UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Case No.**
	)	
WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., and WATSON PHARMA, INC.,	)	**1:10-cv-0549SEB-JMS**
	)	
Defendants.	)	

COMPLAINT

Plaintiff, Eli Lilly and Company, (hereinafter "Lilly") brings this action for patent infringement against Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., and Watson Pharma, Inc. (hereinafter collectively "Watson"). This action concerns patents related to Lilly's pharmaceutical product EVISTA®, a prescription drug widely used to treat and prevent postmenopausal osteoporosis.

Parties

1. Eli Lilly and Company is an Indiana corporation having its corporate offices and principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. Lilly is engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

2. On information and belief, Watson Pharmaceuticals, Inc. is a Nevada corporation having corporate offices and a principal place of business at 311 Bonnie Circle, Corona, California, 92880; Watson Laboratories, Inc., a wholly-owned subsidiary of Watson Pharmaceuticals, Inc., is a Nevada corporation having corporate offices and a principal place of

business at 311 Bonnie Circle, Corona, California, 92880; and Watson Pharma, Inc., also a wholly-owned subsidiary of Watson Pharmaceuticals, Inc., is a Delaware corporation having corporate offices and a principal place of business at 360 Mt. Kemble Avenue, Morristown, New Jersey 07960. On information and belief, Watson is engaged in the development, manufacture, marketing , and distribution of generic pharmaceutical products for sale throughout the United States.

Jurisdiction and Venue

3. This is a complaint for patent infringement and for declaratory judgment of patent infringement. The jurisdiction of this Court is properly founded under 28 U.S.C. §§ 1331 and 1338(a) as well as 28 U.S.C. §§ 2201 and 2202.

4. Venue in this Court is proper under 28 U.S.C. §§ 1391 and 1400(b).

Claim for Relief

5. On information and belief, Watson is a drug company that manufactures its products for distribution and sale throughout the United States, including substantial sales in the State of Indiana and the Southern District of Indiana. Watson filed Abbreviated New Drug Application No. 200825 ("the ANDA") for its infringing product and issued a certification under 21 U.S.C. § 355(j)(2)(A)(vii)—the acts which give rise to the instant litigation—with knowledge that Lilly would be injured by such actions in Indiana. On information and belief, Watson intends to directly or indirectly market and distribute the infringing product in this district upon approval, Watson has maintained continuous and systematic contacts with Indiana, and Watson has purposefully availed itself of the privileges of doing business under the laws of Indiana. Thus, Watson is subject to personal jurisdiction in this judicial district.

The Patents-in-Suit

6. Lilly is the owner of U.S. Patent No. 6,458,811 ("the '811 patent"), entitled "Benzothiophenes Formulations Containing Same and Methods" (attached as **Exhibit A**), which is a valid patent, legally issued on October 1, 2002.

7. Lilly is the owner of U.S. Patent No. 6,797,719 ("the '719 patent"), entitled "Benzothiophenes, Formulations Containing Same, and Methods" (attached as **Exhibit B**), which is a valid patent, legally issued on September 28, 2004.

8. Lilly is the owner of U.S. Patent No. 6,894,064 ("the '064 patent"), entitled "Benzothiophenes, Formulations Containing Same, and Methods" (attached as **Exhibit C**), which is a valid patent, legally issued on May 17, 2005.

9. The commercial embodiment encompassed by the patents-in-suit is raloxifene hydrochloride ("raloxifene"). Lilly sells raloxifene under the trademark EVISTA®. The United States Food and Drug Administration ("FDA") has approved EVISTA® for the prevention and treatment of osteoporosis in postmenopausal women and for the reduction in risk of invasive breast cancer in postmenopausal women with osteoporosis and in postmenopausal women at high risk of invasive breast cancer.

10. The '811 patent, the '719 patent, and the '064 patent relate to the formulation of raloxifene for pharmaceutical or therapeutic purposes.

The Infringing Conduct by Defendant

11. On information and belief, Watson filed the ANDA with the United States Food and Drug Administration ("FDA") for governmental approval to manufacture and sell raloxifene. As part of this application, Watson filed Paragraph IV Certifications alleging that the '811, '719,

and '064 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the drug product described in the ANDA.

12. The filing of the ANDA by Watson constitutes infringement of the '811 patent, the '719 patent, and the '064 patent ("the Lilly patents").

13. As a result of Watson's infringement of the Lilly patents, Lilly has been and will continue to be damaged unless said infringement is enjoined by this Court.

Count I - Patent Infringement of the '811 Patent

14. Lilly realleges and incorporates by reference paragraphs 1-13.

15. By submitting the ANDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of its raloxifene formulation before the expiration of the '811 patent, Watson has directly infringed, induced infringement, and/or contributed to infringement of the '811 patent under 35 U.S.C. § 271(e)(2).

Count II - Declaratory Judgment of Infringement of the '811 Patent

16. Lilly realleges and incorporates by reference paragraphs 1-15.

17. Watson has filed or caused to be filed an application with the FDA, seeking authorization to import, market, use, offer for sale, and sell its raloxifene formulation for one or more indications. On information and belief, doctors prescribing the raloxifene formulation according to the indications sought by Watson will be using such raloxifene in a manner that would infringe one or more claims of the '811 patent.

18. On information and belief, Watson is expecting approval of the ANDA.

19. On information and belief, Watson plans to begin marketing, selling, and offering to sell its raloxifene formulation with a product insert specifying one or more raloxifene indications soon after the FDA has approved such indications.

20. Such conduct will constitute infringement of one or more claims of the '811 patent under 35 U.S.C. § 271(a), inducement of infringement of the '811 patent under 35 U.S.C. § 271(b), and contributory infringement of the '811 patent under 35 U.S.C. § 271(c).

21. Watson's infringing activity complained of herein is imminent and will begin following FDA approval of its application seeking one or more raloxifene indications.

22. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Lilly and Watson as to liability for the infringement of the '811 patent. Watson's actions have created in Lilly's mind a reasonable apprehension of irreparable harm and loss resulting from Watson's threatened imminent actions.

Count III - Patent Infringement of the '719 Patent

23. Lilly realleges and incorporates by reference paragraphs 1-22.

24. By submitting the ANDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of its raloxifene formulation before the expiration of the '719 patent, Watson has directly infringed, induced infringement, and/or contributed to infringement of the '719 patent under 35 U.S.C. § 271(e)(2).

Count IV - Declaratory Judgment of Infringement of the '719 Patent

25. Lilly realleges and incorporates by reference paragraphs 1-24.

26. Watson has filed or caused to be filed an application with the FDA, seeking authorization to import, market, use, offer for sale, and sell its raloxifene formulation for one or more indications. On information and belief, doctors prescribing the raloxifene formulation according to the indications sought by Watson will be using such raloxifene in a manner that would infringe one or more claims of the '719 patent.

27. On information and belief, Watson is expecting approval of the ANDA.

28. On information and belief, Watson plans to begin marketing, selling, and offering to sell its raloxifene formulation with a product insert specifying one or more raloxifene indications soon after the FDA has approved such indications.

29. Such conduct will constitute infringement of one or more claims of the '719 patent under 35 U.S.C. § 271(a), inducement of infringement of the '719 patent under 35 U.S.C. § 271(b), and contributory infringement of the '719 patent under 35 U.S.C. § 271(c).

30. Watson's infringing activity complained of herein is imminent and will begin following FDA approval of its application seeking one or more raloxifene indications.

31. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Lilly and Watson as to liability for the infringement of the '719 patent. Watson's actions have created in Lilly's mind a reasonable apprehension of irreparable harm and loss resulting from Watson's threatened imminent actions.

Count V - Patent Infringement of the '064 Patent

32. Lilly realleges and incorporates by reference paragraphs 1-31.

33. By submitting the ANDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of its raloxifene formulation before the expiration of the '064 patent, Watson has directly infringed, induced infringement, and/or contributed to infringement of the '064 patent under 35 U.S.C. § 271(e)(2).

Count VI - Declaratory Judgment of Infringement of the '064 Patent

34. Lilly realleges and incorporates by reference paragraphs 1-33.

35. Watson has filed or caused to be filed an application with the FDA, seeking authorization to import, market, use, offer for sale, and sell its raloxifene formulation for one or more indications. On information and belief, doctors prescribing the raloxifene formulation

according to the indications sought by Watson will be using such raloxifene in a manner that would infringe one or more claims of the '064 patent.

36. On information and belief, Watson is expecting approval of the ANDA.

37. On information and belief, Watson plans to begin marketing, selling, and offering to sell its raloxifene formulation with a product insert specifying one or more raloxifene indications soon after the FDA has approved such indications.

38. Such conduct will constitute infringement of one or more claims of the '064 patent under 35 U.S.C. § 271(a), inducement of infringement of the '064 patent under 35 U.S.C. § 271(b), and contributory infringement of the '064 patent under 35 U.S.C. § 271(c).

39. Watson's infringing activity complained of herein is imminent and will begin following FDA approval of its application seeking one or more raloxifene indications.

40. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Lilly and Watson as to liability for the infringement of the '064 patent. Watson's actions have created in Lilly's mind a reasonable apprehension of irreparable harm and loss resulting from Watson's threatened imminent actions.

Relief Requested

Wherefore, Lilly prays for judgment and relief including:

(A) A declaration that United States Patent Nos. 6,458,811, 6,797,719, and 6,894,064 are valid and enforceable;

(B) A declaration that Watson will infringe one or more claims of United States Patent Nos. 6,458,811, 6,797,719, and 6,894,064 by its threatened acts of importation, use, offering to sell, and sale of its raloxifene formulation drug product prior to expiration of said patents;

(C) A declaration that the effective date of any approval of Watson's raloxifene formulation drug product is not to be earlier than the latest date of expiration of United States Patent Nos. 6,458,811, 6,797,719, and 6,894,064 under 35 U.S.C. § 271(e)(4)(A);

(D) A declaration that Watson has no legal or equitable defense to Lilly's allegations of infringement;

(E) A permanent injunction pursuant to 35 U.S.C. § 283, enjoining Watson and its officers, agents, servants, employees, privies, and others acting for, on behalf of, or in concert with any of them from infringing any claims of the Lilly patents under 35 U.S.C. § 271(e)(4)(B);

(F) An accounting and award of damages incurred by Lilly as a result of Watson's infringement if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States under 35 U.S.C. § 271(e)(4)(C); and,

(G) Such other and further equitable relief as this Court may deem just and proper.

Date: May 3, 2010

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