IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KING PHARMACEUTICALS, INC. and MERIDIAN MEDICAL TECHNOLOGIES, INC.,	)	
Plaintiffs,	)	Civil Action No. _____
v.	)	
TEVA PARENTERAL MEDICINES, INC., and TEVA PHARMACEUTICALS USA, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs King Pharmaceuticals, Inc. ("King Pharmaceuticals") and Meridian Medical Technologies, Inc. ("Meridian") (collectively, "Plaintiffs") bring this action for patent infringement against Defendants Teva Parenteral Medicines, Inc. ("TPM") and Teva Pharmaceuticals USA, Inc. ("Teva USA"), (collectively, "Defendants" or "Teva"). Plaintiffs allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement under the patent laws of the United States, Title 35, United States Code, arising out of Defendant TPM's filing of Abbreviated New Drug Application ("ANDA") No. 90-589 with the United States Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Plaintiff Meridian's highly successful EpiPen® Auto-Injector prior to the expiration of U.S. Patent No. 7,449,012 B2, which expires on September 11, 2025.

THE PARTIES

2. Plaintiff King Pharmaceuticals is a Tennessee corporation with its principal place of business at 501 Fifth Street, Bristol, Tennessee 37620. King Pharmaceuticals is in the business of developing, manufacturing, and bringing innovative medicines and technologies to market, primarily in specialty-driven markets including neuroscience, hospital and acute care medicines.

3. Plaintiff Meridian is a Delaware corporation with its principal place of business at 10240 Old Columbia Road, Columbia, Maryland 21046. Meridian is a wholly-owned subsidiary of King Pharmaceuticals.

4. Meridian is the holder of approved New Drug Application No. 019-430, which has the proprietary name EpiPen® (epinephrine) Auto-Injector 0.3/0.15 mg ("EpiPen® Auto-Injector"). On July 17, 2009, as required by the Federal Food, Drug, and Cosmetic Act and FDA regulations, Meridian submitted information concerning the '012 patent for listing in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, a publication that is often referred to as the "Orange Book." Meridian developed and manufactures the EpiPen® Auto-Injector, an easy-to-use, disposable drug delivery system featuring spring activation and a concealed needle. The EpiPen® Auto-Injector is sold throughout the United States and worldwide.

5. Upon information and belief, Defendant TPM is a Delaware corporation with its principal place of business at 19 Hughes, Irvine, California 92618. Upon information and belief, TPM is a wholly-owned and directly controlled subsidiary of Defendant Teva USA. Upon information and belief, TPM acts as an agent of Defendant Teva USA and develops and markets

generic injectable drug products for sale and use throughout the United States, including this judicial district.

6. Upon information and belief, Defendant Teva USA is a Delaware corporation with its principal place of business at 1090 Harsham Road, North Wales, Pennsylvania 19454. Upon information and belief, Teva USA markets a wide range of generic drug products and regularly conducts business throughout the United States, including in the State of Delaware. Teva USA specifically markets injectable drug products through, and in connection with, TPM, its wholly-owned subsidiary.

7. Upon information and belief, TPM's preparation and submission of ANDA No. No. 90-589 was completed in collaboration with, and oversight by, Teva USA and Teva Ltd.

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States of America. This court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. This Court has personal jurisdiction over TPM and Teva USA because, among other things, each is a Delaware corporation. By virtue of their incorporation under Delaware law, TPM and Teva USA have submitted themselves to the personal jurisdiction of the courts in Delaware.

10. This Court also has personal jurisdiction over the Defendants by virtue of the fact that, among other things, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Plaintiffs, which manufacture numerous drugs for sale and use throughout the United States, including this judicial district. This Court has personal jurisdiction

over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

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

BACKGROUND

12. The EpiPen® Auto-Injector is designed for self-administration of epinephrine in acute allergic emergencies (anaphylaxis), by providing a rapid, convenient dose of epinephrine for individuals needing protection from potentially fatal allergic reactions.

13. Meridian developed and manufactures the EpiPen® Auto-Injector pursuant to New Drug Application No. 019-430, which was approved by the FDA.

14. United States Patent No. 7,449,012 B2 ("the '012 patent"), entitled "Automatic Injector" was duly and legally issued by the United States Patent and Trademark Office on November 11, 2008. The '012 patent, owned by Meridian, will expire on September 11, 2025.

15. The EpiPen® Auto-Injector is covered by one or more claims of the '012 patent, and as such, the '012 patent was listed in connection with the EpiPen® Auto-Injector in the FDA's Orange Book.

16. Upon information and belief, TPM submitted ANDA No. 90-589 under 21 U.S.C. § 355(j)(2) in order to obtain FDA approval to engage in the commercial manufacture, use, and/or sale of a generic version of the EpiPen® Auto-Injector prior to the expiration of Meridian's '012 patent.

17. By letter dated July 20, 2009, TPM, notified Plaintiffs that TPM submitted ANDA 90-589 concerning its proposed drug product epinephrine injectable, intramuscular ("Teva's ANDA product") as required by § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act ("FDC Act"). *See* 21 U.S.C. § 355(j)(2)(B)(ii).

18. TPM's July 20 letter further notified Plaintiffs that TPM had filed with the FDA, pursuant to § 505(j)(2)(A)(vii)(IV), a certification with respect to the '012 patent ("Paragraph IV certification"), alleging, along with the letter, that the '012 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale of Teva's ANDA product.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 7,449,012 B2

19. Plaintiffs reallege and incorporate by reference paragraphs 1-18, above.

20. Meridian is the owner by assignment of the '012 patent and has the right to sue for infringement thereof. A true and correct copy of the '012 patent is attached as Exhibit A.

21. Upon information and belief, Teva's ANDA product, when offered for sale, sold, and/or imported, and then used as directed, would be used in a manner that would directly infringe one or more of the claims of the '012 patent.

22. Upon information and belief, TPM's submission of ANDA No. 90-589 seeking approval for the commercial manufacture, use, offer for sale, and/or sale of Teva's ANDA product before the expiration of the '012 patent constitutes an act of infringement of one or more claims of the '012 patent under 35 U.S.C. § 271(e)(2)(A).

23. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Teva's ANDA product would infringe one or more claims of the '012 patent.

24. Upon information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA product, with its proposed labeling, immediately and imminently upon approval of ANDA No. 90-589.

25. Upon information and belief, immediately upon approval of ANDA No. 90-589, Teva will infringe the '012 patent by making, using, offering to sell, selling, and/or importing Teva's ANDA product in the United States, and by actively inducing and contributing to infringement by others under 35 U.S.C. §§ 271(b) and (c), unless this Court orders that the effective date of any FDA approval of ANDA No. 90-589 shall be no earlier than the expiration date of the '012 patent.

26. Upon information and belief, the use of Teva's ANDA product constitutes a material part of at least one or more claims of the '012 patent; Teva knows that its product is especially made or adapted for use in a manner infringing at least one or more claims of the '012 patent; and Teva's ANDA product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

27. Upon information and belief, the offering to sell, sale, and/or importation of Teva's ANDA product would contributorily infringe one or more claims of the '012 patent.

28. Upon information and belief, Teva had knowledge of the '012 patent and, by its promotional activities and package insert for Teva's ANDA product, knows or should know that it will actively aid and abet another's direct infringement of one or more claims of the '012 patent.

29. Upon information and belief, the offering to sell, sale, and/or importation of Teva's ANDA product would actively induce infringement of one or more claims of the '012 patent.

30. Unless Teva is enjoined from infringing the '012 patent, actively inducing infringement of the '012 patent, and/or contributing to the infringement by others of the '012

patent, Plaintiffs King Pharmaceuticals and Meridian will be substantially and irreparably harmed. Plaintiffs have no adequate remedy at law.

COUNT II
DECLARATORY JUDGMENT

31. Plaintiffs reallege and incorporate by reference paragraphs 1-30, above.

32. Upon information and belief, if ANDA No. 90-589 is approved, Teva's ANDA product will be distributed in the United States by or through TPM and/or Teva USA and their affiliates.

33. Upon information and belief, Defendants know that patients will use Teva's ANDA product in accordance with the labeling sought by ANDA No. 90-589 and Defendants will therefore infringe one or more claims of the '012 patent.

34. Upon information and belief, Defendants plan to begin marketing, selling, and offering to sell Teva's ANDA product immediately after the FDA approves ANDA No. 90-589. Such conduct will constitute infringement of one or more claims of the '012 patent under 35 U.S.C. § 271.

35. Upon information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Teva's ANDA product complained of herein will begin immediately after the FDA approves ANDA No. 90-589.

36. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs King Pharmaceuticals and Meridian, and Defendants TPM and Teva USA, concerning liability for the infringement of the '012 patent.

37. Plaintiffs Meridian and King Pharmaceuticals will be substantially and irreparably harmed by Teva's infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(1) a declaratory judgment that, under 35 U.S.C. § 271(e)(2)(A), TPM's submission to the FDA of ANDA No. 90-589 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Teva's ANDA product before the expiration of the '012 patent was an act of infringement of one or more claims of the '012 patent;

(2) a declaratory judgment that Teva's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Teva's ANDA product would constitute infringement of one or more claims of the '012 patent;

(3) an order that the effective date of any FDA approval of Teva's ANDA product shall be no earlier than the expiration of the '012 patent, in accordance with 35 U.S.C. § 271(e)(4)(A);

(4) a permanent injunction enjoining Teva, its affiliates and subsidiaries, and all persons and entities acting in concert with Teva from commercially manufacturing, using, offering for sale, or selling Teva's ANDA product within the United States, or importing Teva's ANDA product into the United States, until the expiration of the '012 patent, in accordance with 35 U.S.C. § 271(e)(4)(B);

(5) an award of damages or other relief if Teva engages in the commercial manufacture, use, offer to sell, sale, marketing, distribution, and/or importation of Teva's ANDA product, or any product that infringes the '012 patent, prior to the expiration of the '012 patent, in accordance with 35 U.S.C. § 271(e)(4)(C);

(6) a declaration that this is an exceptional case, and an award of attorneys' fees to Plaintiffs, in accordance with 35 U.S.C. § 285;

(7) an award to Plaintiffs of their costs and expenses in this action; and

(8) such further and additional relief as this Court deems just and proper.

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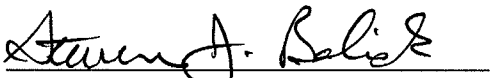

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Date: August 28, 2009