of the '103 patent.

COUNT 2

DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF

U.S. PATENT NO. 6,166,213

18. Defendants repeat and incorporate by reference paragraphs 1-17.

19. The manufacture, use, offer for sale, sale or importation of the esomeprazole magnesium products that are the subject of ANDA 91-324 will not infringe any valid claim of the '213 patent.

20. The filing of ANDA 91-324 did not infringe the '213 patent because the manufacture, use, offer for sale, sale, or importation of the esomeprazole magnesium products that are the subject of ANDA 91-324 will not infringe any valid claim of the '213 patent.

COUNT 3

DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF

U.S. PATENT NO. 6,191,148

21. Defendants repeat and incorporate by reference paragraphs 1-20.
22. The manufacture, use, offer for sale, sale or importation of the esomeprazole magnesium products that are the subject of ANDA 91-324 will not infringe any valid claim of the '148 patent.
23. The filing of ANDA 91-324 did not infringe the '148 patent because the manufacture, use, offer for sale, sale, or importation of the esomeprazole magnesium products that are the subject of ANDA 91-324 will not infringe any valid claim of the '148 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs seek judgment against Defendant as follows:

- A. That judgment be entered in favor of Plaintiffs, including an Order adjudging U.S. Patent Nos. 6,147,103; 6,166,213; and 6,191,148 to be not infringed by Plaintiffs;
- C. That Plaintiffs be awarded their fees and costs in defending this litigation pursuant to 35 U.S.C. § 285; and
- D. That Plaintiffs be awarded such other and further relief as the Court deems just and proper.

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