IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICAL COMPANY LTD., a Japanese Corporation, and TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., a Delaware Corporation,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
WATSON LABORATORIES, INC. – FLORIDA, a Florida Corporation, WATSON PHARMA, INC., a Delaware Corporation and WATSON PHARMACEUTICALS, INC., a Nevada Corporation,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Takeda Pharmaceutical Company Ltd. ("TPC") and Takeda Pharmaceuticals North America, Inc. ("TPNA") (collectively "Takeda") for their Complaint against Defendants Watson Laboratories, Inc. – Florida ("Watson Florida"), Watson Pharma, Inc. ("Watson Pharma"), and Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals") (collectively "Watson") hereby allege as follows:

THE PARTIES

1. Plaintiff TPC is a Japanese corporation having a principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka, Japan. Plaintiff TPNA is a wholly owned United States subsidiary of TPC. TPNA is organized and existing under the laws of the State of Delaware, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

2. As part of its business, Takeda is engaged in the business of research, development, and marketing of pharmaceutical products.

3. Upon information and belief, Defendant Watson Pharmaceuticals is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at 311 Bonnie Circle, Corona, California 92880.

4. Upon information and belief, Defendant Watson Florida is a Florida corporation having a place of business at 4955 Orange Drive, Davie, Florida 33314. Upon information and belief, Watson Florida has identified its mailing address as 311 Bonnie Circle, Corona, California 92880.

5. Upon information and belief, Watson Florida was formerly known as Andrx Pharmaceuticals, Inc. Watson Florida is a wholly-owned subsidiary of Andrx Corp., a Delaware corporation that is a wholly-owned subsidiary of Defendant Watson Pharmaceuticals.

6. Upon information and belief, Defendant Watson Pharma is a Delaware corporation having a principal place of business at 360 Mount Kemble Avenue, Morristown, New Jersey 07962.

7. Upon information and belief, Watson Pharma is a wholly-owned subsidiary of Watson Pharmaceuticals.

8. Upon information and belief, Watson Pharmaceuticals sells pharmaceutical products through its wholly-owned subsidiary Watson Pharma. Upon information and belief, Watson Pharma distributes pharmaceutical products throughout the United States including in this judicial district and is the distributor of drugs that Watson Florida manufactures or for which Watson Florida is the named applicant on approved Abbreviated New Drug Applications ("ANDAs").

9. Watson Pharmaceuticals, Watson Florida, and Watson Pharma work in concert with one another and with other direct and indirect subsidiaries of Watson Pharmaceuticals ("Watson subsidiaries") to develop, manufacture, and market pharmaceutical products throughout the United States, including in this judicial district.

JURISDICTION AND VENUE

10. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, and jurisdiction exists under 28 U.S.C. §§ 1331 and 1338(a).

11. This Court has personal jurisdiction over Watson Pharma by virtue of its incorporation in Delaware.

12. This Court has personal jurisdiction over Defendants Watson Pharmaceuticals, Watson Florida, and Watson Pharma, by virtue of the fact that, *inter alia*, they have committed, aided, abetted, contributed to, and/or participated in the commission of the tortious act of patent infringement, or actively induced another to do so, that has led to foreseeable harm and injury to Plaintiff TPNA, a Delaware corporation, and Plaintiff TPC.

13. This Court has personal jurisdiction over Defendants Watson Pharmaceuticals, Watson Florida, and Watson Pharma because, *inter alia*, they, either directly or through an agent, including each other, regularly do or solicit business in Delaware, engage in other persistent courses of conduct in Delaware, and/or derive substantial revenue from services or things used or consumed in Delaware. These activities further demonstrate that Watson Pharmaceuticals, Watson Florida, and Watson Pharma have continuous and systematic contacts with Delaware.

14. Watson Pharmaceuticals, Watson Florida, and Watson Pharma are agents of each other and/or work in concert with respect to the development, regulatory approval,

marketing, sale and distribution of pharmaceutical products, including Watson's drug product Ramelteon Tablets, 8 mg described in ANDA No. 91-610 (defined below).

15. In a letter to Takeda from Watson Florida dated November 12, 2009 ("Watson's Notice Letter"), Watson Florida directed Takeda to send any correspondence or requests for confidential access regarding ANDA No. 91-610 to Mr. Matthew O. Brady, who is registered in the United States Patent and Trademark Office as an attorney at the Legal Department of Watson Pharmaceuticals. Upon information and belief, Watson Pharmaceuticals, at least through its Legal Department, has contributed to ANDA No. 91-610.

16. Watson Pharmaceuticals, through its own actions and the actions of one or more Watson subsidiaries, actively engages in a concerted effort to sell generic products throughout the United States, including in Delaware. Upon information and belief, Watson Pharmaceuticals organizes its operations by division -- Generic, Brand, and Distribution -- and reports its financial results in its Securities and Exchange Commission ("SEC") filings by reference to the divisions. Watson Pharmaceuticals consolidates its financial results with the Watson subsidiaries in its SEC filings at least for 2007 to date and does not provide separate financial reports to the SEC for each Watson subsidiary.

17. Upon information and belief, the Generic Division, which is responsible for developing and submitting ANDAs, as well as manufacturing and marketing generic pharmaceuticals, relies on contributions from Watson Pharmaceuticals, Watson Florida, and Watson Pharma, each of which works in concert with the others to further the aims of the Generic Division. Upon information and belief, Watson Florida submits ANDAs and manufactures Generic Division products. These and other Generic Division products are marketed and sold by Watson Pharma.

18. Upon information and belief, Watson Pharmaceuticals, Watson Florida, and Watson Pharma share common employees, officers, and directors.

19. Upon information and belief, Watson Pharmaceuticals and Watson Pharma share common employees, officers, and directors. Upon information and belief, Watson Florida and Watson Pharma share common employees, officers, and directors.

20. Watson Pharmaceuticals identifies on its website the address of a Watson Pharma facility (360 Mount Kemble Avenue, Morristown, New Jersey) as one of its own locations. Conversely, Watson Florida provided Watson Pharmaceuticals' Corona, California address as its mailing address on its annual report filed with the Secretary of State in Florida in January 2009. Watson Pharmaceuticals also issues press releases on behalf of its subsidiaries, including Watson Florida, and on more than one occasion has claimed actions of its subsidiaries as its own.

21. Watson Pharmaceuticals' website states that its Generic Division has a portfolio of 150 pharmaceutical products, including Watson Florida products, and states that the Generic Division filed 13 new ANDAs and launched 11 new products. In its 2008 Annual Report, Watson Pharmaceuticals explains that "We sell our generic prescription products primarily under the 'Watson Laboratories' and 'Watson Pharma' labels." The ANDAs for the majority of these products in Watson Pharmaceuticals' portfolio are nominally in the name of Watson Florida and another subsidiary, Watson Laboratories, Inc. - Nevada.

22. Upon information and belief, Watson Florida is the named applicant on ANDAs for numerous generic drugs ("Watson Florida ANDAs"), including many that are actively being sold and used in the United States. Drugs manufactured under these ANDAs are sold in Delaware and elsewhere.

23. Upon information and belief, Watson Florida also manufactures at least some of the drugs for which it is the nominal ANDA applicant.

24. Upon information and belief, Watson Pharma, a Delaware corporation, is the distributor of drugs for which Watson Florida is the named applicant in the FDA's Approved Drug Product List. Watson Pharma, acting as the agent of Watson Florida and Watson Pharmaceuticals, markets and sells many, if not all, of these drugs in Delaware. Upon information and belief, Watson Florida and Watson Pharma are parties to one or more contractual agreements for distributing drugs made under Watson Florida ANDAs. Upon information and belief, these agreements are less than arms length.

25. Watson Pharma is licensed to do business in Delaware and, upon information and belief, has sales personnel assigned to cover Delaware for the purpose of marketing and selling Generic Division products, including Watson Florida products.

26. For example, various drugs for which Watson Florida is the named ANDA applicant are distributed by Watson Pharma and are available at various retail pharmacies in Delaware including Walgreens/Happy Harry's and Rite Aid. Upon information and belief, Watson Pharmaceuticals and/or Watson Florida realizes revenue from the distribution of Watson Florida drugs by Watson Pharma, where such distribution results in sales of the drugs in Delaware or to persons in Delaware.

27. In addition, upon information and belief, Watson Florida is a wholly owned subsidiary of Andrx Corp., a Delaware corporation, and several Watson Florida drugs are still manufactured and sold under the Andrx trademark.

28. Upon information and belief, each of Watson Pharmaceuticals, Watson Florida, and Watson Pharma, as part of Watson Pharmaceuticals' Generic Division, will

manufacture, market, and/or sell within the United States Watson's drug product Ramelteon Tablets, 8 mg described in ANDA No. 91-610 if FDA approval is granted.

29. Upon information and belief, if ANDA No. 91-610 is approved, Watson's generic Ramelteon Tablets, 8 mg that infringe the '239 patent (defined below) would be marketed and distributed in Delaware, prescribed by physicians practicing and dispensed by pharmacies located within Delaware, and/or used by persons in Delaware, all of which would have a substantial effect on Delaware.

30. Venue is proper in this Court under 28 U.S.C. §§ 1391(b), (c) and/or (d) and 1400(b).

FACTS PERTINENT TO ALL CLAIMS FOR RELIEF

31. Plaintiff TPC is the record owner of United States Patent No. 6,034,239 ("the '239 patent"), which was duly and legally issued on March 7, 2000, and is titled "Tricyclic Compounds, Their Production and Use." Plaintiff TPNA is an exclusive licensee with respect to the '239 patent. A copy of the '239 patent is attached as Exhibit A.

32. The '239 patent was reexamined by the United States Patent and Trademark Office. An "*Ex Parte* Reexamination Certificate" was issued on May 20, 2008 and is attached to the '239 patent in Exhibit A.

33. Takeda, via Takeda Global Research & Development Center, Inc. ("TGRD") which is a wholly owned subsidiary of TPNA, is the holder of New Drug Application ("NDA") No. 21-782 by which the United States Food and Drug Administration ("FDA") first granted approval for 8 mg ramelteon tablets. The ramelteon tablets described in NDA No. 21-782 are indicated, *inter alia*, for the treatment of insomnia characterized by difficulty with sleep

onset. TPNA markets ramelteon tablets in the United States under the trade name "ROZEREM®."

34. The '239 patent is listed in a publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the "Orange Book") as covering ROZEREM®.

35. On November 6, 2009, Takeda sued Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively "Teva") in this Court alleging that Teva's filing of ANDA No. 91-693 seeking approval to manufacture, use, and sell 8 mg ramelteon tablets in the United States prior to the expiration of the '239 patent infringes that patent. That action was assigned case No. 09-841-SLR and is pending before the Honorable Sue L. Robinson.

36. Upon information and belief, Watson Florida submitted to the FDA ANDA No. 91-610 seeking approval to manufacture, use, and sell 8 mg ramelteon tablets ("the Watson ANDA Product") in the United States prior to the expiration of the '239 patent. Upon information and belief, Watson Florida submitted ANDA No. 91-610 to the FDA on or about July 22, 2009.

37. Upon information and belief, ANDA No. 91-610 included a certification with respect to the '239 patent under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that certain claims in the '239 patent are invalid and/or not infringed.

38. Plaintiffs TPC and TPNA received Watson's Notice Letter, which was dated November 12, 2009, and in which Watson Florida represented that it had filed ANDA No. 91-610 for the Watson ANDA Product, including a certification with respect to the '239 patent, and that it sought approval of the ANDA prior to the expiration of the patent-in-suit. Watson's

Notice Letter was signed by Janet Vaughn, Director, Regulatory Affairs, Watson Laboratories, Inc. - Florida. Upon information and belief, Janet Vaughn has also identified herself as Director, Regulatory Affairs, Watson Pharmaceuticals.

39. Plaintiffs commenced this action within 45 days of the date of delivery of Watson's Notice Letter.

CLAIM FOR RELIEF
INFRINGEMENT BY WATSON OF U.S. PATENT NO. 6,034,239

40. Plaintiffs re-allege paragraphs 1-39 as if fully set forth herein.

41. By seeking approval of its ANDA No. 91-610 to engage in the commercial manufacture, use, or sale of a drug product as claimed in the '239 patent before its expiration, Watson has infringed the '239 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

42. Watson Pharmaceuticals, Watson Florida, and Watson Pharma are jointly and severally liable for any infringement of the '239 patent. This is because, upon information and belief, Watson Pharmaceuticals, Watson Florida, and Watson Pharma actively and knowingly caused to be submitted, assisted with, participated in, contributed to and/or directed the submission of ANDA No. 91-610, the certification to the FDA pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and/or the 21 U.S.C. § 355(j)(2)(B)(iv)(II) allegations included in Watson's Notice Letter. Watson Pharma and Watson Pharmaceuticals' active and knowing participation in, contribution to, aiding, abetting and/or inducement of the submission to the FDA of ANDA No. 91-610, the certification to the FDA pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and/or the 21 U.S.C. § 355(j)(2)(B)(iv)(II) allegations constitutes infringement of the '239 patent under 35 U.S.C. § 271(e)(2)(A).

43. Watson does not dispute in Watson's Notice Letter that the commercial manufacture, use, offer to sell, sale, or import into the United States of the Watson ANDA

Product described in ANDA No. 91-610 would infringe claims 25, 34-36, 40 and 41 of the '239 patent to the extent those claims are not proven invalid.

44. Watson's Notice Letter asserts that claims 25, 34-36, 40 and 41 of the '239 patent are invalid for obviousness under 35 U.S.C. § 103. The only defense to infringement of claims 25, 34-36, and 40 of the '239 patent asserted in Watson's Notice Letter is obviousness under 35 U.S.C. § 103.

45. The 21 U.S.C. § 355(j)(2)(B)(iv)(II) allegations included in Watson's Notice Letter with respect to claims 25, 34-36, 40, and 41 of the '239 patent are baseless assertions that the claims are invalid as obvious under 35 U.S.C. § 103, and that claim 41 is invalid as indefinite under 35 U.S.C. § 112.

46. Watson infringes at least claims 25, 34-36, 40 and 41 of the '239 patent, to the extent Watson does not prove that those claims are invalid.

47. Watson's Notice Letter also alleges, without sufficient support, that certain other claims of the '239 patent are either not infringed and/or are invalid as indefinite under 35 U.S.C. § 112.

48. Takeda is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Watson's ANDA be a date that is not earlier than the expiration of the '239 patent, or any later expiration of any patent term extension or exclusivity for the '239 patent to which Takeda is or becomes entitled.

49. Takeda will be irreparably harmed by Watson's infringing activities unless those activities are enjoined by this Court. Takeda does not have an adequate remedy at law.

50. Upon information and belief, Watson was aware of the existence of the '239 patent before the submission of ANDA No. 91-610 and was aware that the filing of its

ANDA and certification with respect to the '239 patent constituted an act of infringement of that patent. Upon information and belief, before the date of Watson's Notice Letter, Watson was aware of Takeda's lawsuit against Teva for infringement of the '239 patent.

51. This case is an exceptional one, and Takeda is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

Plaintiffs request:

a. An order adjudging and decreeing that Watson has infringed the '239 patent by submitting the aforesaid ANDA;

b. A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) restraining and enjoining said Defendants, officers, agents, attorneys, and employees, and those acting in privity or concert with them, and their successors in interest, from infringing the '239 patent by the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug and/or any other product claimed in the '239 patent.

c. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any approval of ANDA No. 91-610 be a date that is not earlier than the expiration date of the '239 patent, or any later expiration of any patent term extension or exclusivity for the patent to which Plaintiffs are or become entitled;

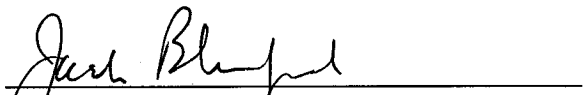
d. That Takeda be awarded monetary relief to the extent Defendants commercially manufacture, use, offer for sale, or sell the Watson's ANDA Product, or any other product that infringes or induces or contributes to the infringement of the '239 patent, within the United States prior to the expiration of that patent, including any later expiration of any patent

term extension or exclusivity for the patent to which Plaintiffs are or become entitled, and that any such monetary relief be awarded to Takeda with prejudgment interest;

e. A declaration that this case is exceptional, and that Plaintiffs are entitled to their reasonable attorney fees pursuant to 35 U.S.C. § 285; and

f. Such other and further relief as the Court may deem just and proper under the circumstances be ordered.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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