

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

ADAMIS PHARMACEUTICALS
CORPORATION,

Plaintiff,

CASE No: 8:18-cv-02379-WFJ-AAS

v.

BELCHER PHARMACEUTICALS, LLC,

Defendant.

_____ /

**PLAINTIFF BELCHER PHARMACEUTICALS, LLC'S
INITIAL INFRINGEMENT CONTENTIONS**

Pursuant to the Scheduling Order entered December 19, 2018, [Dkt. 18], Defendant Belcher Pharmaceuticals, LLC (“Belcher”) provides the following Initial Infringement Contentions for Plaintiff Adamis Pharmaceuticals Corporation (“Adamis”). These contentions are preliminary and based solely on information in Belcher’s possession, custody, or control. Belcher reserves the right to supplement these contentions as appropriate based upon further discovery and the schedule of this case.

Dated: January 7, 2019

/s/ Stefan V. Stein

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INITIAL INFRINGEMENT CONTENTIONS

With regard to the various elements contained within Claims 6 and 7 of U.S. Patent Number 9,283,197 (the “’197 Patent”), below is a chart indicating where each of the relevant limitations can be found in publicly available documents.

'197 Patent Claim 6	Evidence of Infringement
<p>An injectable liquid pharmaceutical formulation of l-epinephrine sterile solution;</p>	<p>Inject SYMJEPI intramuscularly or subcutaneously into the anterolateral aspect of the thigh with the needle facing downwards. It can be injected through clothing if necessary.</p> <p>http://www.adamispharmaceuticals.com/wp-content/uploads/2018/10/prescribing-info.pdf at 2.</p> <p>Each SYMJEPI (epinephrine injection, USP) syringe contains 0.8 mL of sterile aqueous solution of epinephrine for intramuscular or subcutaneous administration. The syringe is overfilled: more than half of the solution remains in the syringe after use and CANNOT BE REUSED.</p> <p>http://www.adamispharmaceuticals.com/wp-content/uploads/2018/10/prescribing-info.pdf at 6.</p>
<p>said liquid pharmaceutical formulation having a pH between 2.8 and 3.3;</p>	<p>Belcher disputes Adamis’ contention that this claim requires an in-process pH between 2.8 and 3.3. The plain language of the claim states that “said liquid pharmaceutical formulation” has the stated pH range which logically and grammatically refers to the final product.</p> <p>The pH range is 2.2-5.0.</p> <p>http://www.adamispharmaceuticals.com/wp-content/uploads/2018/10/prescribing-info.pdf at 6.</p> <p>https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/207534Orig1s0000ChemR.pdf at 12. This document is heavily redacted and the final pH is obscured. As such, on information and belief, the final product has a pH in the claimed range.</p>

<p>said injectable liquid pharmaceutical formulation compounded in an aqueous solution as 1.0 to 1.06 mg/mL 1-epinephrine,</p>	<p>Each SYMJJEPI (epinephrine injection, USP) syringe contains 0.8 mL of sterile aqueous solution of epinephrine for intramuscular or subcutaneous administration. The syringe is overfilled: more than half of the solution remains in the syringe after use and CANNOT BE REUSED.</p> <p>http://www.adamispharmaceuticals.com/wp-content/uploads/2018/10/prescribing-info.pdf at 6. On information and belief, the product must be compounded in an aqueous solution if the final product is an aqueous solution.</p> <p>Further, the Chemistry Review from the publicly available portions of the SYMJJEPI NDA as summarized by the FDA states that the drug is sold as 1 mg/mL.</p> <p>https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/207534Orig1s0000ChemR.pdf at 29.</p>
<p>and further including a tonicity agent;</p>	<p>Each 0.3 mL in SYMJJEPI 0.3 mg contains 0.3 mg epinephrine, 1.8 mg sodium chloride, 0.5 mg sodium metabisulfite, hydrochloric acid to adjust pH, and Water for Injection. The pH range is 2.2-5.0.</p> <p>Each 0.3 mL in SYMJJEPI 0.15 mg contains 0.15 mg epinephrine, 1.8 mg sodium chloride, 0.3 mg sodium metabisulfite, hydrochloric acid to adjust pH, and Water for Injection. The pH range is 2.2-5.0.</p> <p>http://www.adamispharmaceuticals.com/wp-content/uploads/2018/10/prescribing-info.pdf at 6.</p>
<p>said liquid pharmaceutical formulation including no more than about 6% d-epinephrine and no more than about 0.5% adrenalone at release,</p>	<p>Based on stability data, Adamis is requesting a shelf-life (expiry date) of 18 months when stored at room temperature 77°F in the plastic case provided. The Stability data support an 18-month expiry.</p> <p>https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/207534Orig1s0000SumR.pdf at 4.</p> <p>Protect from light. Epinephrine is light sensitive and should be stored in the case provided to protect it from light . . . Before using, check to make sure the solution in the syringe is clear and colorless.</p>

	<p>Replace the product if the solution is discolored (pinkish or brown color), cloudy, or contains particles.</p> <p>http://www.adamispharmaceuticals.com/wp-content/uploads/2018/10/prescribing-info.pdf at 8.</p> <p>On information and belief, the SYMJEPI liquid pharmaceutical formulation includes no more than about 6% d-epinephrine and no more than about 0.5% adrenalone at release based on these indications.</p>
<p>and no more than about 12% d-epinephrine and no more than about 0.5% adrenalone over a shelf-life of at least 12 months.</p>	<p>Based on stability data, Adamis is requesting a shelf-life (expiry date) of 18 months when stored at room temperature 77°F in the plastic case provided. The Stability data support an 18-month expiry.</p> <p>https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/207534Orig1s0000SumR.pdf at 4.</p> <p>Protect from light. Epinephrine is light sensitive and should be stored in the case provided to protect it from light . . . Before using, check to make sure the solution in the syringe is clear and colorless. Replace the product if the solution is discolored (pinkish or brown color), cloudy, or contains particles.</p> <p>http://www.adamispharmaceuticals.com/wp-content/uploads/2018/10/prescribing-info.pdf at 8.</p> <p>On information and belief, the SYMJEPI liquid pharmaceutical formulation includes no more than about 12% d-epinephrine and no more than about 0.5% adrenalone over a shelf-life of at least 12 months based on these indications.</p>

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