IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, and WARNER-LAMBERT COMPANY LLC,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 08-948 (LDD)
APOTEX INC., and APOTEX CORP.,	)	
Defendants.	)	

FIRST AMENDED COMPLAINT

Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company LLC, formerly Warner-Lambert Company (collectively referred to as "Pfizer"), by their attorneys, for their First Amended Complaint against Apotex Inc. and Apotex Corp. (collectively "Apotex"), allege as follows:

1. This is an action by Pfizer against Apotex for infringement of United States Letters Patent Nos. 5,273,995 ("the '995 patent") and RE 40,667 ("the '667 reissue patent"). A copy of the '995 patent is attached hereto as Exhibit A. A copy of the '667 reissue patent is attached hereto as Exhibit B.

2. On December 28, 1993, the United States Patent and Trademark Office ("PTO") issued the '995 patent, entitled "[R-(R*R*)]-2-(4-Fluorophenyl)-β, δ-Dihydroxy-5-(1-Methylethyl-3-Phenyl-4-[(Phenylamino) Carbonyl]-1H-Pyrrole-1-Heptanoic Acid, Its Lactone Form And Salts Thereof", on an application filed by Bruce D. Roth and assigned to Warner-Lambert Company.

3. On March 17, 2009, the PTO issued the '667 reissue patent, entitled "[R-(R*R*)]-2-(4-FLUOROPHENYL) -β, δ-DIHYDROXY-5-(1-METHYLETHYL-3-PHENYL-4-[(PHENYLAMINO) CARBONYL]-1H-PYRROLE-1-HEPTANOIC ACID, ITS LACTONE FORM AND SALTS THEREOF", on an application filed by Bruce D. Roth and assigned to Warner-Lambert Company LLC.

4. The '667 reissue patent constitutes, *inter alia*, a reissue of former claim 6 of the '995 patent.

PARTIES, JURISDICTION AND VENUE

5. 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.

6. 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 '995 patent since its issuance.

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

8. 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. Warner-Lambert Company LLC has been the owner of record of the '667 patent since its issuance.

9. 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.

10. The exclusive licensee of the '995 patent is Pfizer Ireland Pharmaceuticals.

11. The exclusive licensee of the '667 reissue patent is Pfizer Ireland Pharmaceuticals.

12. Pfizer holds an approved New Drug Application for an atorvastatin calcium formulation which it sells under the registered name Lipitor®.

13. The '995 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 Lipitor® product.

14. The '667 reissue 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 Lipitor® product.

15. On information and belief, Defendant Apotex Inc. is a corporation operating and existing under the laws of Canada with its principal place of business at 150 Signet Drive, Weston, Ontario M9L 1T9 Canada.

16. On information and belief, Defendant Apotex Corp. ("Apotex U.S.A.") is a sister corporation of Apotex Inc. and is a corporation operating and existing under the laws of Delaware with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326 USA.

17. On information and belief, Apotex Inc. and/or Apotex U.S.A. filed with the FDA, in Rockville, Maryland, ANDA No. 90-548 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

atorvastatin calcium tablets in 10 mg, 20 mg, 40 mg and 80 mg dosage strengths, which are generic versions of Plaintiffs' Lipitor® tablets.

18. By letters dated November 4, 2008, and March 18, 2009, Apotex Inc. notified Plaintiffs that it had filed an ANDA seeking FDA approval to market atorvastatin calcium tablets in 10 mg, 20 mg, 40 mg and 80 mg dosage strengths, and that it was providing information to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c)(1).

19. The November 4, 2008, and March 18, 2009 letters purported to contain an "Offer of Confidential Access to Application" pursuant to 21 U.S.C. § 355(j)(5)(C).

20. Each purported "Offer of Confidential Access to Application" contained restrictions on the access and use of the information not contemplated or permitted by 21 U.S.C. § 355(j)(5)(C)(III).

21. The November 4, 2008 letter addressed the '995 patent, while the March 18, 2009 letter addressed the '667 reissue patent and each asserted that patents were invalid, unenforceable and/or not infringed by Apotex's proposed ANDA No. 90-548 product.

22. Apotex voluntarily sent its November 2, 2008 and March 18, 2009 ANDA Notice Letters to Pfizer's Delaware counsel.

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. Upon information and belief, Apotex Inc. is subject to personal jurisdiction in this District.

25. Apotex U.S.A. is subject to personal jurisdiction in this District.

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

27. On information and belief, Apotex Inc. is in the business of developing and manufacturing generic pharmaceutical products.

28. From its inception, Apotex Inc. was set up to manufacture generic drugs for export into the United States. For example, Apotex's web site states: "This site [Etobicoke Canada was] established in 1993 to service the US market."

29. On information and belief, Apotex Inc. sells and delivers its pharmaceutical products to Apotex U.S.A. in Florida.

30. On information and belief, Apotex U.S.A. is the agent, affiliate, representative, and/or alter ego of, and/or acts in concert with, Apotex Inc. for the purposes of marketing, distributing, and selling generic pharmaceutical products within the United States, including the State of Delaware.

31. On information and belief, Apotex U.S.A., as the authorized agent of Apotex Inc. and/or in its own capacity, participated in the preparation and filing with the FDA of the Apotex ANDA for approval to market generic atorvastatin calcium in the United States.

32. On information and belief, Apotex Inc. develops and manufactures generic drugs and, directly or indirectly through Apotex U.S.A., markets, distributes, and sells its generic drugs throughout the United States, including the State of Delaware.

33. Personal jurisdiction over Apotex Inc. is proper because it purposefully avails itself of the privilege of selling its generic products in the State of Delaware and can therefore reasonably expect to be subject to jurisdiction in Courts in Delaware. Among other things, upon information and belief, Apotex Inc., directly or through its sister corporation Apotex U.S.A.,

places goods into the stream of commerce for distribution throughout the United States, including the State of Delaware.

34. A generic drug company's need to litigate patents covering FDA-approved branded drug products is the central feature of its business model.

35. Over the last six years, in Delaware alone, Apotex Inc. has been a party to nine other ANDA-related patent suits.

36. In one, Apotex Inc. was a plaintiff in a declaratory judgment suit.

37. In seven of the remaining Delaware cases (the eighth was dismissed before the Answer was filed), Apotex Inc. answered the Complaint, raised Counterclaims, and never challenged personal jurisdiction. Apotex thereby affirmatively sought relief in Delaware courts.

38. As recently as February of 2009, Apotex Inc. again consented to personal jurisdiction in this District.

39. Apotex Inc. has recently, unequivocally admitted in another ANDA patent case that personal jurisdiction over it was proper in this District.

40. In these nine other cases, Apotex Inc. engaged the services of various Delaware law firms to represent it and repeatedly entered this State to further its primary business activity before this Court.

41. Personal jurisdiction over Apotex U.S.A. is proper because Apotex U.S.A. is incorporated in Delaware and has purposely availed itself of the privilege of doing business in this State. Further, Apotex U.S.A. maintains continuous and systematic contacts with the State of Delaware so as to reasonably allow jurisdiction to be exercised over it.

42. Apotex U.S.A. is registered with the Delaware Board of Pharmacy as a "Distributor/Manufacturer CSR" and "Pharmacy-Wholesale" pursuant to 24 Del. C. § 2540.

43. An amended final judgment declaring claim 6 of the '995 patent invalid pursuant to the provisions of 35 U.S.C. § 112, ¶ 4 has been entered by the United States District Court for the District of Delaware in Civil Action No. 03-209-JJF, by Orders of the Court dated November 7, 2006, and November 30, 2006 (D.I. 338 and 344). A copy of the final judgment, as amended, is attached as Exhibit C. No relief is sought herein pursuant to claim 6 of the '995 patent.

44. Claim 6 of the '995 patent was declared invalid by the United States Court of Appeals for the Federal Circuit solely on the basis that claim 6 was an improper dependent claim under 35 U.S.C. § 112, paragraph 4 because it depended from Claim 2 of the '995 patent.

45. In the '667 reissue patent, claim 6 of the '995 patent was reissued as independent claim thus curing any improper dependency. Claim 6 of the '667 reissue patent is identical in scope to claim 6 of the '995 patent.

FIRST CLAIM FOR RELIEF;
INFRINGEMENT OF THE '995 PATENT

46. Pfizer realleges paragraphs 1 through 45 above as if fully set forth herein.

47. Pfizer has received a letter dated November 4, 2008, from Apotex which notified Pfizer that Apotex had filed an Abbreviated New Drug Application (ANDA No. 90-548), seeking approval from FDA to engage in the commercial manufacture, use, and sale of a product containing atorvastatin calcium prior to the expiration of the '995 patent.

48. The expiration date for the '995 patent is December 28, 2010.

49. Lipitor® was granted a further period of exclusivity under section 505 of the Food, Drug and Cosmetic Act to June 28, 2011.

50. Apotex has infringed the '995 patent under 35 U.S.C. § 271(e)(2) by filing Apotex's ANDA 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 '995 patent.

Pfizer will be irreparably harmed if Apotex is not enjoined from infringing the '995 patent.

SECOND CLAIM FOR RELIEF;
INFRINGEMENT OF THE '667 REISSUE PATENT

51. Pfizer realleges paragraphs 1 through 50 above as if fully set forth herein.

52. Pfizer has received a letter dated March 18, 2009, from Apotex which notified Pfizer that Apotex had filed an Abbreviated New Drug Application (ANDA No. 90-548), seeking approval from FDA to engage in the commercial manufacture, use, and sale of a product containing atorvastatin calcium prior to the expiration of the '667 reissue patent.

53. The expiration date for the '667 reissue patent is December 28, 2010.

54. Lipitor® was granted a further period of exclusivity under section 505 of the Food, Drug and Cosmetic Act to June 28, 2011.

55. Apotex has infringed the '667 reissue patent under 35 U.S.C. § 271(e)(2) by filing Apotex's ANDA 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 '667 reissue patent.

56. Pfizer will be irreparably harmed if Apotex is not enjoined from infringing the '667 reissue 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 Apotex's ANDA No. 90-548 be no earlier than June 28, 2011, the date of expiration of the '995 Patent including the period of exclusivity granted to Lipitor® under section 505 of the Food, Drug and Cosmetic Act;

B. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Apotex, each of its 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 Apotex's ANDA No. 90-548 until June 28, 2011, the expiration date of the '995 patent including the period of exclusivity granted to Lipitor® under section 505 of the Food, Drug and Cosmetic Act;

C. A judgment providing that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any FDA approval for Apotex's ANDA No. 90-548 be no earlier than June 28, 2011, the date of expiration of the '667 reissue patent including the period of exclusivity granted to Lipitor® under section 505 of the Food, Drug and Cosmetic Act;

D. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Apotex, each of its 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 Apotex's ANDA No. 90-548 until June 28, 2011, the expiration date of the '667

patent including the period of exclusivity granted to Lipitor® under section 505 of the Food, Drug and Cosmetic Act;

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

Rudolf E. Hutz (#484)
Jeffrey B. Bove (#998)
Mary W. Bourke (#2356)
Daniel C. Mulveny (#3984)
CONNOLLY BOVE LODGE & HUTZ LLP
1007 North Orange Street
Wilmington, DE 19899
(302) 658-9141

OF COUNSEL:
William E. McShane
CONNOLLY BOVE LODGE & HUTZ LLP
1875 Eye Street, NW
Suite 1100
Washington, DC 20006
(202) 572-0335

Attorneys for Plaintiffs Pfizer Inc., Pfizer Ireland Pharmaceuticals, and Warner-Lambert Company LLC, formerly Warner-Lambert Company

Dated: March 23, 2009

671303_1.DOC

CERTIFICATE OF SERVICE

I hereby certify that on March 23, 2009, a true copy of the foregoing ***FIRST AMENDED COMPLAINT*** was electronically filed with the Clerk of the Court using CM/ECF which will send notification of such filing to the following and the document is available for viewing and downloading from CM/ECF:

John C. Phillips, Jr.
Phillips, Goldman & Spence, P.A.
1200 North Broom Street
Wilmington, DE 19806

I hereby certify that on March 23, 2009, I have sent by U.S. Mail the foregoing document to the following non-registered participant:

William A. Rakoczy, Esquire
Rakoczy Molino Mazzochi Siwik LLP
6 West Hubbard Street
Chicago, IL 60610

/s/ Rudolf E. Hutz
Rudolf E. Hutz (#484)
Jeffrey B. Bove (#998)
Mary W. Bourke (#2356)
Daniel C. Mulveny (#3984)
1007 N. Orange Street
P.O. Box 2207
Wilmington, DE 19899-2207
(302) 658-9141

Attorneys for Plaintiffs