IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EXELA PHARMA SCIENCES, LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 20-00365-MN
	)	
ETON PHARMACEUTICALS, INC.,	)	**JURY TRIAL DEMANDED**
	)	
Defendant.	)	

ETON PHARMACEUTICALS, INC.'S ANSWER
AND AFFIRMATIVE DEFENSES TO COMPLAINT

Defendant Eton Pharmaceuticals, Inc. ("Eton"), by and through its attorneys, hereby provides the following Answer and Affirmative Defenses to the Complaint filed by Plaintiff Exela Pharma Sciences, LLC ("Plaintiff"). Unless otherwise specifically admitted below, Eton denies all allegations in Plaintiff's Complaint. *See* Fed. R. Civ. P. 8(b)(3).

NATURE OF ACTION

1. Eton admits that Plaintiff's Complaint purports to bring an action for infringement of U.S. Patent Nos. 10,478,453 ("'453 Patent") and 10,583,155 ("'155 Patent) (collectively, "Patents-in-Suit") and that this action purports to arise 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 remainder of Paragraph 1 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Eton denies the remaining allegations of Paragraph 1.

THE PARTIES

2. Eton lacks sufficient knowledge and information to form a belief as to the allegations of Paragraph 2 and therefore denies the same.

3. Eton admits that it is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 21925 West Field Parkway, Suite 235, Deer Park, IL 60010.

JURISDICTION AND VENUE

4. Paragraph 4 contains legal conclusions to which no response is required. To the extent a response is required, Eton does not contest subject matter jurisdiction over Plaintiff's allegations against Eton under 35 U.S.C. § 271(e)(2) pursuant to 28 U.S.C. §§ 1331 and 1338(a) for purposes of this action only. Eton denies the remaining allegations of Paragraph 4.

5. Paragraph 5 contains legal conclusions to which no response is required. To the extent a response is required, Eton does not contest personal jurisdiction for purposes of this action only and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiff. Eton also admits that "COGENCY GLOBAL INC., 850 NEW BURTON ROAD SUITE 201, DOVER, DE, 19904" is provided under the "REGISTERED AGENT INFORMATION" section of the State of Delaware's Division of Corporations website as Eton's registered agent in Delaware and is authorized to accept service on Eton's behalf. Eton denies the remaining allegations of Paragraph 5.

6. Paragraph 6 contains legal conclusions to which no response is required. To the extent a response is required, Eton does not contest venue for purposes of this action only and expressly reserves the right to contest venue in any other case as to any party, including Plaintiff.

FACTUAL BACKGROUND

A. The Development and FDA Approval of Exela's ELCYS® L-Cysteine Product

7. Eton lacks sufficient knowledge and information to form a belief as to the allegations of Paragraph 7 and therefore denies the same.

8. Eton admits that L-cysteine is an amino acid that can be naturally synthesized in small amounts by humans, and that it may be provided as an L-Cysteine Hydrochloride Injection solution which, after combination with an Amino Acid Injection solution, is administered parenterally to meet the amino acid requirements of patients receiving total parenteral nutrition ("TPN"). Eton lacks sufficient knowledge and information to form a belief as to the remaining allegations of Paragraph 8 and therefore denies the same.

9. Eton is without knowledge as to the timeframe during which Exela began developing its L-cysteine product, and therefore, it lacks sufficient knowledge to admit or deny that there was no FDA-approved intravenous L-cysteine hydrochloride product on the market in the United States at that time. Eton notes, however, that, in the 1980s, FDA approved a L-cysteine hydrochloride product ("Hospira L-cysteine product"). And, that no later than 2010, Sandoz Inc. offered an L-cysteine hydrochloride product ("Sandoz L-cysteine product") in the United States market. Eton admits that aluminum is a known toxic impurity in parenteral nutritional compositions but denies that all L-cysteine products were known to contain high amounts of aluminum prior to the effective date of Exela's purported invention. For example, the Sandoz L-cysteine product contained low levels of aluminum. Eton lacks sufficient knowledge and information to form a belief as to the remaining allegations of Paragraph 9 and therefore denies the same.

10. Eton admits that the literature known to the pharmaceutical industry identifies various health problems associated with aluminum toxicity. Eton denies that all TPN admixtures, including those without L-cysteine, necessarily had high levels of aluminum. Eton lacks sufficient knowledge and information to form a belief as to the remaining allegations of Paragraph 10 and therefore denies the same.

11. Eton admits that the FDA amended the labeling requirements for parenteral drug products, that these amendments were codified at 21 C.F.R. § 201.323, and that Paragraph 11 includes a portion of the warning required by the FDA. Eton lacks sufficient knowledge and information to form a belief as to the remaining allegations of Paragraph 11 and therefore denies the same.

12. Upon information and belief, Eton admits that Exela secured FDA approval in April 2019, for an injectable L-cysteine hydrochloride product. Eton denies that the product fulfilled a long-felt need for a low-aluminum injectable cysteine product. Eton lacks sufficient knowledge and information to form a belief as to the remaining allegations of Paragraph 12 and therefore denies the same.

13. Eton admits that the *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the "Orange Book") identifies EXELA PHARMA SCIENCES LLC as the purported "Applicant Holder" for NDA 210660, purportedly for a solution containing CYSTEINE HYDROCHLORIDE as the "Active Ingredient," and identifies ELCYS as the "Proprietary Name" for this product. Eton lacks sufficient knowledge and information to form a belief as to the remaining allegations of Paragraph 13 and therefore denies the same.

14. Eton admits that Exhibit B purports to be a copy of ELCYS's "HIGHLIGHTS OF PRESCRIBING INFORMATION," revised 04/2019, and states in "11 DESCRIPTION," that "ELCYS contains no more than 120 mcg/L of aluminum." Eton lacks sufficient knowledge and information to form a belief as to the remaining allegations of Paragraph 14 and therefore denies the same.

15. Eton admits that Exhibit B purports to be a copy of ELCYS's "HIGHLIGHTS OF PRESCRIBING INFORMATION," revised 04/2019, and states in "11 DESCRIPTION," that "ELCYS (cysteine hydrochloride injection) is a sterile, nonpyrogenic solution for intravenous use" and that "[e]ach 10 mL of ELCYS contains 500 mg of cysteine hydrochloride, USP (equivalent to 345 mg of cysteine) in water for injection." Eton lacks sufficient knowledge and information to form a belief as to the remaining allegations of Paragraph 15 and therefore denies the same.

16. Eton admits that pyruvic acid and cystine were known oxidative degradation products of L-cysteine. Eton lacks sufficient knowledge and information to form a belief as to the remaining allegations of Paragraph 16 and therefore denies the same.

17. Eton admits that Exhibit B purports to be a copy of ELCYS's "HIGHLIGHTS OF PRESCRIBING INFORMATION," revised 04/2019, and states in "1 INDICATIONS AND USAGE," that "ELCYS is indicated for use as an additive to amino acid solutions to meet the nutritional requirements of newborn infants requiring total parenteral nutrition (TPN) and of adult and pediatric patients with severe liver disease who may have impaired enzymatic processes and require TPN" and that ELCYS "can also be added to amino acid solutions to provide a more complete profile of amino acids for protein synthesis." Eton lacks sufficient knowledge and information to form a belief as to the remaining allegations of Paragraph 17 and therefore denies the same.

18. Eton admits that Exhibit B purports to be a copy of ELCYS's "HIGHLIGHTS OF PRESCRIBING INFORMATION," revised 04/2019, and includes, in "2 DOSAGE AND ADMINISTRATION," the following sections: "2.1 Important Administration Information"; "2.2 Preparation and Administration Instructions"; "2.3 Preparation Instructions for Admixing Using

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