IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS NORTH AMERICA, INC. TAKEDA PHARMACEUTICALS LLC, TAKEDA PHARMACEUTICALS AMERICA, INC., and ETHYPHARM, S.A.,	)	
Plaintiffs,	)	C.A. No. 07-331-SLR
v.	)	
TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	)	
Defendants.	)	

AMENDED COMPLAINT

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"), in accordance with the Court's order of October 28, 2008, hereby amend their Complaint against defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively "Defendants"), and 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 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 under the patents to import lansoprazole orally-disintegrating tablets under the patents 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. 4,628,098 ("the '098 Patent") and U.S. Patent No. 5,045,321 ("the '321 Patent"), and is the exclusive sublicensee in the field of use for lansoprazole of U.S. Patent No. 5,464,632 ("the '632 Patent").

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 21 rue Saint Matthieu 78550, Houdan, 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 in respect to the '632 Patent.

6. On information and belief, defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation, having a principal place of business located at 1090 Horsham Road, North Wales, Pennsylvania, 19454 and is engaged in the manufacture and sale of pharmaceutical products.

7. On information and belief, defendant Teva Pharmaceuticals Industries, Ltd. ("Teva Industries") is an Israeli corporation, having a principal place of business located at 5 Basel St., Petach Tikva 49131, Israel. On information and belief, Teva Industries manufactures bulk pharmaceutical products.

8. On information and belief, Teva Industries owns 100% of the ownership and voting interest in Teva USA.

9. On information and belief, Teva USA is controlled and/or dominated by Teva Industries.

10. On information and belief, Teva Industries conducts its North American operations, in part, through Teva USA.

JURISDICTION AND VENUE

11. 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).

12. Teva USA is subject to personal jurisdiction in this District by virtue of, *inter alia*, its incorporation in Delaware, its conduct of business in this District, its purposeful availment of the rights and benefits of Delaware law, and its substantial and continuing contacts with the State.

13. On information and belief, Teva Industries regularly transacts business within this District, including but not limited to directing the operations and management of Teva USA, as well as shipping pharmaceuticals to Teva USA from locations outside the United States for distribution by Teva USA within the United States generally, and within this District specifically.

14. On information and belief, Teva USA acts as an agent of Teva Industries with respect to the acts complained of herein.

15. On information and belief, the acts of Teva USA complained of herein were done at the direction of, with the authorization of, with the cooperation, participation, and assistance of, and, in part, for the benefit of Teva Industries.

16. On information and belief, Teva Industries directed Teva USA to perform the acts complained of herein to, in whole or in part, shield itself from liability for patent infringement based upon those acts.

17. Teva USA's acts and contacts with this District, as an agent of Teva Industries, are attributable to Teva Industries for jurisdictional purposes.

18. Teva Industries is subject to the personal jurisdiction in this District by virtue of, *inter alia,* its incorporation of Teva USA in Delaware, its conduct of business in this District, its purposeful availment of the rights and benefits of Delaware law, and its substantial and continuing contacts with the State.

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

FACTS PERTINENT TO ALL CLAIMS FOR RELIEF

20. On December 9, 1986, the United States Patent and Trademark Office ("the PTO") issued the '098 Patent, entitled "2-[2-Pyridylmethylthio-(Sulfinyl)-]Benzimidazoles," to Takeda Chemical Industries, Ltd., the assignee of the named inventors Akira Nohara and Yoshitaka Maki. Plaintiff Takeda is the record owner of the '098 Patent, and Plaintiff Takeda LLC is the exclusive licensee. A copy of the '098 Patent is attached hereto as Exhibit A.

21. The original expiration date of the '098 Patent was July 29, 2005.

22. On January 6, 1997, the PTO granted the '098 Patent a term extension of 1381 days pursuant to 35 U.S.C. § 156, extending the expiration date of the '098 Patent to May 10, 2009.

23. On September 3, 1991, the PTO issued the '321 Patent, entitled "Stabilized Pharmaceutical Composition and Its Production," to Takeda Chemical Industries, Ltd., the assignee of the named inventors Tadashi Makino, Tetsuro Tabata, and Shin-ichiro Hirai. Plaintiff Takeda is the record owner of the '321 Patent, and Plaintiff Takeda LLC is the exclusive licensee. A copy of the '321 Patent is attached hereto as Exhibit B.

24. On November 7, 1995, the PTO issued U.S. Patent No. 5,464,632, 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 an exclusive license to the '632 Patent with the right to sublicense. Plaintiff Ethypharm subsequently acquired Laboratoires Prographarm and is the record owner of the '632 Patent. Plaintiff Takeda LLC is the exclusive sublicensee for lansoprazole to the '632 Patent. 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 C.

25. All three patents have also received a pediatric extension of 6 months beginning from the expiration of these patents, during which no ANDA can be approved. Thus, no ANDA that infringes the '098 patent can be approved prior to November 10, 2009, no ANDA that infringes the '321 patent can be approved until March 3, 2009, and no ANDA that infringes the '632 patent can be approved prior to May 7, 2013.

26. 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 it sells under the name Prevacid® SoluTab™.

27. The '098, '321, and '632 Patents (collectively, "the patents-in-suit") are listed in a publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the "Orange Book") as covering Prevacid® SoluTab™, delayed release orally disintegrating tablets, 15 and 30 mg.

28. On information and belief, through the coordinated efforts of research and development staff in Israel, Europe and North America, Teva Industries seeks to constantly expand the range of generic products it sells.

29. On information and belief, Teva USA and Teva Industries 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 Delaware specifically.

30. On information and belief, Teva Industries actively reviews pharmaceutical patents and seeks opportunities to challenge those patents.

31. On information and belief, Teva Industries 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.

32. On information and belief, Teva USA and Teva Industries collaborated in the research, development, preparation and filing of ANDA No. 78-730 for lansoprazole delayed release orally disintegrating tablets.

33. On information and belief, Teva USA submitted to FDA ANDA No. 78-730 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.

34. Plaintiffs have received a letter dated April 12, 2007 from Teva USA notifying them that Teva USA's ANDA No. 78-730 includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") that, in Teva USA's opinion, the patents-in-suit are invalid, unenforceable 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. 78-730.

35. On information and belief, Teva Industries made the ultimate decision to file ANDA No. 78-730 with the FDA, and encouraged and directed Teva USA to file ANDA No. 78-730 and Paragraph IV certification, and Teva USA did so at Teva Industries' direction.

36. On information and belief, Teva Industries was necessarily aware of the patents-in-suit when it directed Teva USA to file ANDA No. 78-730 and Paragraph IV certification.

37. Plaintiffs commenced this action within 45 days of the date they received Teva USA's notice of ANDA No. 78-730 containing the Paragraph IV certification.

38. On information and belief, Teva USA and Teva Industries continue to collaborate in seeking approval of ANDA No. 78-730 from the 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 Delaware) in the event that FDA approves ANDA No. 78-730.

FIRST CLAIM FOR RELIEF
(Direct Infringement of the '098 Patent by Teva USA and Teva Industries)

39. Plaintiff Takeda repeats and realleges each and every allegation contained in paragraphs 1 through 38 hereof, as if fully set forth herein.

40. Through the conduct alleged above, Teva USA and Teva Industries (collectively "Teva") have directly infringed, and continue to directly infringe, one or more claims of the '098 Patent.

41. By filing ANDA No. 78-730 with a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of the lansoprazole delayed release orally disintegrating tablet products described therein, prior to the expiration of the '098 Patent, Teva has infringed the '098 Patent under 35 U.S.C. § 271(e)(2).

42. Teva was aware of the existence of the '098 Patent prior to filing ANDA No. 78-730 but took such action knowing that it would constitute an infringement of the '098 Patent.

43. On information and belief, Teva acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '098 Patent.

44. Teva does not dispute that the lansoprazole delayed release orally disintegrating tablet products described in ANDA No. 78-730 infringe claims 1, 2, 5, 6, 8, and 10 of the '098 Patent. Instead, Teva's Paragraph IV certification is premised upon a baseless assertion that claims 1, 2, 5, 6, 8, and 10 of the '098 Patent are invalid as obvious under 35 U.S.C. § 103 or unenforceable for inequitable conduct.

45. Teva disregarded its duty to exercise due care by making these baseless assertions of invalidity and unenforceability, and therefore, this case is "exceptional" as described in 35 U.S.C. § 285.

46. Plaintiff Takeda will be irreparably harmed if Teva is not enjoined from infringing the '098 Patent.

SECOND CLAIM FOR RELIEF
(Inducement of Infringement of the '098 Patent by Teva Industries)

47. Plaintiff Takeda repeats and realleges each and every allegation contained in paragraphs 1 through 46 hereof, as if fully set forth herein.

48. Through the conduct alleged above, Teva Industries has knowingly and actively induced Teva USA to infringe, and continue to infringe, one or more claims of the '098 Patent.

49. By reason of Teva Industries' inducement of Teva USA's direct infringement of the '098 Patent, Teva Industries has caused and continues to cause irreparable harm to Plaintiff Takeda.

50. On information and belief, Teva Industries' inducement of Teva USA's direct infringement of the '098 Patent will continue unless enjoined by this Court.

51. Plaintiff Takeda has no adequate remedy at law for Teva Industries' inducement of Teva USA's direct infringement of the '098 Patent.

52. 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 '321 Patent by Teva USA and Teva Industries)

53. Plaintiff Takeda repeats and realleges each and every allegation contained in paragraphs 1 through 52 hereof, as if fully set forth herein.

54. Through the conduct alleged above, Teva has directly infringed, and continues to directly infringe, one or more claims of the '321 Patent.

55. By filing ANDA No. 78-730 with a Paragraph IV certification seeking FDA 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 '321 Patent, Teva has infringed the '321 Patent under 35 U.S.C. § 271(e)(2).

56. Teva was aware of the existence of the '321 Patent prior to filing ANDA No. 78-730 but took such action knowing that it would constitute an infringement of the '321 Patent.

57. On information and belief, Teva acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '321 Patent.

58. Teva's conduct renders this case "exceptional" as described in 35 U.S.C. § 285.

59. Plaintiff Takeda will be irreparably harmed if Teva is not enjoined from infringing the '321 Patent.

FOURTH CLAIM FOR RELIEF
(Inducement of Infringement of the '321 Patent by Teva Industries)

60. Plaintiff Takeda repeats and realleges each and every allegation contained in paragraphs 1 through 59 hereof, as if fully set forth herein.

61. Through the conduct alleged above, Teva Industries has knowingly and actively induced Teva USA to infringe, and continue to infringe, one or more claims of the '321 Patent.

62. By reason of Teva Industries' inducement of Teva USA's direct infringement of the '321 Patent, Teva Industries has caused and continues to cause irreparable harm to Plaintiff Takeda.

63. On information and belief, Teva Industries' inducement of Teva USA's direct infringement of the '321 Patent will continue unless enjoined by this Court.

64. Plaintiff Takeda has no adequate remedy at law for Teva Industries' inducement of Teva USA's direct infringement of the '321 Patent.

65. 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 '632 Patent by Teva USA and Teva Industries)

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

67. Through the conduct alleged above, Teva has directly infringed, and continues to directly infringe, one or more claims of the '632 Patent.

68. By filing ANDA No. 78-730 with a Paragraph IV certification seeking FDA 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 '632 Patent, Teva has infringed the '632 Patent under 35 U.S.C. § 271(e)(2).

69. Teva was aware of the existence of the '632 Patent prior to filing ANDA No. 78-730 but took such action knowing that it would constitute an infringement of the '632 Patent.

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

71. Teva's conduct renders this case "exceptional" as described in 35 U.S.C. § 285.

72. Plaintiffs will be irreparably harmed if Teva is not enjoined from infringing the '632 Patent.

SIXTH CLAIM FOR RELIEF
(Inducement of Infringement of the '632 Patent by Teva Industries)

73. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 72 hereof, as if fully set forth herein.

74. Through the conduct alleged above, Teva Industries has knowingly and actively induced Teva USA to infringe, and continue to infringe, one or more claims of the '632 Patent.

75. By reason of Teva Industries' inducement of Teva USA's direct infringement of the '632 Patent, Teva Industries has caused and continues to cause irreparable harm to Plaintiffs.

76. On information and belief, Teva Industries' inducement of Teva USA's direct infringement of the '632 Patent will continue unless enjoined by this Court.

77. Plaintiffs have no adequate remedy at law for Teva Industries' inducement of Teva USA's direct infringement of the '632 Patent.

78. 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 Teva USA and Teva Industries have infringed the patents-in-suit;

B. An order adjudging and decreeing that Teva Industries 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. 78-730 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 Teva USA and Teva Industries, 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. 78-730 or any other

ANDA not colorably different from ANDA No. 78-730 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.

ASHBY & GEDDES

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