EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICAL COMPANY, LTD., a Japanese Corporation, and TAP PHARMACEUTICAL PRODUCTS INC., a Delaware Corporation, Plaintiffs,	)	
v.	)	C.A. No. 06-33-SLR
TEVA PHARMACEUTICALS USA, INC. a Delaware Corporation, and TEVA PHARMACEUTICAL INDUSTRIES LTD., an Israeli Corporation, Defendants.	)	

AMENDED COMPLAINT

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

THE PARTIES

1. Plaintiff Takeda Pharmaceutical Company Ltd. ("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. 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.

4. 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. Teva Industries manufactures bulk pharmaceutical products.

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

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

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

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. 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.

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

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

12. 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.

13. 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.

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

15. 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.

16. 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

17. 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.

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

19. 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.

20. On June 25, 1991, the PTO issued U.S. Patent No. 5,026,560 ("the '560 Patent"), entitled "Spherical Granules Having Core and Their 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 '560 Patent, and Plaintiff TAP is the exclusive licensee. A copy of the '560 Patent is attached hereto as Exhibit B.

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 C.

22. On March 3, 1992, the PTO issued U.S. Patent No. 5,093,132 ("the '132 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 '132 Patent, and Plaintiff TAP is the exclusive licensee. A copy of the '132 Patent is attached hereto as Exhibit D.

23. On July 18, 1995, the PTO issued U.S. Patent No. 5,433,959 ("the '959 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 '959 Patent, and Plaintiff TAP is the exclusive licensee. A copy of the '959 Patent is attached hereto as Exhibit E.

24. On May 10, 1995, the United States Food and Drug Administration ("FDA") approved New Drug Application ("NDA") No. 20-406 for lansoprazole delayed release capsules, 15 and 30 mg. TAP is the holder of NDA No. 20-406 for lansoprazole delayed release capsules, which it sells under the registered name PREVACID®.

25. The '098, '560, '321, '132 and '959 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®, lansoprazole delayed release capsules, 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 to constantly expand the range of generic products sold by it.

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®, including estimates of the revenues generated by the sale of Prevacid®, and decided to file an Abbreviated New Drug Application ("ANDA"), seeking approval to market lansoprazole delayed release capsules.

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. 77-255 for lansoprazole delayed release capsules.

31. On information and belief, Teva USA submitted to FDA an amendment to ANDA No. 77-255 seeking approval to engage in the commercial manufacture, use and sale of lansoprazole delayed release capsules, 15 and 30 mg, prior to the expiration of the patents in suit.

32. Plaintiffs have received a letter dated December 5, 2005 from Teva USA notifying them that Teva USA amended ANDA No. 77-255 to include 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 capsule products described in ANDA No. 77-255.

33. On information and belief, Teva Industries made the ultimate decision, and encouraged and directed Teva USA to file ANDA No. 77-255 and 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. 77-255 and Paragraph IV certification.

35. Plaintiffs commenced this action within 45 days of the date they received Teva USA's notice of ANDA No. 77-255 containing the Paragraph IV certification.

36. On information and belief, Teva USA and Teva Industries continue to collaborate in seeking approval of ANDA No. 77-255 from the FDA and intend to collaborate in the commercial manufacture, marketing, and sale of lansoprazole delayed release capsules (including commercial marketing and sale of such products in the State of Delaware) in the event that FDA approves ANDA No. 77-255.

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

37. Plaintiffs 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 amending ANDA No. 77-255 to contain a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of the lansoprazole

delayed release capsule 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. On information and belief, Teva was aware of the existence of the '098 Patent prior to amending ANDA No. 77-255 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 capsule products described in ANDA No. 77-255 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.

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

44. Plaintiffs 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 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.

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 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 attorney fees.

THIRD CLAIM FOR RELIEF
(Direct Infringement of the '560 Patent by Teva USA and Teva Industries)

51. Plaintiffs 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 '560 Patent.

53. By amending ANDA No. 77-255 to contain a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of lansoprazole delayed release capsules, 15 and 30 mg, prior to the expiration of the '560 Patent, it is believed that Teva has infringed the '560 Patent under 35 U.S.C. § 271(e)(2).

54. On information and belief, Teva was aware of the existence of the '560 Patent prior to amending ANDA No. 77-255 but took such action knowing that it would constitute an infringement of the '560 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 '560 Patent.

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

57. Plaintiffs will be irreparably harmed if Teva is not enjoined from infringing the '560 Patent.

FOURTH CLAIM FOR RELIEF
(Inducement of Infringement of the '560 Patent by Teva Industries)

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, Teva Industries has knowingly and actively induced Teva USA to infringe, and continue to infringe, one or more claims of the '560 Patent.

60. By reason of Teva Industries' inducement of Teva USA's direct infringement of the '560 Patent, Teva Industries has caused and continues to cause irreparable harm to Plaintiffs.

61. On information and belief, Teva Industries' inducement of Teva USA's direct infringement of the '560 Patent will continue unless enjoined by this Court.

62. Plaintiffs have no adequate remedy at law for Teva Industries' inducement of Teva USA's direct infringement of the '560 Patent.

63. 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 '321 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 '321 Patent.

66. By amending ANDA No. 77-255 to contain a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of lansoprazole delayed release capsules, 15 and 30 mg, prior to the expiration of the '321 Patent, it is believed that Teva has infringed the '321 Patent under 35 U.S.C. § 271(e)(2).

67. On information and belief, Teva was aware of the existence of the '321 Patent prior to amending ANDA No. 77-255 but took such action knowing that it would constitute an infringement of the '321 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 '321 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 '321 Patent.

SIXTH CLAIM FOR RELIEF
(Inducement of Infringement of the '321 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 '321 Patent.

73. 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.

74. On information and belief, Teva Industries' inducement of Teva USA's direct infringement of the '321 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 '321 Patent.

76. 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 '132 Patent by Teva USA and Teva Industries)

77. Plaintiffs 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 '132 Patent.

79. By amending ANDA No. 77-255 to contain a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of lansoprazole delayed release capsules, 15 and 30 mg, prior to the expiration of the '132 Patent, it is believed that Teva has infringed the '132 Patent under 35 U.S.C. § 271(e)(2).

80. On information and belief, Teva was aware of the existence of the '132 Patent prior to amending ANDA No. 77-255 but took such action knowing that it would constitute an infringement of the '132 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 '132 Patent.

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

83. Plaintiffs will be irreparably harmed if Teva is not enjoined from infringing the '132 Patent.

EIGHTH CLAIM FOR RELIEF
(Inducement of Infringement of the '132 Patent by Teva Industries)

84. Plaintiffs 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 '132 Patent.

86. By reason of Teva Industries' inducement of Teva USA's direct infringement of the '132 Patent, Teva Industries has caused and continues to cause irreparable harm to Plaintiffs.

87. On information and belief, Teva Industries' inducement of Teva USA's direct infringement of the '132 Patent will continue unless enjoined by this Court.

88. Plaintiffs have no adequate remedy at law for Teva Industries' inducement of Teva USA's direct infringement of the '132 Patent.

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

NINTH CLAIM FOR RELIEF
(Direct Infringement of the '959 Patent by Teva USA and Teva Industries)

90. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 89 hereof, as if fully set forth herein.

91. Through the conduct alleged above, Teva has directly infringed, and continues to directly infringe, one or more claims of the '959 Patent.

92. By amending ANDA No. 77-255 to contain a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of lansoprazole delayed release capsules, 15 and 30 mg, prior to the expiration of the '959 Patent, it is believed that Teva has infringed the '959 Patent under 35 U.S.C. § 271(e)(2).

93. On information and belief, Teva was aware of the existence of the '959 Patent prior to amending ANDA No. 77-255 but took such action knowing that it would constitute an infringement of the '959 Patent.

94. On information and belief, Teva acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '959 Patent.

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

96. Plaintiffs will be irreparably harmed if Teva is not enjoined from infringing the '959 Patent.

TENTH CLAIM FOR RELIEF
(Inducement of Infringement of the '959 Patent by Teva Industries)

97. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 96 hereof, as if fully set forth herein.

98. 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 '959 Patent.

99. By reason of Teva Industries' inducement of Teva USA's direct infringement of the '959 Patent, Teva Industries has caused and continues to cause irreparable harm to Plaintiffs.

100. On information and belief, Teva Industries' inducement of Teva USA's direct infringement of the '959 Patent will continue unless enjoined by this Court.

101. Plaintiffs have no adequate remedy at law for Teva Industries' inducement of Teva USA's direct infringement of the '959 Patent.

102. 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. 77-255 be no earlier than May 10, 2009, the date on which the '098 Patent expires, or the date of the last to expire of the patents in suit;

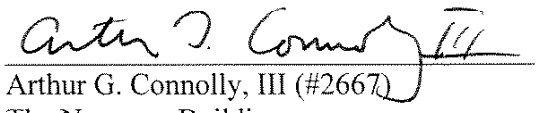
D. A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) restraining and enjoining Teva USA and Teva Industries, their officers, agents, attorneys, and employees,

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. 77-255 until May 10, 2009 or the date of the last to expire of the patents in suit;

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;

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

CONNOLLY BOVE LODGE & HUTZ LLP



Arthur G. Connolly, III (#2667)
The Nemours Building
1007 North Orange Street
Wilmington, DE 19801
(302) 658-9141

Attorneys for Plaintiffs
Takeda Pharmaceutical Company Ltd. and TAP Pharmaceutical Products Inc.

Of Counsel:

Eric J. Lobenfeld
Tedd W. Van Buskirk
Arlene L. Chow
HOGAN & HARTSON L.L.P.
875 Third Avenue
New York, New York 10022
(212) 918-3000

Philippe Y. Riesen
HOGAN & HARTSON L.L.P.
Shinjuku Center Building, 46th Floor
25-1 Nishi-Shinjuku 1-chome
Shinjuku, Tokyo 163-0646
Japan
(81) 3-5908-4070

Attorneys for Plaintiff Takeda Pharmaceutical Company Ltd.

William F. Cavanaugh
Stuart E. Pollack
Chad J. Peterman
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, New York 10036
(212) 336-2000

Attorneys for Plaintiff TAP Pharmaceuticals Products Inc.

Dated: June 13, 2006