IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., PFIZER PHARMACEUTICALS, LLC, PFIZER IRELAND PHARMACEUTICALS, PFIZER LIMITED, and C.P. PHARMACEUTICALS INTERNATIONAL C.V.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. _____
DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC.,	)	
Defendants.	)	

COMPLAINT

Pfizer Inc., Pfizer Pharmaceuticals, LLC, Pfizer Ireland Pharmaceuticals, Pfizer Limited, and C.P. Pharmaceuticals International C.V. (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 United States Patent No. 6,455,574 and its Reexamination Certificate (collectively "the '574 patent"). A copy of the '574 patent and its Reexamination certificate is attached hereto as Exhibit A.

PATENT IN SUIT

2. On September 24, 2002, the United States Patent and Trademark Office ("USPTO") issued the '574 patent, entitled "Therapeutic Combination," on an application filed by Jan Buch and assigned to Pfizer Inc. On December 13, 2011, the USPTO issued an Ex Parte Reexamination Certificate for the '574 patent.

THE PARTIES

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. Pfizer Inc. is the assignee of the '574 patent.

4. Pfizer Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware with offices at 235 East 42nd Street, New York, New York 10017. Pfizer Pharmaceuticals, LLC is a wholly owned subsidiary of Pfizer Inc.

5. Pfizer Limited is a company incorporated under the laws of England with offices at Ramsgate Road, Sandwich, Kent, England CT13 9NJ. Pfizer Limited is a wholly owned, indirect subsidiary of Pfizer Inc.

6. Pfizer Ireland Pharmaceuticals is an Irish unlimited liability company having its registered office at Operations Support Group, Ringaskiddy, Co. Cork. Pfizer Ireland Pharmaceuticals is an indirect wholly owned subsidiary of Pfizer Inc.

7. Pfizer Limited and Pfizer Ireland Pharmaceuticals are beneficial owners of the '574 patent.

8. C.P. Pharmaceuticals International C.V. is a limited partnership (*commanditaire vennootschap*) organized under the laws of the Netherlands, having its registered seat in Rotterdam, and registered at the trade register held by the Chamber of Commerce in Rotterdam, the Netherlands, under number 24280998. C.P. Pharmaceuticals International C.V. is a wholly owned subsidiary of Pfizer Inc.

9. C.P. Pharmaceuticals International C.V. is the exclusive licensee of Pfizer Limited under the '574 patent.

10. Pfizer Pharmaceuticals, LLC is the exclusive licensee of the '574 patent by assignment from C.P. Pharmaceuticals International C.V.

11. Pfizer has all the right, title, and interest in the '574 patent and the right to sue for infringement thereof.

12. C.P. Pharmaceuticals International C.V. holds an approved New Drug Application ("NDA") No. 21-540 for formulations comprised of the active ingredients amlodipine besylate and atorvastatin calcium, including 2.5mg/10mg, 2.5mg/20mg, 2.5mg/40mg, 5mg/10mg, 5mg/20mg, 5mg/40mg, 5mg/80mg, 10mg/10mg, 10mg/20mg, 10mg/40mg, and 10mg/80mg dosage strengths, which it sells in the United States under the registered name CADUET®.

13. The '574 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 CADUET® products.

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

15. On information and belief, Defendant Dr. Reddy's Laboratories, 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.

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

JURISDICTION AND VENUE

17. On information and belief, Defendants filed with the FDA, in Rockville, Maryland, Abbreviated New Drug Application ("ANDA") No. 203874 under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, importation, offer for sale, and sale in the United States of tablets containing, in various dosage strengths, the active ingredients amlodipine besylate and atorvastatin calcium that are generic versions of Pfizer's CADUET® tablets.

18. By letter dated March 1, 2012 (the "ANDA Notice Letter"), Defendant Dr. Reddy's Laboratories, Inc., on behalf of Defendant Dr. Reddy's Laboratories, Ltd., notified Pfizer that the Defendants have filed ANDA No. 203874 seeking FDA approval to market tablets containing, in various dosage strengths, the active ingredients amlodipine besylate and atorvastatin calcium, and that Defendants were providing information to Pfizer pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 CFR § 314.95. A copy of the ANDA Notice Letter is attached hereto as Exhibit B.

19. On information and belief, both Defendants participated in the preparation and/or filing of ANDA No. 203874.

20. On information and belief, and as stated in the ANDA Notice Letter, the FDA received ANDA No. 203874 from Defendants.

21. 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 28 U.S.C. §§ 1331 and 1338.

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

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

24. 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.

25. 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.

26. 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.

27. On information and belief, Defendant Dr. Reddy's Laboratories, 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.

28. On information and belief, Defendant Dr. Reddy's Laboratories, 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.

29. 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.

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

31. 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.

32. 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.

33. 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.

34. 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.

35. 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 five cases since 2004, and because Defendants have employed Delaware counsel to assist in obtaining that relief.

36. In *Merck & Co., Inc. v. Dr. Reddy's Labs., Ltd.*, No. 04cv1313 GMS, Defendants admitted that they are "subject to personal jurisdiction in this judicial district," *i.e.*, the District of Delaware. Similarly, in *Forest Labs., Inc. et al. v. Dr. Reddy's Labs., Inc. et al.*, No. 08cv52 GMS and *Roche Palo Alto LLC et al. v. Dr. Reddy's Labs, Ltd., et al.*, No. 11cv1264 GMS Defendants did not contest that the District of Delaware Court has personal jurisdiction over themselves.

37. Personal jurisdiction over Defendants is also proper because, by filing their ANDA No. 203874 for generic tablets containing amlodipine besylate and atorvastatin calcium as active ingredients, 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 '574 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 '574 patent is August 11, 2018.

41. The ANDA Notice Letter notified Pfizer that Defendants, by filing ANDA No. 203874, seek approval from the FDA to engage in the commercial manufacture, use, and sale of tablets containing various dosage strengths of amlodipine besylate and atorvastatin calcium as the active ingredients prior to the expiration of the '574 patent.

42. The ANDA Notice Letter addressed the '574 patent and asserted that the patent was invalid.

43. The ANDA Notice Letter did not provide any explanation of why the claims of the '574 patent are not infringed, as would be required by 21 CFR § 314.95(c)(6)(i) if Defendants contended that the claims were not infringed.

44. Defendants have infringed the '574 patent under 35 U.S.C. § 271(e)(2)(A) by filing their ANDA No. 203874 seeking approval from the FDA to engage in the commercial manufacture, use, or sale of tablets containing various dosage strengths of amlodipine besylate and atorvastatin calcium as the active ingredients prior to the expiration of the '574 patent.

45. Pfizer will be irreparably harmed if Defendants' ANDA No. 203874 is approved prior to the expiration date of the '574 patent.

46. Pfizer will be irreparably harmed if Defendants are not enjoined from infringing the '574 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 for Defendants' ANDA No. 203874 be no earlier than August 11, 2018, the expiration date of the '574 patent;

B. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendants, their officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them, from making, using, selling, offering to sell, or importing the amlodipine besylate and atorvastatin calcium products described in Defendants' ANDA No. 203874 until August 11, 2018, the expiration date of the '574 patent;

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,

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Dated: April 13, 2012

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