IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS, INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA, Plaintiffs, v. **WATSON PHARMACEUTICALS, INC., WATSON PHARMA, INC., WATSON LABORATORIES, INC. (DE), WATSON LABORATORIES, INC. (NV), WATSON LABORATORIES, INC. (NY), WATSON LABORATORIES, INC. (CT), and WATSON LABORATORIES, INC. - FLORIDA,** Defendants.	Civil Action No.: _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha, for their Complaint against Watson Pharmaceuticals, Inc., Watson Pharma, Inc., Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (NY), Watson Laboratories, Inc. (CT), and Watson Laboratories, Inc. - Florida, hereby state as follows:

Nature of the Action

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and in particular under 35 U.S.C. § 271(e). This action relates to a New Drug Application ("NDA") filed by or for the benefit of Watson Pharmaceuticals, Inc., Watson Pharma, Inc., Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (NY), Watson Laboratories, Inc. (CT), and Watson Laboratories, Inc. - Florida with the United States Food and Drug Administration

("FDA") for approval to market versions of Plaintiffs' highly successful CRESTOR® pharmaceutical products that are sold in the United States.

Parties

2. Plaintiff AstraZeneca UK Limited ("AZ UK") is a corporation operating and existing under the laws of the United Kingdom, with its principal place of business at 2 Kingdom Street, London, W2 6BD, England.

3. Plaintiff IPR Pharmaceuticals, Inc. ("IPR") is a corporation operating and existing under the laws of Puerto Rico, with its principal place of business at Carr 188 Lote 17, San Isidro Industrial Park, Canovanas, Puerto Rico 00729.

4. Plaintiff Shionogi Seiyaku Kabushiki Kaisha ("Shionogi") is a corporation operating and existing under the laws of Japan, with its principal place of business at 1-8, Doshomachi 3- chome, Chuo-ku, Osaka 541-0045 Japan.

5. On information and belief, Defendant Watson Pharma, Inc. ("Watson Pharma") is a corporation operating and existing under the laws of Delaware, with its principal place of business at 360 Mount Kemble Avenue, Morristown, NJ 07960.

6. On information and belief, Defendant Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals") is a corporation operating and existing under the laws of Nevada, with its principal place of business at 311 Bonnie Circle, Corona, CA 92880. On information and belief, Watson Pharmaceuticals also maintains sales, marketing, and administration offices at 360 Mount Kemble Avenue, Morristown, NJ 07960.

7. On information and belief, Defendant Watson Laboratories, Inc. (DE) ("Watson Labs (DE)") is a corporation operating under the name Watson Laboratories, Inc., and is operating and existing under the laws of Delaware, with its principal place of business at 311 Bonnie Circle, Corona, CA 92880.

8. On information and belief, Defendant Watson Laboratories, Inc. (NV) ("Watson Labs (NV)") is a corporation also operating under the name Watson Laboratories, Inc., and is operating and existing under the laws of Nevada, with its principal place of business at 311 Bonnie Circle, Corona, CA 92880.

9. On information and belief, Defendant Watson Laboratories, Inc. (NY) ("Watson Labs (NY)") is a corporation also operating under the name Watson Laboratories, Inc., and is operating and existing under the laws of New York, with its principal place of business at 311 Bonnie Circle, Corona, CA 92880.

10. On information and belief, Defendant Watson Laboratories, Inc. (CT) ("Watson Labs (CT)") is a corporation also operating under the name Watson Laboratories, Inc., and is operating and existing under the laws of Connecticut, with its principal place of business at 131 West St., Danbury, CT 06810, and official corporate mailing address at 311 Bonnie Circle, Corona, CA 92880.

11. On information and belief, Defendant Watson Laboratories, Inc. - Florida ("Watson Labs (FL)") is a corporation also operating under the name Watson Laboratories, Inc., and is operating and existing under the laws of Florida, with its principal place of business at 4955 Orange Dr., Davie, FL 33314, and official corporate mailing address at 311 Bonnie Circle, Corona, CA 92880.

12. On information and belief, Watson Pharma is a wholly-owned subsidiary of Watson Pharmaceuticals, Inc., and has some officers and directors in common with Watson Pharmaceuticals, Watson Labs (DE), Watson Labs (NV), Watson Labs (NY), Watson Labs (CT), and Watson Labs (FL).

13. On information and belief, Watson Labs (DE), Watson Labs (NV), Watson Labs (NY), Watson Labs (CT), and Watson Labs (FL) are wholly-owned subsidiaries of Watson Pharmaceuticals, and each has some officers and directors in common with Watson Pharmaceuticals and Watson Pharma.

Background

14. IPR is the holder of approved NDA No. 021366 for CRESTOR® Tablets, in 5 mg, 10 mg, 20 mg, and 40 mg dosage forms, containing rosuvastatin calcium.

15. CRESTOR® (rosuvastatin calcium) is a prescription drug belonging to a group of medicines (called statins) that are used to treat high cholesterol. CRESTOR® is one of the most effective lipid-lowering statins available. Over 21 million patients have been prescribed CRESTOR®, and over 281 million prescriptions have been written worldwide for CRESTOR®. Rosuvastatin calcium is the active ingredient in CRESTOR®.

16. Plaintiffs, themselves and through other AstraZeneca entities, manufacture, market, promote, educate the public and physicians about, and conduct research and development on existing and new indications for CRESTOR® Tablets. Plaintiffs financially benefit from sales of CRESTOR® Tablets in the United States.

17. By letter dated September 28, 2010, an entity named Watson Laboratories, Inc. notified Plaintiffs that it had filed with the FDA NDA No. 202172 seeking FDA approval to market in the United States rosuvastatin zinc tablets in 5 mg, 10 mg, 20 mg, and 40 mg dosage strengths ("Watson Rosuvastatin Tablets"), and that it was providing information to Plaintiffs pursuant to 21 U.S.C. § 355(b)(3).

18. The notice letter is on letterhead bearing at the top Watson Pharmaceutical's logo, and at the bottom the name and address Watson Laboratories, Inc., 360 Mount Kemble Avenue, Morristown, NJ 07960. It was signed by Joyce DelGaudio, with the title Executive Director,

Regulatory Affairs, Watson Laboratories, Inc. On information and belief, Ms. DelGaudio also holds the position Executive Director, Regulatory Affairs, Watson Pharmaceuticals, Inc. The letter referred Plaintiffs to an in-house counsel, Matthew O. Brady, at "Watson, 311 Bonnie Circle, Corona, CA 92880." On information and belief, Mr. Brady holds the position Senior IP Counsel at Watson Pharmaceuticals, Inc.

19. On October 19 and 20, 2010, Plaintiffs asked Mr. Brady to identify which of the multiple subsidiaries of Watson Pharmaceuticals that are named Watson Laboratories, Inc. submitted NDA No. 202172 to the FDA. As of the time of filing this Complaint, Plaintiffs have not received that information.

20. On information and belief, Watson Labs (DE), Watson Labs (NV), Watson Labs (NY), Watson Labs (CT), or Watson Labs (FL) (collectively or individually, "Watson Labs") filed with the FDA, in Rockville, Maryland, NDA No. 202172 under 21 U.S.C. § 355(b)(2) to obtain FDA approval for the commercial manufacture, use, importation, offer for sale, and sale of the Watson Rosuvastatin Tablets in the United States. On information and belief, the Watson Rosuvastatin Tablets contain a zinc salt form of rosuvastatin and are versions of Plaintiffs' CRESTOR® Tablets in 5 mg, 10 mg, 20 mg, and 40 mg dosage strengths. On information and belief, NDA No. 202172 relies upon safety and efficacy investigations of Plaintiffs' CRESTOR® Tablets.

Jurisdiction and Venue

21. Subject matter jurisdiction is proper under 28 U.S.C. § 1331 and 1338(a).

22. On information and belief, Watson Pharmaceuticals, both directly and through its wholly-owned subsidiaries, including Watson Pharma and Watson Labs, is engaged in the development, marketing, sale, and distribution of generic and brand pharmaceutical products throughout the United States, including Delaware.

23. On information and belief, Watson Pharmaceuticals organizes its operations by operating segment, including the Global Generics segment. On information and belief, the Global Generics segment is responsible for preparing, developing, and submitting NDAs and Abbreviated New Drug Applications ("ANDA") for generic counterparts to brand pharmaceutical products. On information and belief, the Global Generics segment relies upon contributions from Watson Pharmaceuticals, Watson Pharma, and Watson Labs in preparing, developing, and submitting NDAs and ANDAs, and in developing, manufacturing, marketing, and selling generic drug products. On information and belief, the Global Generic segment's products for the United States, including Delaware, are manufactured by Watson Labs and marketed and sold by Watson Pharma.

24. On information and belief, Watson Pharmaceuticals and Watson Labs have regularly sold products in Delaware, and elsewhere in the United States, through Watson Pharma. On information and belief, they have regularly done or solicited business, or engaged in a persistent course of conduct, in Delaware.

25. Personal jurisdiction over Watson Pharmaceuticals, Watson Pharma, and Watson Labs is proper because of, *inter alia*, their regular marketing and sales activities in Delaware, including the substantial, continuous, and systematic distribution and sales of generic drug products to residents of Delaware. They purposefully avail themselves of the privilege of selling Watson Pharmaceuticals' Global Generic segment's generic products in Delaware and can therefore reasonably expect to be subject to jurisdiction in Courts in Delaware.

26. In addition, personal jurisdiction over Watson Pharma and Watson Labs (DE) is proper, because each is incorporated in Delaware and purposely avails itself of the privilege of doing business in Delaware.

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

Infringement of United States Patent No. RE37,314 Under 35 U.S.C. § 271(e)(2)

28. Plaintiffs incorporate by reference paragraphs 1-27 of this Complaint as if fully set forth herein.

29. United States Patent No. RE37,314 ("the '314 patent"), entitled "Pyrimidine Derivatives," was duly and legally reissued by the United States Patent and Trademark Office on August 7, 2001. Plaintiffs hold all substantial rights in the '314 patent and have the right to sue for infringement thereof. A true and correct copy of the '314 patent is attached as Exhibit A.

30. Shionogi owns the '314 patent by assignment from the inventors. AZ UK is Shionogi's exclusive licensee under the '314 patent, and IPR is AZ UK's exclusive sublicensee under the '314 patent.

31. On information and belief, Watson Pharmaceuticals, Watson Pharma, and Watson Labs submitted to the FDA NDA No. 202172 in order to obtain approval to market the Watson Rosuvastatin Tablets in the United States before the expiration of the '314 patent. On information and belief, they submitted to the FDA, pursuant to 21 U.S.C. § 355(b)(2)(A)(iv), a certification alleging that the claims of the '314 patent are not infringed by the manufacture, use, or sale of the Watson Rosuvastatin Tablets.

32. Under 35 U.S.C. § 27l(e)(2)(A), the submission by Watson Pharmaceuticals, Watson Pharma, and Watson Labs to the FDA of NDA No. 202172 to obtain approval for the commercial manufacture, use, or sale of the Watson Rosuvastatin Tablets before the expiration of the '314 patent constitutes infringement of one or more claims of the '314 patent, either literally or under the doctrine of equivalents.

33. On information and belief, Watson Pharmaceuticals, Watson Pharma, and Watson Labs have acted in concert, actively supporting, participating in, and encouraging the submission

to the FDA of NDA No. 202172. On information and belief, they did so in preparation to market and sell in the United States, including Delaware, the Watson Rosuvastatin Tablets. On information and belief, they intend to market and sell the Watson Rosuvastatin Tablets in the United States before the expiration of the '314 patent and any additional periods of exclusivity, if the FDA approves NDA No. 202172 before then.

34. On information and belief, when NDA No. 202172 was submitted to the FDA, Watson Pharmaceuticals, Watson Pharma, and Watson Labs had knowledge of the '314 patent, and knowingly infringed the '314 patent. On information and belief, they submitted NDA No. 202172 to the FDA despite an objectively high likelihood that their actions constitute infringement of a valid patent, and this risk was either known to them, or so obvious that it should have been known to them.

35. On information and belief, Watson Pharmaceuticals', Watson Pharma's, and Watson Labs' refusal to identify the Watson Laboratories, Inc. entity that filed NDA No. 202172 with the FDA, which necessitates the filing of civil actions against multiple defendants in this and various jurisdictions, reflects their intent and willful infringement.

36. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in its favor as follows:

(1) holding that the claims of the '314 patent are valid and enforceable;

(2) holding that the submission of NDA No. 202172 by Watson Pharmaceuticals and Watson Pharma, and by Watson Labs (DE), Watson Labs (NV), Watson Labs (NY), Watson

Labs (CT), or Watson Labs (FL), infringes one or more claims of the '314 patent under 35 U.S.C. § 271(e)(2)(A);

(3) ordering, pursuant to 35 U. S.C. § 271(e)(4)(A), that the effective date of any FDA approval of the Watson Rosuvastatin Tablets shall be no earlier than the expiration date of the '314 patent and any additional periods of exclusivity;

(4) enjoining Watson Pharmaceuticals, Watson Pharma, Watson Labs (DE), Watson Labs (NV), Watson Labs (NY), Watson Labs (CT), and Watson Labs (FL), and all persons acting in concert with any of them, from commercially manufacturing, using, offering for sale, or selling the Watson Rosuvastatin Tablets within the United States or importing into the United States the Watson Rosuvastatin Tablets prior to the expiration of the '314 patent and any additional periods of exclusivity;

(5) declaring this to be an exceptional case and awarding Plaintiffs their attorney fees under 35 U.S.C. § 285;

(6) awarding Plaintiffs their costs and expenses in this action; and

(7) awarding Plaintiffs any further and additional relief as this Court deems just and proper.

	Respectfully Submitted: */s/ Mary W. Bourke* _____
Ford F. Farabow Charles E. Lipsey Kenneth M. Frankel York M. Faulkner FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P. 901 New York Avenue, N.W. Washington, D.C. 20001 Telephone: (202) 408-4000 Facsimile: (202) 408-4400	Mary W. Bourke (#2356) CONNOLLY BOVE LODGE & HUTZ LLP 1007 N. Orange Street P.O. Box 2207 Wilmington, DE 19899 Telephone: (302) 658-9141 Facsimile: (302) 658-5614 mbourke@cblh.com *Attorneys for Plaintiffs AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha*
Henry J. Renk FITZPATRICK, CELLA, HARPER & SCINTO 1290 Avenue of the Americas New York, NY 10104-3800 Telephone: (212) 218-2100 Facsimile: (212) 218-2200 *Of Counsel for Plaintiffs AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha*	Thomas A. Stevens (#3039) ASTRAZENECA PHARMACEUTICALS LP 1800 Concord Pike Wilmington, DE 19850-5437 Telephone: (302) 885-5457 Facsimile: (302) 886-8037 *Attorney for Plaintiffs AstraZeneca UK Limited and IPR Pharmaceuticals, Inc.*
Dated: October 26, 2010	