

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
Civil Action No.:**

DEPOMED, INC.,

Plaintiff,

v.

**BANNER PHARMACAPS INC. and
WATSON LABORATORIES, INC. ,**

Defendants.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Depomed, Inc. brings this action against defendants Banner Pharmacaps Inc. and Watson Laboratories, Inc. and alleges as follows:

THE PARTIES

1. Plaintiff Depomed, Inc. (“Depomed”), is a corporation organized under the laws of California, having its principal place of business at 7999 Gateway Boulevard, Suite 300, Newark, California 94560.

2. Upon information and belief, Banner Pharmacaps Inc. (“Banner”) is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 4125 Premier Drive, High Point, North Carolina.

3. Upon information and belief, Watson Laboratories, Inc. (“Watson”) is a corporation organized and existing under the laws of Delaware with principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. On information and belief, Watson is in the business of developing, manufacturing, marketing, distributing and/or selling generic pharmaceutical products in the United States market and is a wholly-owned subsidiary of Actavis Inc.

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 Banner filing 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 Zipsor[®] prior to the expiration of U.S. Patent Nos. 6,365,180, 7,662,858, 7,884,095, 7,939,518 and 8,110,606.

5. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Banner because, *inter alia*, it has purposely availed itself of the benefits and protections of North Carolina’s laws such that it should reasonably anticipate being haled into court here. On information and belief, Banner has had persistent, substantial, systematic and continuous contacts with North Carolina. Banner maintains executive offices in North Carolina, conducts business in the State of North Carolina, and has a past practice of consenting to personal jurisdiction in this Court for other litigation matters.

7. This Court has personal jurisdiction over Watson by virtue of its systematic and continuous contacts with this jurisdiction, as alleged herein, as well as because of the injury to Plaintiff, and the causes of action Plaintiff has raised, as alleged herein.

8. Specifically, this Court has personal jurisdiction over Watson because it, either directly or through an agent, regularly does or solicits business in this jurisdiction, engages in other persistent courses of conduct in this jurisdiction, and/or derives substantial revenue from services or things used or consumed in this jurisdiction. For example, Watson engages in national sales of its products which include North Carolina. Watson has also induced the infringement of the Depomed Patents through its licensing of the ANDA application from Banner, based in North Carolina.

9. On information and belief, Watson has previously availed itself of this forum for purposes of litigating its disputes. For example, Watson has consented to personal jurisdiction in *Allergan, Inc. et al. v. Watson Pharmaceuticals, Inc.*, Civil Action No. 12-cv-321 and *Allergan, Inc. v. Apotex, Inc., et al.*, Civil Action No. 1:13-cv-16.

10. Upon information and belief, Banner and Watson will manufacture, market, and/or sell within the United States the generic 25 mg diclofenac potassium capsules described in Banner's ANDA No. 204648 if FDA approval is granted. If ANDA No. 204648 is approved, the generic 25 mg diclofenac potassium capsules charged with infringing the patents-in-suit, would, among other things, be marketed and distributed in North Carolina, prescribed by physicians in North Carolina, and dispensed by pharmacies located within North Carolina, and/or used by persons in North Carolina, all of which would have a substantial effect on North Carolina.

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

THE PATENTS-IN-SUIT

12. United States Patent No. 6,365,180 (the "'180 Patent") entitled "Oral Liquid Compositions" issued on April 2, 2002, and Depomed is the assignee of the inventors. (A copy of the '180 Patent is attached as Exhibit 1.)

13. United States Patent No. 7,662,858 (the "'858 Patent") entitled "Method of Treating Post-Surgical Acute Pain" issued on February 16, 2010, and Depomed is the assignee of the inventors. (A copy of the '858 Patent is attached as Exhibit 2.)

14. On February 8, 2011, United States Patent No. 7,884,095 (the "'095 Patent") entitled "Method of Treating Post-Surgical Acute Pain" issued on February 8, 2011, and Depomed is the assignee of the inventors. (A copy of the '095 Patent is attached as Exhibit 3.)

15. United States Patent No. 7,939,518 (the "'518 Patent") entitled "Method of Treating Post-Surgical Acute Pain" issued on May 10, 2011, and Depomed is the assignee of the inventors. (A copy of the '518 Patent is attached as Exhibit 4.)

16. United States Patent No. 8,110,606 (the “‘606 Patent”) entitled “Method of Treating Post-Surgical Acute Pain” issued on February 7, 2012, and Depomed is the assignee of the inventors. (A copy of the ‘606 Patent is attached as Exhibit 5.)

ZIPSOR[®]

17. Depomed holds approved New Drug Application No. 022202 (the “Depomed NDA”) for diclofenac potassium capsules, 25mg dosage strengths, which are sold under the trade name Zipsor[®].

18. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the ‘180, ‘858, ‘095, ‘518, and ‘606 Patents are listed in the FDA publication, “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”), with respect to Zipsor[®].

BANNER’S ANDA

19. On information and belief, Banner submitted ANDA No. 204648 to the FDA, seeking approval to engage in the commercial manufacture, use or sale of generic diclofenac potassium capsules in 25 mg dosage strengths. The generic diclofenac potassium capsules described in the Banner ANDA are herein referred to as the “Banner Product.”

20. On information and belief, the Banner ANDA refers to and relies upon the Zipsor[®] NDA and contains data that demonstrate the bioequivalence of the Banner Product and Zipsor[®].

21. Depomed received from Banner a letter, dated June 27, 2013, stating that Banner had included a certification in the Banner ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the claims of the ‘180, ‘858, ‘095, ‘518, and ‘606 Patents are invalid or will not be infringed by the commercial manufacture, use, or sale of the Banner Product (the “Banner Notification Letter”). (A true and correct copy of the Banner Notification Letter is attached hereto as Exhibit 6.)

22. The Banner Notification Letter states that Banner has granted to Watson the exclusive license and right under the Banner ANDA to sell, market, distribute, or otherwise commercialize Banner's ANDA product.

FIRST CAUSE OF ACTION
(Infringement and Declaratory Judgment of Infringement of the '180 Patent)

23. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-22.

24. On information and belief, Defendants have infringed or induced the infringement of the '180 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Banner ANDA, by which Banner seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Banner Product prior to the expiration of the '180 Patent.

25. On information and belief, Defendants will infringe the '180 Patent, pursuant to 35 U.S.C. § 271(a)-(c), by engaging in the commercial manufacture, use, offer to sell, sale, or importation of the patented methods prior to the expiration of the '180 Patent, or inducing or contributing to the use of such methods. Accordingly, an actual and immediate controversy exists regarding Banner's and Watson's infringement of the '180 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

26. Plaintiff will be substantially and irreparably harmed if Defendants are not enjoined from infringing the '180 Patent.

27. Plaintiff has no adequate remedy at law.

28. 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 '858 Patent)

29. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-22.

30. On information and belief, Defendants have infringed or induced the infringement of the '858 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Banner ANDA, by which Banner seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Banner Product prior to the expiration of the '858 Patent.

31. On information and belief, Defendants will infringe the '858 Patent, pursuant to 35 U.S.C. § 271(a)-(c), by engaging in the commercial manufacture, use, offer to sell, sale, or importation of the patented methods prior to the expiration of the '858 Patent, or inducing or contributing to the use of such methods. Accordingly, an actual and immediate controversy exists regarding Banner's and Watson's infringement of the '858 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

32. Plaintiff will be substantially and irreparably harmed if Defendants are not enjoined from infringing the '858 Patent.

33. Plaintiff has no adequate remedy at law.

34. 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 '095 Patent)**

35. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-22.

36. On information and belief, Defendants have infringed or induced the infringement of the '095 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Banner ANDA, by which Banner seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Banner Product prior to the expiration of the '095 Patent.

37. On information and belief, Defendants will infringe the '095 Patent, pursuant to 35 U.S.C. § 271(a)-(c), by engaging in the commercial manufacture, use,

offer to sell, sale, or importation of the patented methods prior to the expiration of the '095 Patent, or inducing or contributing to the use of such methods. Accordingly, an actual and immediate controversy exists regarding Banner's and Watson's infringement of the '095 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

38. Plaintiff will be substantially and irreparably harmed if Defendants are not enjoined from infringing the '095 Patent.

39. Plaintiff has no adequate remedy at law.

40. 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 '518 Patent)**

41. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-22.

42. On information and belief, Defendants have infringed or induced the infringement of the '518 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Banner ANDA, by which Banner seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Banner Product prior to the expiration of the '518 Patent.

43. On information and belief, Defendants will infringe the '518 Patent, pursuant to 35 U.S.C. § 271(a)-(c), by engaging in the commercial manufacture, use, offer to sell, sale, or importation of the patented methods prior to the expiration of the '518 Patent, or inducing or contributing to the use of such methods. Accordingly, an actual and immediate controversy exists regarding Banner's and Watson's infringement of the '518 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

44. Plaintiff will be substantially and irreparably harmed if Defendants are not enjoined from infringing the '518 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.

**FIFTH CAUSE OF ACTION
(Infringement and Declaratory Judgment of Infringement of the '606 Patent)**

47. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-22.

48. On information and belief, Defendants have infringed or induced the infringement of the '606 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Banner ANDA, by which Banner seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Banner Product prior to the expiration of the '606 Patent.

49. On information and belief, Defendants will infringe the '606 Patent, pursuant to 35 U.S.C. § 271(a)-(c), by engaging in the commercial manufacture, use, offer to sell, sale, or importation of the patented methods prior to the expiration of the '606 Patent, or inducing or contributing to the use of such methods. Accordingly, an actual and immediate controversy exists regarding Banner's and Watson's infringement of the '606 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

50. Plaintiff will be substantially and irreparably harmed if Defendants are not enjoined from infringing the '606 Patent.

51. Plaintiff has no adequate remedy at law.

52. 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

53. 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 filed suit on July 26, 2013 seeking to enjoin Banner and Watson from infringing the '180, '858, '095, '518 and '606 patents in the District of New Jersey. Defendant Watson is

based in New Jersey, and defendant Banner sells generally into New Jersey and further licensed the infringing application and product to Watson in New Jersey. Plaintiff did so to exercise its rights under the Hatch Waxman Act to sue within 45 days of receiving the Defendant's 21 U.S.C. §355(j)(2)(A)(vii)(IV) notification letter to stay the FDA approving Defendants' application. Judicial economy would be promoted and Plaintiff's choice of forum respected, if the claims related to Plaintiff's action for infringement of the '180, '858, '095, '518 and '606 patents were to be addressed in the District of New Jersey.

54. Therefore, Plaintiff filed this action as a protective measure to preserve its rights and interests, out of an abundance of caution given the possible consequence if Defendants were to succeed in challenging personal jurisdiction over them in New Jersey. Plaintiff expects that personal jurisdiction in the District of New Jersey will be confirmed and that the action will proceed in that forum, in which case this second action will be unnecessary.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against defendants Banner Pharmacaps Inc. and Watson Laboratories, Inc., and respectfully requests the following relief:

1. A judgment that the '180, '858, '095, '518 and '606 Patents have been infringed by Defendants;
2. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) for a preliminary and permanent injunction enjoining Banner, 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 the selling Banner Product within the United States, or importing the Banner Product into the United States, prior to the expiration of the '180, '858, '095, '518 and/or '606 Patents, including any extensions;

3. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) for a preliminary and permanent injunction enjoining Watson, 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 Banner Product within the United States, or importing the Banner Product into the United States, prior to the expiration of the '180, '858, '095, '518 and/or '606 Patents, including any extensions;

4. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 204648 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 '180, '858, '095, '518 and/or '606 Patents, including any extensions;

5. A judgment declaring and enjoining Banner, 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 Banner Product within the United States, or importing the Banner Product into the United States, prior to the expiration dates of the '180, '858, '095, '518 and/or '606 Patents, including any extensions;

6. A judgment declaring and enjoining Watson, 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 Banner Product within the United States, or importing the Banner Product into the United States, prior to the expiration dates of the '180, '858, '095, '518 and/or '606 Patents, including any extensions;

7. If either Defendant commercially manufactures, uses, offers to sell, or sells the Banner Product within the United States, or imports the Banner Product into the United States, prior to the expiration of any of the '180, '858, '095, '518 and/or '606

Patents, including any extensions, a judgment awarding Plaintiff monetary relief together with interest;

8. 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;

9. 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;

10. Costs and expenses in this action; and

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

This 9th day of August, 2013.

s/ John R. Wester

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