IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICAL COMPANY LIMITED, a Japanese Corporation, TAP PHARMACEUTICAL PRODUCTS INC., a Delaware Corporation, and ETHYPHARM, S.A., a French Corporation, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., a Delaware Corporation, and TEVA PHARMACEUTICAL INDUSTRIES LTD., an Israeli Corporation, Defendants.	)	C.A. No. _____

COMPLAINT

Plaintiffs Takeda Pharmaceutical Company Limited, TAP Pharmaceutical Products Inc., and Ethypharm, S.A. (collectively, "Plaintiffs"), as and for their Complaint against defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively "Defendants"), allege as follows:

THE PARTIES

1. Plaintiff Takeda Pharmaceutical Company Limited ("Takeda") 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 TAP Pharmaceutical Products Inc. ("TAP") is a Delaware corporation, having a principal place of business at 675 North Field Drive, Lake Forest, Illinois

60045. As part of its business, TAP is involved in the research, development, and marketing of pharmaceutical products.

3. 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 U.S. Patent No. 5,464,632 ("the '632 Patent"). Ethypharm seeks relief in this action solely in respect to the '632 Patent.

4. 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.

5. 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.

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

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

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

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. 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.

11. 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.

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

13. 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.

14. 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.

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

16. 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.

17. 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

18. On December 9, 1986, the United States Patent and Trademark Office ("the PTO") issued U.S. Patent No. 4,628,098 ("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 TAP is the exclusive licensee. A copy of the '098 Patent is attached hereto as Exhibit A.

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

20. 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.

21. On September 3, 1991, the PTO issued U.S. Patent No. 5,045,321 ("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 TAP is the exclusive licensee. A copy of the '321 Patent is attached hereto as Exhibit B.

22. 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 TAP is the exclusive sublicensee 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.

23. On December 11, 2001, the PTO issued U.S. Patent No. 6,328,994 ("the '994 Patent"), entitled "Orally Disintegrating Tablets," to Takeda Chemical Industries, Ltd., the assignee of the named inventors Toshihiro Shimizu, Shuji Morimoto, and Tetsuro Tabata. Plaintiff Takeda is the record owner of the '994 Patent, and Plaintiff TAP is the exclusive licensee. A copy of the '994 Patent is attached hereto as Exhibit D.

24. 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. TAP is the holder of NDA No. 21-428 for lansoprazole delayed release orally disintegrating tablets, which it sells under the name Prevacid® SoluTab™.

25. The '098, '321, '632 and '994 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.

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

27. 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.

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

29. 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.

30. On information and belief, Teva USA and Teva Industries collaborated in the research, development, preparation and filing of Abbreviated New Drug Application ("ANDA") No. 78-730 for lansoprazole delayed release orally disintegrating tablets.

31. 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.

32. 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.

33. 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 the Paragraph IV certification, and Teva USA did so at Teva Industries' direction.

34. 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 the Paragraph IV certification.

35. 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.

36. 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

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

38. 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.

39. 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).

40. 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.

41. 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.

42. 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.

43. 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.

44. Plaintiffs Takeda and TAP 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

45. Plaintiffs Takeda and TAP 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, Teva Industries has knowingly and actively induced Teva USA to infringe, and continue to infringe, one or more claims of the '098 Patent.

47. 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 Plaintiffs Takeda and TAP.

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

49. Plaintiffs Takeda and TAP have no adequate remedy at law for Teva Industries' inducement of Teva USA's direct infringement of the '098 Patent.

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

THIRD CLAIM FOR RELIEF
DIRECT INFRINGEMENT OF THE '321 PATENT BY TEVA USA AND TEVA INDUSTRIES

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

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

53. 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).

54. 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.

55. 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.

56. Teva’s conduct renders this case “exceptional” as described in 35 U.S.C. § 285.

57. Plaintiffs Takeda and TAP 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

58. Plaintiffs Takeda and TAP 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, Teva Industries has knowingly and actively induced Teva USA to infringe, and continue to infringe, one or more claims of the ’321 Patent.

60. 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 Plaintiffs Takeda and TAP.

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

62. Plaintiffs Takeda and TAP have no adequate remedy at law for Teva Industries' inducement of Teva USA's direct infringement of the '321 Patent.

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

FIFTH CLAIM FOR RELIEF
DIRECT INFRINGEMENT OF THE '632 PATENT BY TEVA USA AND TEVA INDUSTRIES

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

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

66. 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).

67. 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.

68. 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.

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

70. 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

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

73. 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.

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

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

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

SEVENTH CLAIM FOR RELIEF
DIRECT INFRINGEMENT OF THE '994 PATENT BY TEVA USA AND TEVA INDUSTRIES

77. Plaintiffs Takeda and TAP repeat and reallege each and every allegation contained in paragraphs 1 through 76 hereof, as if fully set forth herein.

78. Through the conduct alleged above, Teva has directly infringed, and continues to directly infringe, one or more claims of the '994 Patent.

79. 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 ’994 Patent, Teva has infringed the ’994 Patent under 35 U.S.C. § 271(e)(2).

80. Teva was aware of the existence of the ’994 Patent prior to filing ANDA No. 78-730, but took such action knowing that it would constitute an infringement of the ’994 Patent.

81. On information and belief, Teva acted without a reasonable basis for a good faith belief that it would not be liable for infringing the ’994 Patent.

82. Teva’s conduct renders this case “exceptional” as described in 35 U.S.C. § 285.

83. Plaintiffs Takeda and TAP will be irreparably harmed if Teva is not enjoined from infringing the ’994 Patent.

EIGHTH CLAIM FOR RELIEF
INDUCEMENT OF INFRINGEMENT OF THE ’994 PATENT BY TEVA INDUSTRIES

84. Plaintiffs Takeda and TAP repeat and reallege each and every allegation contained in paragraphs 1 through 83 hereof, as if fully set forth herein.

85. 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 ’994 Patent.

86. By reason of Teva Industries’ inducement of Teva USA’s direct infringement of the ’994 Patent, Teva Industries has caused and continues to cause irreparable harm to Plaintiffs Takeda and TAP.

87. On information and belief, Teva Industries’ inducement of Teva USA’s direct infringement of the ’994 Patent will continue unless enjoined by this Court.

88. Plaintiffs Takeda and TAP have no adequate remedy at law for Teva Industries' inducement of Teva USA's direct infringement of the '994 Patent.

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

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