IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

KING PHARMACEUTICALS, INC. and MERIDIAN MEDICAL TECHNOLOGIES, INC.,	)	
Plaintiffs,	)	Civil Action No. _____
v.	)	
INTELLIJECT, INC.,	)	
Defendant.	)	

KING PHARMACEUTICALS, INC. AND
MERIDIAN MEDICAL TECHNOLOGIES, INC.'S ORIGINAL COMPLAINT

Plaintiffs King Pharmaceuticals, Inc. ("King Pharmaceuticals") and Meridian Medical Technologies, Inc. ("Meridian") (collectively, "Plaintiffs") bring this action for patent infringement against Defendant Intelliject, Inc. ("Intelliject" or "Defendant"). Plaintiffs allege for their Complaint 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. This action arises out of Defendant Intelliject's filing of New Drug Application ("NDA") No. 201739 with the United States Food and Drug Administration ("FDA"). Defendant's NDA seeks approval to manufacture and sell an epinephrine auto-injector product prior to the September 11, 2025 expiration of U.S. Patent No. 7,794,432 B2 (the "'432 Patent").

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. 019430 ("Meridian's NDA"). Pursuant to this NDA, Meridian developed, manufactures and markets products with the proprietary names EpiPen® Auto-Injector and EpiPen Jr.® Auto-Injector, 0.3 mg and 0.15 mg respectively, (collectively "EpiPen® Auto-Injector"). The EpiPen® Auto-Injector is an easy-to-use, disposable drug delivery system sold throughout the United States and worldwide.

5. In connection with Meridian's NDA, Meridian submitted information concerning U.S. Patent No. 7,449,012 B2 (the "'012 Patent") and the '432 Patent for listing in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") as required by the Federal Food, Drug, and Cosmetic Act ("FFDCA") and FDA regulations. Meridian submitted the '012 Patent on July 17, 2009 and the '432 Patent on September 15, 2010.

6. Defendant Intelliject is a Delaware corporation with its principal place of business at 111 Virginia Street, Suite 405, Richmond, Virginia 23219. Intelliject is engaged in commercial medical research and development of drug delivery systems, including an epinephrine auto-injector that it intends to market and distribute throughout the United States.

JURISDICTION AND VENUE

7. 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.

8. This Court has personal jurisdiction over Intelliject because, among other things, Intelliject is a Delaware corporation. By virtue of its incorporation under Delaware law, Intelliject has submitted itself to personal jurisdiction in the Courts of Delaware.

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

BACKGROUND

10. The EpiPen® Auto-Injector is designed for assisted or 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.

11. Meridian developed, manufactures, and markets the EpiPen® Auto-Injector pursuant to NDA No. 019430, which was approved by the FDA.

12. The '432 Patent, entitled "Automatic Injector with Kickback Attenuation," was duly and legally issued by the United States Patent and Trademark Office on September 14, 2010. The '432 Patent, owned by Meridian, will expire on September 11, 2025. A copy of the '432 Patent is attached hereto as Exhibit 1.

13. The EpiPen® Auto-Injector is covered by one or more claims of the '432 Patent, and as such this patent was listed in connection with the EpiPen® Auto-Injector in the FDA's Orange Book.

14. Sometime after the '432 Patent was listed in the FDA's Orange Book, Intelliject submitted NDA No. 201739 under § 505(b)(2) of the FFDCA, 21 U.S.C. § 355(b)(2). This NDA seeks approval to engage in the commercial manufacture, use, and/or sale of its epinephrine auto-injector prior to the expiration of Meridian's '432 Patent.

15. On December 9, 2010 Plaintiffs received a letter from Intelliject ("Intelliject's Letter") stating that Intelliject had submitted, and the FDA had received, NDA No.

201739 concerning Intellijject's proposed drug product, epinephrine auto-injector 0.3 mg (epinephrine injection USP 1:1000) and 0.15 mg (epinephrine injection USP 1:1000) ("Intellijject's NDA Product"), as required by § 505(b)(3)(B) of the FFDCA. *See* 21 U.S.C. § 355(b)(3)(B).

16. Intellijject's Letter further stated that, pursuant to § 505(b)(2)(A)(iv) of the FFDCA, Intellijject had filed with the FDA a Paragraph IV certification with respect to the '432 Patent, alleging that the claims of the '432 Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale, or offer for sale of Intellijject's NDA Product. *See* 21 U.S.C. § 355(b)(2)(A)(iv).

17. Intellijject's submission of NDA No. 201739 seeking approval for the commercial manufacture, use, offer for sale, and/or sale of Intellijject's NDA Product before the expiration of the '432 Patent constitutes an act of infringement of one or more claims of the '432 Patent under 35 U.S.C. § 271(e)(2)(A).

18. Plaintiffs have commenced this action within 45 days after the date on which they received Intellijject's Letter pursuant to § 505(b)(3)(B) of the FFDCA, and therefore FDA's approval of Intellijject's NDA Product may be made effective only upon the expiration of the thirty-month period beginning on the date Intellijject's letter was received. *See* 21 U.S.C. § 355(c)(3)(C).

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 7,794,432 B2

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

20. Meridian is the owner by assignment of the '432 Patent and has the right to sue for infringement thereof.

21. Intellijject's submission of NDA No. 201739 seeking approval for the commercial manufacture, use, offer for sale, and/or sale of Intellijject's NDA Product before the expiration of the '432 Patent constitutes an act of infringement of one or more claims of the '432 Patent under 35 U.S.C. § 271(e)(2)(A).

22. Intellijject's NDA Product, when offered for sale, sold, and/or imported, and then used as directed, directly infringes one or more claims of the '432 Patent, including but not limited to claims 10 and 20 of the '432 Patent. 35 U.S.C. § 271(a).

23. Upon information and belief, Intellijject has engaged in activities that infringe one or more claims of the '432 Patent under 35 U.S.C. § 271(a), including but not limited to manufacturing and using Intellijject's NDA Product.

24. If NDA No. 201739 is approved, Intellijject intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Intellijject's NDA Product, with its proposed labeling. Such activities will infringe one or more claims of the '432 Patent, including but not limited to claims 10 and 20 of the '432 Patent.

25. Unless Intellijject is enjoined from infringing the '432 Patent, Plaintiffs will be substantially and irreparably harmed. Plaintiffs have no adequate remedy at law.

COUNT II
DECLARATORY JUDGMENT − U.S. PATENT NO. 7,794,432 B2

26. Plaintiffs reallege and incorporate by reference paragraphs 1-25 above.

27. If NDA No. 201739 is approved before the '432 Patent expires, Intellijject presently plans to begin and will immediately commence commercial activities with respect to Intellijject's NDA Product. Those commercial activities include at least the manufacture, use, offering to sell and sale of Intellijject's NDA Product.

28. Intellijject's commercial activities, including the manufacture, use, offering to sell and sale of Intellijject's NDA Product constitute direct infringement of one or more claims of the '432 Patent, including claims 10 and 20, under 35 U.S.C. § 271(a).

29. Intellijject's infringing activity, including the commercial manufacture, use, offer to sell, and sale of Intellijject's NDA Product complained of herein will begin immediately after the FDA approves NDA No. 201739.

30. As a result of Intellijject's NDA filing No. 201739 and planned commercial activities, there is a real, substantial, and continuing justiciable controversy concerning liability for infringement of the '432 Patent between Plaintiffs and Intellijject.

31. Plaintiffs will be substantially and irreparably harmed by Intellijject'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:

32. A declaratory judgment that, under 35 U.S.C. § 271(e)(2)(A), Intellijject's submission to the FDA of NDA No. 201739 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Intellijject's NDA Product before the expiration of the '432 Patent is an act of infringement of one or more claims of the '432 Patent.

33. An order that the effective date of any FDA approval of Intellijject's NDA Product shall be no earlier than the expiration of the '432 Patent, in accordance with 35 U.S.C. § 271(e)(4)(A).

34. A declaratory judgment that the claims of the '432 Patent are valid and enforceable and that Intellijject's commercial manufacture, use, offer for sale, or sale in, or

importation into, the United States of Intellijject's NDA Product would constitute direct infringement of one or more claims of the '432 Patent.

35. A permanent injunction enjoining Intellijject, and any affiliates, subsidiaries or persons within its control, from commercially manufacturing, using, offering for sale, or selling Intellijject's NDA Product within the United States, or importing Intellijject's NDA Product into the United States, until the expiration of the '432 Patent, in accordance with 35 U.S.C. § 271(e)(4)(B).

36. An award of damages or other relief to the extent Intellijject has engaged or engages in the commercial manufacture, use, offer to sell, sale, marketing, distribution, and/or importation of Intellijject's NDA Product, or any product that infringes one or more claims of the '432 Patent, prior to the expiration of the '432 Patent, in accordance with 35 U.S.C. § 271(e)(4)(C).

37. An award to Plaintiffs of their costs and expenses in this action.

38. Such further and additional relief as this Court deems just and proper.

By: */s/ Richard K. Herrmann*

Dated: January 19, 2011

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