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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WARNER CHILCOTT COMPANY, LLC, Plaintiff, v. WATSON LABORATORIES, INC., WATSON PHARMA, INC., and WATSON PHARMACEUTICALS, INC., Defendants.	)	C. A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Warner Chilcott Company, LLC by its undersigned attorneys, brings this action against Defendants Watson Laboratories, Inc., Watson Pharma, Inc. and Watson Pharmaceuticals, Inc., and hereby alleges as follows:

THE PARTIES

1. Plaintiff Warner Chilcott Company, LLC ("Warner Chilcott") is a limited liability company organized and existing under the laws of Puerto Rico, having offices at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico.

2. Upon information and belief, Defendant Watson Laboratories, Inc. ("Watson Laboratories") is a corporation organized and existing under the laws of the State of Nevada, having a place of business at 311 Bonnie Circle, Corona, California 92880.

3. Upon information and belief, Defendant Watson Laboratories is in the business of, among other things, developing and manufacturing generic copies of branded pharmaceutical products for the U.S. market.

4. Upon information and belief, Defendant Watson Pharma, Inc. ("Watson Pharma") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business located at 400 Interpace Parkway, Parsippany, New Jersey 07054.

5. Upon information and belief, Watson Pharma is in the business of, among other things, distributing and selling generic copies of branded pharmaceutical products for the U.S. market, including on behalf of Watson Laboratories.

6. Upon information and belief, Defendant Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals") is a corporation organized and existing under the laws of the State of Nevada, having its headquarters located at 400 Interpace Parkway, Parsippany, New Jersey 07054.

7. Upon information and belief, Watson Pharmaceuticals develops, manufactures and/or markets pharmaceuticals products throughout the United States, including in this District, through its own actions and through the actions of its agents and operating subsidiaries, including Watson Laboratories and Watson Pharma.

8. Upon information and belief, Watson Laboratories has previously purposefully availed itself of the benefits and protections of the U.S. District Court for the District of New Jersey including by, *inter alia*, asserting counterclaims in this Court, and seeking a transfer of *Shire LLC et al. v. Watson Laboratories, Inc.*, C.A. No. 11-5565-AHM to this Court from the U.S. District Court for the Central District of California because, *inter alia*, "the parties agree that [the California] action could have been brought in the District of New Jersey" (D.I. 48 at 2; *see also* D.I. 50).

JURISDICTION AND VENUE

9. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code. This Court has subject matter jurisdiction over this action based on 28 U.S.C. §§ 1331 and 1338(a).

10. Upon information and belief, this Court has personal jurisdiction over Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma because, *inter alia*, they have committed, aided, abetted, actively induced, contributed to or participated in the commission of a tortious act of patent infringement leading to a foreseeable harm and injury to Warner Chilcott, namely, the submission to the U.S. Food and Drug Administration ("FDA") of the Abbreviated New Drug Application ("ANDA") at issue in this case.

11. Upon information and belief, this Court has personal jurisdiction over Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma because, *inter alia*, they

have purposefully availed themselves of the benefits and protections of New Jersey's laws such that they should anticipate being haled into court here. Upon information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma have had persistent, continuous, and systematic contacts with this judicial district, including, *inter alia*, maintaining executive offices in New Jersey, and, either directly or through an agent, deriving substantial revenue from the development, manufacture, and/or sale of pharmaceutical products that are sold in New Jersey.

12. Upon information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma share at least some common employees, officers, and directors.

13. Upon information and belief, Watson Pharmaceuticals organizes its operations by division, including at least the Generic, Brand and Distribution divisions, and reports its financial results in its Securities and Exchange Commission ("SEC") filings by reference to these divisions.

14. Upon information and belief, Watson Pharmaceuticals' Generic division, which develops, manufactures, and sells generic copies of branded pharmaceutical products for the U.S. market, relies on the respective coordinated contributions of at least Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma.

15. Upon information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma are agents of each other and/or operate in concert as integrated parts of Watson Pharmaceuticals' Generic division.

16. Upon information and belief, Watson Pharma, acting as the agent of Watson Pharmaceuticals and Watson Laboratories, distributes and sells in New Jersey and elsewhere in the United States, various generic pharmaceutical products including some that are

manufactured by Watson Laboratories and/or for which Watson Laboratories is the named applicant of the approved ANDAs. Upon information and belief, Watson Laboratories and Watson Pharma are parties to one or more contractual agreements regarding the distribution of such generic pharmaceutical products.

17. Upon information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma are agents of each other with respect to the development, regulatory approval, marketing, sale and distribution of generic pharmaceutical products, including the generic product described in ANDA No. 202982 (the "Watson ANDA product"). For instance, by letter dated April 4, 2012, Watson Laboratories directed Warner Chilcott to send any written notice regarding confidential access concerning ANDA No. 202982 to Mr. Brian Anderson, Esq. of Watson Pharmaceuticals, 400 Interpace Parkway, Parsippany, New Jersey 07054, which is the principal business address of both Watson Pharmaceuticals and Watson Pharma. The Defendants, as part of Watson Pharmaceuticals' Generic division, will collaborate in the manufacturing, marketing, and/or sale of the Watson ANDA product, including in the State of New Jersey, should FDA approval be granted.

18. If ANDA No. 202982 is approved, the Watson ANDA product which is charged with infringing the patents-in-suit, would, among other things, be marketed and distributed in New Jersey, prescribed by physicians practicing in New Jersey and dispensed by pharmacies located within New Jersey, all of which would have a substantial effect on New Jersey.

19. Accordingly, this Court has personal jurisdiction over Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma because, among others, they, either directly or through an agent, including each other, regularly do or solicit business in New Jersey,

engage in other persistent courses of conduct in New Jersey, and derive substantial revenue from services or things used or consumed in New Jersey.

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

BACKGROUND

21. Warner Chilcott is the holder of New Drug Application ("NDA") No. 22-501, for Lo Loestrin® Fe, which contains the active ingredients norethindrone acetate and ethinyl estradiol. Lo Loestrin® Fe was approved by the FDA on October 21, 2010 and is indicated for the prevention of pregnancy in women who elect to use it as a method of contraception. Lo Loestrin® Fe is sold as a 28-day oral contraceptive regimen which includes 24 active tablets comprising 1 mg norethindrone acetate and 0.01 mg ethinyl estradiol, 2 active tablets comprising 0.01 mg ethinyl estradiol, followed by 2 ferrous fumarate tablets (placebo).

22. U.S. Patent No. 5,552,394 ("the '394 patent") entitled "Low Dose Oral Contraceptives with Less Breakthrough Bleeding and Sustained Efficacy" lawfully issued from the United States Patent and Trademark Office on September 3, 1996. A copy of the '394 patent is attached as Exhibit A.

23. Warner Chilcott is the sole owner of the '394 patent.

24. The '394 patent claims, *inter alia*, a method of female contraception which comprises monophasicly administering a combination of estrogen and progestin in which the daily amounts of estrogen and progestin are equivalent to about 0.001 to 0.035 mg of ethinyl estradiol and about 0.025 to 10 mg of norethindrone acetate, and in which the weight ratio of estrogen to progestin is at least 1:45 calculated as ethinyl estradiol to norethindrone acetate for 24 days of a 28 day cycle.

25. U.S. Patent No. 7,704,984 ("the '984 patent") entitled "Extended Estrogen Dosing Contraceptive Regimen" lawfully issued from the United States Patent and Trademark Office on April 27, 2010. A copy of the '984 patent is attached as Exhibit B.

26. Warner Chilcott is the sole owner of the '984 patent.

27. The '984 patent claims, inter alia, a method of female contraception which comprises administering (a) a first composition containing a progestin in an amount equivalent to about 0.3 to about 1.5 mg norethindrone acetate wherein the progestin is selected from norethindrone acetate or norethindrone and 5 to 15 mcg of ethinyl estradiol for 24 days, (b) a second composition containing 5 to 15 mcg of ethinyl estradiol and substantially free of a progestin for 2 days, and (c) a third composition that is a placebo, wherein the sequential administration of the first composition, the second composition and the third composition, is performed on a daily basis over a 28 day cycle.

28. The '394 and '984 patents each cover the use of Lo Loestrin® Fe in accordance with the respective labeling approved by the FDA and are listed in the FDA *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for that product.

29. Upon information and belief, Watson submitted to the FDA an ANDA filed under 21 U.S.C. § 355(j), to obtain approval to engage in the commercial manufacture, use, or sale of a generic version of Lo Loestrin® Fe (the "Watson ANDA Product") prior to the expiration of the '394 patent and the '984 patent.

30. Upon information and belief, Watson's ANDA directed to its proposed generic Lo Loestrin® Fe product has been assigned No. 202982.

31. Upon information and belief, the composition that is the subject of Watson's ANDA is directed to 24 tablets containing 1 mg norethindrone acetate and 0.01 mg ethinyl estradiol, 2 tablets containing 0.01 mg ethinyl estradiol and 2 tablets containing ferrous fumarate (placebo).

COUNT I
CLAIM FOR INFRINGEMENT OF THE '394 PATENT

32. Upon information and belief, Watson's ANDA was submitted with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the '394 patent is purportedly invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of Watson's ANDA Product.

33. Upon information and belief, Watson sent notice of that certification to Warner Chilcott on or about April 4, 2012. Warner Chilcott received Watson's notice letter on or about April 5, 2012.

34. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the manufacture, use or sale of the Watson ANDA Product before the expiration of the '394 patent, Watson has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2)(A). Further, the manufacture, use or sale of the Watson ANDA Product will also infringe one or more claims of the '394 patent.

35. Upon approval of Watson's ANDA, Watson will actively induce and/or contribute to infringement of the '394 patent.

36. Warner Chilcott is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order from this Court that the effective date of the approval of Watson's ANDA be a date that is not earlier than the expiration date of the '394 patent, or any later expiration of exclusivity to which Warner Chilcott is or becomes entitled.

37. This is an exceptional case, and Warner Chilcott is entitled to its costs and reasonable attorney fees.

COUNT II
CLAIM FOR INFRINGEMENT OF THE '984 PATENT

38. Upon information and belief, Watson's ANDA was submitted with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the '984 patent is purportedly invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of the Watson ANDA Product.

39. Upon information and belief, Watson sent notice of that certification to Warner Chilcott on or about April 4, 2012. Warner Chilcott received Watson's notice letter on or about April 5, 2012.

40. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the manufacture, use or sale of the Watson ANDA Product before the expiration of the '984 patent, Watson has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2)(A). Further, the manufacture, use or sale of the Watson ANDA Product will also infringe one or more claims of the '984 patent.

41. Upon approval of Watson's ANDA, Watson will actively induce and/or contribute to infringement of the '984 patent.

42. Warner Chilcott is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order from this Court that the effective date of the approval of Watson's ANDA be a date that is not earlier than the expiration date of the '984 patent, or any later expiration of exclusivity to which Warner Chilcott is or becomes entitled.

43. This is an exceptional case, and Warner Chilcott is entitled to its costs and reasonable attorney fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

(a) Judgment that Defendants Watson Laboratories, Inc., Watson Pharma, Inc. and Watson Pharmaceuticals, Inc. have infringed one or more claims of the '394 patent by submitting ANDA No. 202982;

(b) A permanent injunction be issued restraining and enjoining Defendants Watson Laboratories, Inc., Watson Pharma, Inc., and Watson Pharmaceuticals, Inc., their officers, agents, attorneys, and employees, and those acting in privity or concert with them, and their successors and assigns, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of compositions that would infringe, induce infringement and/or contribute to infringement of the '394 patent;

(c) An order that the effective date of any approval of Watson's ANDA No. 202982, be a date that is not earlier than the expiration of the '394 patent, or any later expirations of exclusivity to which Plaintiff is or becomes entitled;

(d) Judgment that Defendants Watson Laboratories, Inc., Watson Pharma, Inc., and Watson Pharmaceuticals, Inc. have infringed one or more claims of the '984 patent by submitting ANDA No. 202982;

(e) A permanent injunction be issued restraining and enjoining Defendants Watson Laboratories, Inc., Watson Pharma, Inc., and Watson Pharmaceuticals, Inc., their officers, agents, attorneys, and employees, and those acting in privity or concert with them, and their successors and assigns, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of compositions that would infringe, induce infringement and/or contribute to infringement of the '984 patent;

(f) An order that the effective date of any approval of Watson's ANDA No. 202982, be a date that is not earlier than the expiration of the '984 patent, or any later expirations of exclusivity to which Plaintiff is or becomes entitled;

(g) Declaring this to be an exceptional case and awarding Plaintiff its attorney fees under 35 U.S.C. § 285; and

(h) Such other and further relief as the Court may deem just and proper.

Dated: May 16, 2012

Respectfully submitted,

s/William J. O'Shaughnessy
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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiff, by its undersigned counsel, hereby certifies pursuant to L. Civ. R. 11.2 that the matters in controversy in the instant action overlap with the subject matter of another action pending in this Court regarding the same patents (U.S. Patent Nos. 5,552,394 and 7,704,984) and the same product, Lo Loestrin® Fe. That other pending action was filed on September 1, 2011 and is captioned *Warner Chilcott Company, LLC v. Lupin Ltd. et al.*, 11-cv-05048-JAP-TJB.

Further, Plaintiff hereby certifies that the matters in controversy in the instant action partially overlap with the subject matter of another action pending in this Court in that there is one patent common to the litigations (U.S. Patent No. 5,552,394). That other pending case was filed on June 2, 2011 and is captioned *Warner Chilcott Company, LLC v. Mylan Inc. et al.*, 11-cv-03262-JAP-TJB (hereinafter "Mylan Action"). The instant action, however, also has unique issues which do not overlap with the above action, including that (a) there is a second patent at issue in this action that is not at issue in the Mylan Action (U.S. Patent No. 7,704,984), (b) the products involved in each action have different dosage strengths and employ different regimens, and (c) the defendants in each action are different.

Dated: May 16, 2012

Respectfully submitted,

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