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. _____
TEVA PHARMACEUTICALS USA, INC., a Delaware Corporation, and TEVA PHARMACEUTICAL INDUSTRIES LTD., an Israeli Corporation,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Takeda Pharmaceutical Company Ltd. ("TPC") and Takeda Pharmaceuticals North America, Inc. ("TPNA") (collectively "Takeda") for their Complaint against Defendants Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") (collectively "Teva") 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 Teva USA is a Delaware corporation having a principal place of business located at 1090 Horsham Road, North Wales, Pennsylvania 19454 and is engaged in the manufacture and sale of pharmaceutical products. Teva USA is a wholly owned subsidiary and agent of Defendant Teva Ltd.

4. Upon information and belief, Teva Ltd. is an Israeli corporation having a principal place of business at 5 Basel Street, Petah Tiqva 49131, Israel. Upon information and belief, Teva Ltd., itself and/or through its wholly owned subsidiary Teva USA, manufactures generic drugs for sale and use throughout the United States, including in this judicial district.

JURISDICTION AND VENUE

5. 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).

6. Teva USA is subject to personal jurisdiction in this District by virtue of, *inter alia*, its incorporation in Delaware, its conduct of business in this District, its purposeful availment of the rights and benefits under the laws of the State of Delaware, and its substantial and continuing contacts with the State. Teva USA has previously consented to personal jurisdiction in this Court.

7. Upon information and belief, Teva Ltd. regularly transacts business within this District, including but not limited to directing the operations and management of Teva USA, as well as shipping pharmaceutical materials to Teva USA from locations outside the United States for distribution by Teva USA within the United States generally, and within this District specifically.

8. Upon information and belief, Teva USA acts as an agent of Teva Ltd. with respect to the acts complained of herein.

9. Upon information and belief, the acts of Teva USA complained of herein were done at the direction of, with the authorization of, with the cooperation, participation, and/or assistance of, and/or, in part, for the benefit of Teva Ltd.

10. Upon information and belief, Teva Ltd. directed Teva USA to perform the acts complained of herein, in whole or in part, to attempt to shield itself from liability for patent infringement based upon those acts.

11. Teva USA's acts and contacts with this District, as an agent of Teva Ltd., are attributable to Teva Ltd. for jurisdictional purposes.

12. Teva Ltd. is subject to personal jurisdiction in this District by virtue of, *inter alia*, its incorporation of Teva USA in Delaware, its conduct of business in this District, its purposeful availment of the rights and benefits under the laws of the State of Delaware, and/or its substantial and continuing contacts with the State. Teva Ltd. has previously consented to personal jurisdiction in this Court.

13. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth above and below and for other reasons that will be presented to the Court if such jurisdiction were to be challenged.

14. 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

15. 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.

16. 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.

17. 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®."

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

19. Upon information and belief, Defendant Teva Ltd. submitted to the FDA Drug Master File ("DMF") No. 22-882 on or about June 22, 2009 directed to "ramelteon as manufactured in Beer Sheva, Israel."

20. Upon information and belief, Teva USA submitted to the FDA Abbreviated New Drug Application ("ANDA") No. 91-693 seeking approval to manufacture, use, and sell 8 mg ramelteon tablets ("the Teva ANDA Product") in the United States prior to the expiration of the '239 patent. Upon information and belief, Teva USA submitted ANDA No. 91-693 to the FDA on or about July 22, 2009.

21. Upon information and belief, ANDA No. 91-693 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.

22. Plaintiff TPC and TGRD received a letter from Teva USA ("Teva's Notice Letter"), which was dated October 7, 2009, in which Teva USA represented that it had filed ANDA No. 91-693 for the Teva 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.

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

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

24. Plaintiffs re-allege paragraphs 1-23 as if fully set forth herein.

25. By seeking approval of its ANDA No. 91-693 to engage in the commercial manufacture, use, or sale of a drug product as claimed in the '239 patent before its expiration, Teva has infringed the '239 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

26. Teva USA and Teva Ltd. are jointly and severally liable for any infringement of the '239 patent. This is because, upon information and belief, Teva USA and Teva Ltd. actively and knowingly caused to be submitted, assisted with, participated in, contributed to and/or directed the submission of ANDA No. 91-693, 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 Teva's Notice Letter. Teva Ltd.'s active and knowing participation in, contribution to, aiding, abetting and/or inducement of the submission to the FDA of ANDA No. 91-693, 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).

27. Teva does not dispute in Teva's Notice Letter that the commercial manufacture, use, offer to sell, sale, or import into the United States of the Teva ANDA Product described in ANDA No. 91-693 would infringe claims 25 and 34-41 of the '239 patent, to the extent those claims are not proven invalid.

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

29. The 21 U.S.C. § 355(j)(2)(B)(iv)(II) allegations included in Teva's Notice Letter with respect to claims 25 and 34-41 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.

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

31. Teva'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.

32. 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 Teva'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.

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

34. Upon information and belief, Teva was aware of the existence of the '239 patent before the submission of ANDA No. 91-693 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.

35. 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 Teva 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 Defendants, their 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. 91-693 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 Teva'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

Jack B. Blumenfeld (#1014)
Rodger D. Smith II (#3778)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19801
(302) 658-9200
jblumenfeld@mnat.com
rsmith@mnat.com

Attorneys for Plaintiffs
Takeda Pharmaceutical Company Ltd. and
Takeda Pharmaceuticals North America, Inc.

OF COUNSEL:

Bruce M. Wexler
Joseph M. O'Malley, Jr.
Gary Ji
Charles Minkoff
PAUL, HASTINGS, JANOFSKY & WALKER LLP
75 East 55th Street
New York, NY 10022
(212) 318-6000

November 6, 2009