IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

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

Plaintiffs,

- against -

LUPIN LIMITED

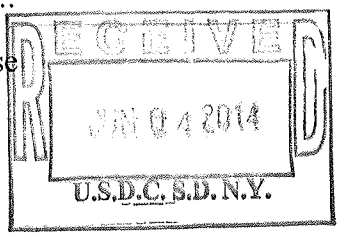
Defendant.

JUDGE SCHOFIELD

14 CV 4055

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 Lupin Limited and Lupin Pharmaceuticals, Inc., (collectively, "Lupin"), 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 Lupin Limited is a corporation organized under the laws of India, with a principal place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India.

5. On information and belief, Defendant Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Virginia and having a principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202.

6. On information and belief, Lupin Limited is a pharmaceutical company that conducts its North American operations, in part, through Lupin Pharmaceuticals, Inc. and together they collaborate in formulating, manufacturing, packaging and marketing generic drug products for distribution in the State of New York and throughout the United States.

JURISDICTION AND VENUE

7. 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).

8. On information and belief, this Court has personal jurisdiction over Lupin.

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

10. On information and belief, Lupin manufactures pharmaceuticals and pharmaceutical products that are sold and used throughout the United States, including in New York and this District.

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

12. On information and belief, Lupin, itself or through one of its wholly-owned subsidiaries, has authorized distributors in the State of New York to distribute Lupin's pharmaceutical drug products throughout the State of New York.

13. On information and belief, Lupin's submission of abbreviated New Drug Application ("ANDA") No. 205943, discussed below, indicates its intention to engage in the commercial manufacture, use, sale and/or importation of products that will compete directly with Plaintiff's QUARTETTE® product, which is currently being sold throughout the United States, including in New York and this District.

14. On information and belief, Lupin has previously consented to personal jurisdiction in this District.

15. 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

16. 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.

17. 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 '332 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 LUPIN

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

19. 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.

20. By letter dated April 18, 2014 ("Lupin's Notice Letter"), Lupin notified Teva that Lupin had submitted ANDA No. 205943 to the FDA seeking approval to manufacture, sell, and distribute a generic version of Teva's QUARTETTE® product.

21. According to Lupin's Notice Letter, the purpose of Lupin's filing of the ANDA is to obtain approval under the Federal Food, Drug, and Cosmetic Act for Lupin 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.

22. Lupin submitted its 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 Lupin's opinion "the '332 patent and '299 patent are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the drug product described in Lupin's ANDA." Lupin's filing of the ANDA with the Paragraph IV certification infringed the '332 and '299 patents under 35 U.S.C. § 271(e)(2).

23. Lupin's Notice Letter indicates that in filing its ANDA, Lupin intends to engage in the commercial manufacture, use, and sale of the Lupin 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 Lupin's ANDA.

24. Lupin's Notice Letter includes a statement of the legal and factual basis for its 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 Lupin's proposed ANDA product. Notably, Lupin does not deny that the manufacture, use, and sale of its proposed ANDA product would infringe claims 1-10 of the '332 patent and claims 1-7 and 9-12 of the '299 patent should those claims be found valid.

25. On information and belief, Lupin intends to continue to pursue approval of its ANDA by the FDA.

26. On information and belief, Lupin was aware of the '332 and '299 patents when it filed ANDA 205943 including the Paragraph IV certification.

27. Teva commenced this action within 45 days of the date they received Lupin's Notice letter regarding Lupin's submission of its ANDA containing the Paragraph IV certification to the FDA.

FIRST CAUSE OF ACTION
(INFRINGEMENT OF THE '332 PATENT)

28. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1-27.

29. 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 Lupin ANDA, by which Defendants seek approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Lupin ANDA Products prior to the expiration of the '332 patent.

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

31. Upon information and belief, Defendants' manufacture, use, offer to sell, or sale of the Lupin ANDA Product within the United States, or importation of the Lupin 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.

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

33. Plaintiffs have no adequate remedy at law.

34. 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)

35. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1-34.

36. 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 Lupin ANDA, by which Defendants seek approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Lupin ANDA Products prior to the expiration of the '299 Patent.

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

38. Defendants' manufacture, use, offer to sell, or sale of the Lupin ANDA Product within the United States, or importation of the Lupin 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.

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

40. Plaintiffs have no adequate remedy at law.

41. 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), Lupin infringed the '332 patent by submitting ANDA No. 205943 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell or import into the United States Lupin's 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 Lupin's ANDA No. 205943 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 the Lupin ANDA Products within the United States, or importing the Lupin ANDA Products into the United States, prior to the expiration of the '332 Patent, and (ii) seeking, obtaining or maintaining approval of the Lupin 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. 205943 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 the Lupin ANDA Products within the United States, or import the Lupin 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), Lupin infringed the '299 patent by submitting ANDA No. 205943 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell or import into the United States Lupin's 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 Lupin's ANDA No. 205943 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 the Lupin ANDA Products within the United States, or importing the Lupin ANDA Products into the United States, prior to the expiration of the '299 Patent, and (ii) seeking, obtaining or maintaining approval of the Lupin 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. 205943 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 the Lupin ANDA Products within the United States, or import the Lupin 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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Dated: June 4, 2014