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. _____
TEVA PHARMACEUTICALS USA, INC. a Delaware Corporation, Defendant.	)	

COMPLAINT

Plaintiffs Takeda Pharmaceutical Company Ltd. and TAP Pharmaceutical Products Inc. (collectively "Plaintiffs"), for their Complaint against defendant Teva Pharmaceuticals USA, Inc., 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, Teva Pharmaceuticals USA, Inc. ("Teva") 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.

JURISDICTION AND VENUE

4. 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).

5. Teva is subject to personal jurisdiction in this District.

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

FACTS PERTINENT TO ALL CLAIMS FOR RELIEF

7. 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.

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

9. 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.

10. 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.

11. 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.

12. 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.

13. 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.

14. 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®.

15. 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.

16. On information and belief, Teva submitted to FDA an amendment to Abbreviated New Drug Application ("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.

17. Plaintiffs have received a letter dated December 5, 2005 from Teva notifying them that Teva 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'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.

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

FIRST CLAIM FOR RELIEF
(Infringement of the '098 Patent)

19. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 18 hereof, as if fully set forth herein.

20. 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).

21. 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.

22. 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.

23. 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.

24. 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.

25. Plaintiffs will be irreparably harmed if Teva is not enjoined from infringing the '098 Patent.

SECOND CLAIM FOR RELIEF
(Infringement of the '560 Patent)

26. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 18 hereof, as if fully set forth herein.

27. 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).

28. 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.

29. 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.

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

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

THIRD CLAIM FOR RELIEF
(Infringement of the '321 Patent)

32. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 18 hereof, as if fully set forth herein.

33. 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).

34. 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.

35. 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.

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

37. Plaintiffs will be irreparably harmed if Teva is not enjoined from infringing the '321 Patent.

FOURTH CLAIM FOR RELIEF
(Infringement of the '132 Patent)

38. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 18 hereof, as if fully set forth herein.

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 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).

40. 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.

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 '132 Patent.

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

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

FIFTH CLAIM FOR RELIEF
(Infringement of the '959 Patent)

44. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 18 hereof, as if fully set forth herein.

45. 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).

46. 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.

47. 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.

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

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

WHEREFORE, Plaintiffs respectfully request the following relief:

A. An order adjudging and decreeing that Teva has infringed the patents in suit;

B. 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;

C. A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) restraining and enjoining Teva, its 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;

D. 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;

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

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