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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CIPHER PHARMACEUTICALS INC., GALEPHAR PHARMACEUTICAL RESEARCH, INC., RANBAXY, INC., and RANBAXY PHARMACEUTICALS, INC.,

Plaintiffs,

v.

Civil Action No. _____

ACTAVIS LABORATORIES FL, INC., ANDRX CORP., ACTAVIS, INC., and ACTAVIS PHARMA, INC.,

Defendants.

COMPLAINT

Plaintiffs Ranbaxy, Inc., Ranbaxy Pharmaceuticals, Inc. (together, "Ranbaxy"), Cipher Pharmaceuticals Inc. ("Cipher"), and Galephar Pharmaceutical Research, Inc. ("Galephar") (collectively, "Plaintiffs") for their Complaint against defendants Actavis Laboratories FL, Inc. ("ALF"), Andrx Corp. ("Andrx), Actavis, Inc. ("Actavis"), and Actavis Pharma, Inc. ("Actavis Pharma") (collectively, "Defendants"), allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Defendants' submission of an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Plaintiff Ranbaxy's Absorica® (isotretinoin) capsules prior to the expiration of United States Patent No. 7,435,427 ("the '427 Patent").

THE PARTIES

2. Plaintiff Ranbaxy, Inc. ("RI") is a corporation organized and existing under the laws of the State of Delaware, having its principle place of business at 600 College Road East, Princeton, New Jersey 08540.

3. Plaintiff Ranbaxy Pharmaceuticals, Inc. ("RPI") is a corporation organized under the laws of Florida, having its principal place of business at 9431 Florida Mining Boulevard East, Jacksonville, Florida 32257.

4. Plaintiff Cipher is a corporation organized under the laws of Canada, having its principal place of business at 5650 Tomken Road, Mississauga, Ontario, Canada.

5. Plaintiff Galephar is a corporation organized under the laws of Puerto Rico, having its principal place of business at Juncos Industrial Park, Juncos, Puerto Rico 00777-3873.

6. On information and belief, ALF (formerly known as Watson Laboratories, Inc. - Florida[1]) is a corporation organized and existing under the laws of the State of Florida, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany,

[1] On information and belief, the entity's name was changed from Watson Laboratories, Inc. - Florida to ALF on April 21, 2014.

New Jersey 07054. On information and belief, ALF is in the business of, inter alia, developing, manufacturing, and obtaining regulatory approval of generic copies of branded pharmaceutical products throughout the United States, including within this district.

7. On information and belief, Defendant Actavis Pharma (formerly known as Watson Pharma, Inc.) is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. On information and belief, Actavis is in the business of, inter alia, selling and distributing generic copies of branded pharmaceutical products in New Jersey and throughout the United States, including some that are manufactured by ALF and/or for which ALF is the named applicant of the approved ANDAs.

8. On information and belief, Defendant Actavis (formerly known as Watson Pharmaceuticals, Inc. ("WPI")) is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business in Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. On information and belief, Actavis is in the business of, inter alia, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products throughout the United States, including within this district, through its own actions and through the actions of its agents and subsidiaries, including at least ALF, Actavis Pharma, and Andrx.

9. On information and belief, Defendant Andrx is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 4955 Orange Drive, Davie, Florida 33314. On information and belief, Andrx is in the business of, inter alia, marketing, selling, and distributing generic copies of branded pharmaceutical

products throughout the United States, including within this district, through its own actions and through the actions of its agents and subsidiaries, including at least ALF.

10. On information and belief, WPI acquired Andrx Pharmaceuticals, Inc. on or around November 3, 2006. On information and belief, WPI renamed Andrx Pharmaceuticals, Inc. as ALF.

11. On information and belief, ALF is a wholly-owned subsidiary of Andrx, which is a wholly owned subsidiary of Actavis.

12. On information and belief, Actavis Pharma is another wholly-owned subsidiary of Actavis.

13. On information and belief, ALF, Andrx, and Actavis Pharma are within the control of Actavis for purposes of responding to discovery in this action.

14. On information and belief, ALF, Andrx, Actavis, and Actavis Pharma share certain common officers and directors and 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.

15. On information and belief, until January 23, 2013, Actavis was operating under the name of WPI. WPI 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. On information and belief, the name change from WPI to Actavis did not impact the organization of its operations.

16. On information and belief, until January 23, 2013, WPI's 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 at least ALF, Actavis Pharma, and Andrx. On information and belief, the name change from WPI to Actavis did not impact the role of WPI's Global Generics Division.

17. As reported in its 2012 Annual Report on behalf of itself and its subsidiaries (collectively, "Actavis"), Actavis operates as "a leading integrated global specialty pharmaceutical company engaged in the development, manufacturing, marketing, sale and distribution of," inter alia, generic, branded generic, and brand pharmaceutical products. As described in that Annual Report, one of Actavis' business segments is "Actavis Pharma," formerly known as WPI's "Global Generics" segment, which markets a "U.S. portfolio of approximately 250 generic pharmaceutical product families." On information and belief, ALF, which is a wholly-owned subsidiary of Actavis, Inc., is part of Actavis' "Actavis Pharma" segment.

18. On information and belief, Actavis directs the activities of the other Actavis entities, including ALF, and, directly or through related companies, is responsible for sales of Actavis products to customers in New Jersey, from which Actavis, Inc. derives substantial revenue.

19. On information and belief, Defendants collaborated in the research and development of ALF's ANDA No. 205063 ("the Actavis ANDA") for isotretinoin capsules ("the Actavis ANDA Products"), continue to collaborate in seeking approval of that application by the FDA, and intend to collaborate in the commercial manufacture, marketing, offer for sale, and

sale of the Actavis ANDA Products throughout the United States, including in the State of New Jersey, in the event the FDA approves Actavis' ANDA.

20. On information and belief, ALF (formerly Watson Labs., Inc. - Florida) has submitted to the jurisdiction of this Court in prior New Jersey actions (*Astrazeneca AB, et al. v. Watson Labs., Inc. – Florida, et al.*, Civil Action No. 13-3038; *Astrazeneca AB, et al. v. Watson Labs., Inc. – Florida*, Civil Action No. 13-1669; *Depomed, Inc. v. Actavis Elizabeth LLC, et al.*, Civil Action No. 12-1358; *Warner Chilcott Co., et al. v. Watson Labs., Inc. – Florida*, Civil Action No. 11-5989; *Abbott Labs., et al. v. Watson Labs., Inc. – Florida, et al.*, Civil Action No. 10-3241; *Mallinckrodt Inc. v. Watson Labs., Inc. – Florida, et al.*, Civil Action No. 10-6424). On information and belief, ALF has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in prior New Jersey action (*Astrazeneca AB, et al. v. Watson Labs., Inc. – Florida, et al.*, Civil Action No. 13-1669).

21. On information and belief, Actavis has submitted to the jurisdiction of this Court in prior New Jersey actions (*Astrazeneca AB, et al. v. Watson Labs., Inc. – Florida, et al.*, Civil Action No. 13-3038; *Auxilium Pharms., Inc., et al. v. Watson Labs., Inc. et al.*, Civil Action No. 12-3084;[2] *Depomed, Inc. v. Actavis Elizabeth LLC, et al.*, Civil Action No. 12-1358; *Noven Pharms. v. Watson Labs., Inc., et al.*, Civil Action No. 11-5997;[3] *Shire LLC, et al. v. Amneal Pharms. LLC, et al.*, Civil Action No. 11-3781; *King Pharms. Inc., et al. v. Actavis, Inc., et al.*, Civil Action No. 09-6585; *Shire LLC v. Actavis South Atlantic, LLC, et al.*, Civil Action No. 09-479; *King Pharms. Inc., et al. v. Actavis, Inc., et al.*, Civil Action No. 07-5041; *Sanofi-Aventis U.S. LLC, et al. v. Actavis Totowa LLC, et al.*, Civil Action No. 07-3142). On information and

[2] WPI submitted to the jurisdiction of this Court on July 6, 2012. WPI thereafter changed its name to Actavis Inc.

[3] WPI submitted to the jurisdiction of this Court on November 4, 2011. WPI thereafter changed its name to Actavis Inc.

belief, Actavis has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in prior New Jersey action (*Auxilium Pharms., Inc., et al. v. Watson Labs., Inc. et al.*, Civil Action No. 12-3084).

22. On information and belief, Actavis Pharma has submitted to the jurisdiction of this Court in prior New Jersey actions (*Astrazeneca AB, et al. v. Watson Labs., Inc. – Florida, et al.*, Civil Action No. 13-3038; *Auxilium Pharms., Inc., et al. v. Watson Labs., Inc. et al.*, Civil Action No. 12-3084;[4] *Abbott Labs., et al. v. Watson Labs., Inc. – Florida, et al.*, Civil Action No. 10-3241;[5] *Teva Neuroscience, Inc., et al. v. Watson Pharma, Inc., et al.*, Civil Action No. 10-5078;[6] *Duramed Pharms. v. Watson Pharma, Inc.*, Civil Action No. 07-5941;[7] *Hoffman La-Roche Inc., et al. v. Cobalt Pharms. Inc., et al.*, Civil Action No. 07-4539).[8] On information and belief, Actavis Pharma has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in prior New Jersey action (*Auxilium Pharms., Inc., et al. v. Watson Labs., Inc. et al.*, Civil Action No. 12-3084).

JURISDICTION AND VENUE

23. 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).

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[4] Watson Pharma, Inc. submitted to the jurisdiction of this Court on July 6, 2012. WPI thereafter changed its name to Actavis Pharma, Inc.

[5] Watson Pharma, Inc. submitted to the jurisdiction of this Court on May 3, 2010. WPI thereafter changed its name to Actavis Pharma, Inc.

[6] Watson Pharma, Inc. submitted to the jurisdiction of this Court on December 23, 2010. WPI thereafter changed its name to Actavis Pharma, Inc.

[7] Watson Pharma, Inc. submitted to the jurisdiction of this Court on March 3, 2008. WPI thereafter changed its name to Actavis Pharma, Inc.

[8] Watson Pharma, Inc. submitted to the jurisdiction of this Court on September 1, 2011. WPI thereafter changed its name to Actavis Pharma, Inc.

24. This Court has personal jurisdiction over Defendants by virtue of, inter alia, their presence in this State, having conducted business in this State, having availed themselves of the rights and benefits of New Jersey law such that they should reasonably anticipate being haled into court in this judicial district, previously consenting to personal jurisdiction in this Court, availing themselves of the jurisdiction of this Court and having engaged in systematic and continuous contacts with the State of New Jersey through the marketing and sales of generic drugs throughout the United States, and in particular within this judicial district, through the receipt of revenue from the sales and marketing of generic drug products, including ALF products, within this judicial district, and through their intent to market and sell the Actavis ANDA Products, if approved, to residents of this judicial district.

THE PATENT-IN-SUIT

25. On October 14, 2008, the United States Patent and Trademark Office duly and legally issued the '427 Patent, entitled "Pharmaceutical Semi-Solid Composition of Isotretinoin," to Galephar as assignee of the inventors. A true and correct copy of the '427 Patent is attached as Exhibit 1. Cipher obtained an exclusive license to use the '427 patent rights from Galephar in or about January 2001. On or about November 12, 2012, Ranbaxy obtained, inter alia, an exclusive license to distribute the ABSORICA® product in the United States, its territories, possessions, and the Commonwealth of Puerto Rico.

INFRINGEMENT BY DEFENDANTS

26. RI is the owner of the approved New Drug Application No. 021- 951 (the "NDA") for isotretinoin capsules, for oral use in 10 mg, 20 mg, 30 mg, and 40 mg dosages, which are sold under the trade name ABSORICA®.

27. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, U.S. Patent No. 8,367,102 ("the '102 Patent") and the '427 Patent are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book"), with respect to ABSORICA® in 10 mg, 20 mg, 30 mg, and 40 mg dosages.

28. The claims of the '102 and '427 patents cover the ABSORICA® product.

29. On information and belief, Watson (now Actavis Laboratories FL, Inc.) submitted ANDA No. 205063 to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market isotretinoin capsules, for oral use in 10 mg, 20 mg, 30 mg, and 40 mg dosages.

30. The Actavis ANDA refers to and relies upon the ABSORICA® NDA, and contains data that, according to ALF, demonstrate the bioequivalence of the Actavis ANDA Products and ABSORICA®.

31. Plaintiffs received a letter from Watson (now Actavis Laboratories FL, Inc.) on or about September 17, 2013, stating it had included a certification in the Actavis ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, inter alia, certain claims of the '102 and '427 Patents are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Actavis ANDA Products (the "Paragraph IV Certification").

CAUSE OF ACTION
(Infringement of the '427 Patent)

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

33. Defendants have infringed at least one claim of the '427 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Actavis ANDA, by which

Defendants seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Actavis ANDA Products prior to the expiration of the '427 Patent.

34. Defendants have declared their intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Actavis ANDA Products in the event that the FDA approves the Actavis ANDA. Accordingly, an actual and immediate controversy exists regarding Defendants' infringement of the '427 Patent under 35 U.S.C. § 271 (a), (b) and/or (c).

35. Defendants' manufacture, use, offer to sell, or sale of the Actavis ANDA Products within the United States, or importation of the Actavis ANDA Products into the United States during the term of the '427 Patent would further infringe at least one claim of the '427 Patent under 35 U.S.C. § 271 (a), (b) and/or (c).

36. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing the '427 Patent.

37. Plaintiffs have no adequate remedy at law.

38. 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 respectfully request that the Court enter judgment against Defendants ALF, Andrx, Actavis, and Actavis Pharma and for the following relief:

a. A judgment that Defendants have infringed at least one claim of the '427 Patent;

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 the Defendants, their officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from: (i) manufacturing, using, offering to sell, or selling the Actavis ANDA Products within the United States, or importing the Actavis ANDA Products into the United States, prior to the expiration of the '427 Patent, and (ii) seeking, obtaining or maintaining approval of the Actavis ANDA until expiration of the '427 patent, or such other later time as the Court may determine;

c. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 205063 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 date of the '427 Patent including any extensions;

d. If any of the Defendants manufactures, uses, offers to sell, or sells the Actavis ANDA Products within the United States, or imports the Actavis ANDA Products into the United States, prior to the expiration of any of the '427 Patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

e. A 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;

f. Costs and expenses in this action; and

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

Respectfully Submitted,

s/ Theodora McCormick
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Dated: June 6, 2014