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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., and TAKEDA PHARMACEUTICALS AMERICA, INC., Plaintiffs, v. SUN PHARMA GLOBAL FZE, SUN PHARMACEUTICAL INDUSTRIES, LTD., and CARACO PHARMACEUTICAL LABORATORIES, LTD., 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., and Takeda Pharmaceuticals America, Inc. (collectively, "Plaintiffs"), as and for their Complaint against Defendants Sun Pharma Global FZE, Sun Pharmaceutical Industries, Ltd., and Caraco Pharmaceutical Laboratories, Ltd. (collectively, "Defendants" or "Sun"), 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. Takeda Japan manufactures lansoprazole orally disintegrating tablets.

2. Plaintiff Takeda Japan is the owner of record and assignee 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, "the patents-in-suit").

3. 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 research, development, and marketing of pharmaceutical products. Takeda U.S.A. is the registered holder of approved New Drug Application No. 21-428. In addition, Takeda U.S.A. has the exclusive right to import lansoprazole orally disintegrating tablets into the United States. Takeda U.S.A. purchases from Takeda Japan and imports into the United States, lansoprazole orally disintegrating tablets manufactured by Takeda Japan.

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 purchase lansoprazole orally disintegrating tablets from Takeda U.S.A. and sell those tablets to the public in the United States. Takeda America sells lansoprazole orally disintegrating tablets manufactured by Takeda Japan that it purchases from Takeda U.S.A. to the public in the United States.

5. On information and belief, defendant Sun Pharma Global FZE ("Sun FZE") is a corporation organized and existing under the laws of the United Arab Emirates, having a principal place of business at Office # 43, Block Y, SAIF-Zone, P.O. Box #122304, Sharjah, United Arab Emirates, and is a wholly-owned subsidiary of Sun Pharma Global, Inc., which in turn is a wholly-owned subsidiary of Sun Pharmaceutical Industries, Ltd. On information and belief, Sun FZE 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 Sun Pharmaceutical Industries, Ltd. ("Sun Ltd.") is a corporation organized and existing under the laws of India, having a principal place of business at Acme Plaza, Andheri-Kurla Rd., Andheri (E), Mumbai - 400 059, India. On information and belief, Sun 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.

7. On information and belief, defendant Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") is a corporation organized and existing under the laws of the State of Michigan, having a principal place of business at 1150 Elijah McCoy Drive, Detroit, Michigan 48202, and is a wholly-owned subsidiary of Sun Ltd. On information and belief, Caraco 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.

8. On information and belief, Sun FZE, Sun Ltd., and Caraco operate and act in concert as an integrated, unitary business for purposes of manufacturing, marketing, selling, and distributing generic pharmaceutical products.

JURISDICTION AND VENUE

9. 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).

10. On information and belief, Sun FZE has consented to personal jurisdiction in this District. *See e.g., Novartis Pharmaceuticals Corp. et al. v. Sun Pharma Global FZE et al.*, Civil Action No. 12-04393 (SDW)(MCA) (D.N.J.); *The Medicines Co. v. Sun Pharma Global FZE et al.*, Civil Action No. 3:11-cv-06819 (PGS)(DEA) (D.N.J). Sun FZE is also 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.

11. On information and belief, Sun Ltd. has consented to personal jurisdiction in this District. *See e.g., Novartis Pharmaceuticals Corp. et al. v. Sun Pharma Global FZE et al.*, Civil Action No. 12-04393 (SDW)(MCA) (D.N.J.); *The Medicines Co. v. Sun Pharma Global FZE et*

al., Civil Action No. 3:11-cv-06819 (PGS)(DEA) (D.N.J). Sun Ltd. is also 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.

12. Caraco is subject to personal jurisdiction in this District because it has availed itself to the benefits and protections of New Jersey's law by, among other things, registering to do business in New Jersey, including distribution of pharmaceutical products, with an authorized agent at 820 Tavern Road, West Trenton, NJ 08628.

13. On information and belief, Caraco has consented to personal jurisdiction in this District. *See, e.g., The Medicines Co. v. Sun Pharma Global FZE et al.*, Civil Action No. 3:11-cv-06819 (PGS)(DEA) (D.N.J). Caraco is also 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.

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

FACTS PERTINENT TO ALL CLAIMS FOR RELIEF

15. On December 11, 2001, the United States Patent and Trademark Office ("PTO") issued the '994 Patent, entitled "Orally Disintegrable 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. A copy of the '994 Patent is attached hereto as Exhibit A.

16. 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. A copy of the '942 Patent is attached hereto as Exhibit B.

17. 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. A copy of the '485 Patent is attached hereto as Exhibit C.

18. 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. A copy of the '292 Patent is attached hereto as Exhibit D.

19. 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™.

20. 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.

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

22. 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.

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

24. 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.

25. On information and belief, Defendants collaborated in the research, development, preparation and filing of ANDA No. 206013 for lansoprazole delayed release orally disintegrating tablets.

26. On information and belief, Sun FZE submitted to FDA ANDA No. 206013 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.

27. Plaintiffs received a letter from Sun FZE, dated June 3, 2014, notifying Plaintiffs that ANDA No. 206013 includes a certification under 21 U.S.C. 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") that, in Sun FZE's opinion, no valid, enforceable claim of the patents-in-suit will be infringed by the commercial manufacture, use or sale of the lansoprazole delayed release orally disintegrating tablet products described in ANDA No. 206013.

28. On information and belief, Sun Ltd. and Caraco made the ultimate decision to file ANDA No. 206013 with FDA, and encouraged and directed Sun FZE to file ANDA No. 206013 with a Paragraph IV certification, and Sun FZE did so at Sun Ltd.'s and Caraco's direction.

29. Defendants were aware of the patents-in-suit when Sun FZE filed its ANDA No. 206013 with a Paragraph IV certification.

30. Plaintiffs commenced this action within 45 days of the date they received Sun FZE's notice of ANDA No. 206013 containing the Paragraph IV certification.

31. On information and belief, Sun FZE, Sun Ltd., and Caraco will continue to collaborate in seeking approval of ANDA No. 206013 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. 206013.

FIRST CLAIM FOR RELIEF
(Direct Infringement of the '994 Patent by Defendants)

32. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 31 hereof, as if fully set forth herein.

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

34. By filing ANDA No. 206013 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).

35. Defendants were aware of the existence of the '994 Patent prior to filing ANDA No. 206013 but took such action knowing that it would constitute infringement of the '994 Patent.

36. 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.

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

38. 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 Sun Ltd. and Caraco)

39. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 38 hereof, as if fully set forth herein.

40. Through the conduct alleged above, Sun Ltd. and Caraco have knowingly and actively induced Sun FZE to infringe, and continue to infringe, one or more claims of the '994 patent.

41. By reason of Sun Ltd.'s and Caraco's inducement of Sun FZE's direct infringement of the '994 Patent, Sun Ltd. and Caraco have caused and continue to cause irreparable harm to Plaintiffs.

42. On information and belief, Sun Ltd.'s and Caraco's inducement of Sun FZE's direct infringement of the '994 Patent will continue unless enjoined by this Court.

43. Plaintiffs have no adequate remedy at law for Sun Ltd.'s and Caraco's inducement of Sun FZE's direct infringement of the '994 Patent.

44. 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 Defendants)

45. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 44 hereof, as if fully set forth herein.

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

47. By filing ANDA No. 206013 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).

48. Defendants were aware of the existence of the '942 Patent prior to filing ANDA No. 206013 but took such action knowing that it would constitute infringement of the '942 Patent.

49. 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.

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

51. 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 Sun Ltd. and Caraco)

52. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 51 hereof, as if fully set forth herein.

53. Through the conduct alleged above, Sun Ltd. and Caraco have knowingly and actively induced Sun FZE to infringe, and continue to infringe, one or more claims of the '942 patent.

54. By reason of Sun Ltd.'s and Caraco's inducement of Sun FZE's direct infringement of the '942 Patent, Sun Ltd. and Caraco have caused and continue to cause irreparable harm to Plaintiffs.

55. On information and belief, Sun Ltd.'s and Caraco's inducement of Sun FZE's direct infringement of the '942 Patent will continue unless enjoined by this Court.

56. Plaintiffs have no adequate remedy at law for Sun Ltd.'s and Caraco's inducement of Sun FZE's direct infringement of the '942 Patent.

57. 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 Defendants)

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

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

60. By filing ANDA No. 206013 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).

61. Defendants were aware of the existence of the '485 Patent prior to filing ANDA No. 206013 but took such action knowing that it would constitute infringement of the '485 Patent.

62. 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.

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

64. 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 Sun Ltd. and Caraco)

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

66. Through the conduct alleged above, Sun Ltd. and Caraco have knowingly and actively induced Sun FZE to infringe, and continue to infringe, one or more claims of the '485 patent.

67. By reason of Sun Ltd.'s and Caraco's inducement of Sun FZE's direct infringement of the '485 Patent, Sun Ltd. and Caraco have caused and continue to cause irreparable harm to Plaintiffs.

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

69. Plaintiffs have no adequate remedy at law for Sun Ltd.'s and Caraco's inducement of Sun FZE's 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 Defendants)

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. 206013 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. 206013 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 Sun Ltd. and Caraco)

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

79. Through the conduct alleged above, Sun Ltd. and Caraco have knowingly and actively induced Sun FZE to infringe, and continue to infringe, one or more claims of the '292 patent.

80. By reason of Sun Ltd.'s and Caraco's inducement of Sun FZE's direct infringement of the '292 Patent, Sun Ltd. and Caraco have caused and continue to cause irreparable harm to Plaintiffs.

81. On information and belief, Sun Ltd.'s and Caraco's inducement of Sun FZE's direct infringement of the '292 Patent will continue unless enjoined by this Court.

82. Plaintiffs have no adequate remedy at law for Sun Ltd.'s and Caraco's inducement of Sun FZE's direct infringement of the '292 Patent.

83. 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 Defendants have infringed the patents-in-suit;

B. An order adjudging and decreeing that Sun Ltd. and Caraco have 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. 206013 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 Defendants, 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. 206013 or any other ANDA not colorably different from ANDA No. 206013 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: July 9, 2014

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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 the following actions pending in this District: *Takeda Pharm. Co. Ltd. et al. v. Zydus Pharms. USA Inc. et al.*, Civil Action No. 10-01723 (JAP) (TJB) (D.N.J.) (U.S. Patent No. 6,328,994); *Takeda Pharm. Co. Ltd. et al. v. Lupin Ltd. et al*, Civ. Action No. 3:12-07333 (JAP) (TJB) (D.N.J.) (U.S. Patent No. 6,328,994); *Takeda Pharm. Co. Ltd. et al. v. Wockhardt Bio AG et al.*, Civil Action No. 3:13-06427 (JAP) (TJB) (D.N.J.) (U.S. Patent Nos. 6,328,994, 7,431,942, and 7,875,292).

Respectfully submitted,

Dated: July 9, 2014

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