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

DR. REDDY'S LABORATORIES, LTD., and :  
DR. REDDY'S LABORATORIES, INC., :

Plaintiffs, :

v. :

ASTRAZENECA AB, AKTIEBOLAGET :  
HÄSSLE, ASTRAZENECA LP, and MERCK :  
& CO., INC :

Defendants :

Civil Action No. \_\_\_\_\_

**DR. REDDY'S LABORATORIES, LTD.'S AND  
DR. REDDY'S LABORATORIES, INC.'S  
COMPLAINT FOR DECLARATORY JUDGMENT**

Plaintiffs Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.  
(collectively, "DRL") for their Complaint against AstraZeneca AB, Aktiebolaget Hässle,  
AstraZeneca LP (collectively, "AstraZeneca"), and Merck & Co., Inc. ("Merck") allege  
and aver as follows:

**PARTIES**

1. Plaintiff Dr. Reddy's Laboratories, Ltd. is an Indian corporation, with its principal place of business at 7-1-27, Ameerpet, Hyderabad, India.

2. Plaintiff Dr. Reddy's Laboratories, Inc. is a New Jersey corporation, with its principal place of business at 200 Somerset Corporate Boulevard, Bridgewater, New Jersey.

3. On information and belief, Defendant AstraZeneca AB is a Swedish company, with its principal place of business at Södertälje, Sweden.

4. On information and belief, Defendant Aktiebolaget Hässle is a Swedish company, with its principal place of business at Mölndal, Sweden.

5. On information and belief, Defendant AstraZeneca L.P. is a Delaware limited partnership, with its principal place of business at Wilmington, Delaware.

6. On information and belief, Defendant Merck & Co., Inc. is a New Jersey corporation, with its principal place of business at Whitehouse Station, New Jersey.

**JURISDICTION AND VENUE**

7. This is an action for declaratory judgment pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, together with such further and other relief that may be necessary or proper. The basis for declaratory judgment is an actual controversy between DRL and Defendants AstraZeneca and Merck arising under the United States Patent Laws, Title 35 of the United States Code. This Court has subject matter jurisdiction over the action based on 28 U.S.C. §§ 1331 and 1338.

8. This Court has personal jurisdiction over AstraZeneca because of its continuous and systematic contacts with the State of New Jersey, including its conducting

of substantial and regular business therein through the marketing and sales of its pharmaceutical products in New Jersey.

9. This Court has personal jurisdiction over Merck because of its continuous and systematic contacts with the State of New Jersey, including is maintaining a principal place of business in this District.

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

### **BACKGROUND**

11. On information and belief, AstraZeneca or an affiliated entity is the owner of approved New Drug Application (“NDA”) No. 21-153 for esomeprazole magnesium in capsule form, 20 mg and 40 mg.

12. On information and belief, AstraZeneca, by themselves or through affiliated entities, market NEXIUM<sup>®</sup> esomeprazole magnesium 20 mg and 40 mg capsules throughout the United States under NDA No. 21-153.

13. AstraZeneca has informed the United States Food and Drug Administration (“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]”: U.S. Patent Nos. 4,738,974 (“the ‘974 patent”), 4,786,505 (“the ‘505 patent), 4,853,230 (“the ‘230 patent”), 5,690,960 (“the ‘960 patent”), 5,714,504 (“the ‘504 patent”), 5,877,192 (“the ‘192 patent”), 5,900,424 (“the ‘424 patent”), 6,147,103 (“the ‘103 patent”), 6,166,213 (“the ‘213 patent”), 6,191,148 (“the ‘148 patent”), 6,369,085 (“the ‘085 patent”), 6,428,810 (“the ‘810 patent”), and 6,875,872 (“the ‘872 patent”),. *See* 21

U.S.C. § 355(b)(1), (c)(2). The FDA listed these patents 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).

14. Upon FDA approval of DRL’s Esomeprazole Magnesium Delayed Release Capsules (equivalent to 20 mg and 40 mg of omeprazole free base), DRL intends to market this product in the United States after the expiration of the ‘974, ‘505, and ‘230 patents. DRL seeks to market its Esomeprazole Magnesium Delayed Release Capsules before the expiration of the ‘960, ‘504, ‘192, ‘424, ‘103, ‘213, ‘148, ‘085, ‘810 and ‘872 patents, and filed a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a “Paragraph IV certification”) certifying that these patents are either invalid or will not be infringed by the manufacture, use or sale of DRL’s proposed Esomeprazole Magnesium Delayed Release Capsules.

15. In connection with the filing of its Paragraph IV certification, DRL provided Defendants with an offer of confidential access to its ANDA in accordance with 21 U.S.C. §§ 355(j)(5)(C)(i)(I)(cc) and (III).

#### **THE CONTROVERSY**

16. On information and belief, AstraZeneca owns the ‘960 patent, entitled “Pharmaceutical Formulation of Omeprazole,” a copy of which is attached hereto as Exhibit A.

17. On information and belief, AstraZeneca owns the ‘424 patent, entitled “Omeprazole Magnesium Salt Form,” a copy of which is attached hereto as Exhibit B.

18. On information and belief, AstraZeneca owns the '103 patent, entitled "Omeprazole Process and Compositions Thereof," a copy of which is attached hereto as Exhibit C.

19. On information and belief, Merck owns the '213 patent, entitled "Omeprazole Process and Compositions Thereof," a copy of which is attached hereto as Exhibit D.

20. On information and belief, Merck owns the '148 patent, entitled "Omeprazole Process and Compositions Thereof," a copy of which is attached hereto as Exhibit E.

21. On information and belief, AstraZeneca owns the '810 patent, entitled "Pharmaceutical Formulation Comprising Omeprazole," a copy of which is attached hereto as Exhibit F.

22. On January 17, 2008, AstraZeneca sued DRL, alleging, *inter alia*, infringement of the '504, '872, and '085 patents; it did not allege infringement of the '960, '192, '424, '103, '213, '148 and '810 patents. *See AstraZeneca AB, et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 08-(D.N.J). The 45-day period following Defendants' receipt of DRL's notice of Paragraph IV certification has expired.

23. Because Defendants did not assert the '960, '424, '103, '213, '148 and '810 patents within the 45 days following receipt of DRL's notice of Paragraph IV certification, DRL faces uncertainty and great potential risk if AstraZeneca should assert any of the '960, '424, 103, '213, '148 and '810 patents after DRL begins commercially marketing its Esomeprazole Magnesium Delayed Release Capsules.

24. Accordingly, there is an actual, substantial, and continuing justiciable case and controversy between DRL and Defendants AstraZeneca and Merck regarding the validity and infringement of the '960, '424, '103, '213, '148 and '810 patents, over which this Court can and should exercise jurisdiction and declare the rights of the parties. DRL is therefore entitled to bring and maintain this action for declaratory judgment. 21 U.S.C. § 355(j)(5)(C).

**COUNT I**  
**DECLARATORY JUDGMENT OF NONINFRINGEMENT**

25. DRL's commercial manufacture, use, offer for sale, sale or importation of its generic equivalents of Nexium<sup>®</sup> or the active ingredient thereof would not infringe the '960 patent.

**COUNT II**  
**DECLARATORY JUDGMENT OF NONINFRINGEMENT**

26. DRL's commercial manufacture, use, offer for sale, sale or importation of its generic equivalents of Nexium<sup>®</sup> or the active ingredient thereof would not infringe the '424 patent.

**COUNT III**  
**DECLARATORY JUDGMENT OF NONINFRINGEMENT**

27. DRL's commercial manufacture, use, offer for sale, sale or importation of its generic equivalents of Nexium<sup>®</sup> or the active ingredient thereof would not infringe the '103 patent.

**COUNT IV**  
**DECLARATORY JUDGMENT OF NONINFRINGEMENT**

28. DRL's commercial manufacture, use, offer for sale, sale or importation of its generic equivalents of Nexium<sup>®</sup> or the active ingredient thereof would not infringe the '213 patent.

**COUNT V**  
**DECLARATORY JUDGMENT OF NONINFRINGEMENT**

29. DRL's commercial manufacture, use, offer for sale, sale or importation of its generic equivalents of Nexium<sup>®</sup> or the active ingredient thereof would not infringe the '148 patent.

**COUNT VI**  
**DECLARATORY JUDGMENT OF NONINFRINGEMENT**

30. DRL's commercial manufacture, use, offer for sale, sale or importation of its generic equivalents of Nexium<sup>®</sup> or the active ingredient thereof would not infringe the '810 patent.

**PRAYER FOR RELIEF**

WHEREFORE, DRL respectfully requests the Court enter judgment against AstraZeneca and Merck to include:

A. a declaration that DRL's manufacture, use or sale of its generic equivalents of Nexium<sup>®</sup> or the active ingredient thereof will not infringe United States Patent No. 5,690,960;

B. a declaration that DRL's manufacture, use or sale of its generic equivalents of Nexium<sup>®</sup> or the active ingredient thereof will not infringe United States Patent No. 5,900,424;

C. a declaration that DRL's manufacture, use or sale of its generic equivalents of Nexium<sup>®</sup> or the active ingredient thereof will not infringe United States Patent No. 6,147,103;

D. a declaration that DRL's manufacture, use or sale of its generic equivalents of Nexium<sup>®</sup> or the active ingredient thereof will not infringe United States Patent No. 6,166,213;

E. a declaration that DRL's manufacture, use or sale of its generic equivalents of Nexium<sup>®</sup> or the active ingredient thereof will not infringe United States Patent No. 6,191,148;

F. a declaration that DRL's manufacture, use or sale of its generic equivalents of Nexium<sup>®</sup> or the active ingredient thereof will not infringe United States Patent No. 6,428,810;

G. an award of DRL's reasonable costs and attorneys' fees in connection with this action; and

H. all such other and further relief as the Court may deem just and proper.

Respectfully submitted,  
BUDD LARNER, P.C.

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