

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI**

WESTPORT PHARMACEUTICALS, LLC; AND
HIGHLAND PHARMACEUTICALS, LLC,

Plaintiffs,

V.

ACURA PHARMACEUTICALS, INC.,

Defendant.

Case No. 4:14-CV-770

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiffs Westport Pharmaceuticals, LLC, and Highland Pharmaceuticals, LLC (collectively “Westport”), by and through undersigned counsel, hereby bring this Complaint for Declaratory Judgment against Acura Pharmaceuticals, Inc. (“Acura”), and allege as follows:

NATURE OF THE ACTION

1. This is a declaratory judgment action seeking a declaration of non-infringement of United States Patent No. 8,409,616 (“the ‘616 patent”; see, Ex. A), to enable Westport to continue to sell its over-the-counter Zephrex-D[®] (pseudoephedrine hydrochloride; 30 mg) product, to allow retail distributors to continue to sell Westport’s Zephrex-D[®] product in the marketplace, and to allow the public to continue to enjoy the benefits of Westport’s Zephrex-D[®] product, untainted by meritless claims of purported patent infringement by Acura.

THE PARTIES

2. Westport Pharmaceuticals, LLC is a limited liability company organized under the laws of the State of Missouri, having a principal place of business at 11960 Westline Industrial Drive, Suite 180, St. Louis, Missouri 63146.

3. Highland Pharmaceuticals, LLC is a limited liability company organized under the laws of the State of Missouri, having a principal place of business at 11960 Westline Industrial Drive, Suite 180, St. Louis, Missouri 63146.

4. Westport Pharmaceuticals, LLC is wholly owned by Highland Pharmaceuticals, LLC, and is a seller and distributor of Highland Pharmaceuticals, LLC's Zephrex-D[®] product.

5. On information and belief, Acura Pharmaceuticals, Inc. is a corporation organized under the laws of the State of New York, having a principal place of business at 616 N. North Court, Suite 120, Palatine, Illinois 60067.

JURISDICTION AND VENUE

6. This Complaint arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, based upon an actual controversy between the parties to declare that Westport is free to manufacture, use, market, sell, offer to sell, import and/or export its Zephrex-D[®] product, notwithstanding the '616 patent.

7. This Court has original jurisdiction over the subject matter of these claims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Acura at least because of: 1) Acura's initial and continuing assertion of patent infringement claims against a Missouri limited liability company in the State of Missouri; and 2) Acura's continuous and systematic contacts with the State of Missouri, including conducting substantial and regular business therein through

marketing and sales of pharmaceutical products in Missouri.

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

PATENT IN SUIT

10. The ‘616 patent, entitled “Extended Release Opioid Abuse Deterrent Compositions and Methods of Making Same” indicates on its face that it was issued by the United States Patent and Trademark Office on April 2, 2013. (*See* Ex. A.)

11. According to current publically available record of the United States Patent and Trademark Office, Acura Pharmaceuticals, Inc., is the assignee of the ‘616 patent.

BACKGROUND STATEMENT OF FACTS RELEVANT TO ALL COUNTS

12. Westport is a specialty pharmaceutical company located in St. Louis, Missouri. Using an innovative, tamper-resistant technology, Westport delivers pharmaceuticals in a format that maintains patient efficacy while deterring misuse of a medication. Westport’s drug delivery system provides a new and unconventional approach to combat drug misuse.

13. Zephrex-D[®], a 30 mg pseudoephedrine pill, is Westport’s first commercially available product. Zephrex-D[®], comprises a tamper-resistant formulation that physiochemically locks the pseudoephedrine hydrochloride active ingredient within the formulation components so that it cannot be used in commonly known methods of methamphetamine manufacture, while at the same time maintaining the full efficacy of providing necessary clinical benefits for patients.

14. Illicit methamphetamine manufacturers use various methods to convert the pseudoephedrine ingredient found in cold and sinus products into methamphetamine. The most common meth-making method today, and clearly the most volatile and dangerous, is the “One Pot” process, commonly known as “Shake and Bake.” Using this method, law enforcement officials have rigorously tested Zephrex-D[®] and were repeatedly unsuccessful in their attempts

to make methamphetamine. Further testing by independent laboratories concluded that known illicit extraction/conversion methods are also practically ineffective with Zephrex-D[®].

15. Zephrex-D is made using Tarex[®], an innovative, patented technology which significantly disrupts the meth-making process, while still providing unsurpassed congestion relief for patients. The Zephrex-D[®] tamper-resistant formulation allows patients to get the decongestant relief they need in a highly meth-resistant formulation. The technology used in the tamper-resistant Zephrex-D[®] formulation makes communities safer by protecting against the crimes and perils associated with illicit and illegal methamphetamine manufacture.

16. Westport's Zephrex-D[®] is sold over-the-counter in retail outlets throughout the United States, and was first introduced to consumers in or about November, 2012. Zephrex-D[®] has enjoyed wide and growing commercial success.

ACURA'S IMPROPER ACTIONS GIVING RISE TO THIS SUIT

17. On May 28, 2013, Acura, by letter through its counsel, accused Westport of infringing the '616 patent, stating that "...the manufacture, offer for sale and sale of Zephrex-D infringes the '616 patent."

18. In response to Acura's threats and customer harassment, Westport notified Acura on August 12, 2013, in writing through Westport's counsel that Westport's Zephrex-D[®] product does not infringe the '616 patent. In its August 12, 2013, letter, Westport provided a copy of its current ingredients label demonstrating clear non-infringement of the '616 patent.

19. Despite Westport's clear and unequivocal showing of non-infringement, Acura has persisted in its accusations of infringement. By letter dated September 9, 2013, through its counsel, Acura once again claimed that Westport's Zephrex-D[®] infringes the '616 patent.

20. Acura's persistent and continuing improper accusations of patent infringement by Westport has created an environment detrimental to Westport's ability to conduct its normal business operations with respect to the sale, offering for sale, marketing and growth of its Zephrex-D[®] product, as it should be able to do in the ordinary course of business.

21. Westport desires and is entitled to continue to sell, offer for sale, market, and grow its Zephrex-D[®] product, with both retail customers and potential investors, without the improper and potentially deleterious business effects of improper and on-going threats of patent infringement from Acura.

22. Westport has suffered and will continue to suffer immediate and irreparable harm as a result of Acura's persistent and continuing improper accusations of patent infringement, for which West port has no adequate remedy at law.

COUNT I

DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '616 PATENT

23. Westport repeats and realleges each of the allegations in paragraphs 1-22 as if fully set forth herein.

24. Because Westport's Zephrex-D[®] product does not meet each and every limitation of any claim of the '616 patent, either literally or under the doctrine of equivalents, the manufacture, marketing, use, sale, offer for sale, importation and/or exportation of Westport's Zephrex-D[®] product does not infringe any claim of the '616 patent.

25. Because of statements contained in the specification of the '616 patent and/or statements made during prosecution of the application which matured into the '616 patent, the scope of the allowed claims of the '616 patent cannot properly be construed (or properly

expanded by further prosecution means) by Acura in such a way as to cover, literally or under the doctrine of equivalents, each and every element of Westport's Zephrex-D[®] product.

26. There is a substantial and continuing controversy between Westport and Acura, and a declaration of rights is both necessary and appropriate to establish that Westport does not infringe any claim of the '616 patent and to allow Westport, its customers, and its potential investors, to continue to market, sell, offer for sale, distribute, and grow Westport's Zephrex-D[®] product with the public, without factually and legally improper on-going threats of patent infringement from Acura.

27. Westport is being injured and has suffered damages as a result of Acura's legally and factually baseless accusations of infringement of the '616 patent. For example, Acura's accusations of purported infringement of the '616 patent by Westport have hampered, impeded and delayed, and will continue to hamper, impede and delay, Westport's ability to market, sell, offer for sale, and distribute its Zephrex-D[®] product, and to attract and maintain investors in its Zephrex-D[®] product.

28. Westport's ongoing injury can be redressed by the relief it seeks. A declaratory judgment of non-infringement would provide business certainty to Westport, its customers and its investors. If Acura's claims of purported infringement by Westport are allowed to continue unabated, Westport will continue to suffer economic injury as, *inter alia*, it will lose potential sales of its Zephrex-D[®] product by the public and/or retailers concerned about the claims of purported infringement and will be improperly deprived of an economic opportunity to expand its Zephrex-D[®] product with both retailers and/or investors in the marketplace. Until the overhang of Acura's specious allegations of patent infringement are stopped, the public also is likely to be

harmful as well, as the availability of a safe, tamper-resistant decongestant formulation that is found in the Zephrex-D[®] product may be curtailed by retailers.

EXCEPTIONAL CASE

29. In response to Acura's initial inaccurate claims of purported infringement to Westport, Acura was made aware of Westport's current formulation ingredients that showed clear non-infringement of the '616 patent. Despite being presented with clear and convincing evidence that Westport's Zephrex-D[®] product does not infringe the '616 patent, Acura continued to persist with its specious claims of infringement.

30. Acura has no factual or legal basis to continue to accuse Westport of infringing the '616 patent; Acura's continuing spurious actions render this an exceptional case.

PRAYER FOR RELIEF

WHEREFORE, Westport prays for the following relief:

A. A declaration and judgment that Westport's Zephrex-D[®] product does not infringe and will not infringe, directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner, any valid and enforceable claim of the '616 patent;

B. A declaration and judgment that the manufacture, marketing, use, offer for sale, sale, distribution, importation and/or exportation of Zephrex-D[®] does not infringe, or induce or contribute to the infringement by others, of any claim of the '616 patent;

C. An injunction enjoining Acura, its officers, employees, agents, representatives, salespeople, attorneys and others acting for or on its behalf, and all those acting in concert with Acura, from threatening, initiating or otherwise alleging infringement of the '616 patent with respect to Zephrex-D[®], against Westport or its customers, dealers, suppliers, doctors, patients, or

any prospective or present sellers, dealers, distributors or customers or investors of Westport, or charging them either orally or in writing with purported infringement of the '616 patent with respect to Zephrex-D[®];

D. A declaration and judgment that this is an exceptional case within the meaning of 35 U.S.C. § 285, and that Westport is entitled to recover its reasonable attorney's fees and costs upon prevailing in this action; and

E. An award to Westport of such other and further relief as this Court may deem necessary, just and proper.

Dated: April 18, 2014

Respectfully submitted,

/s/ Mary Ann L. Wymore

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