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

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS LLC, TAKEDA PHARMACEUTICALS AMERICA, INC., and ETHYPHARM, S.A., Plaintiffs, v. MYLAN INC. and MYLAN 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 North America, Inc., Takeda Pharmaceuticals LLC, and Takeda Pharmaceuticals America, Inc. (collectively, "Takeda") and Ethypharm, S.A. ("Ethypharm") (Takeda and Ethypharm together, "Plaintiffs"), as and for their Complaint against defendants Mylan Inc. and Mylan 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 North America, Inc. ("TPNA") is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015. As part of its business, TPNA is involved in the research, development, and marketing of pharmaceutical products. TPNA 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 (the " '994 Patent") and is the exclusive sublicensee in the field of use for lansoprazole of U.S. Patent No. 5,464,632 (the " '632 Patent") (the '994 Patent and the '632 Patent together, the "Patents").

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.

5. Plaintiff Ethypharm, S.A. ("Ethypharm") is a French corporation, having a principal place of business at 194 Bureaux de la Colline, Batiment D, 92213 Saint Cloud, France. As part of its business, Ethypharm is involved in the research, development, manufacturing, and licensing of pharmaceutical products. Ethypharm appears as a plaintiff in this action solely by virtue of being the record owner of the '632 Patent. Ethypharm seeks relief in this action solely with respect to the '632 Patent.

6. On information and belief, defendant Mylan Inc. is a Pennsylvania corporation with its principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317. On information and belief, defendant Mylan Inc. operates administrative offices in this District, and manufactures numerous generic drugs for sale and use throughout the United States, including in this District, alone and/or through its wholly owned subsidiary and agent, defendant Mylan Pharmaceuticals Inc.

7. On information and belief, defendant Mylan Pharmaceuticals Inc. is a West Virginia corporation and a wholly-owned subsidiary and agent of defendant Mylan Inc. with its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Upon information and belief, Mylan Pharmaceuticals Inc. is registered as a foreign business with the State of New Jersey. Upon information and belief, Mylan Pharmaceuticals Inc.'s registration identifies Corporation Service Company, 830 Bear Tavern Road, West Trenton, New Jersey

08628 as its registered agent for service of process in this District. Upon information and belief, defendant Mylan Pharmaceuticals Inc. manufactures numerous generic drugs for sale and use throughout the United States, including in this District, alone and/or through its parent Mylan Inc.

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. Mylan Inc. 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 operation of offices in New Jersey, its sales of products in New Jersey and derivation of substantial revenues there from, and its filing of claims and counterclaims in this District.

10. Mylan Pharmaceuticals Inc. 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 designation of an agent for service of process in New Jersey, its substantial and continuing contacts with the State, including but not limited to its operation of offices in New Jersey, its sales of products in New Jersey and derivation of substantial revenues there from, and its filing of claims and counterclaims in this District.

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

FACTS PERTINENT TO ALL CLAIMS FOR RELIEF

12. 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.

13. On November 7, 1995, the PTO issued the '632 Patent, entitled "Rapidly Disintegratable Multiparticular Tablet," to Laboratoires Prographarm, the assignee of the named inventors Gerard Cousin, Etienne Bruna, and Edouard Gendrot. Laboratoires Prographarm granted Plaintiff Takeda Japan an exclusive license to the '632 Patent for lansoprazole with the right to sublicense. Plaintiff Ethypharm subsequently acquired Laboratoires Prographarm and is the record owner of the '632 Patent. Plaintiff Takeda Japan granted Plaintiff Takeda LLC an exclusive sublicensee to the '632 Patent for lansoprazole. On February 20, 2001, the PTO issued a Reexamination Certificate for the '632 Patent. A copy of the '632 Patent and its Reexamination Certificate is attached hereto as Exhibit B.

14. 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 TPNA 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™.

15. The '994 and '632 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™, delayed release orally disintegrating lansoprazole tablets, 15 and 30 mg.

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

17. 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.

18. On information and belief, Defendants actively review pharmaceutical patents and seeks opportunities to challenge those patents.

19. 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.

20. On information and belief, Defendants collaborated in the research, development, preparation and filing of ANDA No. 202-396 for lansoprazole delayed release orally disintegrating tablets.

21. On information and belief, Mylan Pharmaceuticals Inc. submitted to FDA ANDA No. 202-396 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.

22. Plaintiffs have received a letter from Mylan Pharmaceuticals Inc. notifying them that Mylan Pharmaceutical Inc.'s ANDA No. 202-396 includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") that, in Mylan Pharmaceuticals Inc.'s opinion, the patents-in-suit are not infringed by the commercial manufacture, use or sale of the lansoprazole delayed release orally disintegrating tablet products described in ANDA No. 202-396.

23. On information and belief, Mylan Inc. made the ultimate decision to file ANDA No. 202-396 with FDA, and encouraged and directed Mylan Pharmaceuticals Inc. to file ANDA No. 202-396 with a Paragraph IV certification, and Mylan Pharmaceuticals Inc. did so at Mylan Inc.'s direction.

24. On information and belief, Mylan Inc. was necessarily aware of the patents-in-suit when it directed Mylan Pharmaceuticals Inc. to file ANDA No. 202-396 with a Paragraph IV certification.

25. Plaintiffs commenced this action within 45 days of the date they received Mylan Pharmaceuticals Inc.'s notice of ANDA No. 202-396 containing the Paragraph IV certification.

26. On information and belief, Mylan Pharmaceuticals Inc. and Mylan Inc. continue to collaborate in seeking approval of ANDA No. 202-396 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. 202-396.

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

27. Takeda repeats and realleges each and every allegation contained in paragraphs 1 through 26 hereof, as if fully set forth herein.

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

29. By filing ANDA No. 202-396 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).

30. Defendants were aware of the existence of the '994 Patent prior to filing ANDA No. 202-396 but took such action knowing that it would constitute infringement of the '994 Patent.

31. 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.

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

33. 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 Mylan Inc.)

34. Takeda repeats and realleges each and every allegation contained in paragraphs 1 through 33 hereof, as if fully set forth herein.

35. Through the conduct alleged above, Mylan Inc. has knowingly and actively induced Mylan Pharmaceuticals Inc. to infringe, and continue to infringe, one or more claims of the '994 Patent.

36. By reason of Mylan Inc.'s inducement of Mylan Pharmaceuticals Inc.'s direct infringement of the '994 Patent, Mylan Inc. has caused and continues to cause irreparable harm to Takeda.

37. On information and belief, Mylan Inc.'s inducement of Mylan Pharmaceuticals Inc.'s direct infringement of the '994 Patent will continue unless enjoined by this Court.

38. Takeda has no adequate remedy at law for Mylan Inc.'s inducement of Mylan Pharmaceuticals Inc.'s direct infringement of the '994 Patent.

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

THIRD CLAIM FOR RELIEF
(Direct Infringement of the '632 Patent by Mylan Pharmaceuticals Inc. and Mylan Inc.)

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

41. Through the conduct alleged above, Defendants have directly infringed, and continue to directly infringe, one or more claims of the '632 Patent.

42. By filing ANDA No. 202-396 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 '632 Patent with pediatric exclusivity, Defendants have infringed the '632 Patent under 35 U.S.C. § 271(e)(2).

43. Defendants were aware of the existence of the '632 Patent prior to filing ANDA No. 202-396 but took such action knowing that it would constitute infringement of the '632 Patent.

44. On information and belief, Defendants acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '632 Patent.

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

46. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '632 Patent.

FOURTH CLAIM FOR RELIEF
(Inducement of Infringement of the '632 Patent by Mylan Inc.)

47. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 46 hereof, as if fully set forth herein.

48. Through the conduct alleged above, Mylan Inc. has knowingly and actively induced Mylan Pharmaceuticals Inc. to infringe, and continue to infringe, one or more claims of the '632 Patent.

49. By reason of Mylan Inc.'s inducement of Mylan Pharmaceuticals Inc.'s direct infringement of the '632 Patent, Mylan Inc. has caused and continues to cause irreparable harm to Plaintiffs.

50. On information and belief, Mylan Inc.'s inducement of Mylan Pharmaceuticals Inc.'s direct infringement of the '632 Patent will continue unless enjoined by this Court.

51. Plaintiffs have no adequate remedy at law for Mylan Inc.'s inducement of Mylan Pharmaceuticals Inc.'s direct infringement of the '632 Patent.

52. 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 Mylan Pharmaceuticals Inc. and Mylan Inc. have infringed the patents-in-suit;

B. An order adjudging and decreeing that Mylan Inc. 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. 202-396 be no earlier than the expiration date of the last of the patents-in-suit, including any extensions;

D. A preliminary and permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) restraining and enjoining Mylan Pharmaceuticals Inc. and Mylan Inc., 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. 202-396 or any other ANDA not colorably different from ANDA No. 202-396 until the expiration date of the last of the patents-in-suit, including any extensions;

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: May 2, 2011

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CERTIFICATION PURSUANT TO LOCAL RULE 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the patents-in-suit in the above-captioned action are the subject of another action 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.).

Respectfully submitted,

Dated: May 2, 2011

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