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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. _____

WATSON LABORATORIES, INC. -
FLORIDA, 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 Watson Laboratories, Inc. - Florida (“WLF”), Andrx Corp. (“Andrx), Actavis, Inc. (“Actavis”), and Actavis Pharma, Inc. (“Actavis Pharma”), 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. 8,367,102 ("the '102 patent" or "the patent-in-suit").

THE PARTIES

2. Plaintiff Ranbaxy, Inc. ("RI") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 600 College Road East, Princeton, NJ 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, FL 32257.

4. Plaintiff Cipher Pharmaceuticals, Inc. ("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 Pharmaceutical Research, Inc. ("Galephar") is a corporation organized under the laws of Puerto Rico, having its principal place of business at Carolina, Puerto Rico, 00984-33468.

6. On information and belief, WLF (formerly known as Andrx Pharmaceuticals, Inc.) 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, WLF 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, Inc. (“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 WLF and/or for which WLF is the named applicant of the approved ANDAs.

8. On information and belief, Defendant Actavis, Inc. (“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 WLF, Actavis Pharma and Andrx Corporation.

9. On information and belief, Defendant Andrx Corporation (“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 WLF.

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 WLF.

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

14. On information and belief, WLF, 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 Watson Pharmaceuticals, Inc. 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 WLF, Actavis Pharma and Andrx. On information and belief, the name change from Watson Pharmaceuticals 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, WLF, 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 WLF, 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 WLF's ANDA No. 205063 ("the Watson ANDA") for isotretinoin capsules ("the Watson 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 Watson ANDA Products throughout the United States, including in the State of New Jersey, in the event the FDA approves Watson's ANDA.

20. On information and belief, WLF 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, WLF 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;¹ Depomed, Inc. v. Actavis Elizabeth LLC, et al., Civil Action No. 12-

¹ WPI submitted to the jurisdiction of this Court on July 6, 2012. WPI thereafter changed its name to Actavis Inc.

1358; Noven Pharms. v. Watson Labs., Inc., et al., Civil Action No. 11-5997²; 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 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;³ *Abbott Labs., et al. v. Watson Labs., Inc. – Florida, et al.*, Civil Action No. 10-3241;⁴ *Teva Neuroscience, Inc., et al. v. Watson Pharma, Inc., et al.*, Civil Action No. 10-5078;⁵ *Duramed Pharms. v. Watson Pharma, Inc.*, Civil Action No. 07-5941;⁶ *Hoffman La-Roche Inc., et al. v. Cobalt Pharms. Inc., et al.*, Civil Action No. 07-4539).⁷ On information and belief, Actavis Pharma has availed itself of the rights, benefits, and privileges of this Court by

² WPI submitted to the jurisdiction of this Court on November 4, 2011. WPI thereafter changed its name to Actavis Inc.

³ Watson Pharma, Inc. submitted to the jurisdiction of this Court on July 6, 2012. WPI thereafter changed its name to Actavis Pharma, Inc.

⁴ Watson Pharma, Inc. submitted to the jurisdiction of this Court on May 3, 2010. WPI thereafter changed its name to Actavis Pharma, Inc.

⁵ Watson Pharma, Inc. submitted to the jurisdiction of this Court on December 23, 2010. WPI thereafter changed its name to Actavis Pharma, Inc.

⁶ Watson Pharma, Inc. submitted to the jurisdiction of this Court on March 3, 2008. WPI thereafter changed its name to Actavis Pharma, Inc.

⁷ Watson Pharma, Inc. submitted to the jurisdiction of this Court on September 1, 2011. WPI thereafter changed its name to Actavis Pharma, Inc.

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).

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 WLF products, within this judicial district, and through their intent to market and sell the Watson ANDA Products, if approved, to residents of this judicial district.

THE PATENTS-IN-SUIT

25. On February 5, 2013, the U.S. Patent and Trademark Office ("PTO") duly and legally issued United States Patent No. 8,367,102 (the '102 Patent") entitled "Pharmaceutical Semi-Solid Composition of Isotretinoin" to Galephar as assignee of the inventors. A true and correct copy of the '102 Patent is attached as Exhibit 1. Cipher obtained an exclusive license

to the '102 patent from Galephar in or about February 2002. 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 WATSON

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

27. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '102 Patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to ABSORICA™ in in 10, 20, 30 and 40 dosages.

28. The '102 patent covers the ABSORICA™ product.

29. On information and belief, Watson submitted ANDA No. 205063 (the "Watson ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market isotretinoin capsules, for oral use in 10g, 20g, 30g and 40g dosages. The isotretinoin capsules in the Watson ANDA are herein referred to as the "the Watson ANDA Product."

30. The Watson ANDA refers to and relies upon the ABSORICA™ NDA, and contains data that, according to Watson, demonstrate the bioequivalence of the Watson ANDA Product and ABSORICA.

31. Plaintiffs received a letter from Watson on or about September 17, 2013, stating it had included a certification in the Watson ANDA, pursuant to 21 U.S.C. §

355(j)(2)(A)(vii)(IV), that, inter *alia*, certain claims of the '102 Patents are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Watson ANDA Product (the "Paragraph IV Certification").

FIRST CAUSE OF ACTION
(Infringement of the '102 Patent)

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

33. Defendants have infringed at least one claim of the '102 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Watson ANDA, by which Defendants seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Watson ANDA Products prior to the expiration of the '102 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 Watson ANDA Product in the event that the FDA approves the Watson ANDA. Accordingly, an actual and immediate controversy exists regarding Defendants' infringement of the '102 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c)

35. Defendants' manufacture, use, offer to sell, or sale of the Watson ANDA Product within the United States, or importation of the Watson ANDA Product into the United States during the term of the '102 Patent would further infringe at least one claim of the '102 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 '102 Patent.

37. Plaintiffs have no adequate remedy at law.

38. This case is exceptional, and Plaintiffs is 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 WLF, Andrx, Actavis, and Actavis Pharma and for the following relief:

- a. A judgment that Defendants have infringed at least one claim of the '102 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 Watson ANDA Products within the United States, or importing the Watson ANDA Products into the United States, prior to the expiration of the '102 Patent, and (ii) seeking, obtaining or maintaining approval of the Watson ANDA until expiration of the '102 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 '102 Patent including any extensions;
- d. If any of the Defendants manufactures, uses, offers to sell, or sells the Watson

ANDA Products within the United States, or imports the Watson ANDA Products into the United States, prior to the expiration of any of the '102 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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