IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

PFIZER INC, Plaintiff, v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC., Defendants.	)	Civil Action No. 04 CV 1349

COMPLAINT

Pfizer Inc ("Pfizer"), by its attorneys, for its complaint against Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively "Reddy") alleges as follows:

1. This is an action by Pfizer against Reddy for infringement of United States Patent Nos. 4,572,909 (the "'909 patent") and 4,879,303 (the "'303 patent").

PARTIES, JURISDICTION AND VENUE

2. Pfizer is a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at 235 East 42nd Street, New York, New York. Pfizer invests extensively in designing, developing, and testing and evaluating new and innovative pharmaceutical products and it sells pharmaceutical products to the public throughout the United States.

3. Upon information and belief, Dr. Reddy's Laboratories, Ltd. is a corporation organized and existing under the laws of India and has its principal place of business in Hyderabad, India.

4. Upon information and belief, Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey and has its principal place of business at One Park Way, Upper Saddle River, New Jersey.

5. Upon information and belief, Dr. Reddy's Laboratories, Inc. is a wholly owned subsidiary of Dr. Reddy's Laboratories, Ltd. and is the designated United States agent for Dr. Reddy's Laboratories, Ltd.

6. Upon information and belief, Dr. Reddy's Laboratories, Ltd. is in the business of making and selling generic drug products.

7. Upon information and belief, Dr. Reddy's Laboratories, Ltd. and/or Dr. Reddy's Laboratories, Inc. sell and contract to sell generic drug products in the United States, including in the State of New York.

8. Upon information and belief, Reddy assembled and caused to be filed with the United States Food and Drug Administration (the "FDA"), pursuant to 21 U.S.C. § 355(j)(2), Abbreviated New Drug Application No. 76-692 ("ANDA No. 76-692"), addressed to a proposed drug product identified as "amlodipine besylate tablets" (2.5 mg, 5 mg and 10 mg strengths) ("Reddy Amlodipine Besylate Tablets").

9. 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, 1338, 2201 and 2202.

10. Defendants are subject to personal jurisdiction in this judicial district.

11. Venue is proper in this judicial district pursuant to the provisions of 28 U.S.C. §§ 1391 and 1400(b).

FIRST CLAIM FOR RELIEF: INFRINGEMENT OF THE '909 PATENT

12. Pfizer realleges paragraphs 1 through 11 above as if fully set forth herein.

13. On February 25, 1986, the United States Patent and Trademark Office (the "PTO") issued to Pfizer the '909 patent, entitled "2-(Secondary Aminoalkoxymethyl) Dihydropyridine Derivatives as Anti-Ischaemic and Antihypertensive Agents," based on an application filed by Simon F. Campbell, Peter E. Cross, and John K. Stubbs, which had been assigned to Pfizer. Pfizer currently holds, and it continuously has held title to the '909 patent since it was issued. A copy of the '909 patent is attached hereto as Exhibit A.

14. The '909 patent discloses and claims, inter alia, a genus of dihydropridine compounds, including amlodipine, or their pharmaceutically acceptable acid addition salts, pharmaceutical compositions comprising the claimed compounds, and methods of treating ischaemic heart disease and hypertension by administering the claimed compounds.

15. Pfizer holds an approved New Drug Application for amlodipine besylate tablets, 2.5 mg, 5 mg and 10 mg dosage strengths, which it sells under the registered name Norvasc®. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA promulgated pursuant thereto, the '909 patent is listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to the Norvasc® drug product.

16. On December 6, 1993, the PTO issued a certificate extending the term of the '909 patent for 1,252 days, until July 31, 2006 (the "Patent Term Restoration"). The Norvasc® product is also entitled to six months of "pediatric exclusivity" pursuant to the provisions of 21 U.S.C. § 355a. Consequently, the Orange Book lists the '909 patent's expiration date as January 31, 2007.

17. On January 16, 2004, Pfizer received from Reddy a "Notice of Paragraph IV Certification," dated January 13, 2004, stating that Reddy had filed ANDA No. 76-692 with

the FDA, seeking approval to market and sell its Reddy Amlodipine Besylate Tablets before the '909 patent's expiration date of January 31, 2007, as listed in the Orange Book ("Reddy's Notice Letter").

18. Reddy's Notice Letter states that Reddy's ANDA No. 76-692 certifies, pursuant to 21 C.F.R. § 314.94(a)(12)(i)(A)(4) ("paragraph IV certification as to the '909 patent"), that the manufacture, use or sale of its Reddy Amlodipine Besylate Tablets will not infringe the '909 patent.

19. Reddy has infringed the '909 patent under 35 U.S.C. § 271(e)(2)(A) by submitting to the FDA ANDA No. 76-692, which includes the paragraph IV certification as to the '909 patent and which seeks approval from the FDA to engage in the commercial manufacture, use, or sale of its Reddy Amlodipine Besylate Tablets prior to the expiration of the '909 patent.

20. Upon information and belief, Reddy is committed to selling and intends to market its Reddy Amlodipine Besylate Tablets promptly following FDA approval of ANDA No. 76-692.

21. Upon information and belief, Reddy has knowingly and willfully infringed the '909 patent.

22. Pfizer will be irreparably harmed if Reddy is not enjoined from infringing the '909 patent.

SECOND CLAIM FOR RELIEF: INFRINGEMENT OF THE '303 PATENT

23. Pfizer realleges paragraphs 1 through 22 above as if fully set forth herein.

24. On November 7, 1989, the PTO issued to Pfizer the '303 patent, entitled "Pharmaceutically Acceptable Salts," based on an application filed by Edward Davison and James I. Wells, which had been assigned to Pfizer. Pfizer currently holds, and it continuously

has held title to the '303 patent since it was issued. A copy of the '303 patent is attached hereto as Exhibit B.

25. The '303 patent discloses and claims the besylate salt of amlodipine, which is useful as an anti-hypertensive, antiischaemic, and angina-alleviating agent, and tablet and capsule formulations of the besylate salt of amlodipine.

26. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA promulgated pursuant thereto, the '303 patent is listed in the Orange Book with respect to the Norvasc® drug product.

27. As stated above, the Norvasc® product is entitled to six months of "pediatric exclusivity" pursuant to the provisions of 21 U.S.C. § 355a. Consequently, the Orange Book lists the '303 patent's expiration date as September 25, 2007.

28. Reddy's Notice Letter also states that Reddy's ANDA No. 76-692, filed with the FDA, seeks approval to market and sell its Reddy Amlodipine Besylate Tablets before the '303 patent's expiration date of September 25, 2007, as listed in the Orange Book.

29. Reddy's Notice Letter states that Reddy's ANDA No. 76-692 certifies, pursuant to 21 C.F.R. § 314.94(a)(12)(i)(A)(4) ("paragraph IV certification as to the '303 patent"), that the manufacture, use or sale of its Reddy Amlodipine Besylate Tablets will not infringe the '303 patent.

30. Reddy has infringed the '303 patent under 35 U.S.C. § 271(e)(2)(A) by submitting to the FDA ANDA No. 76-692, which includes the paragraph IV certification as to the '303 patent and which seeks approval from the FDA to engage in the commercial manufacture, use, or sale of its Reddy Amlodipine Besylate Tablets prior to the expiration of the '303 patent.

31. Upon information and belief, Reddy is committed to selling and intends to market its Reddy Amlodipine Besylate Tablets promptly following FDA approval of ANDA No. 76-692.

32. Upon information and belief, Reddy has knowingly and willfully infringed the '303 patent.

33. Pfizer will be irreparably harmed if Reddy is not enjoined from infringing the '303 patent.

WHEREFORE, Pfizer Inc requests the following relief:

1. A judgment providing that the effective date of any FDA approval for Reddy to make, use, sell, offer for sale, or import the Reddy Amlodipine Besylate Tablets described in ANDA No. 76-692 be no earlier than the date on which the '909 patent term, including the term granted under the Patent Term Restoration and the pediatric exclusivity period, expires, and no earlier than the date on which the '303 patent term, including the pediatric exclusivity period, expires;

2. A judgment permanently enjoining Reddy from making, using, selling, offering to sell, or importing the Reddy Amlodipine Besylate Tablets described in ANDA No. 76-692 until after expiration of the '909 patent term, including the term granted under the Patent Term Restoration and the pediatric exclusivity period, expires, and no earlier than the date on which the '303 patent term, including the pediatric exclusivity period, expires;

3. A judgment declaring that Reddy's making, using, selling, offering to sell, or importing into the United States the Reddy Amlodipine Besylate Tablet described in ANDA No. 76-692 will infringe the '909 and '303 patents;

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

5. Costs and expenses incurred in pursuing this action; and

6. Such further and other relief as this Court may determine to be just and proper.

Dated: February 18, 2004

_s/_____
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