IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EXELA PHARMA SCIENCES, LLC,

Plaintiff,

v.

AVADEL LEGACY PHARMACEUTICALS, LLC; and AVADEL US HOLDINGS, INC.,

Defendants.

Civil Action No.: _____

JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Exela Pharma Sciences, LLC ("Plaintiff" or "Exela") by its attorneys, hereby alleges as follows:

NATURE OF ACTION

1. This is an action for a declaratory judgment of infringement of U.S. Patent No. 10,478,453 ("the '453 patent") under 28 U.S.C. §§ 2201 and 2202 and the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, including §§ 271(a)-(c). Exela brings this action to enforce its patent rights covering ELCYS® brand L-cysteine hydrochloride injection, which is approved by the United States Food and Drug Administration ("FDA") 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.

THE PARTIES

2. Plaintiff Exela Pharma Sciences, LLC ("Exela") is a company existing under the laws of the state of Delaware and having a principal place of business at 1245 Blowing Rock Blvd., Lenoir, NC 28645.

3. On information and belief, Defendant Avadel Legacy Pharmaceuticals, LLC is a company existing under the laws of the State of Delaware and having a principal place of business at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, MO 63005.

4. On information and belief, Defendant Avadel US Holdings Inc. is a company existing under the laws of the State of Delaware and having a principal place of business at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, MO 63005.

5. On information and belief, Avadel Legacy Pharmaceuticals, LLC is a wholly-owned subsidiary of Avadel US Holdings, Inc.

6. On information and belief, Defendants Avadel Legacy Pharmaceuticals, LLC and Avadel US Holdings, Inc. (collectively, "Avadel") are in the business of formulating, developing, manufacturing, importing, marketing, offering for sale, and/or selling pharmaceutical products that are distributed in and sold throughout the United States, including in this District.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338(a), 2201 and 2202, because the action concerns a federal question arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.

8. This Court has personal jurisdiction over Avadel US Holdings, Inc., and Avadel Legacy Pharmaceuticals, LLC, because each is incorporated in this District and is doing business in this District.

9. Venue is proper in this District with respect to Avadel US Holdings, Inc., and Avadel Legacy Pharmaceuticals, LLC, pursuant to 28 U.S.C. § 1391 and § 1400(b) because each resides in this District.

10. Joinder of both Defendants in this action is proper under 35 U.S.C. § 299(a) because Plaintiff's right to relief is asserted against the parties jointly and arising out of the same transaction, occurrence, or series of transactions or occurrences relating to the making, using, importing into the United Sates, offering for sale, and/or selling of the same accused product or process; and questions of fact common to all Defendants will arise in the action.

FACTUAL BACKGROUND

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

11. Exela is a relatively small but fast-growing specialty pharmaceutical company focused on developing, manufacturing, and marketing injectable products, including L-cysteine.

12. L-cysteine is an amino acid that is important for human life. While healthy adults can naturally synthesize small amounts, high-risk patients such as preterm and/or low birth weight infants and patients with severe liver disease require L-cysteine supplementation by parenteral administration (i.e., injection or intravenous infusion). For these patients, L-cysteine is administered as a component of a nutritional supplement regimen referred to as "total parenteral nutrition" (TPN).

13. Before Exela began work on developing its L-cysteine product, there was no FDA-approved intravenous L-cysteine hydrochloride product on the market in the United States. However, multiple unapproved and compounded L-cysteine products were on the market during that time that were used in TPN regimens. One significant drawback of such L-cysteine products is that they were known to contain high amounts of aluminum, for example, 5,000 mcg/L.

14. TPN solutions were also known to contain high amounts of aluminum, and aluminum toxicity from their use had been reported. Aluminum toxicity can cause serious health problems including dementia, impaired neurologic development, Alzheimer's disease, metabolic bone disease (including impaired bone growth, growth failure, bone pain, muscle weakness, nonhealing fractures, and premature osteoporosis), encephalopathy, and cholestasis (liver disease), among others.

15. In 2000, FDA issued regulations requiring manufacturers to reduce aluminum levels of parenteral products. 65 Fed. Reg. 4103 (Jan. 26, 2000). That regulation became final in 2004. 68 Fed. Reg. 32,979 (June 3, 2003). It requires manufacturers of TPN components to include the following warning on their product labeling: "Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 [micro]g/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity." 65 Fed. Reg. 4103, 4111 (Jan. 26, 2000). These regulations are codified at 21 C.F.R. § 201.323.

16. In April of 2019, after extensive effort, research and development, including substantial work to achieve the ≤ 145 mcg/L aluminum level FDA mandated for the product, [Ex. A (8/4/2017 FDA Letter)], Exela secured FDA approval for an injectable L-cysteine hydrochloride product containing low aluminum levels, finally fulfilling a long-felt need for a low-aluminum injectable cysteine product.

17. Exela's FDA approved L-cysteine hydrochloride product, sold under the brand name ELCYS®, is labeled to contain no more than 120 micrograms/liter ("mcg/L," "µg/L" or, more commonly, parts per billion or ppb) of aluminum, and is the only FDA approved L-cysteine product available on the market today. [Ex. B (ELCYS® Label), §11.]

18. Exela's ELCYS® product is a sterile, nonpyrogenic solution for intravenous use. Each 10 mL of ELCYS® contains 500 mg of cysteine hydrochloride, USP (equivalent of 345 mg of cysteine) in water for injection. [*Id.* at §11.]

19. The FDA-approved labeling for Exela's ELCYS® product instructs healthcare providers 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. It can also be added to amino acid solutions to provide a more complete profile of amino acids for protein synthesis." [*Id.* at §1.]

20. The FDA-approved labeling for Exela's ELCYS® product instructs healthcare providers that "Prior to administration, ELCYS *must be diluted and used as an admixture* in parenteral nutrition (PN) solutions." [*Id.* at §2.1.] It further instructs, "ELCYS is for addition to amino acid solutions prior to further admixing with dextrose injection using a PN container." [*Id.* at §2.2.]

21. The FDA-approved labeling for Exela's ELCYS® product instructs healthcare providers:

- "Transfer the required amount of ELCYS to an amino acid solution . . . ."
- "The amino acid solution containing ELCYS can then be used to prepare admixtures in the PN container . . . ."
- "Amino acid solutions containing ELCYS may be mixed with dextrose injection. The following proper mixing sequence must be followed to minimize pH related problems:

    1. Transfer dextrose injection to the parenteral nutrition pooling container

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