**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, and WARNER-LAMBERT COMPANY LLC, | ) | |
| Plaintiffs, | ) | |
| v. | ) | Civil Action No. _____ |
| DR. REDDY'S LABORATORIES LTD., and DR. REDDY'S LABORATORIES INC., | ) | |
| Defendants. | ) | |

**COMPLAINT**

Pfizer Inc., Pfizer Ireland Pharmaceuticals, and Warner-Lambert Company LLC, formerly Warner-Lambert Company (collectively, "Pfizer"), by their attorneys, for their Complaint against Dr. Reddy's Laboratories Ltd. ("Dr. Reddy's Ltd.") and Dr. Reddy's Laboratories Inc. ("Dr. Reddy's Inc.") (collectively, "Defendants"), allege as follows:

1. This is an action by Pfizer against Defendants for infringement of U.S. Patent No. 5,969,156 and its Reexamination Certificate (collectively "the '156 patent"). A copy of the '156 patent with the '156 Reexamination Certificate is attached hereto as Exhibit A.

**PATENTS IN SUIT**

2. On October 19, 1999, the United States Patent and Trademark Office (the "USPTO") issued the '156 patent, entitled "Crystalline [R-(R*,R*)]-2-(4-Fluorophenyl)-ß,δ-Dihydroxy-5-(1-Methylethyl)-3-Phenyl-4-[(Phenylamino)Carbonyl]-1H-Pyrrole-1-Heptanoic Acid Hemicalcium Salt (Atorvastatin)", on an application filed by Christopher Briggs, *et al.*, and

assigned to Warner-Lambert Company. On September 26, 2006, the USPTO issued an Ex Parte Reexamination Certificate for the '156 patent.

**PARTIES, JURISDICTION AND VENUE**

3. Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware and has a place of business at 235 East 42nd Street, New York, New York 10017.

4. Warner-Lambert Company is a corporation formerly organized under the laws of the State of Delaware with offices for service of process at 235 East 42nd Street, New York, New York 10017. Warner-Lambert Company has been the owner of record of the '156 patent since its issuance.

5. Warner-Lambert Company became a wholly-owned subsidiary of Pfizer Inc. effective June 19, 2000.

6. Warner-Lambert Company was converted into a Delaware limited liability company and changed its name to Warner-Lambert Company LLC on December 31, 2002. Warner-Lambert Company LLC has offices located at 235 East 42nd Street, New York, New York 10017.

7. Pfizer Ireland Pharmaceuticals is a partnership, organized and existing under the laws of Ireland, with registered offices at Pottery Road, Dun Laoghaire, Co. Dublin, Ireland. Pfizer Ireland Pharmaceuticals is a wholly-owned, indirect subsidiary of Pfizer Inc.

8. Pfizer Ireland Pharmaceuticals is the exclusive licensee of the '156 patent.

9. Pfizer has all the right, title, and interest in the '156 patent and the right to sue for infringement thereof.

10. Pfizer holds an approved New Drug Application for atorvastatin calcium formulations, including 10 mg, 20 mg, 40 mg, and 80 mg dosage strengths, which it sells under the registered name Lipitor®.

11. The '156 patent is identified pursuant to 21 U.S.C. § 355(b)(1) and (j)(7) by the United States Food and Drug Administration ("FDA") as covering Pfizer's Lipitor® product.

12. By letter dated October 26, 2009 (the "ANDA Notice Letter"), Defendants notified Pfizer that Defendants had filed Abbreviated New Drug Application ("ANDA") No. 91-650 seeking approval to market atorvastatin calcium tablets in 10 mg, 20 mg, and 40 mg dosage strengths, and that Defendants were providing information to Pfizer pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95. A copy of the ANDA Notice Letter on Dr. Reddy's Inc. letterhead is attached hereto as Exhibit B.

13. On information and belief, Defendant Dr. Reddy's Ltd. is a corporation operating and existing under the laws of India with its principal place of business at 7-1-27, Ameerpet, Hyderabad, 500 016, India.

14. On information and belief, Dr. Reddy's Inc. is a corporation operating and existing under the laws of New Jersey with a principal place of business at 200 Somerset Corporate Boulevard, Bridgewater, NJ 08807.

15. On information and belief, Defendant Dr. Reddy's Inc. is a wholly-owned subsidiary of Dr. Reddy's Ltd., and is controlled by Dr. Reddy's Ltd.

16. On information and belief, both Dr. Reddy's Ltd. and Dr. Reddy's Inc. participated in the preparation and/or filing of ANDA No. 91-650.

17. On information and belief and as stated in the ANDA Notice Letter, the FDA received ANDA No. 91-650 from Dr. Reddy's Ltd. and Dr. Reddy's Inc.

18. This action arises under the Patent Laws of the United States, Title 35, United States Code. This Court has subject matter jurisdiction over this action pursuant to the provisions of Title 28, United States Code, Sections 1331 and 1338.

19. On information and belief, Defendants are subject to personal jurisdiction in this District.

20. On information and belief, Defendants are in the business of developing and manufacturing generic and branded pharmaceutical products.

21. On information and belief, Defendants directly, or indirectly through subsidiaries and/or licensed third-party distributors, market, distribute, and sell their generic and branded pharmaceutical products within and throughout the United States, including the State of Delaware.

22. On information and belief, Defendants have purposefully availed themselves of the privilege of doing business in the State of Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including the State of Delaware, and/or by selling, directly or through their agents, pharmaceutical products in the State of Delaware.

23. On information and belief, Defendants maintain distribution and supply agreements to distribute Defendants' pharmaceutical products with companies that operate throughout the United States, including in the State of Delaware, including, *inter alia*, Caremark, Rite-Aid, CVS Distribution Inc., and/or Walgreens (d/b/a Happy Harry's Discount Drug Stores).

24. On information and belief, Defendant Dr. Reddy's Ltd.'s generic versions of Depakote®, Risperdal®, Altace®, Effexor®, Lamictal®, Keppra®, Cipro®, Vasotec®, Floxin®, Daypro®, Zocor®, Coreg®, Norvasc®, Zonegran®, Celexa®, Ambien®, Dynacin®,

and Aleve® are available for purchase, and have been purchased and used, in the State of Delaware.

25. On information and belief, Defendant Dr. Reddy's Inc.'s generic versions of Imitrex®, Prozac®, Zanaflex®, Zocor®, Pravachol®, Lamisil®, and Ibuprofen are available for purchase, and have been purchased and used, in the State of Delaware.

26. On information and belief, Defendants' generic versions of Accupril® and Meprobamate are also available for purchase, and have been purchased and used, in the State of Delaware.

27. On information and belief, Defendants derive substantial revenue from the sale of pharmaceutical products used and/or consumed in the State of Delaware.

28. On information and belief, from January 2009 to October 2009, approximately $1.8 million worth of Defendants' pharmaceutical products were sold and used within the State of Delaware.

29. On information and belief, the sales from January 2009 to October 2009 of Defendants' pharmaceutical products in Delaware represent a greater than two thousand percent (2000%) increase in revenue when compared to sales of Defendants' pharmaceutical products in Delaware in all of 2007.

30. On information and belief, Defendants' maintain a global distribution supply agreement with UPS Supply Chain Solutions to distribute their FDA-approved generic and/or branded drugs throughout the United States, including the State of Delaware.

31. On information and belief, UPS Supply Chain Solutions maintains active Pharmacy-Wholesale and Distributor/Manufacturer CSR licenses with the Delaware Board of

Pharmacy, which allow UPS Supply Chain Solutions to distribute manufactured pharmaceuticals and/or controlled substances within the State of Delaware.

32. On information and belief, personal jurisdiction over Defendants is also proper because Defendants have sought affirmative relief in this jurisdiction by answering complaints and filing counterclaims in at least four cases since 2004, and because Defendants have employed Delaware counsel to assist in obtaining that relief.

33. In one of those cases, *Merck & Co., Inc. v. Dr. Reddy's Labs., Ltd.*, No. 04-1313 (GMS), Defendants admitted that they are "subject to personal jurisdiction in this judicial district," *i.e.*, the District of Delaware.

34. Personal jurisdiction over Defendants is also proper because, on October 26, 2009, the same day as Defendants mailed the ANDA Notice Letter to Pfizer, Defendants chose to send their offer of confidential access to Defendants' ANDA information and a copy of the ANDA Notice Letter directly to Pfizer's counsel, Connolly Bove Lodge & Hutz LLP, a Delaware law firm with a principal place of business at 1007 North Orange Street, Wilmington, DE 19899, in Delaware.

35. Defendants' offer of confidential access is a central part of Defendants' attempt to obtain FDA marketing approval through their ANDA No. 91-650 filing.

36. Defendants purposefully availed themselves of the benefits and protection of the laws of the State of Delaware by voluntarily sending their offer of confidential access directly into Delaware.

37. Personal jurisdiction over Defendants is also proper because, by filing their ANDA No. 91-650 for generic atorvastatin calcium tablets, they have committed the tort of

patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A) and the location of that tort is where the patent holder, Pfizer, resides, *i.e.*, in Delaware.

38. Venue is proper in this District pursuant to the provisions of Title 28, United States Code, Sections 1391(c) and (d), and 1400(b).

**FIRST CLAIM FOR RELIEF:**
**INFRINGEMENT OF THE '156 PATENT**

39. The allegations of paragraphs 1-38 above are repeated and realleged as if set forth fully herein.

40. The expiration date for the '156 patent is July 8, 2016.

41. Patents associated with Lipitor®, including the '156 patent, have been granted a further period of pediatric exclusivity under section 505a of the Food, Drug and Cosmetic Act [21 U.S.C. § 355a].

42. The pediatric exclusivity period associated with the '156 patent will expire January 8, 2017.

43. The ANDA Notice Letter notified Pfizer that Defendants, by filing ANDA No. 91-650, seek approval from the FDA to engage in the commercial manufacture, use, and sale of products containing different strengths of atorvastatin calcium prior to the expiration of the '156 patent.

44. The ANDA Notice Letter addressed the '156 patent and asserted that the patent was not infringed by Defendants' proposed ANDA No. 91-650 atorvastatin calcium product.

45. The ANDA Notice Letter did not provide an explanation of any grounds supporting a contention that any claim of the '156 patent is invalid, as would be required by 21 CFR § 314.95(c)(6)(ii) if Defendants contended that any of the claims were invalid.

46. Defendants have infringed the '156 patent under 35 U.S.C. § 271(e)(2)(A) by filing their ANDA No. 91-650 seeking approval from the FDA to engage in the commercial manufacture, use, or sale of a product containing atorvastatin calcium prior to the expiration of the '156 patent.

47. Pfizer will be irreparably harmed if Defendants' ANDA No. 91-650 is approved prior to the expiration date of the '156 patent.

48. Pfizer will be irreparably harmed if Defendants are not enjoined from infringing the '156 patent.

**PRAYER FOR RELIEF**

WHEREFORE, Pfizer requests the following relief:

A. A judgment providing that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any FDA approval of Defendants' ANDA No. 91-650 be no earlier than January 8, 2017, the date of expiration of the '156 Patent, including the period of exclusivity granted to Lipitor® under section 505a of the Food, Drug and Cosmetic Act;

B. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendants, each of their officers, agents, servants, employees and attorneys, and those persons in active concert or participation with it or any of them, from making, using, selling, offering to sell, or importing the atorvastatin calcium product described in Defendants' ANDA No. 91-650 until January 8, 2017, the expiration date of the '156 patent including the period of exclusivity granted to Lipitor® under section 505a of the Food, Drug and Cosmetic Act;

C. Attorneys' fees in this action pursuant to 35 U.S.C. § 285;

D. Costs and expenses in this action; and

E. Such further and other relief as this Court may deem just and proper.

RESPECTFULLY SUBMITTED,

*/s/ Rudolf E. Hutz*
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Dated: December 8, 2009
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