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Supernus Pharmaceuticals, Inc.*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

**SUPERNUS PHARMACEUTICALS, INC.,**

**Plaintiff,**

**v.**

**ACTAVIS INC., WATSON  
LABORATORIES, INC. – FLORIDA,  
ACTAVIS PHARMA, INC., WATSON  
LABORATORIES, INC., and ANDA, INC.,**

**Defendants.**

**Civil Action No. \_\_\_\_\_**

**COMPLAINT FOR PATENT  
INFRINGEMENT**

**(Filed Electronically)**

**COMPLAINT**

Plaintiff Supernus Pharmaceuticals, Inc. (“Supernus”) by its undersigned attorneys, for its Complaint against defendants Actavis Inc. (“Actavis”), Watson Laboratories, Inc. – Florida (“Watson Florida”), Actavis Pharma, Inc. (“Actavis Pharma”), Watson Laboratories, Inc. (“Watson Laboratories”), and Anda, Inc. (“Anda”) (collectively, “Defendants”) herein allege as follows:

**NATURE OF THE ACTION**

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent No. 8,617,600 (“the ‘600 patent”), attached hereto as Exhibit A.

**THE PARTIES**

2. Plaintiff Supernus is a corporation organized and existing under the laws of Delaware, having its principal place of business at 1550 East Gude Drive, Rockville, Maryland 20850.

3. Upon information and belief, Actavis is a corporation organized under the laws of Nevada and operating at its principal place of business at 400 Interspace Parkway, Parsippany, NJ 07054. Upon information and belief, Actavis is in the business of, *inter alia*, the development, manufacture, marketing, sale, and distribution of generic pharmaceutical products throughout the United States—including throughout the State of New Jersey—through its various subsidiaries, including Watson Florida, Actavis Pharma, Watson Laboratories, and Anda.

4. Upon information and belief, Watson Florida is a company organized and existing under the laws of Florida and operating at its principal place of business at 4955 Orange Drive, Davie, Florida 33314. Upon information and belief, Watson Florida (formerly known as Andrx Pharmaceuticals, Inc.) is wholly-owned by Andrx Corporation, which is wholly-owned by defendant Actavis. Upon information and belief, Watson Florida acts at the direction of, under the control of, and for the direct benefit of Actavis and is controlled and/or dominated by Actavis. Upon information and belief, Actavis and Watson Florida have at least one officer and/or director in common.

5. Upon information and belief, Watson Florida is in the business of: (i) developing generic pharmaceutical products for sale throughout the United States, including throughout the

State of New Jersey; and (ii) preparing and filing Abbreviated New Drug Applications (“ANDAs”) seeking U.S. Food and Drug Administration (“FDA”) approval to market generic drugs throughout the United States.

6. Upon information and belief, Watson Florida filed ANDA No. 205444 (“the Watson ANDA”) with the FDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of generic oxcarbazepine extended-release tablets, containing 150 mg, 300 mg, and 600 mg of oxcarbazepine (“the Watson Product”).

7. Upon information and belief, Actavis Pharma is a corporation organized under the laws of Delaware and operating at its principal place of business at 400 Interspace Parkway, Parsippany, NJ 07054. Actavis Pharma was formerly known as Watson Pharma, Inc. Upon information and belief, Actavis Pharma is wholly-owned by defendant Actavis. Upon information and belief, Actavis Pharma acts at the direction of, under the control of, and for the direct benefit of Actavis and is controlled and/or dominated by Actavis.

8. Upon information and belief, Actavis Pharma is in the business of marketing, selling, and distributing generic pharmaceutical products throughout the United States, including throughout the State of New Jersey. Actavis Pharma is registered as a manufacturer and wholesale drug distributor in the State of New Jersey under the registration number 5003854.

9. Upon information and belief, Watson Laboratories is a corporation organized under the laws of Nevada and operating at its principal place of business at 400 Interspace Parkway, Parsippany, NJ 07054. Upon information and belief, Watson Laboratories is wholly-owned by defendant Actavis. Upon information and belief, Watson Laboratories acts at the direction of, under the control of, and for the direct benefit of Actavis and is controlled and/or

dominated by Actavis. Upon information and belief, Actavis and Watson Laboratories have at least one officer and/or director in common.

10. Upon information and belief, Watson Laboratories is in the business of marketing, selling, and distributing generic pharmaceutical products throughout the United States, including throughout the State of New Jersey.

11. Upon information and belief, Actavis sells its generic pharmaceutical products throughout the United States, including in New Jersey, “primarily under the ‘Watson Laboratories’, ‘Watson Pharma’ and ‘Actavis Pharma’ labels.” *See* Actavis, Inc. Form 10-K for the Year Ended December 31, 2012 at 8.

12. Upon information and belief, Anda is a corporation organized and existing under the laws of Florida and operating at its principal place of business at 2915 Weston Road, Weston, FL 33331. Upon information and belief, Anda is wholly-owned by defendant Actavis. Upon information and belief, Anda acts at the direction of, under the control of, and for the direct benefit of Actavis and is controlled and/or dominated by Actavis. Upon information and belief, Actavis and Anda have at least one officer and/or director in common.

13. Upon information and belief, Anda distributes Actavis’ generic drug products to independent pharmacies, alternate care providers (hospitals, nursing homes, and mail-order pharmacies), pharmacy chains, and physicians’ offices throughout the United States, including distribution to entities in New Jersey. Anda is registered as a manufacturer and wholesale drug distributor in the State of New Jersey under the registration number 5003858.

#### **JURISDICTION AND VENUE**

14. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

15. This Court has personal jurisdiction over Actavis because, *inter alia*: (i) Actavis's principal place of business is located in New Jersey; (ii) Actavis, together with its subsidiaries, has committed, induced, or contributed to acts of patent infringement in New Jersey; (iii) Actavis is doing business in New Jersey and maintains continuous and systematic contacts with this judicial district; (iv) Actavis has submitted to the jurisdiction of this Court in at least ten prior New Jersey actions (*Supernus Pharms., Inc. v. Actavis, Inc., et al.*, Civil Action No. 13-4740; *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;<sup>1</sup> *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;<sup>2</sup> *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); and (v) Actavis has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in at least one prior New Jersey action (*Auxilium Pharms., Inc., et al. v. Watson Labs., Inc., et al.*, Civil Action No. 12-3084).

16. This Court has personal jurisdiction over Actavis Pharma because, *inter alia*: (i) Actavis Pharma's principal place of business is located in New Jersey; (ii) Actavis Pharma, together with Actavis, Watson Florida, Watson Laboratories, and Anda, has committed, induced, or contributed to acts of patent infringement in New Jersey; (iii) Actavis Pharma is doing business in New Jersey and maintains continuous and systematic contacts with this judicial

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<sup>1</sup> Watson Pharmaceuticals, Inc. submitted to the jurisdiction of this Court on July 6, 2012. Watson Pharmaceuticals, Inc. thereafter changed its name to Actavis Inc.

<sup>2</sup> Watson Pharmaceuticals, Inc. submitted to the jurisdiction of this Court on November 4, 2011. Watson Pharmaceuticals, Inc. thereafter changed its name to Actavis Inc.

district; (iv) Actavis Pharma has submitted to the jurisdiction of this Court in at least seven prior New Jersey actions (*Supernus Pharms., Inc. v. Actavis, Inc., et al.*, Civil Action No. 13-4740; *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;<sup>3</sup> *Abbott Labs., et al. v. Watson Labs., Inc. – Florida, et al.*, Civil Action No. 10-3241;<sup>4</sup> *Teva Neuroscience, Inc., et al. v. Watson Pharma, Inc., et al.*, Civil Action No. 10-5078;<sup>5</sup> *Duramed Pharms. v. Watson Pharma, Inc.*, Civil Action No. 07-5941;<sup>6</sup> *Hoffman La-Roche Inc., et al. v. Cobalt Pharms. Inc., et al.*, Civil Action No. 07-4539;<sup>7</sup> (v) Actavis Pharma has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in at least one prior New Jersey action (*Auxilium Pharms., Inc., et al. v. Watson Labs., Inc., et al.*, Civil Action No. 12-3084); and (vi) Actavis Pharma is registered as a manufacturer and wholesale drug distributor in the State of New Jersey under the registration number 5003854.

17. This Court has personal jurisdiction over Watson Laboratories because, *inter alia*: (i) Watson Laboratories' principal place of business is located in New Jersey; (ii) Watson Laboratories, together with Actavis, Watson Florida, Actavis Pharma, and Anda, has committed, induced, or contributed to acts of patent infringement in New Jersey; (iii) Watson Laboratories is doing business in New Jersey and maintains continuous and systematic contacts with this judicial district; (iv) Watson Laboratories has submitted to the jurisdiction of this Court in at least eleven

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

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

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

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

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

prior New Jersey actions (*Supernus Pharms., Inc. v. Actavis, Inc., et al.*, Civil Action No. 13-4740; *Auxilium Pharms., Inc., et al. v. Watson Labs., Inc., et al.*, Civil Action No. 12-3084; *Warner Chilcott Co. v. Watson Labs., Inc.*, Civil Action No. 12-2928; *Janssen Pharms., Inc., et al. v. Watson Labs., Inc., et al.*, Civil Action No. 08-5103; *Duramed Pharms. v. Watson Pharma, Inc, et al.*, Civil Action No. 07-5941; *Hoffman La-Roche Inc., et al. v. Cobalt Pharms. Inc., et al.*, Civil Action No. 07-4539; *Sanofi-Aventis, et al. v. Watson Pharms., Inc., et al.*, Civil Action No. 07-443; *Warner Chilcott Co. v. Watson Pharms., Inc., et al.*, Civil Action No. 07-4697; *Novartis Corp., et al. v. Watson Labs., Inc., et al.*, Civil Action No. 06-1130; *Schering Corp. v. Zydus Pharms., USA, Inc., et al.*, Civil Action No. 06-4715; *Warner Chilcott Co. v. Watson Pharms., Inc., et al.*, Civil Action No. 06-3491); and (v) Watson Laboratories has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in at least one prior New Jersey action (*Auxilium Pharms., Inc., et al. v. Watson Labs., Inc., et al.*, Civil Action No. 12-3084).

18. This Court has personal jurisdiction over Watson Florida because, *inter alia*: (i) Watson Florida, together with Actavis, Watson Laboratories, Actavis Pharma, and Anda, has committed, induced, or contributed to acts of patent infringement in New Jersey; (ii) Watson Florida directly or indirectly through agents, including Actavis, Actavis Pharma, Watson Laboratories, and/or Anda, regularly does or solicits business in New Jersey and/or derives substantial revenue from services or things used or consumed in New Jersey; (iii) Watson Florida is doing business in New Jersey and maintains continuous and systematic contacts with this judicial district; (iv) Watson Florida has submitted to the jurisdiction of this Court in at least seven prior New Jersey actions (*Supernus Pharms., Inc. v. Actavis, Inc., et al.*, Civil Action No. 13-4740; *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); and (v) Watson Florida has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in at least two prior New Jersey actions (*Supernus Pharms., Inc. v. Actavis, Inc., et al.*, Civil Action No. 13-4740; *Astrazeneca AB, et al. v. Watson Labs., Inc. – Florida, et al.*, Civil Action No. 13-1669).

19. This Court has personal jurisdiction over Anda because, *inter alia*: (i) Anda, together with Actavis, Watson Laboratories, Actavis Pharma, and Watson Florida, has committed, induced, or contributed to acts of patent infringement in New Jersey; (ii) Anda directly or indirectly through agents, including Actavis, Actavis Pharma, Watson Laboratories, and/or Watson Florida, regularly does or solicits business in New Jersey and/or derives substantial revenue from services or things used or consumed in New Jersey; (iii) Anda transacts business, performs work, and contracts to supply services or products in New Jersey; (iv) Anda is doing business in New Jersey and maintains continuous and systematic contacts with this judicial district; (v) Anda has submitted to the jurisdiction of this Court in at least one prior New Jersey action (*Supernus Pharms., Inc. v. Actavis, Inc., et al.*, Civil Action No. 13-4740); (vi) Anda has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in at least one prior New Jersey action (*Celgene Corp., et al. v. Natco Pharma Ltd., et al.*, Civil Action No. 10-5197); and (vii) Anda is registered as a manufacturer and wholesale drug distributor in the State of New Jersey under the registration number 5003858.



20. Actavis' Form 10-K, filed with the U.S. Securities and Exchange Commission on February 28, 2013, states that its research and development efforts relating to generic products are being conducted in, *inter alia*, Elizabeth, New Jersey.

21. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

### **FACTS AS TO ALL COUNTS**

22. Supernus owns New Drug Application ("NDA") No. 202810, which was approved by the FDA for the manufacture and sale of oxcarbazepine extended-release tablets, 150 mg, 300 mg, and 600 mg, which Supernus markets under the name Oxtellar XR<sup>TM</sup>.

23. Oxtellar XR<sup>TM</sup> is an antiepileptic drug indicated for: (i) adjunctive therapy in the treatment of partial seizures in adults; and (ii) adjunctive therapy in the treatment of partial seizures in children 6 to 17 years of age.

24. The '600 patent, entitled "Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof" was duly and legally issued by the United States Patent and Trademark Office on December 31, 2013, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns, all rights, title, and interest in the '600 patent.

25. Pursuant to 21 U.S.C. § 355(b)(1), the '600 patent is listed in FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "*Orange Book*") as covering Oxtellar XR<sup>TM</sup>. Supernus submitted the '600 patent to FDA to be listed in the *Orange Book* for NDA No. 202810.

26. Upon information and belief, Defendants worked in concert to prepare, submit, and file the Watson ANDA to FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)), seeking approval to engage in the commercial

manufacture, use, sale, offer for sale, and/or importation of the Watson Product and included a “paragraph IV” certification seeking approval before the expiration of the ’600 patent.

27. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification “include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.” Likewise, 21 C.F.R. § 314.95(c)(6) requires that such a letter include “[a] detailed statement of the factual and legal basis of the applicant’s opinion that the patent is not valid, unenforceable, or will not be infringed.” The detailed statement must include “(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed” and “(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.” 21 C.F.R. § 314.95(c)(6)(i)-(ii).

28. On or about February 19, 2014, Watson sent a letter purportedly pursuant to § 505(j)(2)(B)(iv) of the FDCA and 21 C.F.R. § 314.95 regarding the Watson Product and the ’600 patent (the “February 19 Notice Letter”).

29. The February 19 Notice Letter identified Brian N. Anderson, Esq.—counsel for Actavis, Inc.—as the person to whom follow-up correspondence should be addressed.

30. The February 19 Notice Letter does not include any non-infringement contentions unique to claims 2-9, 11-12, 14, or 16-22 of the ’600 patent.

**FIRST COUNT**  
**(Defendants’ Infringement of the ’600 Patent)**

1. Plaintiff repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

2. Upon information and belief, Defendants seek FDA approval for the manufacture, use, marketing, sale, and/or distribution of the Watson Product.

3. Upon information and belief, Defendants included a paragraph IV certification to the '600 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Watson's Product before the expiration of the '600 patent.

4. Upon information and belief, Defendants will commercially manufacture, use, sell, offer for sale, and/or import Watson's Product upon, or in anticipation of, FDA approval.

5. The submission and filing of ANDA No. 205444 with a paragraph IV certification to the '600 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Watson Product before the expiration of the '600 patent is an act of infringement by Defendants of one or more claims of the '600 patent under 35 U.S.C. § 271(e)(2)(A).

6. Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Watson Product that is the subject of ANDA No. 205444 will infringe one or more claims of the '600 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

7. Defendants' infringement of the '600 patent has caused and will cause Supernus to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '600 patent.

8. As of the date of the February 19 Notice Letter, Defendants were aware of the existence of the '600 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that

they would not be liable for infringement of the '600 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff respectfully requests the following relief:

- i. A Judgment declaring that the '600 patent is valid and enforceable;
- ii. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 205444 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Watson's Product was an act of infringement of the '600 patent by Defendants;
- iii. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), 35 U.S.C. § 271(a), 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation into the United States of Watson's Product prior to the expiration of the '600 patent, including any regulatory extensions, will constitute an act of infringement by Defendants;
- iv. An Order that, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and 283, the effective date of any approval of Watson's Product shall be no earlier than the date on which the '600 patent expires, including any regulatory extensions;
- v. A Judgment pursuant to 35 U.S.C. §§ 271(e)(4)(B), 281, and 283, preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees, and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer for sale, and/or

importation in the United States of the product that is the subject of ANDA No. 205444 until the expiration of the '600 patent, including any regulatory extensions;

- vi. A Judgment awarding Supernus damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 205444 that infringes the '600 patent;
- vii. A Judgment declaring that infringement of the '600 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 205444 that infringes the '600 patent;
- viii. A Judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding Supernus its attorneys' fees and costs;
- ix. Such other and further relief as this Court may deem just and proper.

Dated: March 28, 2014

Respectfully submitted,

By: s/ Charles M. Lizza

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