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

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS U.S.A., INC., TAKEDA PHARMACEUTICALS LLC, and TAKEDA PHARMACEUTICALS AMERICA, INC., Plaintiffs, v. LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC., Defendants.	:	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT AND CERTIFICATION PURSUANT TO LOCAL RULE 11.2**

Plaintiffs Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals LLC, and Takeda Pharmaceuticals America, Inc. (collectively, "Plaintiffs"), as and for their Complaint against defendants Lupin Limited and Lupin Pharmaceuticals, Inc. (together, "Defendants"), allege as follows:

THE PARTIES

1. Plaintiff Takeda Pharmaceutical Company Limited ("Takeda Japan") is a Japanese corporation, having a principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka, Japan. As part of its business, Takeda Japan is involved in the research, development, and marketing of pharmaceutical products.

2. Plaintiff Takeda Pharmaceuticals U.S.A., Inc. ("Takeda U.S.A.") is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015. As part of its business, Takeda U.S.A. is involved in the marketing of pharmaceutical products. Takeda U.S.A. has the exclusive right to import lansoprazole orally disintegrating tablets and to sell them to Takeda Pharmaceuticals LLC.

3. Plaintiff Takeda Pharmaceuticals LLC ("Takeda LLC") is a Delaware limited liability company, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015. As part of its business, Takeda LLC is involved in the purchase and sale of pharmaceutical products. Takeda LLC is the exclusive licensee of U.S. Patent No. 6,328,994 (" '994 Patent"), U.S. Patent No. 7,431,942 (" '942 Patent"), U.S. Patent No. 7,399,485 (" '485 Patent"), and U.S. Patent No. 7,875,292 (" '292 Patent) (collectively, "Patents-in-Suit").

4. Plaintiff Takeda Pharmaceuticals America, Inc. ("Takeda America") is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield,

Illinois 60015. As part of its business, Takeda America is involved in the purchase, sale and marketing of pharmaceutical products. Takeda America has the exclusive right to sell lansoprazole orally disintegrating tablets to the public under the Patents-in-Suit.

5. On information and belief, defendant Lupin Limited ("Lupin Ltd.") is a corporation organized and existing under the laws of India, having a place of business at B/4 Laxmi Towers, Bandra-Kurla Complex, Bandra (E), Mumbai 400 051, India. Lupin Ltd. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products throughout the United States, including in this District.

6. On information and belief, defendant Lupin Pharmaceuticals, Inc. ("Lupin Pharmaceuticals") is a corporation organized and existing under the laws of the Commonwealth of Virginia, having a principal place of business at 111 S. Calvert Street, 21st Floor, Baltimore, Maryland 21202, and is a wholly-owned subsidiary of Lupin Ltd. Lupin Pharmaceuticals is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products throughout the United States, including in this District.

7. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals operate and act in concert as an integrated, unitary business, ultimately controlled by Lupin Ltd., for purposes of manufacturing, marketing, selling and distributing generic pharmaceutical products.

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States of America, Title 35, United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. On information and belief, Lupin Ltd. is subject to personal jurisdiction in this District by virtue of, *inter alia*, its conduct of business in this District, its purposeful availment of the rights and benefits of New Jersey law, its substantial and continuing contacts with the State, including but not limited to its sales of products in New Jersey and derivation of substantial revenues therefrom and its filing of claims and counterclaims in this District. *See, e.g.*, *Lupin Ltd. and Lupin Pharm. Inc. v. Merck, Sharp & Dohme Corp.*, Civ. No. 3:10-CV-683-JAP-TJB (D.N.J.); *AstraZeneca AB et al. v. Lupin Ltd. & Lupin Pharm. Inc.*, Civ. Action No. 3:09-05404-JAP-TJB (D.N.J.).

10. On information and belief, Lupin Pharmaceuticals is subject to personal jurisdiction in this District, by virtue of, *inter alia*, its conduct of business in this District, its purposeful availment of the rights and benefits of New Jersey law, its substantial and continuing contacts with the State, including but not limited to its sales of products in New Jersey and derivation of substantial revenues therefrom and its filing of claims and counterclaims in this District. *See, e.g., Lupin Ltd. & Lupin Pharm. Inc. v. Merck, Sharp & Dohme Corp.*, Civ. No. 3:10-CV-683-JAP-TJB (D.N.J.); *AstraZeneca AB et al. v. Lupin Ltd. & Lupin Pharm. Inc.*, Civ. Action No. 3:09-05404-JAP-TJB (D.N.J.).

11. On information and belief, Lupin Pharmaceuticals is registered to do business in New Jersey (business identification number 0100953673) and has appointed National Registered Agents, Inc., located at 100 Canal Pointe Blvd., Suite 212, Princeton, NJ 08540, as its registered agent for the receipt of service of process.

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

FACTS PERTINENT TO ALL CLAIMS FOR RELIEF

13. On December 11, 2001, the United States Patent and Trademark Office ("PTO") issued the '994 Patent, entitled "Orally Disintegrating Tablets," to Takeda Chemical Industries, Ltd. (now Takeda Pharmaceutical Company Ltd.), the assignee of the named inventors Toshihiro Shimizu, Shuji Morimoto, and Tetsuro Tabata. Plaintiff Takeda Japan is the record owner of the '994 Patent, and Plaintiff Takeda LLC is the exclusive licensee. A copy of the '994 Patent is attached hereto as Exhibit A.

14. On October 7, 2008, the PTO issued the '942 Patent, entitled "Orally Disintegrable Tablets," to Takeda Pharmaceutical Company Limited, the assignee of the named inventors Toshihiro Shimizu, Shuji Morimoto, and Tetsuro Tabata. Plaintiff Takeda Japan is the record owner of the '942 Patent, and Plaintiff Takeda LLC is the exclusive licensee. A copy of the '942 Patent is attached hereto as Exhibit B.

15. On July 15, 2008, the PTO issued the '485 Patent, entitled "Rapidly Disintegrable Solid Preparation," to Takeda Pharmaceutical Company Limited, the assignee of the named inventors Toshihiro Shimizu, Masae Sugaya, and Yoshinori Nakano. Plaintiff Takeda Japan is the record owner of the '485 Patent, and Plaintiff Takeda LLC is the exclusive licensee. A copy of the '485 Patent is attached hereto as Exhibit C.

16. On January 25, 2011, the PTO issued the '292 Patent, entitled "Orally Disintegrable Tablets," to Takeda Pharmaceutical Company Limited, the assignee of the named inventors Toshihiro Shimizu, Shuji Morimoto, and Tetsuro Tabata. Plaintiff Takeda Japan is the record owner of the '292 Patent, and Plaintiff Takeda LLC is the exclusive licensee. A copy of the '292 Patent is attached hereto as Exhibit D.

17. On August 30, 2002, the United States Food and Drug Administration ("FDA") approved New Drug Application ("NDA") No. 21-428 for lansoprazole delayed release orally disintegrating tablets, 15 and 30 mg. Plaintiff Takeda U.S.A. is the holder of NDA No. 21-428 for lansoprazole delayed release orally disintegrating tablets, which Plaintiff Takeda America sells under the name Prevacid® SoluTab™.

18. The '994, '942, '485, and '292 Patents (collectively, "the patents-in-suit") are listed in a FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the "Orange Book") for Prevacid® SoluTab™, lansoprazole delayed release orally disintegrating tablets, 15 and 30 mg.

19. On information and belief, through the coordinated efforts of its staff worldwide, Defendants seek to constantly expand the range of generic products they sell.

20. On information and belief, Defendants collaborate in the manufacture, marketing and sale of many pharmaceutical products (including generic drug products manufactured and sold pursuant to an approved abbreviated new drug application) within the United States generally and the State of New Jersey specifically.

21. On information and belief, Defendants actively review pharmaceutical patents and seek opportunities to challenge those patents.

22. On information and belief, Defendants reviewed the patents-in-suit and certain commercial and economic information relating to Prevacid® SoluTab™, including estimates of the revenues generated by the sale of Prevacid® SoluTab™, and decided to file an Abbreviated New Drug Application ("ANDA"), seeking approval to market lansoprazole delayed release orally disintegrating tablets.

23. On information and belief, Defendants collaborated in the research, development, preparation and filing of ANDA No. 204-263 for lansoprazole delayed release orally disintegrating tablets.

24. On information and belief, Lupin Ltd. submitted to FDA ANDA No. 204-263 seeking approval to engage in the commercial manufacture, use and sale of lansoprazole delayed release orally disintegrating tablets, 15 and 30 mg, prior to the expiration of the patents-in-suit.

25. Plaintiffs received a letter from Lupin Ltd., dated October 18, 2012, notifying Plaintiffs that ANDA No. 204-263 includes a certification under 21 U.S.C. 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") that, in Lupin Ltd.'s opinion, the patents-in-suit are invalid and/or will not be infringed by the commercial manufacture, use or sale of the lansoprazole delayed release orally disintegrating tablet products described in ANDA No. 204-263.

26. Defendants were aware of the patents-in-suit when Lupin Ltd. filed its ANDA No. 204-263 with a Paragraph IV certification.

27. Plaintiffs commenced this action within 45 days of the date they received Lupin Ltd.'s notice of ANDA No. 204-263 containing the Paragraph IV certification.

28. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals will continue to collaborate in seeking approval of ANDA No. 204-263 from FDA and intend to collaborate in the commercial manufacture, marketing, and sale of lansoprazole delayed release orally disintegrating tablets (including commercial marketing and sale of such products in the State of New Jersey) in the event that FDA approves ANDA No. 204-263.

FIRST CLAIM FOR RELIEF
(Direct Infringement of the '994 Patent by Lupin Ltd. and Lupin Pharmaceuticals)

29. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 28 hereof, as if fully set forth herein.

30. Through the conduct alleged above, Defendants have directly infringed, and continue to directly infringe, one or more claims of the '994 Patent.

31. By filing ANDA No. 204-263 with a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of lansoprazole delayed release orally disintegrating tablets products described therein, prior to the expiration of the '994 Patent with pediatric exclusivity, Defendants have infringed the '994 Patent under 35 U.S.C. § 271(e)(2).

32. Defendants were aware of the existence of the '994 Patent prior to filing ANDA No. 204-263 but took such action knowing that it would constitute infringement of the '994 Patent.

33. On information and belief, Defendants acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '994 Patent.

34. Defendants' conduct renders this case "exceptional" as described in 35 U.S.C. § 285.

35. Takeda will be irreparably harmed if Defendants are not enjoined from infringing the '994 Patent.

SECOND CLAIM FOR RELIEF
(Inducement of Infringement of the '994 Patent by Lupin Ltd.)

36. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 35 hereof, as if fully set forth herein.

37. On information and belief, Lupin Ltd. initiates, directs and controls the activities of its subsidiary company, Lupin Pharmaceuticals, with regard to ANDA No. 204-263 and the lansoprazole delayed release orally disintegrating tablets described therein.

38. On information and belief, Lupin Pharmaceuticals, under the control of Lupin Ltd., was involved with the preparation and filing of ANDA No. 204-263 with FDA.

39. By reason of Lupin Ltd.'s inducement of Lupin Pharmaceuticals' direct infringement of the '994 Patent, Lupin Ltd. has caused and continues to cause irreparable harm to Plaintiffs.

40. On information and belief, Lupin Ltd.'s inducement of Lupin Pharmaceuticals' direct infringement of the '994 Patent will continue unless enjoined by this Court.

41. Plaintiffs have no adequate remedy at law for Lupin Ltd.'s inducement of Lupin Pharmaceuticals' direct infringement of the '994 Patent.

42. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

THIRD CLAIM FOR RELIEF
(Direct Infringement of the '942 Patent by Lupin Ltd. and Lupin Pharmaceuticals)

43. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 42 hereof, as if fully set forth herein.

44. Through the conduct alleged above, Defendants have directly infringed, and continue to directly infringe, one or more claims of the '942 Patent.

45. By filing ANDA No. 204-263 with a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of lansoprazole delayed release orally disintegrating tablets described therein, prior to the expiration of the '942 Patent with pediatric exclusivity, Defendants have infringed the '942 Patent under 35 U.S.C. § 271(e)(2).

46. Defendants were aware of the existence of the '942 Patent prior to filing ANDA No. 204-263 but took such action knowing that it would constitute infringement of the '942 Patent.

47. On information and belief, Defendants acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '942 Patent.

48. Defendants' conduct renders this case "exceptional" as described in 35 U.S.C. § 285.

49. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '942 Patent.

FOURTH CLAIM FOR RELIEF
(Inducement of Infringement of the '942 Patent by Lupin Ltd.)

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

51. On information and belief, Lupin Ltd. initiates, directs and controls the activities of its subsidiary company, Lupin Pharmaceuticals, with regard to ANDA No. 204-263 and the lansoprazole delayed release orally disintegrating tablets described therein.

52. On information and belief, Lupin Pharmaceuticals, under the control of Lupin Ltd., was involved with the preparation and filing of ANDA No. 204-263 with FDA.

53. By reason of Lupin Ltd.'s inducement of Lupin Pharmaceuticals' direct infringement of the '942 Patent, Lupin Ltd. has caused and continues to cause irreparable harm to Plaintiffs.

54. On information and belief, Lupin Ltd.'s inducement of Lupin Pharmaceuticals' direct infringement of the '942 Patent will continue unless enjoined by this Court.

55. Plaintiffs have no adequate remedy at law for Lupin Ltd.'s inducement of Lupin Pharmaceuticals' direct infringement of the '942 Patent.

56. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

FIFTH CLAIM FOR RELIEF
(Direct Infringement of the '485 Patent by Lupin Ltd. and Lupin Pharmaceuticals)

57. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 56 hereof, as if fully set forth herein.

58. Through the conduct alleged above, Defendants have directly infringed, and continue to directly infringe, one or more claims of the '485 Patent.

59. By filing ANDA No. 204-263 with a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of lansoprazole delayed release orally disintegrating tablets described therein, prior to the expiration of the '485 Patent with pediatric exclusivity, Defendants have infringed the '485 Patent under 35 U.S.C. § 271(e)(2).

60. Defendants were aware of the existence of the '485 Patent prior to filing ANDA No. 204-263 but took such action knowing that it would constitute infringement of the '485 Patent.

61. On information and belief, Defendants acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '485 Patent.

62. Defendants' conduct renders this case "exceptional" as described in 35 U.S.C. § 285.

63. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '485 Patent.

SIXTH CLAIM FOR RELIEF
(Inducement of Infringement of the '485 Patent by Lupin Ltd.)

64. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 63 hereof, as if fully set forth herein.

65. On information and belief, Lupin Ltd. initiates, directs and controls the activities of its subsidiary company, Lupin Pharmaceuticals, with regard to ANDA No. 204-263 and the lansoprazole delayed release orally disintegrating tablets described therein.

66. On information and belief, Lupin Pharmaceuticals, under the control of Lupin Ltd., was involved with the preparation and filing of ANDA No. 204-263 with FDA.

67. By reason of Lupin Ltd.'s inducement of Lupin Pharmaceuticals' direct infringement of the '485 Patent, Lupin Ltd. has caused and continues to cause irreparable harm to Plaintiffs.

68. On information and belief, Lupin Ltd.'s inducement of Lupin Pharmaceuticals' direct infringement of the '485 Patent will continue unless enjoined by this Court.

69. Plaintiffs have no adequate remedy at law for Lupin Ltd.'s inducement of Lupin Pharmaceuticals' direct infringement of the '485 Patent.

70. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

SEVENTH CLAIM FOR RELIEF
(Direct Infringement of the '292 Patent by Lupin Ltd. and Lupin Pharmaceuticals)

71. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 70 hereof, as if fully set forth herein.

72. Through the conduct alleged above, Defendants have directly infringed, and continue to directly infringe, one or more claims of the '292 Patent.

73. By filing ANDA No. 204-263 with a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of lansoprazole delayed release orally disintegrating tablets described therein, prior to the expiration of the '292 Patent with pediatric exclusivity, Defendants have infringed the '292 Patent under 35 U.S.C. § 271(e)(2).

74. Defendants were aware of the existence of the '292 Patent prior to filing ANDA No. 204-263 but took such action knowing that it would constitute infringement of the '292 Patent.

75. On information and belief, Defendants acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '292 Patent.

76. Defendants' conduct renders this case "exceptional" as described in 35 U.S.C. § 285.

77. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '292 Patent.

EIGHTH CLAIM FOR RELIEF
(Inducement of Infringement of the '292 Patent by Lupin Ltd.)

78. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 77 hereof, as if fully set forth herein.

79. On information and belief, Lupin Ltd. initiates, directs and controls the activities of its subsidiary company, Lupin Pharmaceuticals, with regard to ANDA No. 204-263 and the lansoprazole delayed release orally disintegrating tablets described therein.

80. On information and belief, Lupin Pharmaceuticals, under the control of Lupin Ltd., was involved with the preparation and filing of ANDA No. 204-263 with FDA.

81. By reason of Lupin Ltd.'s inducement of Lupin Pharmaceuticals' direct infringement of the '292 Patent, Lupin Ltd. has caused and continues to cause irreparable harm to Plaintiffs.

82. On information and belief, Lupin Ltd.'s inducement of Lupin Pharmaceuticals' direct infringement of the '292 Patent will continue unless enjoined by this Court.

83. Plaintiffs have no adequate remedy at law for Lupin Ltd.'s inducement of Lupin Pharmaceuticals' direct infringement of the '292 Patent.

84. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

WHEREFORE, Plaintiffs respectfully request the following relief:

A. An order adjudging and decreeing that Lupin Ltd. and Lupin Pharmaceuticals have infringed the patents-in-suit;

B. An order adjudging and decreeing that Lupin Ltd. has induced infringement of the patents-in-suit;

C. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any approval of ANDA No. 204-263 be no earlier than the expiration date of the last of the patents-in-suit, including any extensions and/or exclusivities;

D. A preliminary and permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) restraining and enjoining Lupin Ltd. and Lupin Pharmaceuticals, their officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the lansoprazole products described in ANDA No. 204-263 or any other ANDA not colorably different from ANDA No. 204-263 until the expiration date of the last of the patents-in-suit, including any extensions and/or exclusivities;

E. A declaration that this case is exceptional and an award of attorneys' fees under 35 U.S.C. § 285 and costs and expenses in this action; and

F. Such other and further relief as the Court may deem just and proper.

Respectfully submitted,

Dated: November 29, 2012

By: *s/ John E. Flaherty*

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CERTIFICATION PURSUANT TO LOCAL RULE 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that certain of the patents-in-suit in the above-captioned action are the subject of other actions pending in this District: *Takeda Pharm. Co. Ltd. et al. v. Zydus Pharms. (USA) Inc.*, Civ. Action No. 3:10-1723 (JAP) (TJB) (D.N.J.) (U.S. Patent Nos. 6,328,994 and 7,431,942) and *Takeda Pharm. Co. Ltd. et al. v. Mylan Pharm. Inc.*, Civ. Action No. 3:11-02506 (JAP) (TJB) (D.N.J.) (U.S. Patent No. 6,328,994).

Respectfully submitted,

Dated: November 29, 2012

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