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Attorneys for Plaintiffs Attorneys for Plaintiffs Pfizer Inc., Pfizer Pharmaceuticals, LLC, Pfizer Limited, C.P. Pharmaceuticals International C.V., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, LLC And Warner Lambert Export, Ltd.

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

PFIZER INC., PFIZER PHARMACEUTICALS, LLC, PFIZER LIMITED, C.P. PHARMACEUTICALS INTERNATIONAL C.V., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY, LLC and WARNER-LAMBERT EXPORT, LTD. Plaintiffs, v. RANBAXY LABORATORIES LIMITED, and RANBAXY INC. Defendants.	Civil Action No. 07-___ **COMPLAINT**

Pfizer Inc., Pfizer Pharmaceuticals, LLC, Pfizer Limited, C.P. Pharmaceuticals International C.V., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, Warner-Lambert Company, LLC and Warner-Lambert Export, Limited, (collectively referred to as "Pfizer"), by their attorneys, for their complaint against Ranbaxy Laboratories Limited ("Ranbaxy Laboratories") and Ranbaxy Inc. ("Ranbaxy Inc.")(collectively "Ranbaxy"), allege as follows:

1. This is an action by Pfizer against Ranbaxy for infringement of United States Letters Patent Nos. 4,681,893 ("the '893 patent") and 6,455,574 ("the '574 patent"). A copy of each patent is attached hereto as Exhibits A and B respectively.

2. On July 21, 1987, the United States Patent and Trademark Office ("PTO") issued the '893 patent, entitled "Trans-6-[2-(3- or 4-Carboxamido-Substituted Pyrrol-1-yl)Alkyl]-4-Hydroxypyran-2-One Inhibitors of Cholesterol Synthesis," on an application filed by Bruce D. Roth and assigned to Warner-Lambert Company.

3. On September 24, 2002, the PTO issued the '574 patent, entitled "Therapeutic Combination," on an application filed by Jan Buch and assigned to Pfizer Inc.

PARTIES, JURISDICTION AND VENUE

4. 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. has been the owner of record of the '574 patent since its issuance

5. 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.

6. 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.

7. 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.

8. C.P. Pharmaceuticals International C.V. is the owner of NDA 21-540 for Caduet®.

9. 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 '893 patent since its issuance.

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

11. Warner-Lambert Company was converted into Warner-Lambert Company, LLC, a Delaware limited liability company by certificate dated December 31, 2002. Warner-Lambert Company, LLC has offices located at 235 East 42nd Street, New York, New York 10017.

12. 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.

13. Warner-Lambert Export, Ltd. is a corporation formerly organized under the laws of Ireland with a registered office located at Pottery Road, Dun Laoghaire, Co. Dublin, Ireland.

14. The exclusive licensee of the '893 patent is Pfizer Ireland Pharmaceuticals, formerly Warner-Lambert Export, Ltd.

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

16. Pfizer holds an approved New Drug Application for a formulation comprised of the active ingredients amlodipine besylate and atorvastatin calcium, which it sells in the United States under the registered name Caduet®.

17. The '893 patent is identified pursuant to 21 U.S.C. §355(b)(1) by the United States Food and Drug Administration ("FDA") as covering Pfizer's Caduet® product.

18. The '574 patent is identified pursuant to 21 U.S.C. §355(b)(1) by FDA as covering Pfizer's Caduet® product.

19. Ranbaxy Inc. is a corporation organized and existing under the laws of the State of Delaware, and has a place of business located at 600 College Road East, Princeton, New Jersey 08540.

20. Ranbaxy Inc. was formerly known as Ranbaxy Pharmaceuticals Inc.

21. Upon information and belief, Ranbaxy Laboratories is a corporation organized and existing under the laws of India, with corporate offices located at 19, Nehru Place New Delhi - 110019 India.

22. Upon information and belief, Ranbaxy Inc. is a wholly-owned subsidiary of Ranbaxy Laboratories.

23. 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.

24. Ranbaxy Laboratories and Ranbaxy Inc. are subject to personal jurisdiction in this District.

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

THE PRIOR INFRINGEMENT LITIGATION AGAINST RANBAXY

26. Pfizer, through Parke-Davis Pharmaceutical Research, a division of Warner-Lambert Company, holds an approved New Drug Application for a formulation containing atorvastatin calcium, which it sells under the registered name Lipitor®.

27. Pfizer received letters dated January 23, 2003 from Ranbaxy Pharmaceuticals, Inc. (the "January 23, 2003 letters") which notified Pfizer that Ranbaxy Laboratories had filed an Abbreviated New Drug Application (ANDA), ANDA No. 76-477, seeking approval from FDA to engage in the commercial manufacture, use, and sale of a product containing atorvastatin calcium as its active ingredient ("Ranbaxy's Atorvastatin Product") prior to the expiration of the '893 patent.

28. Pursuant to 35 U.S.C. §271 (e)(2), Pfizer filed suits against Ranbaxy Laboratories and Ranbaxy Pharmaceuticals, Inc. in the United States District Court for the District of Delaware alleging that Ranbaxy's proposed ANDA product infringed the '893 patent.

29. Pfizer's Complaints were consolidated into Civil Action No. 03-209-JJF (collectively the "Lipitor® Litigation").

30. Ultimately, Pfizer alleged infringement of claims 1-4, 8 and 9 of the '893 patent in the Lipitor® Litigation.

31. In response to Pfizer's Complaints, Ranbaxy filed an Answer and several Counterclaims.

32. Ranbaxy's Answer and Counterclaims averred that it did not infringe the '893 patent.

33. Ranbaxy's Answer and Counterclaims also challenged the validity of the patent term extension granted by the PTO for the '893 patent.

34. At no time during the Lipitor® Litigation did Ranbaxy plead or assert that any claim in the '893 patent was invalid for obviousness under 35 U.S.C. §103.

35. EP 247 633 is the European counterpart to the '893 patent.

36. Prior to trial in the Lipitor® Litigation, Ranbaxy was aware of EP 247 633 and its prosecution before the European Patent Office.

37. Specifically, prior to trial in the Lipitor® Litigation, Ranbaxy was aware of the first examination report in the EP 247 633 prosecution, the citation of EP 179 559 in the first examination report and Warner-Lambert's response thereto.

38. EP 247 633 was marked as trial Exhibit PTX 244 in the Lipitor® Litigation.

39. A portion of the prosecution history of EP 247 633 was the subject of a stipulation in the Lipitor® Litigation, dated September 3, 2004 (D.I. 191).

40. EP 179 559 was produced in discovery as document number P0267818 in the Lipitor® Litigation.

41. Ranbaxy did not rely on EP 179 559 as prior art for any purpose in the Lipitor® Litigation or in any briefing filed by Ranbaxy after trial.

42. By its opinion dated December 16, 2005 in the Lipitor® Litigation, the District Court held that the '893 patent was not invalid or unenforceable.

43. The District Court also concluded that the '893 patent claims were not limited to racemic mixtures but also embraced individual trans-form isomers, corresponding to the R-trans and S-trans, as well as their trans-form mixtures, including racemates.

44. The District Court further held that Ranbaxy's Atorvastatin Product, the subject of ANDA No. 76-477, literally infringed claims 1-4 and 8-9 of the '893 patent.

45. The District Court additionally held that the patent term extension of the '893 patent was not invalid or unenforceable.

46. Ranbaxy appealed the District Court's decision in the Lipitor® Litigation to the United States Court of Appeals for the Federal Circuit ("Federal Circuit") in Appeal No. 06-1179 (the "Lipitor® Appeal").

47. In the Lipitor® Appeal, the Federal Circuit affirmed that the '893 patent was infringed, not invalid and not unenforceable.

48. The Federal Circuit further affirmed that the patent term extension of the '893 patent was not invalid and not unenforceable.

49. Ranbaxy filed a Petition for Rehearing and Rehearing En Banc in the Lipitor® Appeal and the Federal Circuit denied that petition.

50. An amended final judgment was entered by the District Court in the Lipitor Litigation, by Orders of the Court dated November 7, 2006 and November 30, 2006. A copy of the final judgment, as amended, is attached as Exhibit C.

51. Judgment has been entered in the Lipitor® Litigation "in favor of plaintiffs Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, Warner-Lambert Company LLC and Warner-Lambert Export, Ltd. (collectively "Pfizer") and against defendants Ranbaxy

Laboratories Limited and Ranbaxy Pharmaceuticals Incorporated (collectively "Ranbaxy") on Pfizer's claims that Ranbaxy has infringed claims 1-4, and 8-9 of the '893 patent…".

52. Judgment has been further entered in the Lipitor® Litigation, "that pursuant to 35 U.S.C. §271 (e)(4)(A), the effective date of any approval of Ranbaxy's Abbreviated New Drug Application No. 76-477 shall be a date which is not earlier than the date of expiration of the '893 Patent and its patent term extension (September 24, 2009, with attached six months of pediatric exclusivity ending on March 24, 2010, to which Pfizer is entitled)."

53. Judgment has also been entered in the Lipitor® Litigation, "that pursuant to 35 U.S.C. §271 (e)(4)(B), defendants Ranbaxy Laboratories Limited and Ranbaxy Pharmaceuticals Incorporated, each of their officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them or either of them are permanently enjoined from engaging in the manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any product comprising atorvastatin calcium covered by, or the use of which is covered by claims 1-4 and 8-9 of the '893 Patent."

54. The judgment entered in Civil Action No. CIV.A. 03-209-JJF is final for purposes of *res judicata.*

55. Ranbaxy is barred by res judicata and collateral estoppel from attacking the validity or enforceability of the patent term extension for the '893 patent and the infringement, validity and enforceability of the '893 patent.

FIRST CLAIM FOR RELIEF; INFRINGEMENTOF THE '893 PATENT

56. Pfizer realleges paragraphs 1 through 55 above as if fully set forth herein.

57. Pfizer has received a letter dated January 24, 2007 from Ranbaxy Inc. (the "January 24, 2007 letter") which notified Pfizer that Ranbaxy Laboratories had filed an Abbreviated New Drug Application ("Ranbaxy's ANDA") seeking approval from FDA to engage in the commercial manufacture, use, and sale of a product containing amlodipine besylate and atorvastatin calcium as the active ingredients ("Ranbaxy's New ANDA Product") prior to the expiration of the '893 patent. A copy of the January 24, 2007 letter is attached hereto as Exhibit D.

58. The January 24, 2007 letter stated that "RLL's ANDA referred to in paragraph (1) has not been assigned a number to date, but this will be supplied to you as it is available."

59. Ranbaxy Inc. is Ranbaxy Laboratories' agent for service of process under Ranbaxy's ANDA.

60. The original expiration date for the '893 patent was May 30, 2006.

61. On July 15, 1998, the PTO granted the '893 patent a 1,213 day patent term extension pursuant to 35 U.S.C. §156, extending the expiration date of the '893 patent to September 24, 2009.

62. Lipitor® was granted a further period of exclusivity under section 505 of the Food, Drug and Cosmetic Act to March 24, 2010.

63. Ranbaxy is barred from challenging the infringement, validity and enforceability of the '893 patent by the final judgment, as amended, entered in the Lipitor® Litigation.

64. Upon information and belief, Ranbaxy's New ANDA Product contains atorvastatin calcium, the same active ingredient contained in Ranbaxy's Atorvastatin Product found to infringe the '893 patent in the Lipitor® Litigation.

65. Ranbaxy Laboratories has infringed the '893 patent under 35 U.S.C. §271(e)(2) by filing Ranbaxy's ANDA seeking approval from the FDA to engage in the commercial manufacture, use, or sale of a product containing atorvastatin calcium as an active ingredient prior to the expiration of the '893 patent.

66. Alternatively, Ranbaxy Inc. has infringed the '893 patent under 35 U.S.C. §271(e)(2) by filing Ranbaxy's ANDA seeking approval from the FDA to engage in the commercial manufacture, use, or sale of a product containing atorvastatin calcium as an active ingredient prior to the expiration of the '893 patent.

67. Alternatively, Ranbaxy Inc. and Ranbaxy Laboratories have jointly infringed the '893 patent under 35 U.S.C. §271(e)(2) by filing Ranbaxy's ANDA seeking approval from the FDA to engage in the commercial manufacture, use, or sale of a product containing atorvastatin calcium as an active ingredient prior to the expiration of the '893 patent.

68. Pfizer will be irreparably harmed if Ranbaxy is not enjoined from infringing the '893 patent.

69. Because Ranbaxy is barred, *inter alia*, by the final judgment, as amended, in the Lipitor® Litigation from challenging the infringement, validity and enforceability of the '893 patent and the validity and enforceability of the '893 patent term extension and further barred from challenging infringement of the '893 patent by its Atorvastatin Product, the filing of the Ranbaxy ANDA containing a Paragraph IV certification to the '893 patent is a willful infringement of the '893 patent under 35 U.S.C. §271(e)(2), making this an exceptional case within the meaning of 35 U.S.C. §285 and thereby entitling Pfizer to its attorneys' fees.

SECOND CLAIM FOR RELIEF:
INFRINGEMENT OF THE '574 PATENT

70. Pfizer realleges paragraphs 1 through 69 above as if fully set forth herein.

71. Ranbaxy's January 24, 2007 Letter further notified Pfizer that Ranbaxy Laboratories had filed Ranbaxy's ANDA seeking approval from FDA to engage in the commercial manufacture, use, and sale of a product containing amlodipine besylate and atorvastatin calcium as the active ingredients prior to the expiration of the '574 patent.

72. The expiration date for the '574 patent is February 25, 2020.

73. Ranbaxy Laboratories has infringed the '574 patent under 35 U.S.C. §271(e)(2) by filing Ranbaxy's ANDA seeking approval from the FDA to engage in the commercial manufacture, use, or sale of a product containing amlodipine besylate and atorvastatin calcium as the active ingredients prior to the expiration of the '574 patent.

74. Alternatively, Ranbaxy Inc. has infringed the '574 patent under 35 U.S.C. §271(e)(2) by filing Ranbaxy's ANDA seeking approval from the FDA to engage in the commercial manufacture, use, or sale of a product containing amlodipine besylate and atorvastatin calcium as the active ingredients prior to the expiration of the '574 patent.

75. Alternatively, Ranbaxy Inc. and Ranbaxy Laboratories have jointly infringed the '574 patent under 35 U.S.C. §271(e)(2) by filing Ranbaxy's ANDA seeking approval from the FDA to engage in the commercial manufacture, use, or sale of a product containing amlodipine besylate and atorvastatin calcium as the active ingredients prior to the expiration of the '574 patent.

76. Pfizer will be irreparably harmed if Ranbaxy is not enjoined from infringing the '574 patent.

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 Ranbaxy's ANDA be no earlier than March 24, 2010, the date of expiration of the '893 Patent and its patent term extension (September 24, 2009, with attached six months of pediatric exclusivity ending on March 24, 2010, to which Pfizer is entitled);

B. A judgment pursuant to 35 U.S.C. §271(e)(4)(B) permanently enjoining Ranbaxy Inc. and Ranbaxy Laboratories, each of their officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them or either of them, from making, using, selling, offering to sell, or importing the atorvastatin product described in Ranbaxy's ANDA until March 24, 2010, the expiration date of the '893 patent;

C. A judgment providing that pursuant to 35 U.S.C. §271(e)(4)(A), the effective date of any FDA approval for Ranbaxy's ANDA be no earlier than February 25, 2020, the date on which the '574 patent expires;

D. A judgment pursuant to 35 U.S.C. §271 (e)(4)(B) permanently enjoining Ranbaxy Inc. and Ranbaxy Laboratories, each of their officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them or either of them, from making, using, selling, offering to sell, or importing the atorvastatin product described in Ranbaxy's ANDA until February 25, 2020, the expiration date of the '574 patent;

E. Attorneys' fees in this action under 35 U.S.C. §285;

F. Costs and expenses in this action; and

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

By _____

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