JUDGE KOELTL

14 CV 4439

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

TEVA WOMEN'S HEALTH, INC., and TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC.,

Plaintiffs,

- against -

WATSON LABORATORIES, INC., ACTAVIS PHARMA, INC., and ACTAVIS, INC.

Defendants.

Case No.:

ECF Case

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Teva Women's Health, Inc. and Teva Branded Pharmaceutical Products R&D, Inc., (collectively, "Teva") for its Complaint against defendants Watson Laboratories, Inc., Actavis Pharma, Inc., and Actavis, Inc., (collectively, "Watson" or "Defendants"), hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Defendants' submission of an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Plaintiffs' QUARTETTE® tablets prior to the expiration of United States Patent Nos. 8,415,332 ("the '332 patent") and 8,450,299 ("the '299 patent") (collectively "the patents-in-suit").

THE PARTIES

2. Plaintiff Teva Women's Health, Inc. is a corporation organized and existing under the laws of the State of Delaware, having an established place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677. Teva Women's Health, Inc. is a proprietary pharmaceutical company that has been an innovator in the area of women's health. Teva Women's Health, Inc. focuses on researching, developing, and providing patients with an array of female healthcare products, with particular emphasis on developing and marketing products that serve the reproductive and menopausal needs of women.

3. Plaintiff Teva Branded Pharmaceutical Products R&D, Inc. is a corporation organized and existing under the laws of the State of Delaware, having an established place of business at 425 Privet Road, Horsham, Pennsylvania 19044.

4. On information and belief, defendant Watson Laboratories, Inc. is a corporation organized under the laws of the State of Nevada, having a principal place of business at 311 Bonnie Circle, Corona, California 92880 and is a wholly-owned subsidiary of Actavis, Inc.

5. On information and belief, defendant Actavis Pharma, Inc. (formerly known as Watson Pharma, Inc.) is a corporation organized under the laws of Delaware and a wholly-owned subsidiary of Actavis, Inc. Actavis Pharma, Inc. has a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

6. On information and belief, defendant Actavis, Inc. (formerly known as Watson Pharmaceuticals, Inc.) is a corporation organized under the laws of the State of Nevada, having a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

7. On information and belief, Watson Laboratories, Inc. and Actavis Pharma, Inc. are wholly owned subsidiaries of Actavis, Inc. On information and belief, Watson Laboratories, Inc.'s preparation and submission of ANDA No. 206201 was done at the direction, under the control, and for the direct benefit of Actavis, Inc. On information and belief, Actavis, Inc. directed Watson Laboratories, Inc. to submit ANDA No. 206201.

8. On information and belief, Watson Laboratories, Inc., Actavis Pharma, Inc., and Actavis, Inc. collaborate in formulating, manufacturing, packaging and marketing generic drug products for distribution in the State of New York and throughout the United States. On information and belief, and consistent with their practice with respect to other generic products, following any FDA approval of ANDA 206201, Actavis, Inc., Watson Laboratories, Inc., and Actavis Pharma, Inc. will act in concert to distribute and sell Defendants' ANDA Product throughout the United States and within the state of New York.

JURISDICTION AND VENUE

9. This action arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

10. On information and belief, this Court has personal jurisdiction over Defendants.

11. On information and belief, Defendants derive substantial revenue from selling various pharmaceutical drug products and doing business in the United States, including in New York and this District.

12. On information and belief, Defendants manufacture pharmaceuticals and pharmaceutical products that are sold and used throughout the United States, including in New York and this District.

13. On information and belief, residents of the State of New York purchase pharmaceutical drug products from Defendants in the State of New York.

14. On information and belief, Defendants, themselves or through one of their wholly-owned subsidiaries, have authorized distributors in the State of New York to distribute their pharmaceutical drug products throughout the State of New York.

15. On information and belief, Defendants' submission of abbreviated New Drug Application ("ANDA") No. 206201 ("the Watson ANDA"), discussed below, indicates their intention to engage in the commercial manufacture, use, sale and/or importation of products that will compete directly with Plaintiffs' QUARTETTE® product, which is currently being sold throughout the United States, including in New York and this District.

16. On information and belief, Defendants have previously consented to personal jurisdiction in this District.

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

THE PATENTS-IN-SUIT

18. On April 9, 2013, the U.S. Patent and Trademark Office ("PTO") duly and legally issued the '332 patent entitled "Methods of Hormonal Treatment Utilizing Ascending-Dose Extended Cycle Regimens" to Teva Women's Health as assignee of the inventors. The '332

patent names Charles E. Diliberti, Kathleen Z. Reape and Lance J. Bronnenkant as inventors. The '332 patent is valid and enforceable. Teva Women's Health is the sole owner of all rights, title and interest in the '332 patent. A true and correct copy of the '332 patent is attached as Exhibit 1.

19. On May 28, 2013, the PTO duly and legally issued the '299 patent entitled "Methods of Hormonal Treatment Utilizing Ascending-Dose Extended Cycle Regimens" to Teva Women's Health as assignee of the inventors. The '299 patent names as Charles E. Diliberti, Kathleen Z. Reape and Lance J. Bronnenkant inventors. The '299 patent is valid and enforceable. Teva Women's Health is the sole owner of all rights, title and interest in the '299 patent. A true and correct copy of the '299 patent is attached as Exhibit 2.

INFRINGEMENT BY DEFENDANTS

20. Teva Branded Pharmaceutical Products R&D, Inc. is the owner of the approved New Drug Application No. 204061 (the "NDA") for its QUARTETTE® product.

21. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '332 and '299 Patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), as covering the QUARTETTE® product.

22. By letter dated May 8, 2014 ("Defendants' Notice Letter"), Watson Laboratories, Inc. notified Teva that Defendants had submitted ANDA No. 206201 to the FDA seeking approval to manufacture, sell, and distribute a generic version of Teva's QUARTETTE® product.

23. According to Defendants' Notice Letter, the purpose of Defendants' filing of the Watson ANDA is to obtain approval under the Federal Food, Drug, and Cosmetic Act for

Defendants to engage in the commercial manufacture, use, and sale of a generic version of QUARTETTE® prior to the expiration of the '332 and '299 patents.

24. Defendants submitted the Watson ANDA to the FDA containing a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Paragraph IV certification") that, in Defendants' opinion "U.S. Patent Nos. 8,415,332 and 8,450,299 are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the drug product described in Watson's ANDA." Defendants' filing of the Watson ANDA with the Paragraph IV certification infringed the '332 and '299 patents under 35 U.S.C. § 271(e)(2).

25. Defendants' Notice Letter indicates that in filing the Watson ANDA, Defendants intend to engage in the commercial manufacture, use, and sale of Defendants' ANDA Product (including, upon information and belief, commercial sale of such product in the State of New York) prior to the expiration of the '332 and '299 patents in the event that the FDA approves the Watson ANDA.

26. Defendants' Notice Letter includes a statement of the legal and factual basis for their belief that the '332 and '299 patents are invalid or that the claims of those patents will not be infringed by the manufacture, use or sale of Defendants' proposed ANDA product. Notably, Defendants do not deny that the manufacture, use, and sale of their proposed ANDA product would infringe claims 1-10 of the '332 patent and claims 1-6 and 9-12 of the '299 patent should those claims be found valid.

27. On information and belief, Defendants intend to continue to pursue approval of the Watson ANDA by the FDA.

28. On information and belief, Defendants were aware of the '332 and '299 patents when it filed ANDA 206201 including the Paragraph IV certification.

29. Teva commenced this action within 45 days of the date they received Defendants' Notice letter regarding the submission of the Watson ANDA containing the Paragraph IV certification to the FDA.

FIRST CAUSE OF ACTION
(Infringement of the '332 Patent)

30. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1-29.

31. Defendants have infringed at least one claim of the '332 patent, pursuant to 35 U.S.C. § 271(e)(2), by submitting, or causing to be submitted the Watson ANDA, by which Defendants seek approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of Defendants' ANDA Products prior to the expiration of the '332 patent.

32. Defendants have declared their intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, Defendants' ANDA Product in the event that the FDA approves the Watson ANDA. Accordingly, an actual and immediate controversy exists regarding Defendants' infringement of the '332 patent under 35 U.S.C. §§ 271.

33. Upon information and belief, Defendants' manufacture, use, offer to sell, or sale of Defendants' ANDA Product within the United States, or importation of Defendants' ANDA Product into the United States during the term of the '332 Patent would infringe at least one claim of the '332 Patent under 35 U.S.C. §§ 271.

34. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing the '332 Patent.

35. Plaintiffs have no adequate remedy at law.

36. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

SECOND CAUSE OF ACTION
(Infringement of the '299 Patent)

37. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1-36.

38. Defendants have infringed at least one claim of the '299 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Watson ANDA, by which Defendants seek approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of Defendants' ANDA Products prior to the expiration of the '299 Patent.

39. Defendants have declared their intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, Defendants' ANDA Product in the event that the FDA approves the Watson ANDA. Accordingly, an actual and immediate controversy exists regarding Defendants' infringement of the '299 Patent under 35 U.S.C. §§ 271.

40. Defendants' manufacture, use, offer to sell, or sale of Defendants' ANDA Product within the United States, or importation of Defendants' ANDA Product into the United States during the term of the '299 Patent would infringe at least one claim of the '299 Patent under 35 U.S.C. §§ 271.

41. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing the '299 Patent.

42. Plaintiffs have no adequate remedy at law.

43. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment against Defendants and for the following relief:

a. A declaration that United States Patent No. 8,415,332 is valid and enforceable;

b. A declaration that, under 35 U.S.C. § 271(e)(2)(A), Defendants infringed the '332 patent by submitting ANDA No. 206201 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell or import into the United States Defendants' ANDA Products prior to expiration of the '332 patent;

c. A final judgment declaring that Defendants' manufacture, sale, offer for sale, marketing and distribution in, or importation into, the United States of the product described in ANDA No. 206201 prior to expiration of the '332 patent will infringe, induce infringement and contribute to the infringement of at least one claim of the '332 patent;

d. A judgment pursuant to 35 U.S.C.§ 271(e)(4)(B) and/or 35 U.S.C. § 283 for a preliminary and permanent injunction enjoining the Defendants, their officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from: (i) manufacturing, using, offering to sell, or selling Defendants' ANDA

Products within the United States, or importing Defendants' ANDA Products into the United States, prior to the expiration of the '332 Patent, and (ii) seeking, obtaining or maintaining approval of the Watson ANDA until expiration of the '332 patent, or such other later time as the Court may determine;

e. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 206201 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration date of the '332 patent including any extensions;

f. If the Defendants manufacture, use, offer to sell, or sell Defendants' ANDA Products within the United States, or import Defendants' ANDA Products into the United States, prior to the expiration of the '332 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

g. A declaration that United States Patent No. 8,450,299 is valid and enforceable;

h. A declaration that, under 35 U.S.C. § 271(e)(2)(A), Defendants infringed the '299 patent by submitting ANDA No. 206201 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell or import into the United States Defendants' ANDA Products prior to expiration of the '299 patent;

i. A final judgment declaring that Defendants' manufacture, sale, offer for sale, marketing and distribution in, or importation into, the United States of the product described in ANDA No. 206201 prior to expiration of the '299 patent will infringe, induce infringement and contribute to the infringement of at least one claim of the '299 patent;

j. A judgment pursuant to 35 U.S.C.§ 271(e)(4)(B) and/or 35 U.S.C. § 283 for a preliminary and permanent injunction enjoining the Defendants, their officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from: (i) manufacturing, using, offering to sell, or selling Defendants' ANDA Products within the United States, or importing Defendants' ANDA Products into the United States, prior to the expiration of the '299 Patent, and (ii) seeking, obtaining or maintaining approval of the Watson ANDA until expiration of the '299 patent, or such other later time as the Court may determine;

k. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 206201 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration date of the '299 Patent including any extensions;

l. If the Defendants manufacture, use, offer to sell, or sell Defendants' ANDA Products within the United States, or import Defendants' ANDA Products into the United States, prior to the expiration of the '299 Patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

m. A declaration that this is an exceptional case action within the meaning of 35 U.S.C. § 285 and that Plaintiffs be awarded their attorneys' fees, costs and expenses incurred in prosecuting this action; and

n. Such other and further relief as the Court deems just and appropriate.

Respectfully Submitted,

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