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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

DEPOMED, INC., a California Corporation,

Plaintiff,

v.

LUPIN PHARMACEUTICALS, INC., a Virginia Corporation, and LUPIN LIMITED, an Indian Corporation,

Defendants.

Case No. 09-CV-05587 PJH

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Depomed, Inc. complains against defendants Lupin Pharmaceuticals, Inc. and Lupin Limited (collectively "Lupin" or "Defendants") as follows:

THE PARTIES

1. Plaintiff Depomed, Inc. ("Depomed") is a corporation organized under the laws of California, having its principal place of business in Menlo Park, California.

2. Upon information and belief, Defendant Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Virginia, having a principal place of business at 111 S. Calvert St., Ste. 2150, Baltimore, Maryland. On information and belief, Lupin Pharmaceuticals, Inc. is registered to do business in the State of California. On information and belief, Lupin Pharmaceuticals, Inc., itself and as the agent and wholly owned

subsidiary of Lupin Limited, is in the business of making and selling generic pharmaceutical products, which it distributes through authorized distributors in the State of California and throughout the United States.

3. On information and belief, Lupin Limited is a company organized and existing under the laws of India, having a principal place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashta 400 051, India. On information and belief, Lupin Limited, itself and through its wholly owned subsidiary and agent, Lupin Pharmaceuticals, Inc., is in the business of making and selling generic pharmaceutical products, which it distributes in the State of California and throughout the United States. Lupin Limited is the alter ego of Lupin Pharmaceuticals, Inc. where a unity of interest and ownership exists between Lupin Limited and Lupin Pharmaceuticals such that separate personalities of the two do not in reality exist. Plaintiff is informed and believes, and on that basis alleges, that the Defendants were at all times relevant the partners, officers, agents, assignees, successors-in-interest, co-conspirators, principals, alter egos, or employees of each other or were otherwise responsible for, contributed to, or participated in the acts and omissions alleged herein, and thereby incurred liability therefore.

JURISDICTION AND VENUE

4. This is an action for patent infringement arising under the patent laws of the United States (Title 35 of the United States Code) and arising from Lupin's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Depomed's product Glumetza® prior to the expiration of U.S. Patent Nos. 6,340,475, 6,488,962 and 6,635,280. The Court has subject matter jurisdiction of this action pursuant to 28 U.S.C. §§ 1331, 1338(a) and Section 2201.

5. This Court has personal jurisdiction over Lupin by virtue of the fact that Lupin conducts business in the State of California, and has availed itself of the rights and benefits under California law, and has engaged in substantial and continuous contacts in the State of California.

6. To the extent that Lupin Ltd. successfully contends that it is not doing business in California, personal jurisdiction over Lupin Ltd. is proper under Federal Rule of Civil Procedure 4(k)(2).

7. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and 1400.

INTRADISTRICT ASSIGNMENT

8. This patent action is in an excepted category for Local Rule 3-2(c), Assignment of a Division, and will be assigned on a district wide basis.

THE PATENTS-IN-SUIT

9. On October 21, 2003, United States Patent No. 6,635,280 (the "'280 Patent") entitled "Extending the Duration of Drug Release Within the Stomach During the Fed Mode" issued to Depomed as assignee of the inventors. (A copy of the '280 Patent is attached as Exhibit 1.)

10. On December 3, 2002, United States Patent No. 6,488,962 (the "'962 Patent") entitled "Tablet Shapes To Enhance Gastric Retention of Swellable Controlled-Release Oral Dosage Forms" issued to Depomed as assignee of the inventors. (A copy of the '962 Patent is attached as Exhibit 2.)

11. On January 22, 2002, United States Patent No. 6,340,475 (the "'475 Patent") entitled "Extending the Duration of Drug Release Within the Stomach During the Fed Mode" issued to Depomed as assignee of the inventors. (A copy of the '475 Patent is attached as Exhibit 3.)

GLUMETZA®

12. Depomed holds approved New Drug Application No. 21-748 (the "Depomed NDA") for metformin hydrochloride tablets in 500 and 1000 mg dosage strengths, which are sold under the trade name Glumetza®.

13. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '280, '962 and '475 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book), with respect to Glumetza® in the 500 mg dosage.

14. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '962 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book), with respect to Glumetza® in the 1000 mg dosage.

LUPIN'S ANDA

15. On information and belief, Lupin submitted ANDA No. 91-664 ("the Lupin ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market metformin hydrochloride extended release tablets in the 500 and 1000 mg dosage strengths. The metformin hydrochloride tablets described in the Lupin ANDA are herein referred to as the "Lupin Products" and the 500 mg dosage strength is referred to as the "Lupin 500 mg Product."

16. The Lupin ANDA refers to and relies upon the Glumetza® NDA and contains data that, according to Lupin, demonstrate the bioequivalence of the Lupin Products and Glumetza®.

17. Depomed received from Lupin a letter, dated November 6, 2009, (the "Lupin Notification"), stating that Lupin had included a certification in the Lupin ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '962, '280 and '475 patents are invalid, or will not be infringed by the commercial manufacture, use, or sale of the Lupin Products (the "Paragraph IV Certification"). (A true and correct copy of the Lupin Notification is attached hereto as Exhibit 4.)

FIRST CAUSE OF ACTION
(Infringement of the '962 Patent)

18. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 – 17.

19. On information and belief, Lupin has infringed the '962 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Lupin ANDA, by which Lupin seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Lupin Products prior to the expiration of the '962 Patent.

20. Lupin's commercial manufacture, use, offer to sell, or sale of the Lupin Products within the United States, or importation of the Lupin Products into the United States during the

term of the '962 patent would further infringe the '962 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

21. Plaintiff will be substantially and irreparably harmed if Lupin is not enjoined from infringing the '962 Patent.

22. Plaintiff has no adequate remedy at law.

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

SECOND CAUSE OF ACTION
(Infringement of the '280 Patent)

24. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 – 17.

25. On information and belief, Lupin has infringed the '280 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Lupin ANDA, by which Lupin seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Lupin 500 mg Product prior to the expiration of the '280 Patent.

26. Lupin's commercial manufacture, use, offer to sell, or sale of the Lupin 500 mg Product within the United States, or importation of the Lupin 500 mg Product into the United States during the term of the '280 Patent would further infringe the '280 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

27. Plaintiff will be substantially and irreparably harmed if Lupin is not enjoined from infringing the '280 Patent.

28. Plaintiff has no adequate remedy at law.

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

THIRD CAUSE OF ACTION
(Infringement of the '475 Patent)

30. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 – 17.

31. On information and belief, Lupin has infringed the '475 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Lupin ANDA, by which Lupin seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Lupin 500 mg Product prior to the expiration of the '475 Patent.

32. Lupin's commercial manufacture, use, offer to sell, or sale of the Lupin 500 mg Product within the United States, or importation of the Lupin 500 mg Product into the United States during the term of the '475 Patent would further infringe the '475 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

33. Plaintiff will be substantially and irreparably harmed if Lupin is not enjoined from infringing the '475 Patent.

34. Plaintiff has no adequate remedy at law.

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

FOURTH CAUSE OF ACTION
(Infringement and Declaratory Judgment of Infringement of the '280 Patent)

36. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 – 17.

37. On information and belief, Lupin has infringed the '280 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Lupin ANDA, by which Lupin seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Lupin 1000 mg Product prior to the expiration of the '280 Patent.

38. As an alternative basis for jurisdiction, Lupin has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or import into the U.S. the Lupin 1000 mg Product in the event that the FDA approves the Lupin ANDA. Indeed, in the face of this suit, Lupin has continued to pursue regulatory approval, further evincing its intent to market an infringing 1000 mg Product upon FDA approval. Moreover, Lupin has sought by way of declaratory relief and adjudication that its 1000 mg Product does not infringe the '280 Patent. *See*

Lupin Counterclaims, Count V. Accordingly, an actual and immediate controversy exists under 28 U.S.C. Section 2201 regarding infringement under Section 271(a) of the '280 Patent by Lupin.

39. Plaintiff will be substantially and irreparably harmed if Lupin is not enjoined from infringing the '280 Patent.

40. Plaintiff has no adequate remedy at law.

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

FIFTH CAUSE OF ACTION
(Infringement and Declaratory Judgment of Infringement of the '475 Patent)

42. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 – 17.

43. On information and belief, Lupin has infringed the '475 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Lupin ANDA, by which Lupin seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Lupin 1000 mg Product prior to the expiration of the '475 Patent.

44. As an alternative basis for jurisdiction, Lupin has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or import into the U.S. the Lupin 1000 mg Product in the event that the FDA approves the Lupin ANDA. Indeed, in the face of this suit, Lupin has continued to pursue regulatory approval, further evincing its intent to market an infringing 1000 mg Product upon FDA approval. Moreover, Lupin has sought by way of declaratory relief and adjudication that its 1000 mg Product does not infringe the '475 Patent. *See* Lupin Counterclaims, Count VII. Accordingly, an actual and immediate controversy exists under 28 U.S.C. Section 2201 regarding infringement under Section 271(a) of the '475 Patent by Lupin.

45. Plaintiff will be substantially and irreparably harmed if Lupin is not enjoined from infringing the '475 Patent.

46. Plaintiff has no adequate remedy at law.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment in against Defendants, Lupin Limited and Lupin Pharmaceuticals, Inc., and respectfully requests the following relief:

1. A judgment that the '962, '280 and '475 Patents have been infringed by Lupin;

2. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) for a preliminary and permanent injunction enjoining Lupin, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from manufacturing, using, offering to sell, or selling Lupin Products within the United States, or importing the Lupin Products into the United States, prior to the expiration of the '962, '280 and/or '475 Patents;

3. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 91-040 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '962, '280 and/or '475 Patents, including any extensions;

4. A judgment declaring and enjoining Lupin, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from manufacturing, using, offering to sell, or selling Lupin Products within the United States, or importing the Lupin Products into the United States, prior to the expiration of the '962, '280 and/or '475 Patents;

5. If Lupin commercially manufactures, uses offers to sell, or sells the Lupin Products within the United States, or imports the Lupin Products into the United States, prior to the expiration of any of the '962, '280 and '475 Patents, including any extensions, a judgment awarding Plaintiff monetary relief together with interest;

6. An award of damages together with interest, and a judgment that the damages so adjudged be trebled pursuant to 35 U.S.C. §§ 283 and 284;

7. Judgment that this is an exceptional case and that Plaintiff be awarded its attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285;

8. Costs and expenses in this action; and

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

Dated: July 12, 2011

Respectfully submitted,

MCDERMOTT WILL & EMERY LLP

By: _____
William G. Gaede

Attorneys for Depomed, Inc.