**IN THE UNITED STATES DISTRICT COURT**

**IN AND FOR THE DISTRICT OF MARYLAND**

**BALTIMORE DIVISION**

DEPOMED, INC.,
1360 O'Brien Drive
Menlo Park, CA 94025,

Plaintiff,

v.

LUPIN PHARMACEUTICALS, INC.,
Harborplace Tower
111 S. Calvert St., Ste. 2150,
Baltimore, Maryland, 21202,
and
LUPIN LIMITED,
Laxmi Towers, B Wing,
Bandra Kurla Complex, Bandra (East),
Mumbai, Maharashta 400 051, India,

Defendants.

Civil Action No. _____

**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 Maryland. 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

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 Maryland 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, 6,635,280 and 6,723,340. The Court has subject matter jurisdiction of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

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

6. Defendants have identified the District of Maryland as a jurisdiction in which they will not contest a protective suit filed by Plaintiff. See Paragraph 2 of the December 16, 2009, Corrected Stipulation and Order for Extension of Time for Defendants to Answer or Otherwise Respond to Plaintiff's Complaint that was filed with the Northern District of California ("12/16/2009 Joint Stipulation") attached hereto as Exhibit 1.

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

**THE PATENTS-IN-SUIT**

8. On April 20, 2004, United States Patent No. 6,723,340 (the "'340 Patent") entitled "Optimal Polymer Mixtures for Gastric Retentive Tablets" issued to Depomed as assignee of the inventors. (A copy of the '340 Patent is attached as Exhibit 2.)

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 3.)

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 4.)

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 5)

**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 '340, '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, '340, '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 6.)

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

18. Plaintiff realleges and incorporate 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 '340 Patent)**

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

25. On information and belief, Lupin has infringed the '340 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 '340 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 '340 Patent would further infringe the '340 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 '340 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 '280 Patent)**

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

31. 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.

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 '280 Patent would further infringe the '280 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 '280 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 of the '475 Patent)**

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

37. 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.

38. 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).

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

**STATEMENT REGARDING PRIOR-FILED SUIT**

42. This is not the first-filed action involving the named Plaintiff and Defendants, the patents, and the counts of patent infringement set forth above. Plaintiff has previously filed an identical action seeking to enjoin Lupin Ltd. and Lupin Pharmaceuticals, Inc. from infringing the '340, '280, '962 and '475 patents in the Northern District of California. Defendants have numerous authorized distribution contacts in the State of California. Defendants are one of the largest generic drug manufacturers in the US market with a quarter billion dollars in sales in 2008-09, and consequentially have substantial sales in the State of California. Judicial economy would be promoted and Plaintiff's choice of forum respected, if the claims related to Plaintiff's action for infringement of the '340, '280, '962 and '475 patents were to be addressed in the Northern District of California.

43. Plaintiff filed this action as a protective measure to preserve its rights and interests, given the possible consequence if Defendants succeeded with such unjustified action, Plaintiff had no choice but to file this second action out of an abundance of caution. *See* Paragraph 3 of the 12/16/2009 Joint Stipulation. Plaintiff expects that personal jurisdiction will be maintained in the Northern District of California and that the action will proceed in that forum, in which case this second action would be unnecessary.

44. Plaintiff and Defendants agree that this second action will be immediately stayed upon filing pending resolution of any jurisdictional issues in the first-filed action. Paragraph 4 of the 12/16/2009 Joint Stipulation.

**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, '340, '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, '340, '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, '340, '280 and/or '475 Patents, including any extensions;

4. 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, '340, '280 and '475 Patents, including any extensions, a judgment awarding Plaintiff monetary relief together with interest;

5. 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;

6. 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;

7. Costs and expenses in this action; and

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

Dated: December 21, 2009

Respectfully submitted,

By: /s/ Michael S. Nadel

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