IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS US LLC, ASTELLAS PHARMA US, INC., and ITEM DEVELOPMENT AB,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
AKORN, INC.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs, Astellas US LLC, Astellas Pharma US, Inc., and Item Development AB (hereinafter collectively "Plaintiffs"), bring this action for patent infringement against Akorn, Inc. (hereinafter "Akorn"). This action concerns a patent relating to the use of adenosine, a prescription drug, as an adjunct to thallium-201 myocardial perfusion scintigraphy, used in the diagnosis of coronary artery disease in patients unable to exercise adequately.

JURISDICTION AND PARTIES

1. Plaintiff Astellas US LLC (hereinafter "Astellas US") is a limited liability company organized under the laws of Delaware having an office and principal place of business at 1 Astellas Way, Northbrook, IL 60062.

2. Plaintiff Astellas Pharma US, Inc. (hereinafter "Astellas Pharma") is a corporation organized under the laws of Delaware having an office and principal place of business at 1 Astellas Way, Northbrook, IL 60062.

3. Astellas US and Astellas Pharma (collectively hereinafter "Astellas") are engaged in the business of sale of pharmaceutical products throughout the United States.

4. Plaintiff Item Development AB (hereinafter "Item"), is a Swedish corporation having an office and principal place of business at Svanholmsvagen 2A, Stocksund, 18207, Sweden.

5. Upon information and belief, Defendant Akorn is a corporation organized and existing under the laws of Louisiana having offices and a principal place of business at 1925 West Field Court, Suite 300, Lake Forest, Illinois 60045. On information and belief, Akorn is in the business of, among other things, manufacturing, marketing, and selling generic pharmaceutical products for distribution throughout the United States, including the State of Delaware.

6. Akorn is subject to personal jurisdiction in this Court because, on information and belief, it regularly and continuously transacts business within the State of Delaware, including, but not limited to, the regular marketing and sale of pharmaceutical products within the State of Delaware. Among other things, on information and belief, Akorn has expressly consented to jurisdiction by registering to do business in the State of Delaware and appointing an agent in Delaware. On information and belief, Akorn has registered with the Delaware Board of Pharmacy as a licensed "Distributor/Manufacturer CSR" (License No. DS0270) and "Pharmacy-Wholesale" (License Nos. A4-0000687 and A4-0000573). Moreover, on information and belief, Akorn is in a Delaware joint venture, Akorn-Strides, LLC.

7. This action for patent infringement arises under the United States Patent Laws, Title 35, United States Code, including 35 U.S.C. § 271 and §§ 281-285. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

BACKGROUND

8. On March 24, 1998, the United States Patent and Trademark Office duly and legally issued United States Patent No. 5,731,296 ("the '296 patent") to Item for SELECTIVE VASODILATION BY CONTINUOUS ADENOSINE INFUSION. A copy of the '296 patent is attached hereto as Exhibit A.

9. Astellas is the exclusive licensee, with right to bring suit, of certain rights in the '296 patent and, pursuant to those rights, sells Adenoscan®, an adenosine-based product approved by the United States Food and Drug Administration ("FDA") for use as an adjunct to thallium-201 myocardial perfusion scintigraphy in patients unable to exercise adequately.

10. The use of Adenoscan® in accordance with its FDA-approved labeling is covered by one or more of the claims of the '296 patent.

11. Upon information and belief, Akorn has filed with the FDA an Abbreviated New Drug Application ("ANDA") No. 90-450 for adenosine injection, 3 mg/ml under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, and sale of adenosine as an adjunct to thallium-201 myocardial perfusion scintigraphy in patients unable to exercise adequately.

12. Upon information and belief, Akorn has filed an amendment to ANDA No. 90-450 containing a purported certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

13. A letter ("the Notice Letter") dated October 10, 2012 and received at Astellas on or about October 12, 2012, was sent on behalf of Akorn by the Senior Vice President, General Counsel and Secretary of Akorn, Joseph Bonaccorsi, notifying Astellas that Akorn had sought approval from the FDA to begin selling adenosine injection, 3 mg/ml as a generic

substitute for Adenoscan® prior to the expiration of the '296 patent and alleging that the '296 patent claims are invalid, unenforceable and/or will not be infringed.

14. Upon information and belief, Akorn's adenosine injection, 3 mg/ml package insert will have the same indications and dosage instructions as those contained in the FDA-approved Adenoscan® intravenous injection product package insert so that use of Akorn's adenosine injection, 3 mg/ml according to its approved labeling will result in infringement of one or more claims of the '296 patent.

15. The Notice Letter contained no allegation of non-infringement for any claim of the '296 patent.

16. Upon information and belief, Akorn intends to engage in the commercial manufacture, use, advertising, importation, offer for sale, and/or sale of Akorn's adenosine injection, 3 mg/ml, with its associated instructions for use and labeling, promptly upon receiving FDA approval to do so.

COUNT I
PATENT INFRINGEMENT

17. Paragraphs 1-16 are incorporated herein by reference.

18. Under 35 U.S.C. § 271(e)(2)(A), Akorn has infringed one or more claims of the '296 patent by submitting to the FDA an ANDA seeking approval for the commercial marketing, before the expiration date of the '296 patent, of adenosine injection, 3 mg/ml labeled for use as an adjunct to thallium-201 myocardial perfusion scintigraphy, a product the manufacture, importation, use, or sale of which would contribute to or induce the direct infringement of one or more claims of the '296 patent by ultimate purchasers.

19. Upon information and belief, Akorn will also induce or contribute to infringement of one or more claims of the '296 patent by actively aiding, abetting, encouraging,

and inducing, upon FDA approval, the sale of such adenosine injection, 3 mg/ml together with instructions and labeling that will result in direct infringement of one or more claims of the '296 patent by ultimate purchasers.

20. Plaintiffs will be substantially and irreparably damaged and harmed if Akorn's infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

COUNT II
DECLARATORY JUDGMENT

21. Paragraphs 1-20 are incorporated herein by reference.

22. Upon information and belief, Akorn has made substantial preparations to sell adenosine injection, 3 mg/ml labeled for the same indications and the same dosage and method of use as the Adenoscan® product sold by Astellas.

23. Upon information and belief, Akorn intends to commence sales of such adenosine injection, 3 mg/ml immediately upon receiving approval from the FDA.

24. The manufacture, importation, use, sale, and offer for sale of adenosine injection, 3 mg/ml so labeled, once approved by the FDA, will directly infringe, induce and/or contribute to infringement of one or more claims of the '296 patent.

25. Plaintiffs will be substantially and irreparably damaged and harmed if Akorn's threatened infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

COUNT III
EXCEPTIONAL CASE

26. Paragraphs 1-25 are incorporated herein by reference.

27. Akorn has proceeded with its unlawful activities with knowledge of the '296 patent.

28. This is an exceptional case warranting imposition of attorney fees against Akorn under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request this Court to enter judgment against Akorn as follows:

(a) finding that Akorn has infringed one or more claims of the '296 patent by the filing of the aforesaid ANDA relating to Akorn's adenosine injection, 3 mg/ml;

(b) prohibiting any approval by the FDA of Akorn's aforesaid adenosine injection, 3 mg/ml on any effective date prior to the date of expiration of the '296 patent, or such later date as the Court may determine;

(c) declaring that Akorn will infringe one or more claims of the '296 patent if Akorn's aforesaid ANDA relating to adenosine injection, 3 mg/ml is approved and the approved product is sold and used in the United States;

(d) enjoining Akorn, its officers, agents, attorneys, and employees, and those acting in privity or concert with them or any of them, from the commercial manufacture, use, importation, or sale of an adenosine injection, 3 mg/ml product labeled for use in myocardial perfusion imaging until the expiration of the '296 patent;

(e) finding that this is an exceptional case and granting Plaintiffs reasonable attorney fees pursuant to 35 U.S.C. § 285; and

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

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