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

TIBOTEC INC. and TIBOTEC PHARMACEUTICALS, and G.D. SEARLE, LLC Plaintiffs, v. LUPIN LIMITED, LUPIN PHARMACEUTICALS INC., MYLAN PHARMACEUTICALS INC., and MYLAN INC., Defendants.	)	Civil Action No.

COMPLAINT FOR PATENT INFRINGEMENT

Tibotec Inc. and Tibotec Pharmaceuticals (collectively, "Tibotec"), and G.D. Searle, LLC ("Searle") (Tibotec and Searle, collectively, "Plaintiffs") for their Complaint against defendants Lupin Limited ("Lupin Ltd."), Lupin Pharmaceuticals Inc. ("Lupin Pharmaceuticals") (collectively "Lupin"), Mylan Pharmaceuticals Inc. ("Mylan Pharmaceuticals") and Mylan Inc. (collectively "Mylan") (Lupin and Mylan, collectively, "Defendants") allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of U.S. Patent Nos. 5,843,946 ("the '946 Patent") and 6,248,775 ("the '775 Patent") (collectively, "the patents-in-suit") arising under the patent laws of the United States, 35 U.S.C. §§ 1 et seq. This action arises out of Defendants' filing of Abbreviated New Drug Applications ("ANDAs") seeking approval to sell generic copies of Plaintiffs' highly successful PREZISTA® (darunavir) 75 mg, 150 mg, 300 mg, 400 mg, and 600 mg products prior to the expiration of the patents-in-suit.

THE PARTIES

2. Plaintiff Tibotec Inc. is a corporation organized under the laws of the State of Delaware, having its headquarters and principal place of business at 1020 Stony Hill Road, Suite 300, Yardley, PA 19067.

3. Plaintiff Tibotec Pharmaceuticals (formerly known as Tibotec Pharmaceuticals Ltd.) is an Irish corporation having its principal place of business as Eastgate Village, Eastgate, Little Island, County Cork, Ireland.

4. Plaintiff G.D. Searle, LLC is a Delaware limited liability company having a principal place of business at 235 East 42nd Street, New York, New York 10017.

5. On information and belief, Lupin Ltd. is an Indian corporation having a place of business at B/4 Laxmi Towers, Bandra-Kurla Complex, Bandra (E), Mumbai 400 051, India, and having a registered office at 159 CST Road, Kalina, Santacruz (E), Mumbai 400 098, India. On information and belief, Lupin Ltd. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market through various operating subsidiaries, including Lupin Pharmaceuticals.

6. On information and belief, Lupin Pharmaceuticals is a corporation organized and existing under the laws of the Commonwealth of Virginia, having a place of principal business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland 21202. On information and belief, Lupin Pharmaceuticals is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market. Lupin Pharmaceuticals is a wholly owned subsidiary of Lupin Ltd.

7. On information and belief, Mylan Pharmaceuticals is a corporation organized under the laws of the state of West Virginia, with its principal place of business located at 781 Chestnut Ridge Road, Morgantown, WV 26505. On information and belief, Mylan Pharmaceuticals is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market. Mylan Pharmaceuticals is a wholly owned subsidiary of Mylan Inc.

8. On information and belief, Mylan Inc. is a corporation organized under the laws of the Commonwealth of Pennsylvania, with its principal place of business located at 1500 Corporate Drive, Canonsburg, Pennsylvania, 15317. On information and belief, Mylan Inc. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market, alone and/or through its wholly owned subsidiary and agent, Mylan Pharmaceuticals.

JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

10. On information and belief, this Court has personal jurisdiction over Lupin Ltd. because Lupin Ltd. has purposely availed itself of the benefits and protections of New

Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Lupin Ltd. has had persistent and continuous contacts with this judicial district, including developing, manufacturing and/or selling pharmaceutical products that are sold in this judicial district.

11. On information and belief, this Court has personal jurisdiction over Lupin Pharmaceuticals because Lupin Pharmaceuticals has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Lupin Pharmaceuticals has had persistent and continuous contacts with this judicial district, including developing, manufacturing and/or selling pharmaceutical products that are sold in this judicial district.

12. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals operate and act in concert as an integrated, unitary business. For example, Lupin Ltd. includes within its Annual Report the activities of Lupin Pharmaceuticals, including revenue earned.

13. On information and belief, Lupin Pharmaceuticals is registered to do business in New Jersey.

14. On information and belief, Lupin Pharmaceuticals has appointed National Registered Agents, Inc. of Princeton, New Jersey as its registered agent for the receipt of service of process.

15. Lupin Ltd. and Lupin Pharmaceuticals have stipulated and/or consented to personal jurisdiction in this district in numerous prior patent cases.

16. On information and belief, this Court has personal jurisdiction over Mylan Pharmaceuticals because Mylan Pharmaceuticals has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court

here. On information and belief, Mylan Pharmaceuticals has had persistent and continuous contacts with this judicial district, including developing, manufacturing and/or selling pharmaceutical products that are sold in this judicial district.

17. On information and belief, Mylan Pharmaceuticals is registered to do business in New Jersey.

18. On information and belief, Mylan Pharmaceuticals has appointed Corporation Service Company, 830 Bear Tavern Road, West Trenton, New Jersey as its registered agent for the receipt of service of process.

19. On information and belief, this Court has personal jurisdiction over Mylan Inc. because Mylan Inc. has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Mylan Inc. has had persistent and continuous contacts with this judicial district, including developing, manufacturing and/or selling pharmaceutical products that are sold in this judicial district, its operation of offices in this district, and its filing of claims and counterclaims in this district.

20. Mylan Pharmaceuticals and Mylan Inc. have previously consented to personal jurisdiction in this district in numerous prior patent cases.

21. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

22. On December 1, 1998, the United States Patent and Trademark Office ("the PTO") issued the '946 Patent, entitled "• - and • -Amino Acid Hydroxyethylamino Sulfonamides Useful as Retroviral Protease Inhibitors". A true and correct copy of the '946 Patent is attached hereto as Exhibit A.

23. Plaintiff Searle holds title to the '946 Patent.

24. Plaintiff Tibotec Pharmaceuticals (formerly known as Tibotec Pharmaceuticals Ltd.) has an exclusive license under the '946 Patent.

25. The '946 Patent expires on December 1, 2015.

26. The United States Food and Drug Administration ("FDA") has awarded 6 months of pediatric exclusivity for PREZISTA®. The period of pediatric exclusivity applicable to the '946 Patent does not expire until June 1, 2016.

27. On June 19, 2001, the PTO issued the '775 Patent, entitled "• - and • - Amino Acid Hydroxyethylamino Sulfonamides Useful as Retroviral Protease Inhibitors". A true and correct copy of the '775 Patent is attached hereto as Exhibit B.

28. Plaintiff Searle holds title to the '775 Patent.

29. Plaintiff Tibotec Pharmaceuticals has an exclusive license under the '775 Patent.

30. The '775 Patent expires on August 13, 2014.

31. The period of pediatric exclusivity applicable to the '775 Patent does not expire until February 13, 2015.

32. Tibotec Inc. is the holder of approved New Drug Application ("NDA") No. 21-976 for PREZISTA®.

33. PREZISTA® is included in the FDA's list of "Approved Drug Products With Therapeutic Equivalence Evaluations" also known as the "Orange Book." Approved drugs may be used as the basis of a later applicant's ANDA to obtain approval of the ANDA applicant's drug product under the provisions of 21 U.S.C. § 355(j).

34. The FDA's "Orange Book" also lists patents associated with approved drugs. The '946 and '775 Patents are listed in the "Orange Book" in association with PREZISTA® (darunavir).

35. On information and belief, Lupin Ltd., itself and/or through its subsidiary, agent and alter ego, Lupin Pharmaceuticals, submitted ANDA No. 202-073 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of generic versions of the PREZISTA® 75 mg, 150 mg, 300 mg, 400 mg and 600 mg tablets ("Lupin's Generic Tablets").

36. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals collaborated in the research, development, preparation and filing of ANDA No. 202-073 for Lupin's Generic Tablets.

37. On information and belief, Lupin Pharmaceuticals will market and/or distribute Lupin's Generic Tablets if ANDA No. 202-073 is approved by the FDA.

38. On information and belief, Lupin Pharmaceuticals participated in, contributed to, aided, abetted and/or induced the submission to the FDA of ANDA No. 202-073.

39. On or about June 24, 2011, Plaintiffs received a letter dated June 21, 2010 ("the Lupin Paragraph IV Letter") stating that Lupin had submitted ANDA No. 202-073 seeking approval to manufacture, use and sell Lupin's Generic Tablets prior to the expiration of the '946 and '775 Patents.

40. The Lupin Paragraph IV Letter also states that the Lupin ANDA No. 202-073 included a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the claims of the '946 and '775 Patents are invalid and/or not infringed.

41. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals continue to collaborate in seeking approval of ANDA No. 202-073 from the FDA and intend to collaborate in the commercial manufacture, marketing and sale of Lupin's Generic Tablets (including the commercial marketing and sale of such products in the State of New Jersey) in the event that the FDA approves ANDA No. 202-073.

42. On information and belief, Mylan Pharmaceuticals submitted ANDA No. 202-136 to the FDA under § 505(j) of the FDCA, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of generic versions of the PREZISTA® 75 mg, 150 mg, 300 mg, 400 mg and 600 mg tablets ("Mylan's Generic Tablets").

43. On or about June 24, 2011, Plaintiffs received a letter dated June 20, 2011 ("the Mylan Paragraph IV Letter") stating that Mylan Pharmaceuticals had submitted ANDA No. 202-136 seeking approval to manufacture, use and sell Mylan's Generic Tablets prior to the expiration of the '946 and '775 Patents.

44. The Mylan Paragraph IV Letter also states that the Mylan ANDA No. 202-136 included a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the claims of the '946 and '775 Patents are invalid and/or will not be infringed by the commercial manufacture, use and sale of Mylan's Generic Tablets.

45. On information and belief, Mylan Inc. and Mylan Pharmaceuticals collaborated in the research, development, preparation and filing of ANDA No. 202-136 for Mylan's Generic Tablets.

46. On information and belief, Mylan Inc. participated in, contributed to, aided, abetted and/or induced the submission to the FDA of ANDA No. 202-136.

47. On information and belief, Mylan Pharmaceuticals and Mylan Inc. continue to seek approval of ANDA No. 202-136 from the FDA and intend to collaborate in the commercial manufacture, marketing and sale of Mylan's Generic Tablets (including the commercial marketing and sale of such products in the State of New Jersey) in the event that the FDA approves ANDA No. 202-136.

48. Plaintiffs commenced this action within forty-five days of the date they received Lupin's Paragraph IV Notice of ANDA No. 202-073 containing the Paragraph IV certification for the '946 and '775 Patents and Mylan's Paragraph IV Notice of ANDA No. 202-136 containing the Paragraph IV certification for the '946 and '775 Patents.

COUNT I

Infringement of the '946 Patent by Lupin

49. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 48 hereof, as if fully set forth herein.

50. Lupin has infringed the '946 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 202-073 with a Paragraph IV certification and seeking FDA approval of ANDA No. 202-073 prior to the expiration of the '946 Patent.

51. Lupin had actual and constructive notice of the '946 Patent prior to filing ANDA No. 202-073.

52. Plaintiffs have no adequate remedy at law to redress the infringement by Lupin.

53. Plaintiffs will be irreparably harmed if Lupin is not enjoined from infringing or actively inducing or contributing to infringement of the '946 Patent.

COUNT II

Infringement of the '775 Patent by Lupin

54. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 53 hereof, as if fully set forth herein.

55. Lupin has infringed the '775 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 202-073 with a Paragraph IV certification and seeking FDA approval of ANDA No. 202-073 prior to the expiration of the '775 Patent.

56. Lupin's Paragraph IV Letter does not dispute that Lupin's Generic Tablets infringe one or more claims of the '775 Patent.

57. Lupin had actual and constructive notice of the '775 Patent prior to filing ANDA No. 202-073.

58. Plaintiffs have no adequate remedy at law to redress the infringement by Lupin.

59. Plaintiffs will be irreparably harmed if Lupin is not enjoined from infringing or actively inducing or contributing to infringement of the '775 Patent.

COUNT III

Infringement of the '946 Patent by Mylan

60. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 59 hereof, as if fully set forth herein.

61. Mylan has infringed the '946 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 202-136 with a Paragraph IV certification and seeking FDA approval of ANDA No. 202-136 prior to the expiration of the '946 Patent.

62. Mylan had actual and constructive notice of the '946 Patent prior to filing ANDA No. 202-136.

63. Plaintiffs have no adequate remedy at law to redress the infringement by Mylan.

64. Plaintiffs will be irreparably harmed if Mylan is not enjoined from infringing or actively inducing or contributing to infringement of the '946 Patent.

COUNT IV

Infringement of the '775 Patent by Mylan

65. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 65 hereof, as if fully set forth herein.

66. Mylan has infringed the '775 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 202-136 with a Paragraph IV certification and seeking FDA approval of ANDA No. 202-136 prior to the expiration of the '775 Patent.

67. Mylan's Paragraph IV Letter does not dispute that Mylan's Generic Tablets infringe one or more claims of the '775 Patent.

68. Mylan had actual and constructive notice of the '775 Patent prior to filing ANDA No. 202-136.

69. Plaintiffs have no adequate remedy at law to redress the infringement by Mylan.

70. Plaintiffs will be irreparably harmed if Mylan is not enjoined from infringing or actively inducing or contributing to infringement of the '775 Patent.

PRAYER

WHEREFORE, Plaintiffs respectfully request relief and judgment as follows:

(a) a judgment that Defendants have infringed the '946 and '775 Patents under 35 U.S.C. § 271(e)(2)(A);

(b) a judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Lupin's ANDA No. 202-073 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) is not earlier than the day after the expiration of the period of pediatric exclusivity applicable to the '946 and '775 Patents;

(c) a judgment declaring that the making, using, selling, offering to sell, or importing of the generic darunavir tablets described in ANDA No. 202-073 would constitute infringement of the '946 and '775 Patents, or inducing or contributing to such conduct, by Lupin pursuant to 35 U.S.C. § 271(a), (b) and/or (c);

(d) a judgment permanently enjoining Lupin and each of its officers, agents, servants and employees, and those persons in active concert or participation with them, from commercially manufacturing, selling or offering for sale, using, or importing the generic darunavir tablets described in ANDA No. 202-073 until the day after the expiration of the period of pediatric exclusivity applicable to the '946 and '775 Patents;

(e) a judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Mylan's ANDA No. 202-136 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) is not earlier than the day after the expiration of the period of pediatric exclusivity applicable to the '946 and '775 Patents;

(f) a judgment declaring that the making, using, selling, offering to sell, or importing of the generic darunavir tablets described in ANDA No. 202-136 would constitute

infringement of the '946 and '775 Patents, or inducing or contributing to such conduct, by Mylan pursuant to 35 U.S.C. § 271(a), (b) and/or (c);

(g) a judgment permanently enjoining Mylan and each of its officers, agents, servants and employees, and those persons in active concert or participation with them, from commercially manufacturing, selling or offering for sale, using, or importing the generic darunavir tablets described in ANDA No. 202-136 until the day after the expiration of the period of pediatric exclusivity applicable to the '946 and '775 Patents;

(h) a declaration that this case is exceptional;

(i) an award of Plaintiffs' costs, expenses, reasonable attorneys' fees and such other relief as the Court deems just and proper pursuant to 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285; and

(j) such other and further relief as the Court may deem just and proper.

Respectfully submitted,

s/John E. Flaherty

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Dated: August 1, 2011

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiffs, by their undersigned counsel, hereby certify pursuant to L. Civ. R. 11.2 that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding. This action involves the same defendants and ANDAs as in *Tibotec Inc. and Tibotec Pharmaceuticals v. Lupin Limited, Lupin Pharmaceuticals Inc., Mylan Pharmaceuticals Inc., and Mylan Inc.*, D.N.J., 10-cv-5954-WHW-MAS and two of the same defendants and the same ANDA as in *Tibotec Inc. and Tibotec Pharmaceuticals v. Lupin Ltd and Lupin Pharmaceuticals Inc.*, D.N.J., 11-cv-4027-WHW-MAS.

Furthermore, this action alleges infringement of U.S. Patent Nos. 5,843,946 and 6,248,775, which are also at issue in *Tibotec Inc., Tibotec Pharmaceuticals, and G.D. Searle, LLC v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd.*, D.N.J., 11-cv-1509-WHW-MCA, and *Tibotec Inc., Tibotec Pharmaceuticals, and G.D. Searle, LLC v. Hetero Drugs, Ltd., Unit III and Hetero USA Inc.*, D.N.J. 11-cv-1696-WHW-MCA.

Respectfully submitted,

s/John E. Flaherty

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