

UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NEW YORK

**FILED**

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U.S. DISTRICT COURT E.D.N.Y.

★ JAN 29 2009 ★

BROOKLYN OFFICE

Case No. 09-0392

WEXLER, J.

\_\_\_\_\_  
ELI LILLY AND COMPANY,  
\_\_\_\_\_  
Plaintiff,  
\_\_\_\_\_  
v. \_\_\_\_\_  
\_\_\_\_\_  
INVAGEN PHARMACEUTICALS, INC.,  
\_\_\_\_\_  
Defendant.  
\_\_\_\_\_

COMPLAINT

WALL, M.J.

Plaintiff, Eli Lilly and Company, (hereinafter "Lilly") brings this action for patent infringement against Invagen Pharmaceuticals, Inc. (hereinafter "Invagen"). This action concerns patents related to Lilly's pharmaceutical product EVISTA<sup>®</sup>, 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. Invagen Pharmaceuticals, Inc. is a New York corporation having its corporate offices and principal place of business at Seven Oser Avenue, Hauppauge New York, 11788. On information and belief, Invagen is engaged in the development and manufacture 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).

5. Invagen is a New York Corporation. On information and belief, Invagen has maintained continuous and systematic contacts with New York, and has purposefully availed itself of the privileges of doing business under the laws of New York. Thus, Invagen is subject to personal jurisdiction in this judicial district.

### **Claim for Relief**

#### **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<sup>®</sup>. The United States Food and Drug Administration (“FDA”) has approved EVISTA<sup>®</sup> 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, Invagen filed an Abbreviated New Drug Application ("ANDA") with the FDA for governmental approval to manufacture and sell raloxifene. As part of this application, Invagen filed Paragraph IV Certifications alleging that the '811 patent, the '719 patent, and '064 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the drug product described in Invagen's ANDA.

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

13. Upon information and belief, Invagen did not exercise due care in analyzing the Lilly patents and presenting arguments in the paragraph IV certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), and Notice Letter, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii).

14. As a result of Invagen'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**

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

16. By submitting its 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, Invagen has directly infringed, induced infringement, and/or contributed to infringement of the '811 patent under 35 U.S.C. § 271(e)(2).

17. Invagen's actions constitute knowing and willful infringement of the Lilly patents.

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

18. Lilly realleges and incorporates by reference paragraphs 1-17.

19. Invagen 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 Invagen will be using such raloxifene in a manner that would infringe one or more claims of the '811 patent.

20. On information and belief, Invagen is expecting approval of its ANDA.

21. On information and belief, Invagen 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.

22. 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).

23. Invagen's infringing activity has been and will continue to be done in willful disregard of Plaintiff's patent rights.

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

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

### **Count III - Patent Infringement of the '719 Patent**

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

27. By submitting its 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, Invagen has directly infringed, induced infringement, and/or contributed to infringement of the '719 patent under 35 U.S.C. § 271(e)(2).

28. Invagen's actions constitute knowing and willful infringement of the Lilly patents.

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

29. Lilly realleges and incorporates by reference paragraphs 1-28.

30. Invagen 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 Invagen will be using such raloxifene in a manner that would infringe one or more claims of the '719 patent.

31. On information and belief, Invagen is expecting approval of its ANDA.

32. On information and belief, Invagen 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.

33. 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).

34. Invagen's infringing activity has been and will continue to be done in willful disregard of Plaintiff's patent rights.

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

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

#### **Count V - Patent Infringement of the '064 Patent**

37. Lilly realleges and incorporates by reference paragraphs 1-36.

38. By submitting its 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, Invagen has directly infringed, induced infringement, and/or contributed to infringement of the '064 patent under 35 U.S.C. § 271(e)(2).

39. Invagen's actions constitute knowing and willful infringement of the Lilly patents.

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

40. Lilly realleges and incorporates by reference paragraphs 1-39.

41. Invagen 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 Invagen will be using such raloxifene in a manner that would infringe one or more claims of the '064 patent.

42. On information and belief, Invagen is expecting approval of its ANDA.

43. On information and belief, Invagen 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.

44. 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).

45. Invagen's infringing activity has been and will continue to be done in willful disregard of Plaintiff's patent rights.

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

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

#### **Relief Requested**

Wherefore, Plaintiff 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;

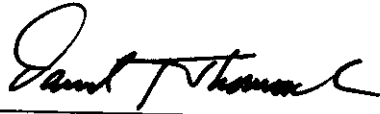
(B) A declaration that Defendant will infringe one or more claims of United States Patent Nos. 6,458,811, 6,797,719, and 6,894,064 by its threatened acts of importation, use, offering to sell, and sale of its raloxifene formulation drug product prior to expiration of said patents;

- (C) A declaration that the effective date of any approval of Invagen'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 Invagen has no legal or equitable defense to Lilly's allegations of infringement;
- (E) A permanent injunction pursuant to 35 U.S.C. § 283, enjoining Defendant 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 Plaintiff as a result of Defendant'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);
- (G) An award declaring this case exceptional pursuant to 35 U.S.C. § 285 and granting Plaintiff its attorneys' fees in pursuing this case; and



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

Date: January 29, 2009



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