

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

TAP PHARMACEUTICAL PRODUCTS, INC.,)	
TAKEDA CHEMICAL INDUSTRIES, LTD., and)	
WAKO PURE CHEMICAL INDUSTRIES, LTD.,)	CASE NO. 99CV2715
)	
Plaintiffs,)	
)	JUDGE: SOLOMON OLIVER, JR.
vs.)	
)	
OWL PHARMACEUTICALS, L.L.C.)	
and OAKWOOD LABORATORIES, L.L.C.,)	
)	
Defendants.)	

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs TAP Pharmaceutical Products Inc., Takeda Chemical Industries, Ltd., and Wako Pure Chemical Industries, Ltd., by their attorneys, as and for their Second Amended Complaint against OWL Pharmaceuticals, L.L.C., and Oakwood Laboratories, L.L.C., allege as follows:

The Parties

1. Plaintiff TAP Pharmaceutical Products Inc. ("TAP") is a Delaware corporation having its principal place of business in Deerfield, Illinois. As part of its business, TAP is involved in the research, development, and marketing of pharmaceutical products.
2. Plaintiff Takeda Chemical Industries, Ltd., ("Takeda") is a Japanese corporation having its principal place of business in Osaka, Japan. As part of its business, Takeda is involved in the research, development, and marketing of pharmaceutical products.

3. Plaintiff Wako Pure Chemical Industries, Ltd. ("Wako") is a Japanese corporation having its principal place of business in Osaka, Japan. As part of its business, Wako is involved in the research, development, and marketing of laboratory chemicals and chemical products.

4. Defendant OWL Pharmaceuticals, L.L.C. ("OWL") is believed to be an Ohio limited liability company having its principal place of business in Cuyahoga County, Ohio. Upon information and belief, OWL is engaged in the manufacture and/or sale of pharmaceutical products.

5. Defendant Oakwood Laboratories, L.L.C. ("Oakwood") is believed to be an Ohio limited liability company having its principal place of business in Cuyahoga County, Ohio. Upon information and belief, Oakwood is engaged in the manufacture and sale of pharmaceutical products.

Jurisdiction and Venue

6. This action arises under the Patent Laws of the United States, Title 35, United States Code, for infringement of U.S. Patent Nos. 4,652,441; 4,677,191; 4,728,721; 4,849,228; 4,917,893; 5,476,663; 5,575,987; 5,631,020; 5,631,021; and 5,716,640 (collectively, the "Takeda patents"). These patents are either owned or co-owned by Takeda.

7. Jurisdiction in this Court is proper pursuant to 28 U.S.C. §1338(a) in that it is a civil action arising under an Act of Congress relating to patents.

8. Venue is proper in this District pursuant to 28 U.S.C. §§1391 and 1400(b) in that it is a civil action for patent infringement and is being brought in a judicial district where the defendants reside.

Facts Pertinent To All Causes of Action

9. The Takeda patents, copies of which are attached as Exhibits 1-10, claim, among other things, microcapsules, sustained-release microcapsules, and polymers for microcapsules, as well as the use and production of the aforementioned. TAP currently sells leuprolide acetate for depot injection pursuant to

a license under the Takeda patents, and is the owner of the New Drug Application by which the United States Food and Drug Administration ("FDA") first granted approval for leuprolide acetate for depot injection.

10. Upon information and belief, OWL has filed Abbreviated New Drug Application 75-645 (the "ANDA") seeking approval from the FDA to market Leuprolide Acetate for Depot Injection under Section 505(j) of the Federal Food, Drug, and Cosmetic Act. In connection with the ANDA, OWL is believed to have filed a certification under Section 505(j)(2)(A)(vii)(IV) that the Takeda patents are invalid or not infringed (the "Certification").

11. Upon information and belief, the purpose of OWL's ANDA and Certification was to seek approval under Section 505(j) of the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, and sale of a drug—specifically Leuprolide Acetate for Depot Injection—claimed in the Takeda patents prior to the expiration of the Takeda patents.

12. Upon information and belief, OWL maintains that it has provided notice to plaintiffs of its ANDA pursuant to Section 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the "ANDA notice"). Plaintiffs have commenced suit within 45 days of the date that OWL alleges that the ANDA notice was received by plaintiffs.

13. Upon information and belief, Oakwood is the manufacturer of the drug that is the subject of the ANDA.

FIRST CAUSE OF ACTION

('441 Patent Infringement)¹

14. Takeda is the owner of United States Patent No. 4,652,441 (the "'441 patent"), which was duly and legally issued on March 24, 1987. A copy of the '441 patent is attached as Exhibit 1.

15. The filing of Abbreviated New Drug Drug Application 75-645 for Leuprolide Acetate for Depot Injection by OWL infringes the '441 patent in violation of 35 U.S.C. §271(e)(2).

16. Upon information and belief, defendants were aware of the existence of the '441 patent prior to filing the ANDA or infringing the '441 patent, but took such actions knowing that they would constitute an infringement of the '441 patent.

17. Defendants have infringed the '441 patent without a reasonable basis for believing in good faith that they had a right to infringe the '441 patent.

18. Defendants' infringement of the '441 patent was and is willful.

SECOND CAUSE OF ACTION

('191 Patent Infringement)²

19. Takeda and Wako are joint owners of United States Patent No.4,677,191 (the "'191 patent"), which was duly and legally issued on June 30, 1987. A copy of the '191 patent is attached as Exhibit 2.

20. The filing of Abbreviated New Drug Application 75-645 for Leuprolide Acetate for Depot Injection by OWL infringes the '191 patent in violation of 35 U.S.C. §271(e)(2).

¹ Plaintiffs recognize that this Cause of Action has already been dismissed by the Court. See Dkt. 107. Plaintiffs have restated this Cause of Action to preserve plaintiffs' rights.

² Plaintiffs recognize that this Cause of Action has already been dismissed by the Court. See Dkt. 107. Plaintiffs have restated this Cause of Action to preserve plaintiffs' rights.

21. Upon information and belief, defendants were aware of the existence of the '191 patent prior to filing the ANDA or infringing the '191 patent, but took such actions knowing that they would constitute an infringement of the '191 patent.

22. Defendants have infringed the '191 patent without a reasonable basis for believing in good faith that they had a right to infringe the '191 patent.

23. Defendants' infringement of the '191 patent was and is willful.

THIRD CAUSE OF ACTION

('721 Patent Infringement)

24. Takeda and Wako are joint owners of United States Patent No. 4,728,721 (the "'721 patent"), which was duly and legally issued on March 1, 1988. A copy of the '721 patent is attached as Exhibit 3.

25. The filing of Abbreviated New Drug Application 75-645 for Leuprolide Acetate for Depot Injection by OWL infringes the '721 patent in violation of 35 U.S.C. §271(e)(2).

26. Upon information and belief, defendants were aware of the existence of the '721 patent prior to filing the ANDA or infringing the '721 patent, but took such actions knowing that they would constitute an infringement of the '721 patent.

27. Defendants have infringed the '721 patent without a reasonable basis for believing in good faith that they had a right to infringe the '721 patent.

28. Defendants' infringement of the '721 patent was and is willful.

FOURTH CAUSE OF ACTION

('228 Patent Infringement)

29. Takeda is the owner of United States Patent No. 4,849,228 (the "'228 patent"), which was duly and legally issued on July 18, 1989. A copy of the '228 patent is attached as Exhibit 4.

30. The filing of Abbreviated New Drug Application 75-645 for Leuprolide Acetate for Depot Injection by OWL infringes the '228 patent in violation of 35 U.S.C. §271(e)(2).

31. Upon information and belief, defendants were aware of the existence of the '228 patent prior to filing the ANDA or infringing the '228 patent, but took such actions knowing that they would constitute an infringement of the '228 patent.

32. Defendants have infringed the '228 patent without a reasonable basis for believing in good faith that they had a right to infringe the '228 patent.

33. Defendants' infringement of the '228 patent was and is willful.

FIFTH CAUSE OF ACTION

('893 Patent Infringement)³

34. Takeda is the owner of United States Patent No. 4,917,893 (the "'893 patent"), which was duly and legally issued on April 17, 1990. A copy of the '893 patent is attached as Exhibit 5.

35. The filing of Abbreviated New Drug Application 75-645 for Leuprolide Acetate for Depot Injection by OWL infringes the '893 patent in violation of 35 U.S.C. §271(e)(2).

36. Upon information and belief, defendants were aware of the existence of the '893 patent prior to filing the ANDA or infringing the '893 patent, but took such actions knowing that they would constitute an infringement of the '893 patent.

37. Defendants have infringed the '893 patent without a reasonable basis for believing in good faith that they had a right to infringe the '893 patent.

38. Defendants' infringement of the '893 patent was and is willful.

³ Plaintiffs recognize that this Cause of Action has already been dismissed by the Court. See Dkt. 107. Plaintiffs have restated this Cause of Action to preserve plaintiffs' rights.

SIXTH CAUSE OF ACTION

('663 Patent Infringement)

39. Takeda is the owner of United States Patent No. 5,476,663 (the "'663 patent"), which was duly and legally issued on December 19, 1995. A copy of the '663 patent is attached as Exhibit 6.

40. The filing of Abbreviated New Drug Application 75-645 for Leuprolide Acetate for Depot Injection by OWL infringes the '663 patent in violation of 35 U.S.C. §271(e)(2).

41. Upon information and belief, defendants were aware of the existence of the '663 patent prior to filing the ANDA or infringing the '663 patent, but took such actions knowing that they would constitute an infringement of the '663 patent.

42. Defendants have infringed the '663 patent without a reasonable basis for believing in good faith that they had a right to infringe the '663 patent.

43. Defendants' infringement of the '663 patent was and is willful.

SEVENTH CAUSE OF ACTION

('987 Patent Infringement)⁴

44. Takeda is the owner of United States Patent No. 5,575,987 (the "'987 patent"), which was duly and legally issued on November 19, 1996. A copy of the '987 patent is attached as Exhibit 7.

45. The filing of Abbreviated New Drug Application 75-645 for Leuprolide Acetate for Depot Injection by OWL infringes the '987 patent in violation of 35 U.S.C. §271(e)(2).

⁴ Plaintiffs recognize that this Cause of Action has already been dismissed by the Court. See Dkt. 107. Plaintiffs have restated this Cause of Action to preserve plaintiffs' rights.

46. Upon information and belief, defendants were aware of the existence of the '987 patent prior to filing the ANDA or infringing the '987 patent, but took such actions knowing that they would constitute an infringement of the '987 patent.

47. Defendants have infringed the '987 patent without a reasonable basis for believing in good faith that they had a right to infringe the '987 patent.

48. Defendants' infringement of the '987 patent was and is willful.

EIGHTH CAUSE OF ACTION

(020 Patent Infringement)

49. Takeda is the owner of United States Patent No. 5,631,020 (the "'020 patent"), which was duly and legally issued on May 20, 1997. A copy of the '020 patent is attached as Exhibit 8.

50. The filing of Abbreviated New Drug Application 75-645 for Leuprolide Acetate for Depot Injection by OWL infringes the '020 patent in violation of 35 U.S.C. §271(e)(2).

51. Upon information and belief, defendants were aware of the existence of the '020 patent prior to filing the ANDA or infringing the '020 patent, but took such actions knowing that they would constitute an infringement of the '020 patent.

52. Defendants have infringed the '020 patent without a reasonable basis for believing in good faith that they had a right to infringe the '020 patent.

53. Defendants' infringement of the '020 patent was and is willful.

NINTH CAUSE OF ACTION

(021 Patent Infringement)

54. Takeda is the owner of United States Patent No. 5,631,021 (the "'021 patent"), which was duly and legally issued on May 20, 1997. A copy of the '021 patent is attached as Exhibit 9.

55. The filing of Abbreviated New Drug Application 75-645 for Leuprolide Acetate for Depot Injection by OWL infringes the '021 patent in violation of 35 U.S.C. §271(e)(2).

56. Upon information and belief, defendants were aware of the existence of the '021 patent prior to filing the ANDA or infringing the '021 patent, but took such actions knowing that they would constitute an infringement of the '021 patent.

57. Defendants have infringed the '021 patent without a reasonable basis for believing in good faith that they had a right to infringe the '021 patent.

58. Defendants' infringement of the '021 patent was and is willful.

TENTH CAUSE OF ACTION

(640 Patent Infringement)

59. Takeda is the owner of United States Patent No. 5,716,640 (the "'640 patent"), which was duly and legally issued on February 10, 1998. A copy of the '640 patent is attached as Exhibit 10.

60. The filing of Abbreviated New Drug Application 75-645 for Leuprolide Acetate for Depot Injection by OWL infringes the '640 patent in violation of 35 U.S.C. §271(e)(2).

61. Upon information and belief, defendants were aware of the existence of the '640 patent prior to filing the ANDA or infringing the '640 patent, but took such actions knowing that they would constitute an infringement of the '640 patent.

62. Defendants have infringed the '640 patent without a reasonable basis for believing in good faith that they had a right to infringe the '640 patent.

63. Defendants' infringement of the '640 patent was and is willful.

WHEREFORE, plaintiffs TAP Pharmaceutical Products Inc., Takeda Chemical Industries, Ltd. and Wako Pure Chemical Industries, Ltd., demand judgement against defendants OWL Pharmaceuticals, L.L.C., and Oakwood Laboratories, L.L.C., for:

a. An order adjudging and decreeing that the filing of Abbreviated New Drug Application 75-645 for Leuprolide Acetate for Depot Injection infringes United States Patent Nos. 4,652,441; 4,677,191; 4,728,721; 4,849,228; 4,917,893; 5,476,663; 5,575,987; 5,631,020; 5,631,021; and 5,716,640;

b. An order decreeing that the effective date of any approval of Abbreviated New Drug Application 75-645 for Leuprolide Acetate for Depot Injection shall not be earlier than the date of the last to expire of United States Patent Nos. 4,652,441; 4,677,191; 4,728,721; 4,849,228; 4,917,893; 5,476,663; 5,575,987; 5,631,020; 5,631,021; and 5,716,640;

c. An order adjudging and decreeing that OWL Pharmaceuticals, L.L.C. has willfully infringed United States Patent Nos. 4,652,441; 4,677,191; 4,728,721; 4,849,228; 4,917,893; 5,476,663; 5,575,987; 5,631,020; 5,631,021; and 5,716,640;

d. An order adjudging and decreeing that Oakwood Laboratories, L.L.C. has willfully infringed United States Patent Nos. 4,652,441; 4,677,191; 4,728,721; 4,849,228; 4,917,893; 5,476,663; 5,575,987; 5,631,020; 5,631,021; and 5,716,640;

e. A permanent injunction be issued, pursuant to 35 U.S.C. §271(e)(4)(B), restraining and enjoining said defendants, their officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States of drug compositions as claimed in United States Patent Nos. 4,652,441; 4,677,191; 4,728,721; 4,849,228; 4,917,893; 5,476,663; 5,575,987; 5,631,020; 5,631,021; and 5,716,640;

- f. An award of attorney fees and costs of suit; and

g. Such other and further relief as this Court deems just and appropriate.

Respectfully submitted,

s/Martha S. Sullivan

Martha S. Sullivan (0064040)

(MSullivan@ssd.com)

SQUIRE, SANDERS & DEMPSEY LLP

4900 Key Tower, 127 Public Square

Cleveland, Ohio 44114-1304

Telephone: (216) 479-8500 (fax -8780)

William F. Cavanaugh

Jeffrey I. D. Lewis (jidlewis@pbwt.com)

Stuart E. Pollack

PATTERSON, BELKNAP, WEBB &

TYLER LLP

1133 Avenue of the Americas

New York, NY 10036

Telephone: (212) 336-2000 (fax -2222)

Robert L. Baechtold

Henry J. Renk (hrenk@fchs.com)

Bruce M. Wexler

FITZPATRICK, CELLA, HARPER &

SCINTO

30 Rockefeller Plaza

New York, New York 10112

Telephone: (212) 218-2100 (fax -2200)

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on July 15, 2002, a copy of the foregoing Second Amended Complaint was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

s/Martha S. Sullivan
Squire, Sanders & Dempsey L.L.P.
4900 Key Tower
127 Public Square
Cleveland, Ohio 44114-1304
(216) 479-8425
(OH #0064040)