

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

DEPOMED, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No.
	)	
WATSON LABORATORIES, INC. –	)	
FLORIDA, ACTAVIS, INC., and	)	
WATSON PHARMA, INC.,	)	
	)	
	)	
Defendants.	)	

**COMPLAINT**

Plaintiff Depomed, Inc. (“Depomed”) for its Complaint against defendants Watson Laboratories, Inc. - Florida (“Watson Laboratories”), Actavis, Inc. (“Actavis”), and Watson Pharma, Inc. (“Watson Pharma”) (collectively “Watson” or the “Watson Defendants”), alleges as follows:

**THE PARTIES**

1. Plaintiff Depomed is a corporation organized under the laws of California, having its principal place of business at 7999 Gateway Boulevard, Suite 300 in Newark, California.

2. Upon information and belief, defendant Watson Laboratories is a corporation organized and existing under the laws of the State of Florida having a place of business at 495 Orange Drive, Davie, Florida 33314. On information and belief, Watson Laboratories is in the business of developing and manufacturing generic pharmaceutical products for the U.S. market and is a wholly owned subsidiary of Actavis. On information and belief, Watson Laboratories’ preparation and submission of Abbreviated New Drug Application (“ANDA”) No. 203755 was done collaboratively with, and for the benefit of Actavis. On information and belief, Watson

Laboratories is the alter ego of Actavis where a unity of interest and ownership exists between Watson Laboratories and Actavis such that separate personalities of the two do not in reality exist. Upon information and belief, Watson Laboratories formerly did business as Andrx Pharmaceuticals, Inc., and is a wholly owned subsidiary of Andrx Corporation, a corporation organized and existing under the laws of the State of Delaware. On information and belief, Andrx Corporation is a wholly-owned subsidiary of Actavis.

3. Upon information and belief, Defendant Actavis is a corporation organized and existing under the laws of the State of Nevada with corporate headquarters at 400 Interpace Parkway, Parsippany New Jersey 07054. On information and belief, Actavis is in the business of developing, manufacturing and/or marketing pharmaceutical products in the United States, including in this judicial district, through at least the actions of its subsidiaries Watson Laboratories and Watson Pharma.

4. Upon information and belief, defendant Watson Pharma is a corporation organized and existing under the laws of Delaware with its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054. On information and belief, Watson Pharma is in the business of distributing and/or selling generic pharmaceutical products in the United States market, including products made by Watson Laboratories and is a wholly owned subsidiary of Actavis. On information and belief, Watson Pharma is the alter ego of Actavis where a unity of interest and ownership exists between Watson Pharma and Actavis such that separate personalities of the two do not in reality exist.

#### **JURISDICTION AND VENUE**

5. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code. 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).

6. This Court has personal jurisdiction over Watson Laboratories, Actavis and Watson Pharma because, *inter alia*, they have each committed, or aided themselves of the benefits and protections of Delaware's laws such that they should reasonably anticipate being haled into court here. On information and belief, Actavis, Watson Laboratories and Watson Pharma have had persistent, systematic and continuous contacts with Delaware, Del. Code Ann. tit. 10, Section 3104(c)(4), as set forth below, and for other reasons that will be presented to the Court if jurisdiction is challenged.

7. Watson Laboratories, Actavis and Watson Pharma directly or through an agent, including each other, regularly do or solicit business in Delaware, engage in persistent courses of conduct in Delaware, and/or derive substantial revenue from the development, manufacture and/or sale of pharmaceutical products that are sold in Delaware.

8. Watson Laboratories, Actavis and Watson Pharma are, at the very least, agents of each other and/or work in concert with each other and/or other direct and indirect subsidiaries of Actavis with respect to the development, regulatory approval, marketing, sale and distribution of pharmaceutical products throughout the United States, including this district.

9. Upon information and belief, Actavis, Watson Pharma and Watson Laboratories share certain common officers and directors. Upon information and belief, Actavis, Watson Laboratories and Watson Pharma operate in whole or in part from one or more shared facilities in New Jersey and California.

10. Upon information and belief, until January 23, 2013, Actavis was operating under the name of Watson Pharmaceuticals. Watson Pharmaceuticals organized its operations into

three business segments - Global Generics, Global Brands, and ANDA Distribution - rather than by subsidiary, and reported its financial results to investors by reference to its divisions, rather than its subsidiaries. Upon information and belief, the name change from Watson Pharmaceuticals to Actavis did not impact the organization of its operations.

11. Upon information and belief, until January 23, 2013, Watson Pharmaceuticals' Global Generics Division, which is responsible for developing and submitting ANDAs, as well as manufacturing and marketing generic pharmaceuticals, relied on the concerted efforts of Watson Laboratories, Actavis and Watson Pharma. Upon information and belief, the name change from Watson Pharmaceuticals to Actavis did not impact the role of Watson Pharmaceuticals' Global Generics Division.

12. Upon information and belief, Actavis, Watson Laboratories and Watson Pharma are, at the very least, agents of each other and/or operate in concert as integrated parts of Watson's Generic division.

13. Upon information and belief, until January 23, 2013, Watson Pharmaceuticals consolidated its financial results and did not provide separate financial reports for each Watson subsidiary. Upon information and belief, Actavis has not reported financial results from between January 24, 2013 to the present.

14. Upon information and belief, Watson Pharma, acting as, at the very least, an agent of Watson Laboratories and Actavis, markets and sells Watson's drug products in Delaware and elsewhere in the United States.

15. Upon information and belief, Actavis and/or Watson Laboratories earn revenue from the distribution in Delaware by Watson Pharma of generic pharmaceutical products that are

manufactured by Watson Laboratories or for which Watson Laboratories is the named applicant on approved ANDAs.

16. Upon information and belief, Actavis, Watson Pharma, and Watson Laboratories will manufacture, market, and/or sell within the United States, including Delaware, the generic 500 mg GLUMETZA® described in Watson’s ANDA No. 203755 if FDA approval is granted. Such marketing, distribution, sale and use in Delaware would have a substantial effect on Delaware.

17. This Court has personal jurisdiction over Watson because it has availed itself of the legal protections of the State of Delaware by, *inter alia*, its involvement of asserting claims, joining claims or admitting jurisdiction in different lawsuits filed in the District of Delaware.

18. This Court has personal jurisdiction over Watson Laboratories, Watson Pharma and Actavis by virtue of, *inter alia*, their respective systematic and continuous contacts with Delaware.

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

19. 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 1.

20. 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 2.

21. 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 3.

22. 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.

### **GLUMETZA®**

23. New Drug Application No. 021748 (the "NDA") is for metformin hydrochloride extended release tablets in 500 and 1000 mg dosage strengths, which are sold under the trade name GLUMETZA®.

24. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '962 Patent, '340 Patent, '280 Patent and '475 Patent 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.

### **INFRINGEMENT BY WATSON**

25. On information and belief, Watson submitted ANDA No. 203755 (the "Watson ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market metformin hydrochloride extended release tablets in the 500 mg dosage strength. The metformin hydrochloride extended release tablet described in the Watson ANDA is herein referred to as the "Watson Product."

26. The Watson ANDA refers to and relies upon the GLUMETZA® NDA, and contains data that, according to Watson, demonstrate the bioequivalence of the Watson Product and GLUMETZA®.

27. Depomed received a letter from Watson on or about January 21, 2013, stating it had included a certification in the Watson ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '962, '340, '280 and '475 Patents are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Watson Product (the "Paragraph IV Certification"). A true and correct copy of this letter is attached hereto as Exhibit 5.

28. Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II), Watson also provided a statement of the factual and legal bases that allegedly support its non-infringement and invalidity positions with the letter.

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

29. Depomed realleges and incorporates by reference the allegations contained paragraphs 1-28.

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

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

32. Watson's manufacture, use, offer to sell, or sale of the Watson Product within the United States, or importation of the Watson 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).

33. Depomed will be substantially and irreparably harmed if Watson is not enjoined from infringing the '962 Patent.

34. Depomed has no adequate remedy at law.

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

**SECOND CAUSE OF ACTION**  
**(Infringement of the '340 Patent)**

36. Depomed realleges and incorporates by reference the allegations contained paragraphs 1-35.

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

38. Watson has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Watson Product in the event that the FDA approves the Watson ANDA. Accordingly, an actual and immediate controversy exists regarding Watson's infringement of the '340 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c)

39. Watson's manufacture, use, offer to sell, or sale of the Watson Product within the United States, or importation of the Watson 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).

40. Depomed will be substantially and irreparably harmed if Watson is not enjoined from infringing the '340 Patent.



41. Depomed has no adequate remedy at law.

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

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

43. Depomed realleges and incorporates by reference the allegations contained paragraphs 1-42.

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

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

46. Watson's manufacture, use, offer to sell, or sale of the Watson Product within the United States, or importation of the Watson 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).

47. Depomed will be substantially and irreparably harmed if Watson is not enjoined from infringing the '280 Patent.

48. Depomed has no adequate remedy at law.

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

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

50. Depomed realleges and incorporates by reference the allegations contained paragraphs 1-49.

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

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

53. Watson's manufacture, use, offer to sell, or sale of the Watson Product within the United States, or importation of the Watson 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).

54. Depomed will be substantially and irreparably harmed if Watson is not enjoined from infringing the '475 Patent.

55. Depomed has no adequate remedy at law.

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

**PRAYER FOR RELIEF**

WHEREFORE, Depomed prays for judgment against Watson Laboratories, Actavis and Watson Pharma and respectfully requests the following relief:

- a. A judgment that the '962, '340, '280, and '475 Patents have been infringed by Watson Laboratories, Actavis and Watson Pharma;
- b. 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 Watson Laboratories, Actavis, and Watson Pharma, their 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 Watson Product within the United States, or importing the Watson Product into the United States, prior to the expiration of the '962, '340, '280, and '475 Patents;
- c. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 203755 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 '475 Patents including any extensions;
- d. If Watson Laboratories, Actavis and Watson Pharma manufactures, uses, offers to sell, or sells the Watson Product within the United States, or imports the Watson Product into the United States, prior to the expiration of any of the '962, '340, '280, and '475 Patents, including any extensions, a judgment awarding Depomed monetary relief together with interest;
- e. An award of damages together with interest, and a judgment that the damages so adjudged be trebled pursuant to 35 U.S.C. § 284;
- f. Judgment that this is an exceptional case and that Depomed be awarded their attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285;
- g. Costs and expenses in this action; and
- h. Such other and further relief as the Court deems just and appropriate.

Respectfully submitted,

/s/ Francis DiGiovanni  
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