

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK**

ALTAIRE PHARMACEUTICALS, INC.,)
)
 Plaintiff/Counterclaim-Defendant,)
)
 v.)
)
 PARAGON BIOTECK, INC.,)
)
 Defendant/Counterclaimant.)
 _____)
)
 PARAGON BIOTECK, INC.,)
)
 Third-Party Plaintiff,)
)
 v.)
)
 SAWAYA AQUEBOGUE, LLC,)
)
 Third-Party Defendant.)
 _____)

Case No.: 2:15-cv-02416 LDW-AYS

**PARAGON’S ANSWER TO
PLAINTIFF’S COMPLAINT AND
COUNTERCLAIMS**

DEMAND FOR JURY TRIAL

**PARAGON BIOTECK, INC.’S ANSWER, AFFIRMATIVE DEFENSES,
COUNTERCLAIMS, AND THIRD-PARTY COMPLAINT**

Paragon BioTeck, Inc. (“Paragon”) answers and responds to each of the allegations of Plaintiff Altaire Pharmaceuticals, Inc.’s (“Altaire”) Complaint as follows:

THE PARTIES

1. Altaire is a New York corporation, having its principal place of business at 311 West Lane, Aquebogue, New York 11931. All of Altaire’s employees, shareholders, officers, and directors are located in New York.

ANSWER: Paragon lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 1 of the Complaint, and on that basis denies them.

2. Paragon is a Nevada corporation, having its principal place of business at 4640 SW Macadam Ave., Suite 80, Portland, Oregon 97239.

ANSWER: Admitted.

3. Witham, an individual, is President and Chief Executive Officer of Paragon and, upon information and belief, a resident and citizen of Oregon.

ANSWER: Paragon admits that Patrick Witham is a resident of Oregon and is the President and Chief Executive Officer of Paragon. To the extent not expressly admitted herein, Paragon denies the remaining allegations in Paragraph 3 of the Complaint.

JURISDICTION AND VENUE

4. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a)(1) in that the parties are citizens of different States and the amount in controversy exceeds \$75,000, exclusive of interest and costs.

ANSWER: Paragraph 4 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required Paragon admits that this Court has subject matter jurisdiction over this action with respect to Paragon. Patrick Witham was dismissed as a party to this action by Order of the Court dated August 5, 2015, and the allegations of the Complaint directed at Patrick Witham require no responsive pleading. To the extent not expressly admitted herein, Paragon denies the remaining allegations in Paragraph 4 of the Complaint.

5. The Court has personal jurisdiction over Defendants under N.Y. C.P.L.R. §§ 301 and 302. Witham, on behalf of Paragon, contacted Altaire representatives in New York to propose a business relationship and traveled to New York to negotiate a written Agreement (the "Agreement") between the parties.¹ The Agreement states, in part: "The parties to this Agreement agree that jurisdiction and venue of any action brought pursuant to this Agreement, to enforce the term hereof or otherwise with respect to the relationships between the parties created or extended pursuant hereto, shall properly lie in the Court(s) of the State of New York or the Court(s) of the United States having jurisdiction over Suffolk County, New York." The Agreement further states: "The validity, construction and enforcement of, and the remedies under, this Agreement shall be governed in accordance with the laws of the State of New York."

ANSWER: Paragraph 5 contains legal conclusions to which no answer is required. For purposes of this action only, Paragon does not contest personal jurisdiction. Patrick Witham was dismissed as a party to this action by Order of the Court dated August 5, 2015, and the allegations of the Complaint directed at Patrick Witham require no responsive pleading. To the

extent not expressly admitted herein, Paragon denies the remaining allegations in Paragraph 5 of the Complaint.

6. Paragon employees have since visited Altaire in New York on numerous occasions during the course of the relationship between the parties, and in relation to the Agreement.

ANSWER: Paragon admits that Patrick Witham has travelled to Altaire's New York facility in pursuance of the parties' May 30, 2011 Agreement. To the extent not expressly admitted herein, Paragon denies the remaining allegations in Paragraph 6 of the Complaint.

7. Venue is proper in this District under 28 U.S.C. § 1391(b)(2), in that a substantial part of the events or omissions giving rise to the claims occurred in this District, and in accordance with the venue provisions referenced in paragraph 5.

ANSWER: Paragraph 7 contains legal conclusions to which no answer is required. Paragon admits that the parties' May 20, 2011 Agreement states, in part: "The parties to this Agreement agree that jurisdiction and venue of any action brought pursuant to this Agreement, to enforce the term hereof or otherwise with respect to the relationships between the parties created or extended pursuant hereto, shall properly lie in the Court(s) of the State of New York or the Court(s) of the United States having jurisdiction over Suffolk County, New York." For purposes of this action only, Paragon does not dispute that venue is proper in this District. Patrick Witham was dismissed as a party to this action by Order of the Court dated August 5, 2015, and the allegations of the Complaint directed at Patrick Witham require no responsive pleading. To the extent not expressly admitted herein, Paragon denies the remaining allegations in Paragraph 7 of the Complaint.

FACTUAL BACKGROUND

The Agreement

8. In 2011, Witham, Paragon's President and CEO, contacted Assad (Al) Sawaya, the President of Altaire, in New York and proposed a business relationship between Paragon and Altaire. Witham and Sawaya were acquainted through Witham's previous employer.

ANSWER: Paragon admits that on May 30, 2011, Paragon and Altaire entered into an agreement (“the Agreement”), in which Altaire agreed to provide the Chemistry, Manufacturing, and Control (“CMC”) sections for New Drug Application (“NDA”) filings made by Paragon on two drug products. To the extent not expressly admitted herein, Paragon denies the remaining allegations in Paragraph 8 of the Complaint.

9. Specifically, Witham proposed that Paragon and Altaire work together to file New Drug Applications (“NDA”s) with the Food and Drug Administration (“FDA”) for certain ophthalmic products, including a solution containing phenylephrine. Phenylephrine is a pupil-dilating agent commonly used by physicians and optometrists during eye examinations. The FDA has categorized phenylephrine as a medically necessary drug.

ANSWER: Paragon admits that on May 20, 2011, Paragon and Altaire entered into the Agreement, in which Altaire agreed to provide the CMC sections for NDA filings made by Paragon on phenylephrine hydrochloride ophthalmic solution, 2.5% and 10%, and on a second drug product. Paragon admits that phenylephrine hydrochloride is a potent pupil-dilating agent that is commonly used by optometrists, ophthalmologists, and other physicians during ocular examinations, and that the Food and Drug Administration (“FDA”) has categorized phenylephrine as a medically necessary drug. To the extent not expressly admitted herein, Paragon denies the remaining allegations in Paragraph 9 of the Complaint.

10. For many years before Witham contacted Altaire, Altaire had been manufacturing and selling its phenylephrine formulations in the marketplace. Altaire agreed to work with Paragon to submit NDAs to the FDA in part because in 2011, the FDA issued stricter guidelines regulating the marketing and selling of drugs unapproved by the FDA. Altaire believed that by working with Paragon to obtain FDA approval for its products, it would achieve greater protection and exclusivity in the marketplace with respect to those products.

ANSWER: Paragon lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 10 of the Complaint, and on that basis denies them.

11. After a period of negotiation, Paragon and Altaire entered into the Agreement on May 30, 2011.

ANSWER: Paragon admits that on May 30, 2011, Paragon and Altaire entered into the Agreement, in which Altaire agreed to provide CMC sections for NDA filings made by Paragon on two drug products. To the extent not expressly admitted herein, Paragon denies the remaining allegations in Paragraph 11 of the Complaint.

12. The Agreement obligated Altaire to provide the Chemistry, Manufacturing, and Control (“CMC”) sections for NDA filings that were to be submitted by Paragon on phenylephrine hydrochloride ophthalmic solution, 2.5% and 10% (“phenylephrine”), and on a second product (hereinafter referred to as “Product B”). Altaire also agreed to manufacture and supply the products in the Agreement. All of the research, development, and drafting of the CMC sections for phenylephrine took place in New York, and all manufacturing of that product takes place in New York. Altaire maintains no other manufacturing site.

ANSWER: Paragon admits that on May 30, 2011, Paragon and Altaire entered into an the Agreement, in which Altaire agreed to provide the CMC sections for NDA filings made by Paragon on phenylephrine hydrochloride ophthalmic solution, 2.5% and 10%, and on a second product (“collectively products”). In consideration for providing the CMC sections, Paragon agreed to give Altaire exclusive manufacturing rights once Paragon obtained FDA approval to market its products. To the extent not expressly admitted herein, Paragon denies the remaining allegations in Paragraph 12 of the Complaint.

13. Pursuant to the Agreement, Altaire was to be the exclusive manufacturer and supplier of the products once Paragon obtained FDA approval to market the products. Paragon was to be the exclusive marketer and distributor of the products.

ANSWER: Paragon admits that pursuant to the Agreement, Paragon agreed to give Altaire exclusive manufacturing rights once Paragon obtained FDA approval to market its products and that Paragon was to be the exclusive marketer and distributor of the products. To the extent not expressly admitted herein, Paragon denies the remaining allegations in Paragraph 13 of the Complaint.

14. The Agreement contained a “Confidentiality/Non-disclosure” section which, in part, acknowledged that all of Altaire’s CMC materials and information disclosed pursuant to the

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