

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

DEPOMED, INC. and VALEANT)	
INTERNATIONAL (BARBADOS) SRL)	
)	
Plaintiffs,)	Civil Action No.
)	
v.)	
)	
WATSON LABORATORIES, INC. –)	
FLORIDA, WATSON)	
PHARMACEUTICALS, INC., and)	
WATSON PHARMA, INC.)	
)	
)	
Defendants.)	

COMPLAINT

Plaintiffs Depomed, Inc. ("Depomed") and Valeant International (Barbados) SRL ("Valeant") (collectively, "Plaintiffs"), for their Complaint against defendant Watson Laboratories, Inc. - Florida ("Watson Laboratories"), Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals"), and Watson Pharma, Inc. ("Watson Pharma") (collectively "Watson" or the "Watson Defendants"), allege as follows:

THE PARTIES

1. Plaintiff Depomed is a corporation organized under the laws of California, having its principal place of business at 1360 O'Brien Drive 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, 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 Watson Pharmaceuticals. 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 Watson Pharmaceuticals. On information and belief, Watson Laboratories is the alter ego of Watson Pharmaceuticals where a unity of interest and ownership exists between Watson Laboratories and Watson Pharmaceuticals, 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 Watson Pharmaceuticals.

4. Upon information and belief, 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 Watson Pharmaceuticals. On information and belief, Watson Pharma is the alter ego of Watson Pharmaceuticals where a unity of interest and ownership exists between Watson Pharma and Watson Pharmaceuticals such that separate personalities of the two do not in reality exist.

5. Upon information and belief, Watson Pharmaceuticals is a corporation organized and existing under the laws of the State of Nevada with corporate headquarters in at 400 Interpace Parkway, Parsippany New Jersey 07054. On information and belief, Watson Pharmaceuticals 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.

JURISDICTION AND VENUE

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 ANDA filed by Watson with the United States Food and Drug Administration ("FDA") for approval to market a generic copy of 1000 mg GLUMETZA® prior to the expiration of U.S. Patent Nos. 6,488,962 and 7,780,987. 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).

7. This Court has personal jurisdiction over Watson Laboratories, Watson Pharmaceuticals 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, Watson Pharmaceuticals, Watson Laboratories and Watson Pharma have had persistent, systematic and continuous contacts with Delaware, 10 Del. C. § 3104(c)(4), as set forth below, and for other reasons that will be presented to the Court if jurisdiction is challenged.

8. Watson Laboratories, Watson Pharmaceuticals, 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.

9. Watson Laboratories, Watson Pharmaceuticals 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 Watson Pharmaceuticals with respect to the development, regulatory approval, marketing, sale and distribution of pharmaceutical products throughout the United States, including this district.

10. Upon information and belief, Watson Pharmaceuticals, Watson Pharma and Watson Laboratories share certain common officers and directors. Upon information and belief,

Watson Pharmaceuticals, Watson Laboratories and Watson Pharma operate in whole or in part from one or more shared facilities in New Jersey and California.

11. Upon information and belief, and according to its website located at <http://www.watson.com>, Watson Pharmaceuticals organizes its operations into three business segments – Global Generics, Global Brands, and ANDA Distribution – rather than by subsidiary, and reports its financial results to investors by reference to its divisions, rather than its subsidiaries.

12. Upon information and belief, the Global Generics Division, which is responsible for developing and submitting ANDAs, as well as manufacturing and marketing generic pharmaceuticals, relies on the concerted efforts of Watson Laboratories, Watson Pharmaceuticals and Watson Pharma.

13. Upon information and belief, Watson Pharmaceuticals, 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.

14. Upon information and belief, Watson Pharmaceuticals consolidates its financial results and does not provide separate financial reports for each Watson subsidiary.

15. Upon information and belief, Watson Pharmaceuticals maintains a single website for all Watson entities, including Watson Pharma and Watson Laboratories, at <http://www.watson.com>.

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

17. Upon information and belief, Watson Pharmaceuticals 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.

18. Upon information and belief, Watson Pharmaceuticals, Watson Pharma, and Watson Laboratories will manufacture, market, and/or sell within the United States, including Delaware, the generic 1000 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.

19. 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.

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

THE PATENTS-IN-SUIT

21. 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.

22. 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 in the United States. A true and correct copy of the '987 Patent is attached as Exhibit 2.

GLUMETZA®

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

24. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '962 Patent and the '987 Patent are listed in the FDA's Orange Book for 1000 mg GLUMETZA®.

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 1000 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 and Valeant received a letter from Watson on or about March 8, 2012, stating that it had included a certification in the Watson ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '962 and '987 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 3.

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

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

29. Plaintiffs reallege and incorporate 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 commercial 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 commercial 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. Plaintiffs will be substantially and irreparably harmed if Watson is not enjoined from infringing the '962 Patent.

34. Plaintiffs have no adequate remedy at law.

35. 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 '987 Patent)

36. Plaintiffs reallege and incorporate by reference the allegations contained paragraphs 1 - 35.

37. On information and belief, Watson has infringed the '987 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 commercial manufacture, use, offer to sell, sale, or importation of the Watson Product prior to the expiration of the '987 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 '987 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

39. Watson's commercial 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 '987 Patent would further infringe the '987 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

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

41. Plaintiffs have no adequate remedy at law.

42. 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 Watson Laboratories, Watson Pharmaceuticals, and Watson Pharma and respectfully request the following relief:

- a. A judgment that the '962 and '987 Patents have been infringed by Watson Laboratories, Watson Pharmaceuticals, and Watson Pharma;
- b. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) for a preliminary and permanent injunction enjoining Watson Laboratories, Watson Pharmaceuticals, 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 and/or '987 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 and/or '987 Patents, including any extensions;
- d. A judgment declaring and enjoining Watson Laboratories, Watson Pharmaceuticals, 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 dates of the '962 and/or '987 Patents, including any extension;

- e. If Watson Laboratories, Watson Pharmaceuticals, and Watson Pharma commercially 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 and/or '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 their 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,

/s/ Francis DiGiovanni
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