

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106-4617
(702) 471-7000 FAX (702) 471-7070

1 STANLEY W. PARRY, ESQ.
Nevada Bar No. 1417
2 BALLARD SPAHR LLP
100 North City Parkway, Suite 1750
3 Las Vegas, Nevada 89106-4617
Telephone: (702) 471-7000
4 Facsimile: (702) 471-7070
Email: *parrys@ballardspahr.com*

5 Charles E. Lipsey
6 FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.
7 Two Freedom Square
8 11955 Freedom Drive
Reston, Virginia 20190
9 Telephone: (571) 203-2700

10 David S. Forman
11 Laura P. Masurovsky
Mark J. Feldstein
12 FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.
13 901 New York Avenue, N.W.
Washington, DC 20001-4413
14 Telephone: (202) 408-4000

15 (Pro Hac Vice Applications Pending)

16 *Attorneys for Plaintiff*
17 *ELI LILLY AND COMPANY*

18 UNITED STATES DISTRICT COURT
19 DISTRICT OF NEVADA

20
21 ELI LILLY AND COMPANY,
22 Plaintiff,

23 v.

24 WATSON PHARMACEUTICALS, INC.,
WATSON LABORATORIES, INC. and
25 WATSON PHARMA, INC.

26 Defendants.

CASE NO.

**COMPLAINT FOR PATENT
INFRINGEMENT**

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

6 Eli Lilly and Company files this Complaint through its local counsel, Ballard Spahr
7 LLP. Counsel for Eli Lilly, Finnegan, Henderson, Farabow, Garrett & Dunner, will file a
8 Verified Pro Hac Vice Application with the U.S. District Court in compliance with LR IA
9 10-12 within forty-five days.

10 **PARTIES**

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

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

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1 **Jurisdiction and Venue**

2 3. This is a complaint for patent infringement and for declaratory judgment of
3 patent infringement. The jurisdiction of this Court is properly founded under 28 U.S.C. §§
4 1331 and 1338(a) as well as 28 U.S.C. §§ 2201 and 2202.

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

6 **Claim for Relief**

7
8 5. On information and belief, Watson is a drug company that manufactures its
9 products for distribution and sale throughout the United States, including substantial
10 sales in the State of Nevada. Watson filed Abbreviated New Drug Application No.
11 200825 (“the ANDA”) for its infringing product and issued a certification under 21 U.S.C.
12 § 355(j)(2)(A)(vii)—the acts which give rise to the instant litigation—with knowledge that
13 Lilly would be injured by such actions in Nevada. On information and belief, Watson
14 intends to directly or indirectly market and distribute the infringing product in this district
15 upon approval, Watson has maintained continuous and systematic contacts with Nevada,
16 and Watson has purposefully availed itself of the privileges of doing business under the
17 laws of Nevada. Thus, Watson is subject to personal jurisdiction in this judicial district.

18 **The Patents-in-Suit**

19 6. Lilly is the owner of U.S. Patent No. 6,458,811 (“the ’811 patent”), entitled
20 “Benzothiofenes Formulations Containing Same and Methods” (attached as **Exhibit A**),
21 which is a valid patent, legally issued on October 1, 2002.

22 7. Lilly is the owner of U.S. Patent No. 6,797,719 (“the ’719 patent”), entitled
23 “Benzothiofenes, Formulations Containing Same, and Methods” (attached as **Exhibit**
24 **B**), which is a valid patent, legally issued on September 28, 2004.

25 8. Lilly is the owner of U.S. Patent No. 6,894,064 (“the ’064 patent”), entitled
26 “Benzothiofenes, Formulations Containing Same, and Methods” (attached as **Exhibit**
27 **C**), which is a valid patent, legally issued on May 17, 2005.

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

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

9 **The Infringing Conduct by Defendant**

10 11. On information and belief, Watson filed the ANDA with the United States
11 Food and Drug Administration (“FDA”) for governmental approval to manufacture and sell
12 raloxifene. As part of this application, Watson filed Paragraph IV Certifications alleging
13 that the '811, '719, and '064 patents are invalid, unenforceable, and/or will not be
14 infringed by the commercial manufacture, use, or sale of the drug product described in
15 the ANDA.

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

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

20 **Count I - Patent Infringement of the '811 Patent**

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

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

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

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

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

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

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

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

14 29. Such conduct will constitute infringement of one or more claims of the
15 '719 patent under 35 U.S.C. § 271(a), inducement of infringement of the '719 patent
16 under 35 U.S.C. § 271(b), and/or contributory infringement of the '719 patent under 35
17 U.S.C. § 271(c).

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

20 31. As a result of the foregoing facts, there is a real, substantial, and continuing
21 justiciable controversy between Lilly and Watson as to liability for the infringement of the
22 '719 patent. Watson's actions have created in Lilly's mind a reasonable apprehension of
23 irreparable harm and loss resulting from Watson's threatened imminent actions.

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

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

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

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

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

6 35. Watson has filed or caused to be filed an application with the FDA, seeking
7 authorization to import, market, use, offer for sale, and sell its raloxifene formulation for
8 one or more indications. On information and belief, doctors prescribing the raloxifene
9 formulation according to the indications sought by Watson will be using such raloxifene in
10 a manner that would infringe one or more claims of the '064 patent.

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

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

15 38. Such conduct will constitute infringement of one or more claims of the
16 '064 patent under 35 U.S.C. § 271(a), inducement of infringement of the '064 patent
17 under 35 U.S.C. § 271(b), and/or contributory infringement of the '064 patent under 35
18 U.S.C. § 271(c).

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

21 40. As a result of the foregoing facts, there is a real, substantial, and continuing
22 justiciable controversy between Lilly and Watson as to liability for the infringement of the
23 '064 patent. Watson's actions have created in Lilly's mind a reasonable apprehension of
24 irreparable harm and loss resulting from Watson's threatened imminent actions.

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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,

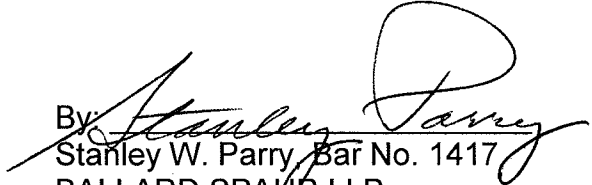
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1 (G) Such other and further equitable relief as this Court may deem just and
2 proper.

3 Date: May 5, 2010

By: 
Stanley W. Parry, Bar No. 1417

BALLARD SPAHR LLP
100 North City Parkway
Suite 1750
Las Vegas, Nevada 89106-4617
Telephone: (702) 471-7000
Facsimile: (702) 471-7070

Charles E. Lipsey
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.
Two Freedom Square
11955 Freedom Drive
Reston, Virginia 20190
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David S. Forman
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FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.
901 New York Avenue, N.W.
Washington, DC 20001-4413
(202) 408-4000

Attorneys for Plaintiff
ELI LILLY AND COMPANY

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