

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

PFIZER INC,)
PFIZER IRELAND PHARMACEUTICALS,)
WARNER-LAMBERT COMPANY,)
WARNER-LAMBERT COMPANY, LLC)
and)
WARNER-LAMBERT EXPORT, LTD.)

Plaintiffs,)

v.)

Civil Action No. 08-

RANBAXY LABORATORIES)
LIMITED,)
RANBAXY PHARMACEUTICALS, INC)
and RANBAXY INC.)

Defendants.)

COMPLAINT

Pfizer Inc., 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”), Ranbaxy Pharmaceuticals, Inc. (“Ranbaxy Pharmaceuticals”) and Ranbaxy Inc. (“Ranbaxy Inc.”)(collectively “Ranbaxy”), allege as follows:

1. This is an action by Pfizer against Ranbaxy for declaratory judgment of infringement of United States Letters Patent No. 6,087,511 (“the ‘511 patent) and United States Letters Patent No. 6,274,740 (“the ‘740 patent’). A copy of the ‘511 patent is attached hereto as Exhibit A. A copy of the ‘740 patent is attached hereto as Exhibit B.

2. On July 11, 2000 the United States Patent and Trademark Office issued the ‘511 patent, entitled “Process for the Production of Amorphous [R-(R*,R*)]-2-(4-Fluorophenyl)-β,δ-Dihydroxy-5-(1-Methylethyl)-3-Phenyl-4-[(Phenylamino)Carbonyl]-1H-Pyrrole-1-Heptanoic

Acid) Calcium Salt (2:1)”, on an application filed by Min Lin, et al. and assigned to Warner-Lambert Company.

3. On August 14, 2001 the United States Patent and Trademark Office issued the ‘740 patent, entitled “Process for the Production of Amorphous [R-(R*,R*)]-2-(4-Fluorophenyl)- β,δ -Dihydroxy-5-(1-Methylethyl)-3-Phenyl-4-[(Phenylamino)Carbonyl]-1H-Pyrrole-1-Heptanoic Acid) Calcium Salt (2:1)”, on an application filed by Lin Min, et al. and assigned to Warner-Lambert Company.

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.

5. 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 ‘511 and the ‘740 patents since their issuance.

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

7. 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.

8. Pfizer Ireland Pharmaceuticals is 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.

9. 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.

10. The exclusive licensee of the '511 patent is Pfizer Ireland Pharmaceuticals, formerly Warner-Lambert Export, Ltd.

11. The exclusive licensee of the '740 patent is Pfizer Ireland Pharmaceuticals, formerly Warner-Lambert Export, Ltd.

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

13. 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.

14. 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.

15. Upon information and belief, Ranbaxy Inc. was formerly known as Ranbaxy Pharmaceuticals Inc.

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

17. Ranbaxy Pharmaceuticals, 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.

18. Upon information and belief, Ranbaxy Inc. and Ranbaxy Pharmaceuticals Inc. are the agents for Ranbaxy Laboratories.

19. 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.

20. Upon information and belief, Ranbaxy Laboratories, Ranbaxy Pharmaceuticals and Ranbaxy Inc. are subject to personal jurisdiction in this District.

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

FIRST CLAIM FOR RELIEF:
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '511 PATENT

22. Pfizer realleges paragraphs 1 through 21 above as if fully set forth herein.

23. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, based upon an actual controversy between the parties.

24. Pfizer has received a letter dated February 28, 2003 from Ranbaxy Pharmaceuticals (the "February 28, 2003 letter") 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 as the active ingredient ("Ranbaxy's Atorvastatin Product") on a date which is prior to the expiration of the '511 patent. A copy of the February 28, 2003 letter is attached hereto as Exhibit C.

25. Ranbaxy has taken immediate and active steps to obtain FDA approval to sell in the United States and to commence sale in the United States of Ranbaxy's Atorvastatin Product immediately following FDA approval.

26. Pursuant to 35 U.S.C. § 271(e)(2) and (e)(4), Pfizer obtained a judgment which enjoins the effective date of approval of Ranbaxy's ANDA No. 76-477 until the date of

expiration of United States Letters Patent Nos. 4,681,893 (“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).

27. The expiration date for the ‘511 patent is July 16, 2016.

28. The ‘511 patent covers a method of making amorphous atorvastatin.

29. Upon information and belief, Ranbaxy intends to import into the United States and/or to offer to sell, sell or use within the United States, all for purposes not exempt under 35 U.S.C. § 271(e)(1), Ranbaxy’s Atorvastatin Product prior to the expiration of the ‘511 patent.

30. Upon information and belief, Ranbaxy’s Atorvastatin Product is made or is intended to be made by a process which if practiced in the United States would infringe the ‘511 patent.

31. Upon information and belief, Ranbaxy’s importation for purposes not exempt under 35 U.S.C. § 271(e)(1) into the United States and/or future offer to sell, sale or use for purposes not exempt under 35 U.S.C. § 271(e)(1) within the United States of Ranbaxy’s Atorvastatin Product will infringe the ‘511 patent pursuant to 35 U.S.C. §271 (g).

32. Pfizer will be irreparably harmed if Ranbaxy is not enjoined from infringing the ‘511 patent.

SECOND CLAIM FOR RELIEF;
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ‘740 PATENT

33. Pfizer realleges paragraphs 1 through 32 above as if fully set forth herein.

34. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, based upon an actual controversy between the parties.

35. Pfizer has received a letter dated February 28, 2003 from Ranbaxy Pharmaceuticals (the “February 28, 2003 letter”) 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 as the active ingredient (“Ranbaxy’s Atorvastatin Product”) on a date which is prior to the expiration of the ‘740 patent. A copy of the February 28, 2003 letter is attached hereto as Exhibit C.

36. Ranbaxy has taken immediate and active steps to obtain FDA approval to sell in the United States and to commence sale in the United States of Ranbaxy’s Atorvastatin Product immediately following FDA approval.

37. Pursuant to 35 U.S.C. § 271(e)(2) and (e)(4), Pfizer obtained a judgment which enjoins the effective date of approval of Ranbaxy’s ANDA No. 76-477 until the date of expiration of United States Letters Patent Nos. 4,681,893 (“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).

38. The expiration date for the ‘740 patent is July 16, 2016.

39. The ‘740 patent covers a method of making amorphous atorvastatin.

40. Upon information and belief, Ranbaxy intends to import into the United States and/or to offer to sell, sell or use within the United States, all for purposes not exempt under 35 U.S.C. § 271(e)(1), Ranbaxy’s Atorvastatin Product prior to the expiration of the ‘740 patent.

41. Upon information and belief, Ranbaxy’s Atorvastatin Product is made or is intended to be made by a process which if practiced in the United States would infringe the ‘740 patent.

42. Upon information and belief, Ranbaxy’s importation for purposes not exempt under 35 U.S.C. § 271(e)(1) and/or offer to sell, sale or use for purposes not exempt under 35

U.S.C. § 271(e)(1) within the United States of Ranbaxy's Atorvastatin Product will infringe the '740 patent pursuant to 35 U.S.C. §271 (g).

43. Pfizer will be irreparably harmed if Ranbaxy is not enjoined from infringing the '740 patent.

WHEREFORE, Pfizer requests the following relief:

- A. A declaratory judgment that Ranbaxy's Atorvastatin Product is made by the use of the process claimed in the '511 patent and that its importation into the United States and its offer for sale, sale and/or use in the United States is an infringement of the '511 patent.
- B. A declaratory judgment that Ranbaxy's Atorvastatin Product is made by the use of the process claimed in the '740 patent and that its importation into the United States and its offer for sale, sale and/or use in the United States is an infringement of the '740 patent.
- C. A judgment permanently enjoining Ranbaxy, each of their officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them or any of them, from making, using, selling, offering to sell, or importing the atorvastatin product described in Ranbaxy's ANDA 76-477 and made by the processes claimed in the '511 patent until July 16, 2016, the expiration date of the '511 patent.
- D. A judgment permanently enjoining Ranbaxy, each of their officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them or any of them, from making, using, selling, offering to sell, or importing the atorvastatin product described in Ranbaxy's ANDA 76-477

and made by the processes claimed in the '740 patent until July 16, 2016, the expiration date of the '740 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.

RESPECTFULLY SUBMITTED,

/s/Rudolf E. Hutz

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