

Leda Dunn Wettre  
ROBINSON, WETTRE & MILLER LLC  
One Newark Center, 19th Floor  
Newark, New Jersey 07102  
Telephone: (973) 690-5400  
Facsimile: (973) 466-2760  
[Lwettre@rwmlegal.com](mailto:Lwettre@rwmlegal.com)

OF COUNSEL:  
William G. Gaede, III  
Bhanu K. Sadasivan  
Shane G. Smith  
MCDERMOTT WILL & EMERY LLP  
275 Middlefield Road, Suite 100  
Menlo Park, CA 94025  
Telephone: (650) 815-7400  
Facsimile: (650) 815-7401

*Attorneys for Plaintiff Depomed, Inc.*

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

---

|                                      |   |                        |
|--------------------------------------|---|------------------------|
| DEPOMED, INC.,                       | ) |                        |
|                                      | ) |                        |
| Plaintiff,                           | ) | CIVIL ACTION NO: _____ |
|                                      | ) |                        |
| v.                                   | ) |                        |
|                                      | ) |                        |
| ZYDUS PHARMACEUTICALS (USA), INC.    | ) |                        |
| and CADILA HEALTHCARE LIMITED D/B/A/ | ) |                        |
| ZYDUS CADILA                         | ) |                        |
|                                      | ) |                        |
| Defendants.                          | ) |                        |
|                                      | ) |                        |

---

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Depomed, Inc., (“Depomed”) complains against defendant Zydus Pharmaceuticals (USA), Inc. (“Zydus USA”) and Cadila Healthcare Limited (“Cadila”) (collectively, “Zydus”) as follows:

### **THE PARTIES**

1. Plaintiff Depomed, Inc. 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 Zydus USA is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at 73 Route 31 N., Pennington, New Jersey 08534. On information and belief, Zydus USA is in the business of developing, manufacturing, and marketing and/or selling generic pharmaceutical products for the U.S. market, including in this judicial district.

3. Upon information and belief, defendant Cadila is an Indian company located at Zydus Tower, Satellite Cross Roads, Ahmedabad – 380015, Gujarat, India that wholly-owns Zydus USA and is in the business of developing, manufacturing, and marketing pharmaceutical products for the U.S. market, including in this judicial district.

4. Upon information and belief, Zydus USA and Cadila are agents of each other and/or work in concert with each other with respect to the development, regulatory approval, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in this district.

5. Upon information and belief, Zydus USA's preparation and submission of Abbreviated New Drug Application ("ANDA") No. 203934 was done collaboratively with, and for the benefit of, Cadila. On information and belief, Zydus USA is the alter ego of Cadila where a unity of interest and ownership exists between Zydus USA and Cadila such that separate personalities of the two do not in reality exist.

### **JURISDICTION AND VENUE**

6. 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 Zydus filing an ANDA with the United States Food and Drug Administration (“FDA”) seeking approval to market a generic version of Depomed’s product Gralise<sup>®</sup> prior to the expiration of U.S. Patent Nos. 6,340,475, 6,488,962, 6,635,280, 6,723,340, 7,438,927 and 7,731,989. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Zydus because, *inter alia*, it has purposely availed itself of the benefits and protections of New Jersey’s laws such that it should reasonably anticipate being haled into court here. On information and belief, Zydus has had persistent, systematic and continuous contacts with New Jersey as set forth below.

8. Zydus has a past practice of consenting to personal jurisdiction in this Court for other litigation matters. For example, Zydus has consented to personal jurisdiction in this Court in *Takeda Pharmaceutical Co. Ltd, et al. v. Zydus Pharmaceuticals (USA), Inc. and Cadila Healthcare Ltd.*, Civil Action No. 3:10-cv-01723-JAP-TJB and *Teva Pharmaceutical Industries Ltd., et al. v. Zydus Pharmaceuticals (USA), Inc. and Cadila Healthcare Ltd.*, Civil Action No. 3:07-cv-04942-GEB-TJB.

9. Zydus USA is a New Jersey corporation that resides in the state of New Jersey and conducts business in the State of New Jersey.

10. Upon information and belief, Zydus offers generic pharmaceutical products for sale in New Jersey and elsewhere in the United States and earns revenue from the distribution and sale in New Jersey of its generic pharmaceutical products. According to its website, Cadila has sold about \$250 million worth of oral solid products in the United States and has had 116 ANDA filings, 67 approvals and 43 product launches in the United States. According to Zydus USA’s website, Zydus USA manufactures and markets about 49 generic pharmaceutical products.

11. Upon information and belief, Zydus will manufacture, market, and/or sell within the United States the generic 300 mg gabapentin oral tablets described in Zydus's ANDA No. 203934 if FDA approval is granted. If ANDA No. 203934 is approved, the generic 300 mg gabapentin oral tablets charged with infringing the patents-in-suit, would, among other things, be marketed and distributed in New Jersey, prescribed by physicians in New Jersey, and dispensed by pharmacies located within New Jersey, and/or used by persons in New Jersey, all of which would have a substantial effect on New Jersey.

12. Upon information and belief, Cadila participated in, contributed to, aided, abetted and/or induced the submission to the FDA of ANDA No. 203934, the ANDA at issue in this litigation.

13. Two related lawsuit involving five different defendants but the same branded product and the same patents-in-suit are currently pending in this Court. On March 2, 2012, Depomed filed suit in this Court against Actavis Elizabeth LLC and Actavis Inc. (collectively "Actavis"), Watson Laboratories, Inc. — Florida, Watson Pharma, Inc. and Watson Pharmaceuticals, Inc. (collectively "Watson") and Incepta Pharmaceuticals Co. Ltd. ("Incepta") seeking a judgment of infringement of the same six patents at issue in this case. On April 10, 2012, Depomed filed suit in this Court against Par Pharmaceutical Companies, Inc, and Par Pharmaceutical, Inc. (collectively, "Par") and Impax Laboratories, Inc, ("Impax") seeking a judgment of infringement of the same six patents at issue in this case. Each of the defendants in the above mentioned two cases have also filed an ANDA seeking approval to market a generic version of Depomed's product Gralise<sup>®</sup> prior to the expiration of the patents in suit.

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

### **THE PATENTS-IN-SUIT**

15. On January 22, 2002, United States Patent No. 6,340,475 B2 (“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 1.)

16. On December 3, 2002, United States Patent No. 6,488,962 B1 (“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.)

17. On October 21, 2003, United States Patent No. 6,635,280 B2 (“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.)

18. On April 20, 2004, United States Patent No. 6,723,340 B2 (“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 4.)

19. On October 21, 2008, United States Patent No. 7,438,927 B2 (“the ‘927 Patent”) entitled “Methods of Treatment Using a Gastric Retained Gabapentin Dosage” issued to Depomed as assignee of the inventors. (A copy of the ‘927 Patent is attached as Exhibit 5.)

20. On June 8, 2010, United States Patent No. 7,731,989 B2 (“the ‘989 Patent”) entitled “Gastric Retained Gabapentin Dosage Form” issued to Depomed as assignee of the inventors. (A copy of the ‘989 Patent is attached as Exhibit 6.)

**GRALISE®**

21. Depomed holds approved New Drug Application No. 022544 (the “Depomed NDA”) for gabapentin extended-release tablets in 300 and 600 mg dosage strengths, which are sold under the trade name Gralise®.

22. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the ‘475, ‘962, ‘280, ‘340, ‘927 and ‘989 Patents are listed in the FDA publication, “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”), with respect to Gralise® in the 300 mg dosage.

### **THE ZYDUS ANDA**

23. On information and belief, Zydus submitted ANDA No. 203934 to the FDA (“the Zydus ANDA”) seeking approval to engage in the commercial manufacture, use or sale of gabapentin oral tablets in the 300 mg dosage strength. The gabapentin oral tablets described in the Zydus ANDA are herein referred to as the “Zydus’s Product.”

24. On information and belief, the Zydus ANDA refers to and relies upon the Gralise® NDA and contains data that demonstrate the bioequivalence of Zydus’s Product and Gralise®.

25. Depomed received from Zydus a letter, dated April 23, 2012, stating that Zydus had included a certification in the Zydus ANDA that no valid claim of the ‘475, ‘280, ‘989, ‘927, ‘340, and ‘962 Patents will be infringed by the commercial manufacture, use, or sale of Zydus’s Product (the “the Zydus Notification Letter”). (A true and correct copy of the Zydus Notification Letter is attached hereto as Exhibit 7.).

### **FIRST CAUSE OF ACTION**

#### **(Infringement and Declaratory Judgment of Infringement of the ‘475 Patent by Zydus)**

26. Plaintiff realleges and incorporates by reference the allegations contained in

paragraphs 1-25.

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

28. Zydus has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., Zydus's Product in the event that the FDA approves the Zydus ANDA. Accordingly, an actual and immediate controversy exists regarding Zydus's infringement of the '475 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

29. Zydus's commercial manufacture, use, offer to sell, or sale of Zydus's Product within the United States, or importation of Zydus's 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).

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

31. Plaintiff has no adequate remedy at law.

32. 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 and Declaratory Judgment of Infringement of the '962 Patent by Zydus )**

33. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-32.

34. On information and belief, Zydus has infringed the '962 Patent, pursuant to 35

U.S.C. § 271(e)(2)(A), by submitting the Zydus ANDA, by which Zydus seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of Zydus's Product prior to the expiration of the '962 Patent.

35. Zydus has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., Zydus's Product in the event that the FDA approves the Zydus ANDA. Accordingly, an actual and immediate controversy exists regarding Zydus's infringement of the '962 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

36. Zydus's commercial manufacture, use, offer to sell, or sale of Zydus's Product within the United States, or importation of Zydus's Product 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).

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

38. Plaintiff has no adequate remedy at law.

39. 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 and Declaratory Judgment of Infringement of the '280 Patent by Zydus)**

40. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-39.

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



Zydus's Product prior to the expiration of the '280 Patent.

42. Zydus has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., Zydus's Product in the event that the FDA approves the Zydus ANDA. Accordingly, an actual and immediate controversy exists regarding Zydus's infringement of the '280 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

43. Zydus's commercial manufacture, use, offer to sell, or sale of Zydus's Product within the United States, or importation of Zydus's 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).

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

45. Plaintiff has no adequate remedy at law.

46. 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 '340 Patent by Zydus)**

47. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-46.

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

49. Zydus has declared its intent to manufacture, use, offer to sell, or sell in the U.S.

or to import into the U.S., Zydus's Product in the event that the FDA approves the Zydus ANDA. Accordingly, an actual and immediate controversy exists regarding Zydus's infringement of the '340 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

50. Zydus's commercial manufacture, use, offer to sell, or sale of Zydus's Product within the United States, or importation of Zydus's 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).

51. Plaintiff will be substantially and irreparably harmed if Zydus is not enjoined from infringing the '340 Patent.

52. Plaintiff has no adequate remedy at law.

53. 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 '927 Patent by Zydus)**

54. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-53.

55. On information and belief, Zydus has infringed the '927 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Zydus ANDA, by which Zydus seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of Zydus's Product prior to the expiration of the '927 Patent.

56. Zydus has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., Zydus's Product in the event that the FDA approves the Zydus ANDA. Accordingly, an actual and immediate controversy exists regarding Zydus's

infringement of the '927 patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

57. Zydus's commercial manufacture, use, offer to sell, or sale of Zydus's Product within the United States, or importation of Zydus's Product into the United States during the term of the '927 Patent, would further infringe the '927 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

58. Plaintiff will be substantially and irreparably harmed if Zydus is not enjoined from infringing the '927 Patent.

59. Plaintiff has no adequate remedy at law.

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

#### **SIXTH CAUSE OF ACTION**

##### **(Infringement and Declaratory Judgment of Infringement of the '989 Patent by Zydus)**

61. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-60.

62. On information and belief, Zydus has infringed the '989 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Zydus ANDA, by which Zydus seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of Zydus's Product prior to the expiration of the '989 Patent.

63. Zydus has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., Zydus's Product in the event that the FDA approves the Zydus ANDA. Accordingly, an actual and immediate controversy exists regarding Zydus's infringement of the '989 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

64. Zydus's commercial manufacture, use, offer to sell, or sale of Zydus's Product

within the United States, or importation of Zydus's Product into the United States during the term of the '989 Patent, would further infringe the '989 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

65. Plaintiff will be substantially and irreparably harmed if Zydus is not enjoined from infringing the '989 Patent.

66. Plaintiff has no adequate remedy at law.

67. 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 against defendants Zydus Pharmaceuticals (USA), Inc. ("Zydus USA") and Cadila Healthcare Limited ("Cadila") (collectively, "Zydus"), and respectfully requests the following relief:

1. A judgment that the '475, '962, '280, '340, '927 and '989 Patents have been infringed by Zydus;
2. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) for a preliminary and permanent injunction enjoining Zydus, 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 Zydus's Product within the United States, or importing Zydus's Product into the United States, prior to the expiration of the '475, '962, '280, '340, '927 and/or '989 Patents, including any extensions;
3. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 203934 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 '475,

‘962, ‘280, ‘340, ‘927 and/or ‘989 Patents, including any extensions;

4. A judgment declaring and enjoining Zydus, 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 Zydus’s Product within the United States, or importing Zydus’s Product into the United States, prior to the expiration dates of the ‘475, ‘962, ‘280, ‘340, ‘927 and/or ‘989 Patents, including any extensions;

5. If Zydus commercially manufactures, uses, offers to sell, or sells Zydus’s Product within the United States, or imports Zydus’s Product into the United States, prior to the expiration of any of the ‘475, ‘962, ‘280, ‘340, ‘927 and/or ‘989 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: May 9, 2012

Respectfully submitted,

By: /s/ Leda Dunn Wettre

Leda Dunn Wettre  
ROBINSON, WETTRE & MILLER LLC  
One Newark Center, 19th Floor  
Newark, New Jersey 07102  
Telephone: (973) 690-5400  
Facsimile: (973) 466-2760  
Email: [lwettre@rwmlegal.com](mailto:lwettre@rwmlegal.com)

OF COUNSEL:

William G. Gaede III  
Bhanu K. Sadasivan  
Shane G. Smith  
MCDERMOTT WILL & EMERY LLP  
275 Middlefield Road, Suite 100  
Menlo Park, CA 94025  
Telephone: (650) 815-7400  
Facsimile: (650) 815-7401  
Email: [wgaede@mwe.com](mailto:wgaede@mwe.com)  
[bsadasivan@mwe.com](mailto:bsadasivan@mwe.com)  
[ssmith@mwe.com](mailto:ssmith@mwe.com)

*Attorneys for Plaintiff Depomed, Inc.*

**CERTIFICATION PURSUANT TO L. CIV. R. 11.2**

Plaintiff, by its undersigned counsel, hereby certifies that the patents in suit and the branded product at issue in this case are the subject of related actions pending in this Court before the Honorable Joel A. Pisano: *Depomed Inc. v. Actavis Elizabeth, LLC et al.*, Case No. 3:12-cv-01358-JAP-TJB and *Depomed Inc. v. Impax Laboratories, Inc, et al.*, 3:12-cv-02154-JAB-TJB. Further, certain of the patents-in-suit at issue here are also the subject of an action before the Honorable Joel A. Pisano: *Depomed, Inc. et al v. Sun Pharma Global FZE et al.*, Case No. 3:11-cv-03553-JAP-TJB.

Dated: May 9, 2012

Respectfully submitted,

By: /s/ Leda Dunn Wettre

Leda Dunn Wettre  
ROBINSON, WETTRE & MILLER LLC  
One Newark Center, 19th Floor  
Newark, New Jersey 07102  
Telephone: (973) 690-5400  
Facsimile: (973) 466-2760  
Email: [lwettre@rwmlegal.com](mailto:lwettre@rwmlegal.com)

OF COUNSEL:  
William G. Gaede III  
Bhanu K. Sadasivan  
Shane G. Smith  
MCDERMOTT WILL & EMERY LLP  
275 Middlefield Road, Suite 100  
Menlo Park, CA 94025  
Telephone: (650) 815-7400  
Facsimile: (650) 815-7401  
Email: [wgaede@mwe.com](mailto:wgaede@mwe.com)  
[bsadasivan@mwe.com](mailto:bsadasivan@mwe.com)  
[ssmith@mwe.com](mailto:ssmith@mwe.com)

*Attorneys for Plaintiff Depomed, Inc.*