IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC., Plaintiff, v. APOTEX, INC. Defendant.	)	C.A. No._____

COMPLAINT FOR PATENT INFRINGEMENT AGAINST APOTEX, INC.

For its Complaint, Plaintiff Merck & Co., Inc. ("Merck") alleges as follows:

THE PARTIES

1. Plaintiff Merck is a corporation incorporated under the laws of New Jersey with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

2. On information and belief, Defendant Apotex, Inc. ("Apotex") is a Canadian company with offices at 150 Signet Drive, Toronto, Canada M9L 1T9. It has authorized Apotex Corp., incorporated under the laws of Delaware and with principal place of business at 2400 North Commerce Parkway, Suite 400 Weston, Florida 33326, to act as agent for service of process with respect to commencement of this patent infringement action.

JURISDICTION AND VENUE

3. This action arises under the patent laws of the United States of America and jurisdiction is founded on Title 28, United States Code §§ 1331 and 1338(a).

4. Venue is proper in this Court under Title 28, United States Code §§ 1391(c) and 1400(b), because the defendant has submitted to personal jurisdiction in this judicial district for this action.

BACKGROUND

5. On October 25, 1994, United States Letters Patent No. 5,358,941 (the "'941 patent"), entitled DRY MIX FORMULATION FOR BISPHOSPHONIC ACIDS WITH LACTOSE, duly and legally issued to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare. The '941 patent is currently set to expire on December 2, 2012. The '941 patent discloses and claims novel pharmaceutical compositions of bisphosphonic acids and salts thereof, which are useful in the treatment and prevention of diseases including osteoporosis, Paget's disease, malignant hypercalcemia, and metastatic bone disease. A copy of the '941 patent is attached to this Complaint as Exhibit 1.

6. On October 28, 1997, United States Letters Patent No. 5,681,590 (the "'590 patent"), entitled DRY MIX FORMULATION FOR BISPHOSPHONIC ACIDS, duly and legally issued to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare. The '590 patent is currently set to expire on December 2, 2012. The '590 patent discloses and claims novel pharmaceutical compositions and novel processes for manufacturing compositions of bisphosphonic acids and salts thereof, which are useful in

the treatment and prevention of diseases including osteoporosis, Paget's disease, malignant hypercalcemia, and metastatic bone disease. A copy of the '590 patent is attached to this Complaint as Exhibit 2.

7. On December 15, 1998, United States Letters Patent No. 5,849,726 (the "'726 patent"), entitled ANHYDROUS ALENDRONATE MONOSIDUM SALT FORMULATIONS, duly and legally issued to Gerald S. Brenner, Drazen Ostovic, Earl R. Oberholtzer, Jr., and J. Eric Thies. The '726 patent is currently set to expire on June 6, 2015. The '726 patent discloses and claims novel pharmaceutical compositions of anhydrous 4-amino-1-hydroxy-butylidene-1,1-bisphosphonic acid monosodium salt, as well as novel methods for treating and preventing bone loss with these compositions. A copy of the '726 patent is attached to this Complaint as Exhibit 3.

8. On December 28, 1999, United States Letters Patent No. 6,008,207 (the "'207 patent"), entitled ANHYDROUS ALENDRONATE MONOSIDUM SALT FORMULATIONS, duly and legally issued to Gerald S. Brenner, Drazen Ostovic, Earl R. Oberholtzer, Jr., and J. Eric Thies. The '207 patent is currently set to expire on June 6, 2015. The '207 patent discloses and claims novel methods for administering anhydrous alendronate monosodium salt formulations. A copy of the '207 patent is attached to this Complaint as Exhibit 4.

9. On July 18, 2000, United States Letters Patent No. 6,090,410 (the "'410 patent"), entitled ANHYDROUS ALENDRONATE MONOSIDUM SALT FORMULATIONS, duly and legally issued to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare. The '410 patent is currently set to expire on December 2, 2012. The '410 patent discloses and claims novel pharmaceutical compositions of

bisphosphonic acids and salts thereof, which are useful in the treatment and prevention of diseases including osteoporosis, Paget's disease, malignant hypercalcemia, and metastatic bone disease. A copy of the '410 patent is attached to this Complaint as Exhibit 5.

10. On February 27, 2001, United States Letters Patent No. 6,194,004 (the "'004 patent"), entitled DRY MIX FORMULATION FOR BISPHOSPHONIC ACIDS, duly and legally issued to Simon R. Bechard, Kenneth A. Kramer, and Ashok V. Katdare. The '004 patent is currently set to expire on December 2, 2012. The '004 patent discloses and claims novel pharmaceutical compositions of bisphosphonic acids and salts thereof, which are useful in the treatment and prevention of diseases including osteoporosis, Paget's disease, malignant hypercalcemia, and metastatic bone disease. A copy of the '004 patent is attached to this Complaint as Exhibit 6.

11. On November 30, 1999, United States Letters Patent No. 5,994,329 (the "'329 patent") duly and legally issued to Anastasia G. Daifotis, Arthur C. Santora, II, and John Yates entitled METHOD FOR INHIBITING BONE RESORPTION. The '329 patent is currently set to expire on July 17, 2018. The '329 patent discloses and claims methods for inhibiting bone resorption in mammals while minimizing the occurrence of or potential for adverse gastrointestinal effects, and pharmaceutical compositions and kits for carrying out these therapeutic methods. A copy of the '329 patent is attached to this Complaint as Exhibit 7.

12. On January 18, 2000, United States Letters Patent No. 6,015,801 (the "'801 patent") duly and legally issued to Anastasia G. Daifotis, A. John Yates, and Arthur C. Santora, II entitled METHOD OF INHIBITING BONE RESORPTION. The '801 patent is currently set to expire on July 17, 2018. The '801 patent discloses and

claims methods for inhibiting bone resorption in mammals while minimizing the occurrence of or potential for adverse gastrointestinal effects, and pharmaceutical compositions and kits for carrying out these therapeutic methods. A copy of the '801 patent is attached to this Complaint as Exhibit 8.

13. On May 1, 2001, United States Letters Patent No. 6,225,294 (the "'294 patent") duly and legally issued to Anastasia G. Daifotis, Arthur C. Santora, II and John Yates entitled METHOD OF INHIBITING BONE RESORPTION. The '294 patent is currently set to expire July 17, 2018. The '294 patent discloses and claims methods for inhibiting bone resorption in mammals while minimizing the occurrence of or potential for adverse gastrointestinal effects, and pharmaceutical compositions and kits for carrying out these therapeutic methods. A copy of the '294 patent is attached to this Complaint as Exhibit 9.

14. Merck is the owner through assignment of the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents. Merck also owns an approved New Drug Application (NDA No. 20-560) for alendronate sodium tablets that are sold under its trademark FOSAMAX®.

15. The publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration ("FDA") under the Federal Food, Drug, and Cosmetic Act. Merck listed the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents in the Orange Book for its FOSAMAX® tablets.

16. The FDA granted a six-month period of market exclusivity beyond the patent terms for Merck's FOSAMAX® drug product due to the timely submission

and acceptance of pediatric studies pursuant to 21 U.S.C. § 355a(c). This six-month period is also listed in the Orange Book. The FDA may therefore not approve to market generic versions of Merck's FOSAMAX® tablets until six months after the expiration dates of the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents. The six-month "pediatric exclusivity period" expires on June 2, 2013, for the '941 patent; June 2, 2013, for the '590 patent; December 6, 2015, for the '726 patent; December 6, 2015, for the '207 patent; June 2, 2013, for the '410 patent; June 2, 2013, for the '004 patent; January 17, 2019, for the '329 patent; January 17, 2019, for the '801 patent; and January 17, 2019, for the '294 patent. The FDA also may not approve to market generic versions of Merck's FOSAMAX® tablets until the expiration of all other patents and the subsequent pediatric exclusivity period listed in the Orange Book.

17. On information and belief, an Abbreviated New Drug Application (ANDA No. 077-982) has been filed on behalf of Apotex, including a certification under Title 21, United States Code § 355(j)(2) with the FDA for 5 mg, 10 mg, 35 mg, and 70 mg alendronate sodium tablets. Apotex's ANDA No. 077-982 allegedly contains a certification of invalidity, unenforceability, and/or noninfringement of the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents. Notice of that certification, but not the certification, was transmitted to Merck on or after February 24, 2006.

18. On information and belief, Apotex filed ANDA No. 077-982 because it seeks to enter the market that FOSAMAX® pharmaceutical products have created due to their benefits and advantages.

COUNT I

19. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

20. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '941 patent, before the expiration of the '941 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

21. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '941 patent, it was aware of the existence of the '941 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

22. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '941 patent.

23. On information and belief, the infringement by Apotex of the '941 patent was and is willful.

24. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

COUNT II

25. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

26. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '590 patent, before the expiration of the '590 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

27. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '590 patent, it was aware of the existence of the '590 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

28. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '590 patent.

29. On information and belief, the infringement by Apotex of the '590 patent was and is willful.

30. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

COUNT III

31. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

32. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '726 patent,

before the expiration of the '726 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

33. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '726 patent, it was aware of the existence of the '726 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

34. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '726 patent.

35. On information and belief, the infringement by Apotex of the '726 patent was and is willful.

36. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

COUNT IV

37. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

38. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '207 patent, before the expiration of the '207 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

39. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '207

patent, it was aware of the existence of the '207 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

40. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '207 patent.

41. On information and belief, the infringement by Apotex of the '207 patent was and is willful.

42. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

COUNT V

43. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

44. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '410 patent, before the expiration of the '410 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

45. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '410 patent, it was aware of the existence of the '410 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

46. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '410 patent.

47. On information and belief, the infringement by Apotex of the '410 patent was and is willful.

48. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

COUNT VI

49. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

50. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '004 patent, before the expiration of the '004 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

51. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '004 patent, it was aware of the existence of the '004 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

52. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '004 patent.

53. On information and belief, the infringement by Apotex of the '004 patent was and is willful.

54. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

COUNT VII

55. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

56. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '329 patent, before the expiration of the '329 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

57. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '329 patent, it was aware of the existence of the '329 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

58. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '329 patent.

59. On information and belief, the infringement by Apotex of the '329 patent was and is willful.

60. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

COUNT VIII

61. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

62. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '801 patent, before the expiration of the '801 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

63. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '801 patent, it was aware of the existence of the '801 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

64. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '801 patent.

65. On information and belief, the infringement by Apotex of the '801 patent was and is willful.

66. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

COUNT IX

67. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

68. Apotex has submitted ANDA No. 077-982 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '294 patent, before the expiration of the '294 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

69. On information and belief, when Apotex filed ANDA No. 077-982 seeking approval to market alendronate sodium tablets before the expiration of the '294 patent, it was aware of the existence of the '294 patent and that the filing of ANDA No. 077-982 constituted an act of infringement of that patent.

70. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '294 patent.

71. On information and belief, the infringement by Apotex of the '294 patent was and is willful.

72. On information and belief, as and to the extent Apotex has committed any infringing act with respect to alendronate other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), such infringement was willful.

REQUESTED RELIEF

Plaintiff Merck respectfully seeks the following relief:

a. That judgment be entered that Apotex has infringed the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents by submitting ANDA No. 077-982;

b. That a permanent injunction be issued under 35 U.S.C. § 271(e) restraining or enjoining Apotex, its officers, agents or attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any therapeutic composition, and/or method of use covered by the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents for the full term thereof, including the terms of other patents and the term of the pediatric exclusivity period listed in the Orange Book for Merck's 5 mg, 10 mg, 35 mg, 40 mg, and 70 mg FOSAMAX® tablets, and from inducing or contributing to such activities;

c. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 077-982 be a date which is not earlier than the last to expire of the asserted patents, including the terms of other patents and the term of the pediatric exclusivity period listed in the Orange Book for Merck's 5 mg, 10 mg, 35 mg, 40 mg, and 70 mg FOSAMAX® tablets;

d. That judgment be entered that Defendant Apotex willfully and deliberately infringed the '941, '590, '726, '207, '410, '004, '329, '801, and '294 patents;

e. That this is an exceptional case under 35 U.S.C. § 285, and that judgment be entered for costs and reasonable attorneys fees to be awarded to Merck; and

f. That this Court award such other and further relief as the Court may deem proper under the circumstances.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Mary B. Graham

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