

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION**

**ADAMIS PHARMACEUTICALS
CORPORATION,**

Plaintiff,

v.

BELCHER PHARMACEUTICALS, LLC,

Defendant.

Case No.:

**COMPLAINT FOR DECLARATORY
JUDGMENT OF PATENT NON-INFRINGEMENT**

Plaintiff Adamis Pharmaceuticals Corporation (“Adamis”) files this complaint for declaratory judgment of patent non-infringement against Belcher Pharmaceuticals, LLC (“Belcher”), and in support thereof alleges as follows:

NATURE OF THE ACTION

1. This is an action for declaratory judgment of non-infringement of U.S. Patent Nos. 9,283,197 (“197 Patent”) and 10,004,700 (“700 Patent”) under the patent laws of the United States, 35 U.S.C. §§ 1, *et. seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

THE PARTIES

2. Adamis is a corporation organized under the laws of Delaware with its principal place of business at 11682 El Camino Real, Suite 300, San Diego, California 92130.

3. Belcher is a corporation organized under the laws of Florida with its principal place of business at 6911 Bryan Dairy Road, Largo, Florida 33777.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a), as well as 28 U.S.C. §§ 2201 and 2202.

5. This Court has personal jurisdiction over Belcher because it is incorporated in the State of Florida and its principal place of business is located in this district.

6. Venue is proper in this district under 28 U.S.C. §§ 1391(b) and 1391(c) at least because Belcher is incorporated in the state of Florida and has its principal place of business in this district.

7. An actual case or controversy has arisen between the parties. Belcher has threatened litigation against Adamis, and has asserted that Adamis is infringing the '197 and '700 patents. These statements threaten injury to Adamis.

FACTUAL BACKGROUND

Adamis and SYMJJEPI

8. Adamis is a specialty biopharmaceutical company focused on developing and commercializing products in the therapeutic areas of respiratory disease and allergy. Adamis provides high quality, lower-cost alternatives to existing allergy and respiratory therapies.

9. Adamis developed SYMJJEPI™ Epinephrine Injection (“SYMJEPI”), an epinephrine auto-injector, to provide a lower-cost alternative in the anaphylaxis market. In June 2017, the FDA approved SYMJJEPI for the emergency treatment of allergic reactions. SYMJJEPI contains 0.5 mg sodium metabisulfite in each 0.3 mL dose. In addition, the pH for the pharmaceutical formulation for SYMJJEPI is manufactured outside of a range between 2.8 and 3.3.

10. Adamis has expended considerable resources in the development of SYMJJEPI and the commercial launch of SYMJJEPI in the United States is imminent.

The '197 Patent

11. The '197 patent, entitled "More Potent and Less Toxic Formulations of Epinephrine and Methods of Medical Use" issued on March 15, 2016. Belcher purports to be the assignee of the '197 Patent. A copy of the '197 Patent is attached hereto as Exhibit A.

12. The '197 Patent generally claims a liquid pharmaceutical formulation of 1 mg per mL l-epinephrine sterile solution for uses including injection. The '197 Patent describes a purportedly new method of preparing the l-epinephrine solution using an in-process pH of 2.8 to 3.3 to reduce racemization of l-epinephrine to d-epinephrine. For example, the '197 Patent states:

Inadvertently, increasing the in-process pH to 2.8-3.3, unexpectedly reduced the racemization of l-epinephrine to d-epinephrine at release by approximately two-thirds, from 14% to 5%, respectively. To the contrary, these results led to the discovery that in a preservative-free, sulfite-free, l-epinephrine solution, racemization was a more significant problem than expected, even more so than oxidation. This discovery led to new methods of manufacturing sulfite-free l-epinephrine solution with in-process pH of 2.8 to 3.3, approximately 3.0, which was a nonobvious solution to the problem of racemization. Most importantly, with these new methods, overages could be greatly reduced.

'197 Patent at 4:48-59.

13. While prosecuting the '197 Patent application, the applicant also stated that there are some "optimal ranges (e.g., pH [2.8 to 3.3] or concentration [around 1.03 mg/mL l-epinephrine]) during compounding that will result in tightly maintaining the drug product concentration from release through shelf-life at 1 mg per mL l-epinephrine." (emphasis added). All of the claims of the '197 patent require an in-process pH between 2.8 and 3.3. Claims 1-5 of the '197 patent further require that the formulation be "sulfite-free."

The '700 Patent

14. The '700 Patent, entitled "More Potent and Less Toxic Formulations of Epinephrine and Methods of Medical Use" issued on June 26, 2018. Belcher purports to be the assignee of the '700 Patent. A copy of the '700 Patent is attached hereto as Exhibit B.

15. The '700 Patent generally claims a method of treating allergic reaction using an injectable liquid pharmaceutical formulation. The '700 Patent describes methods of use and methods of administration of the purportedly new method of preparing the l-epinephrine solution disclosed and claimed in the '197 Patent with an in-process pH of 2.8 to 3.3 to reduce racemization. For example, the '700 Patent specification states:

Inadvertently, increasing the in-process pH to 2.8-3.3, unexpectedly reduced the racemization of l-epinephrine to d-epinephrine at release by approximately two-thirds, from 14% to 5%, respectively. To the contrary, these results led to the discovery that in a preservative-free, sulfite-free, l-epinephrine solution, racemization was a more significant problem than expected, even more so than oxidation. This discovery led to new methods of manufacturing sulfite-free l-epinephrine solution with in-process pH of 2.8 to 3.3, approximately 3.0, which was a nonobvious solution to the problem of racemization. Most importantly, with these new methods, overages could be greatly reduced.

'700 Patent at 4:54-65.

16. In the stating reasons for allowance of the '700 Patent the examiner found the "[a]pplicant inadvertently discovered that increasing the in-process pH to 2.8-3.3, unexpectedly reduced the racemization of l-epinephrine to d-epinephrine."

17. All of the claims of the '700 Patent require the formulation to have an in-process pH between 2.8 and 3.3. Claims 14-16 of the '700 Patent additionally requires that the pharmaceutical formulation be "sulfite-free."

The Present Dispute

18. On July 11, 2017, Belcher sent a letter to Dennis J. Carlo, president and CEO of Adamis, entitled “Notification of Potential Patent Infringement.” A copy of the letter is attached hereto as Exhibit C. In the letter, Belcher claimed that SYMJJEPI may infringe the ’197 Patent.

19. Counsel for Adamis responded to Belcher’s letter on July 17, 2017, and informed Belcher the ’197 patent claims do not read on SYMJJEPI. A copy of the July 24, 2017, letter is attached hereto as Exhibit D. In particular, counsel for Adamis advised Belcher that the ’197 patent claims do not read on SYMJJEPI because it contains 0.5 mg sodium metabisulfite, and therefore is not “sulfite-free” as required by the claims 1-5 of the ’197 Patent. In addition, the in-process pharmaceutical formulation for SYMJJEPI is outside of the pH range of 2.8 to 3.3 as required by the claims.

20. Belcher responded on July 24, 2017, and acknowledged it did not know that the SYMJJEPI release criteria for pH was outside the claimed 2.8 to 3.3 range. A copy of the July 24, 2017, letter is attached hereto as Exhibit E.

21. More than one year later, on August 8, 2018, counsel for Belcher sent a second letter to Adamis, again alleging infringement of the ’197 Patent. The second letter further alleged infringement of the ’700 Patent. A copy of the August 8, 2018, letter is attached hereto as Exhibit F. In the August 8, 2018, letter, Belcher demanded that Adamis “halt any launch” of its SYMJJEPI product and provide information regarding the process used to manufacture SYMJJEPI. Belcher further promised to “enforce its rights” and “take any and all necessary steps.”

COUNT I

Declaratory Judgment of Non-Infringement of the '197 Patent

22. Adamis incorporates by reference the allegations in paragraphs 1 through 21 in support of this Count.

23. Belcher has claimed SYMJEPi infringes the '197 Patent and has threatened to bring a lawsuit against Adamis.

24. SYMJEPi cannot infringe claims 1-7 of the '197 Patent because the in-process pH range of SYMJEPi is outside the claimed 2.8 to 3.3 range, as required by all claims of the '197 Patent. Further, SYMJEPi contains 0.5 mg of sodium metabisulfite in each 0.3 mL dose and therefore is not "sulfite-free" as required by claims 1-5 of the '197 Patent.

25. There exists a real, immediate, and substantial, controversy between Adamis and Belcher concerning whether the marketing, distribution, manufacture, use, sale, offering for sale, and/or importation of SYMJEPi infringes any claim of the '197 Patent.

26. Adamis is entitled to a judicial determination that the marketing, distribution, manufacture, use, sale, offering for sale, and/or importation of the SYMJEPi will not infringe directly or indirectly, any claim of the '197 Patent.

COUNT II

Declaratory Judgment of Non-Infringement of the '700 Patent

27. Adamis incorporates by reference the allegations in paragraphs 1 through 26 in support of this Count.

28. Belcher has claimed SYMJEPi infringes the '700 Patent and has threatened to bring a lawsuit against Adamis.

29. SYMJJEPI cannot infringe claims 1-16 of the '700 Patent because the in-process pH range of SYMJJEPI is outside the claimed 2.8 to 3.3 range, as required by all claims of the '700 Patent. Further, SYMJJEPI contains 0.5 mg of sodium metabisulfite in each 0.3 mL dose and therefore is not "sulfite-free" as required by claims 11-16 of the '700 Patent.

30. There exists a real, immediate, and substantial controversy between Adamis and Belcher concerning whether the marketing, distribution, manufacture, use, sale, offering for sale, and/or importation of SYMJJEPI infringes any claim of the '700 Patent.

31. Adamis is entitled to a judicial determination that the marketing, distribution, manufacture, use, sale, offering for sale, and/or importation of the SYMJJEPI will not infringe directly or indirectly, any claim of the '700 Patent.

PRAYER FOR RELIEF

WHEREFORE, Adamis respectfully requests that:

A. The Court declare that Adamis' marketing, manufacture, use, sale, offering for sale, and/or importation of SYMJJEPI, has not, does not, and will not infringe, directly or indirectly, any claim of the '197 Patent and the '700 Patent.

B. The Court permanently enjoin Belcher from asserting the '197 and the '700 Patents against Adamis.

C. The Court grant Adamis such other relief as the Court deems proper.

Dated: September 25, 2018.

/s/ Jonathan B. Morton

Jonathan B. Morton
FL Bar # 956872
Jonathan.morton@klgates.com
K&L Gates, LLP
Wachovia Financial Center
200 South Biscayne Boulevard
Miami, FL 33131
Telephone: (305) 539-3300
Fax: (305) 358-7095

Alan L. Barry – *pro hac vice pending*
Devon C. Beane – *pro hac vice pending*
Kacy L. Dicke – *pro hac vice pending*

K&L Gates LLP
70 W. Madison, Suite 3100
Chicago, Illinois 60602
Telephone: (312) 372-1121
Fax: (312) 827-8000
alan.barry@klgates.com
devon.beane@klgates.com
kacy.dicke@klgates.com

*Attorneys for Plaintiff Adamis
Pharmaceuticals Corporation*