

Leda Dunn Wettre
ROBINSON, WETTRE & MILLER LLC
One Newark Center, 19th Floor
Newark, New Jersey 07102
(973) 690-5400
LWettre@rwmlegal.com

Of Counsel:
Paul Andre
Lisa Kobialka
KING & SPALDING LLP
333 Twin Dolphin Dr. Suite 400
Redwood Shores, CA 94065
(650) 590-0700

Attorneys for Plaintiffs

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

DEPOMED, INC., and VALEANT)	
INTERNATIONAL (BARBADOS) SRL,)	
)	Civil Action No. _____
Plaintiffs,)	
)	
v.)	
)	
SUN PHARMA GLOBAL FZE, SUN)	
PHARMACEUTICAL INDUSTRIES LTD.,)	
and SUN PHARMACEUTICAL INDUSTRIES)	
INC.)	
Defendants.)	
)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Depomed Inc. ("Depomed") and Valeant International (Barbados) SRL ("Valeant") (collectively "Plaintiffs") for their Complaint against Defendants Sun Pharma Global FZE, Sun Pharmaceutical Industries Ltd., and Sun Pharmaceutical Industries Inc., (collectively, "Sun" or "Defendants") hereby state as follows:

THE PARTIES

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

2. Plaintiff Valeant is an International Society with Restricted Liability organized and existing under the laws of Barbados, having its principal place of business at Welches, Christ Church, Barbados, West Indies BB17154.

3. Upon information and belief, Sun Pharma Global FZE ("Sun FZE") is a company organized and existing under the laws of the United Arab Emirates with a principal place of business at Executive Suite # 43, Block Y, SAIF-Zone, PO Box 122304, Sharjah, U.A.E. Upon information and belief, Sun FZE is a wholly-owned subsidiary of Defendant Sun Pharmaceutical Industries, Ltd.

4. Upon information and belief, Defendant Sun Pharmaceutical Industries Ltd. ("Sun Ltd.") is a company organized and existing under the laws of India, with a place of business at Acme Plaza, Andheri-Kurla Road, Andheri (East), Mumbai-400 059, India. Upon information and belief, Defendant Sun Ltd. manufactures numerous generic drugs for sale and use throughout the United States, including this judicial district.

5. Upon information and belief, Sun Pharmaceutical Industries, Inc. ("Sun USA") is a company organized and existing under the laws of the State of Michigan with a principal place of business at 270 Prospect Plains Road, Cranbury, NJ 08512. Upon information and belief, Defendant Sun USA manufactures numerous generic drugs for sale and use throughout the United States, including this judicial district. Upon information and belief, Sun USA is a wholly-owned subsidiary and agent of Defendant Sun Ltd.

NATURE OF THE ACTION

6. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code. This action relates to an Abbreviated New Drug Application (“ANDA”) filed by Sun Pharma Global FZE with the United States Food and Drug Administration (“FDA”) for approval to market a generic copy of Depomed’s GLUMETZA® pharmaceutical products that are sold in the United States.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States, 35 U.S.C. §§ 1, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

8. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of the tortious action of patent infringement that has led to foreseeable harm and injury to Plaintiffs, which manufacture numerous drugs for sale and use throughout the United States, including this judicial district. This Court has personal jurisdiction over each of the Defendants by virtue of, *inter alia*, their systematic and continuous contacts with the State of New Jersey as set forth below, and for other reasons that will be presented to the Court if such jurisdiction is challenged.

9. Each Defendant has consented to personal jurisdiction in this District on several occasions, and availed itself of the legal protections of the State of New Jersey, having asserted counterclaims in lawsuits filed in the District of New Jersey.

10. This Court has personal jurisdiction over Defendant Sun FZE by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey, including through its

parent corporation Sun Ltd., and also including the substantial revenue it derives from the State of New Jersey through its sister corporations and agents. Among other things, upon information and belief, Sun FZE caused foreseeable harm and injury to Plaintiffs in this judicial district by participating in the commission of the tortious action of patent infringement. Sun FZE has purposefully availed itself of this forum by filing counterclaims within this jurisdiction.

11. This Court has personal jurisdiction over Defendant Sun Ltd. by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. Among other things, upon information and belief, Sun Ltd., directly or through its subsidiaries, places goods into the stream of commerce for distribution throughout the United States, including the State of New Jersey, and has purposefully availed itself of this forum by filing counterclaims in this jurisdiction. Sun Ltd. caused foreseeable harm and injury to Plaintiffs in this judicial district by participating in the commission of the tortious action of patent infringement.

12. This Court has personal jurisdiction over Defendant Sun USA because it maintains its principal place of business within this judicial district.

THE PATENTS-IN-SUIT

13. 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 true and correct copy of the '340 Patent is attached as Exhibit 1.

14. 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 true and correct copy of the '280 Patent is attached as Exhibit 2.

15. 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 true and correct copy of the '962 Patent is attached as Exhibit 3.

16. 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 true and correct copy of the '475 Patent is attached as Exhibit 4.

17. On June 15, 2010, United States Patent No. 7,736,667 (the "'667 Patent") entitled "Shell-and-Core Dosage Form Approaching Zero-Order Drug Release" issued to Depomed as the assignee of the inventors. A true and correct copy of the '667 Patent is attached as Exhibit 5.

18. On August 24, 2010, United States Patent No. 7,780,987 (the "'987 Patent") entitled "Controlled Release Dosage Forms" issued to Valeant (formerly known as Biovail Laboratories International SRL) as the assignee of the inventors, and is exclusively licensed to Depomed. A true and correct copy of the '987 Patent is attached as Exhibit 6.

BACKGROUND

19. 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®.

20. 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.

21. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '962 and the '987 Patents are listed in the FDA Orange Book, with respect to Glumetza® in the 1000 mg dosage.

22. On information and belief, Sun submitted ANDA No. 20-2917 ("the Sun 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 Sun ANDA are herein referred to as the "Sun Products."

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

24. Depomed and Valeant received letters from Sun on or about May 9, 2011, (the "Sun Notification"), stating that it had included a certification in the Sun ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '962, '340, '280, '475 and '987 Patents are invalid, or will not be infringed by the commercial manufacture, use, or sale of the Sun Products (the "Paragraph IV Certification"). A true and correct copy of the Sun Notification is attached hereto as Exhibit 7.

25. Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), Sun provided a statement of the factual and legal bases that allegedly support its non-infringement positions. The statement did not contain any basis for claims of invalidity or unenforceability.

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

26. Plaintiffs reallege and incorporate by reference the allegations contained paragraphs 1 - 25.

27. On information and belief, Sun has infringed the '962 Patent, pursuant to 35 U.S.C. § 271 (e)(2)(A), by submitting the Sun ANDA, by which Sun seeks approval from the

FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Sun Products prior to the expiration of the '962 Patent.

28. Sun's commercial manufacture, use, offer to sell, or sale of the Sun Products within the United States, or importation of the Sun 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).

29. Plaintiffs will be substantially and irreparably harmed if Sun is not enjoined from infringing the '962 Patent.

30. Plaintiffs have no adequate remedy at law.

31. 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 '340 Patent)

32. Plaintiffs reallege and incorporate by reference the allegations contained paragraphs 1 - 31.

33. On information and belief, Sun has infringed the '340 Patent, pursuant to 35 U.S.C. § 271 (e)(2)(A), by submitting the Sun ANDA, by which Sun seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Sun Products prior to the expiration of the '340 Patent.

34. Sun's commercial manufacture, use, offer to sell, or sale of the Sun Products within the United States, or importation of the Sun Products 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).

35. Plaintiffs will be substantially and irreparably harmed if Sun is not enjoined from infringing the '340 Patent.

36. Plaintiffs have no adequate remedy at law.

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

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

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

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

40. Sun's commercial manufacture, use, offer to sell, or sale of the Sun Products within the United States, or importation of the Sun Products 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).

41. Plaintiffs will be substantially and irreparably harmed if Sun is not enjoined from infringing the '280 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.

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

44. Plaintiffs reallege and incorporate by reference the allegations contained paragraphs 1 - 43.

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

46. Sun's commercial manufacture, use, offer to sell, or sale of the Sun Products within the United States, or importation of the Sun Products 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).

47. Plaintiffs will be substantially and irreparably harmed if Sun is not enjoined from infringing the '475 Patent.

48. Plaintiffs have no adequate remedy at law.

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

FIFTH CAUSE OF ACTION
(Infringement of the '667 Patent)

50. Plaintiffs reallege and incorporate by reference the allegations contained paragraphs 1 - 49.

51. Sun's commercial manufacture, use, offer to sell, or sale of the Sun Products within the United States, or importation of the Sun Products into the United States during the term of the '667 Patent infringes the '667 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

52. Plaintiffs will be substantially and irreparably harmed if Sun is not enjoined from infringing the '667 Patent.

53. Plaintiffs have no adequate remedy at law.

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

SIXTH CAUSE OF ACTION
(Infringement of the '987 Patent)

55. Plaintiffs reallege and incorporate by reference the allegations contained paragraphs 1 - 54.

56. On information and belief, Sun has infringed the '987 Patent, pursuant to 35 U.S.C. § 271 (e)(2)(A), by submitting the Sun ANDA, by which Sun seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Sun Products prior to the expiration of the '987 Patent.

57. Sun's commercial manufacture, use, offer to sell, or sale of the Sun Products within the United States, or importation of the Sun Products into the United States during the term of the '987 Patent would further infringe the '987 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

58. Plaintiffs will be substantially and irreparably harmed if Sun is not enjoined from infringing the '987 Patent.

59. Plaintiffs have no adequate remedy at law.

60. 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 pray for judgment against Defendants Sun FZE, Sun Ltd., and Sun USA, respectfully requests the following relief:

a. A judgment that the '962, '340, '280, '475, '667 and '987 Patents have been infringed by Sun;

b. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) for a preliminary and permanent injunction enjoining Sun, 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 the Sun Products within the United States, or importing the Sun Products into the United States, prior to the expiration of the '962, '340, '280, '475, and/or '987 Patents;

c. A judgment pursuant to 35 U.S.C. § 283 for a preliminary and permanent injunction enjoining Sun, 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 the Sun Products within the United States, or importing the Sun Products into the United States, prior to the expiration of the '667 Patent;

d. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 20-2917 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, '475, and/or '987 Patents, including any extensions;

e. If Sun commercially manufactures, uses, offers to sell, or sells the Sun Products within the United States, or imports the Sun Products into the United States, prior to the expiration of any of the '962, '340, '280, '475, '667 and '987 Patents, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

- f. 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;
- g. Judgment that this is an exceptional case and that Plaintiffs be awarded its attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285;
- h. Costs and expenses in this action; and
- i. Such other and further relief as the Court deems just and appropriate.

Respectfully submitted,

Dated: June 20, 2011

By: /s/ Leda Dunn Wettre

Leda Dunn Wettre
ROBINSON, WETTRE & MILLER LLC
One Newark Center, 19th Floor
Newark, New Jersey 07102
(973) 690-5400

Of Counsel:
Paul Andre
Lisa Kobialka
KING & SPALDING LLP
333 Twin Dolphin Dr. Suite 400
Redwood Shores, CA 94065
(650) 590-0700

Attorneys for Plaintiffs

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that certain subject matter in controversy in this action is also subject matter in controversy in the following action: *Depomed, Inc. v. Lupin Pharmaceuticals, Inc. and Lupin Limited*, Case No. 09-cv-05587-PJH (U.S. District Court for the Northern District of California).

Dated: June 20, 2011

By: /s/ Leda Dunn Wettre

Leda Dunn Wettre
ROBINSON, WETTRE & MILLER LLC
One Newark Center, 19th Floor
Newark, New Jersey 07102
(973) 690-5400

Of Counsel:
Paul Andre
Lisa Kobialka
KING & SPALDING LLP
333 Twin Dolphin Dr. Suite 400
Redwood Shores, CA 94065
(650) 590-0700

Attorneys for Plaintiffs