IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EXELA PHARMA SCIENCES, LLC,

Plaintiff,

v.

ETON PHARMACEUTICALS, INC.,

Defendant.

Civil Action No.: 20-00365-MN

JURY TRIAL DEMANDED

ANSWER TO SECOND AMENDED COMPLAINT

Defendant Eton Pharmaceuticals, Inc. ("Defendant" or "Eton") by its attorneys, hereby alleges provides the following Answer to Second Amended Complaint filed by Plaintiff Exela Pharma Sciences, LLC ("Plaintiff" or "Exela"). 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. This is an action for infringement of U.S. Patent No. 10,478,453 ("the '453 patent"), U.S. Patent No. 10,583,155 ("the '155 patent"), U.S. Patent No. 10,653,719 ("the '719 patent"), U.S. Patent No. 10,905,713 ("the '713 patent"), U.S. Patent No. 10,912,795 ("the '795 patent"), and U.S. Patent No. 10,933,089 ("the '089 patent") under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., including §§ 271(e)(2), 271(a)-(c), and for a declaratory judgment of infringement of the '453, '155, '719, '713, '795, and '089 patents under 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. §§ 271(a)-(c). Plaintiff institutes this action to enforce its patent rights covering its FDA-approved ELCYS® brand L-cysteine hydrochloride injection.

ANSWER: Eton admits that Plaintiff's Amended Complaint purports to bring an action

for infringement of U.S. Patent Nos. 10,478,453 ("the '453 patent"), 10,583,155 ("the '155 patent"), and 10,653,719 ("the '719 patent") U.S. Patent No. 10,905,713 ("the '713 patent"), U.S. Patent No. 10,912,795 ("the '795 patent"), and U.S. Patent No. 10,933,089 ("the '089 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.

Eton is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 1, and therefore deny all such allegations.

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.

ANSWER: Eton is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 2, and therefore denies all such allegations.

3. On information and belief, Defendant Eton Pharmaceuticals, Inc. ("Eton") is a corporation organized and existing under the law of the State of Delaware, having a principal place of business at 21925 West Field Parkway, Suite 235, Deer Park, IL 60010.

ANSWER: Admitted.

JURISDICTION AND VENUE

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

ANSWER: Paragraph 4 contains conclusions of law to which no answer is required. To the extent an answer is required, Eton denies the allegations in Paragraph 4.

5. This Court has personal jurisdiction over Eton Pharmaceuticals, Inc. because it is incorporated in Delaware and thus is present in and resides in this District, and because Eton is doing business in this District and thus has purposefully availed itself to the privileges of conducting business in Delaware. On information and belief, Cogency Global Inc., 850 New Burton Road, Suite 201, Dover, Delaware, is Eton's registered agent in Delaware and is authorized to accept service on Eton's behalf.

ANSWER: Eton admits that Cogency Global Inc., is listed as Eton's registered agent in the State of Delaware and is authorized to accept service on Eton's behalf. The remaining allegations of Paragraph 5 contain conclusions of law to which no answer is required. To the extent and answer is required, Eton denies all such allegations. Answering further, Eton is not challenging personal jurisdiction in this case only.

6. Venue is proper in this District pursuant to 28 U.S.C. § 1400(b) and § 1391 because Eton Pharmaceuticals, Inc. is incorporated in Delaware and thus resides in this District.

ANSWER: Paragraph 6 contains contain conclusions of law to which no answer is required. To the extent and answer is required, Eton denies all such allegations. Answering further, Eton is not challenging venue in this case only.

FACTUAL BACKGROUND

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

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

ANSWER: Eton is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 7, and therefore denies all such allegations.

8. 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).

ANSWER: 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. At the time Exela began 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, labeled as containing up to 5,000 mcg/L.

ANSWER: Eton is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 9, and therefore denies all such allegations.

10. TPN admixtures even without L-cysteine 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.

ANSWER: 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. In 2000, FDA issued regulations requiring manufacturers to reduce aluminum levels of parenteral products. Aluminum in Large and Small Volume Parenterals Used in Total Parenteral Nutrition, 65 Fed. Reg. 4103 (Jan. 26, 2000). That regulation became final in 2004. Amendment of Regulations on Aluminum in Large and Small Volume Parenterals Used in Total Parenteral Nutrition; Delay of Effective Date, 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." Aluminum in Large and Small Volume Parenterals Used in Total Parenteral Nutrition, 65 Fed. Reg. 4103, 4111 (Jan. 26, 2000). These regulations are codified at 21 C.F.R. § 201.323.

ANSWER: 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. 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, [Exhibit A (8/4/2017 FDA Letter)], Exela secured the first FDA approval for an injectable L-cysteine hydrochloride product containing low aluminum levels, finally fulfilling a long-felt need for such a low-aluminum injectable cysteine product.

ANSWER: 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. Exela is the holder of approved New Drug Application ("NDA") No. 210660 for cysteine hydrochloride injection, sold under the brand name ELCYS®.

ANSWER: 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. Exela's ELCYS® product is labeled to contain no more than 120 micrograms/liter ("mcg/L," "µg/L" or, more commonly, parts per billion or ppb) of aluminum throughout the shelf life of the product, and is the only FDA approved L-cysteine product available on the market today. [Exhibit B (ELCYS® Label), § 11.]

ANSWER: Eton admits that Exhibit B purports to be a copy of ELCYS's "HIGHLIGHTS OF PRESCRIBING INFORMATION," revised 04/2019. Eton denies that the label includes the language "throughout the shelf life of the product." Eton lacks sufficient knowledge and information to form a belief as to the remaining allegations of Paragraph 14 and therefore denies the same.

15. 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.] The chemical name of L-cysteine hydrochloride is L-cysteine hydrochloride monohydrate. [Id.]

ANSWER: Eton admits that Exhibit B purports to be a copy of ELCYS's "HIGHLIGHTS OF PRESCRIBING INFORMATION," revised 04/2019. Eton lacks sufficient knowledge and information to form a belief as to the remaining allegations of Paragraph 15 and therefore denies the same.

16. Exela's ELCYS® product has a pH in the range of 1.0 to 2.5. [Id.]

ANSWER: Eton admits that Exhibit B purports to be a copy of ELCYS's "HIGHLIGHTS OF PRESCRIBING INFORMATION," revised 04/2019. Eton lacks sufficient knowledge and information to form a belief as to the remaining allegations of Paragraph 16 and therefore denies the same.

17. The FDA approved ELCYS® with a specification limiting the total impurities in the product, including pyruvic acid and cystine, both of which are observed as degradation products of L-cysteine, to no more than 2.0%.

ANSWER: Eton is without knowledge or information sufficient to form a belief as to the truth of any of the allegations of Paragraph 17, and therefore denies all such allegations.

18. The FDA approved ELCYS® with a specification for visual particulate matter of "essentially free of visible particulate matter." Exela's ELCYS® product met that specification throughout 24 months of stability testing. Accordingly, Exela's ELCYS® product remains free of visually detectable particulate matter for at least 24 months from the time of manufacture of the solution. Twenty-four months from the time of manufacture of the solution is the FDA-approved shelf-life of ELCYS®.

ANSWER: Eton is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 18, and therefore denies all such allegations.

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.]

ANSWER: Eton admits that Exhibit B purports to be a copy of ELCYS's "HIGHLIGHTS OF PRESCRIBING INFORMATION," revised 04/2019. The remaining allegations call for a legal conclusion for which no response is necessary, and/or Eton lacks sufficient knowledge and information to form a belief as to the remaining allegations of Paragraph 19 and therefore denies the same.

20. The FDA-approved labeling for ELCYS® further instructs healthcare providers that "ELCYS is for admixing use only. It is not for direct intravenous infusion. Prior to administration, ELCYS must be diluted and used as an admixture in parenteral nutrition (PN) solutions. The resulting solution is for intravenous infusion into a central or peripheral vein." [Id. at § 2.1 (emphases in original).] It goes on to provide instructions for healthcare providers on how to prepare the admixture by following the steps laid out on the label and how to administer PN solutions containing ELCYS®. [Id. at §§ 2.2-2.5.].

ANSWER: Eton admits that Exhibit B purports to be a copy of ELCYS's "HIGHLIGHTS OF PRESCRIBING INFORMATION," revised 04/2019. The remaining allegations call for a legal conclusion for which no response is necessary, and/or Eton lacks sufficient knowledge and information to form a belief as to the remaining allegations of Paragraph 20 and therefore denies the

same.

21. The FDA-approved labeling for ELCYS® further instructs healthcare providers to "Remove ELCYS vial from the carton and inspect for particulate matter." [Id. at § 2.3.]

ANSWER: Eton admits that Exhibit B purports to be a copy of ELCYS's "HIGHLIGHTS OF PRESCRIBING INFORMATION," revised 04/2019. The remaining allegations call for a legal conclusion for which no response is necessary, and/or Eton lacks sufficient knowledge and information to form a belief as to the remaining allegations of Paragraph 21 and therefore denies the same.

22. The FDA-approved labeling for ELCYS® further instructs healthcare providers to "Visually inspect the diluted PN solution containing ELCYS for particulate matter before admixing, after admixing, and prior to administration. The solution should be clear and there should be no precipitates." [Id. at § 2.2.]

ANSWER: Eton admits that Exhibit B purports to be a copy of ELCYS's "HIGHLIGHTS OF PRESCRIBING INFORMATION," revised 04/2019. The remaining allegations call for a legal conclusion for which no response is necessary, and/or Eton lacks sufficient knowledge and information to form a belief as to the remaining allegations of Paragraph 22 and therefore denies the same.

23. The FDA-approved labeling for Exela's ELCYS® product provides recommendage (sic) dosage and volume for pediatric patients from birth to less than 12 years of age, including for neonates and infants, e.g., preterm and term infants less than 1 month of age, and pediatric patients 1 month to less than 1 year of age. [Id. at § 2.5 & Tbl. 1.]

ANSWER: Eton admits that Exhibit B purports to be a copy of ELCYS's "HIGHLIGHTS OF PRESCRIBING INFORMATION," revised 04/2019. The remaining allegations call for a legal conclusion for which no response is necessary, and/or Eton lacks

sufficient knowledge and information to form a belief as to the remaining allegations of Paragraph 23 and therefore denies the same.

24. The FDA-approved labeling for ELCYS® instructs that "[t]he dosage of the final PN solution containing ELCYS must be based on the concentrations of all components in the solution and the recommended nutritional requirements [see Dosage and Administration (2.5)]." [Id. § 2.4.]

ANSWER: Eton admits that Exhibit B purports to be a copy of ELCYS's "HIGHLIGHTS OF PRESCRIBING INFORMATION," revised 04/2019. The remaining allegations call for a legal conclusion for which no response is necessary, and/or Eton lacks sufficient knowledge and information to form a belief as to the remaining allegations of Paragraph 24 and therefore denies the same.

25. The FDA-approved labeling for ELCYS® includes the following warnings related to the level of aluminum patients receive: "Aluminum may reach toxic levels with prolonged parenteral administration in patients with renal impairment. Preterm infants are particularly at risk for aluminum toxicity because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which also contain aluminum. Patients with renal impairment, including preterm infants, who receive greater than 4 to 5 mcg/kg/day of parenteral aluminum can accumulate aluminum to levels associated with central nervous system and bone toxicity." [Id. at § 5.7.] It further instructs, "[e]xposure to aluminum from ELCYS is not more than 0.21 mcg/kg/day when preterm and term infants less than 1 month of age are administered the recommended maximum dosage of ELCYS (15 mg cysteine/g of amino acids and 4 g of amino acids/kg/day) [see Table 1, Dosage and Administration (2.5)]. When prescribing ELCYS for use in PN containing other small volume parenteral products, the total daily patient exposure to aluminum from the admixture should be considered and maintained at no more than 5 mcg/kg/day [see Use in Specific

Populations (8.4)].” [Id.]

ANSWER: Eton admits that Exhibit B purports to be a copy of ELCYS’s “HIGHLIGHTS OF PRESCRIBING INFORMATION,” revised 04/2019. The remaining allegations call for a legal conclusion for which no response is necessary, and/or Eton lacks sufficient knowledge and information to form a belief as to the remaining allegations of Paragraph 25 and therefore denies the same. Answering further, 21 CFR 201.323(e) requires package labels for small volume and large volume parenteral drug products, such as ELCYS to contain this, or a similar warning statement.

B. The Asserted ’453 patent

26. On November 19, 2019, the United States Patent and Trademark Office (“USPTO”) issued the ’453 patent, entitled “Stable, Highly Pure L-Cysteine Compositions for Injection and Methods of Use,” and naming John Maloney, Aruna Koganti, and Phanesh Koneru as inventors. A copy of the ’453 patent is attached to this Complaint as Exhibit C.

ANSWER: Eton admits that Exhibit C purports to be a copy of the ’453 patent and that, on its face, Exhibit C is entitled, “Stable, Highly Pure L-Cysteine Compositions for Injection and Methods of Use.” Eton also admits that Exhibit C, on its face, indicates that the “Date of Patent” is “Nov. 19, 2019” and that the named “Inventors” are John Maloney, Aruna Koganti, and Phanesh Koneru. Eton denies the remaining allegations of Paragraph 26.

27. The ’453 patent is assigned to Plaintiff Exela.

ANSWER: Eton admits that Exhibit C indicates on its face that “Exela Pharma Sciences, LLC, Lenoir, NC (US)” is the “Assignee” of the ’453 patent. Eton lacks sufficient knowledge and information to form a belief as to the remaining allegations of Paragraph 27 and therefore denies the same.

28. On November 19, 2019, Exela submitted the ’453 patent for listing in the “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly referred to as the

"Orange Book," which provides notice concerning patents covering FDA-approved drugs.

ANSWER: Eton admits that the '453 patent is listed in the Orange Book for NDA 210660 and that "11/19/2019" is identified as the "Submission Date" for the '453 patent. Eton lacks sufficient knowledge and information to form a belief as to the remaining allegations of Paragraph 28 and therefore denies the same.

29. On or about November 20, 2019, the FDA published the '453 patent in theOrange Book.

ANSWER: Eton is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 29, and therefore denies all such allegations.

30. Claim 1 of the '453 patent reads as follows:

A stable L-cysteine composition for parenteral administration, comprising:
L-cysteine or a pharmaceutically acceptable salt thereof and/or hydrate thereof in anamount from about 10 mg/mL to about 100 mg/mL;
Aluminum (Al) in an amount from about 1.0 parts per billion (ppb) to about 250ppb;
L-cystine in an amount from about 0.001 wt % to about 2.0 wt % relative to L-cysteine;
pyruvic acid in an amount from about 0.001 wt % to about 2.0 wt % relative to L-cysteine;
a pharmaceutically acceptable carrier, comprising water;
headspace oxygen that is from about 0.5% v/v to 4.0% v/v from the time ofmanufacture to about 1 month from manufacture when stored at room temperature;
dissolved oxygen present in the carrier in an amount from about 0.1 parts per million (ppm) to about 5 ppm from the time of manufacture to about 1 monthfrom manufacture when stored at room temperature,
wherein the composition is enclosed in a single-use container having a volume offrom about 10 mL to about 100 mL.

ANSWER: Admitted

31. Claim 4 of the '453 patent reads as follows:

The composition of claim 1, wherein said Aluminum is present in an amount fromabout 1.0 ppb to about 150 ppb.

ANSWER: Admitted.

32. Claim 22 of the '453 patent reads as follows:

A method of preparing a reduced Aluminum composition for a total parenteral nutrition regimen comprising L-cysteine, the method comprising:

mixing a composition comprising L-cysteine and/or a pharmaceutically acceptablesalt thereof and/or hydrate thereof comprising:

Aluminum in an amount from about 1.0 parts per billion (ppb) to about 250 ppb;L-cystine in an amount from about 0.001 wt % to about 2.0 wt % relative to L-

cysteine; and

pyruvic acid in an amount from about 0.001 wt % to about 2.0 wt % relative to L-cysteine;

with a composition comprising one or more amino acids selected from the group consisting of: leucine, isoleucine, lysine, valine, phenylalanine, histidine, threonine, methionine, tryptophan, alanine, arginine, glycine, proline, serine, andtyrosine; and a pharmaceutically acceptable carrier, comprising water, to form a composition for infusion having a volume of about 100 mL to about 1000 mL,

wherein the Aluminum provided in said parenteral nutrition regimen is from about1-2 to about 4-5 micrograms/kg/day.

ANSWER: Admitted.

33. Exela's ELCYS® product, and its use according to the directions and instructions on the FDA-approved label, is covered by at least claims 1, 4 and 22 of the '453 patent.

ANSWER: Eton is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 29, and therefore denies all such allegations.

C. The Asserted '155 patent

34. On March 10, 2020, the USPTO issued the '155 patent, entitled "Stable, HighlyPure L-Cysteine Compositions for Injection and Methods of Use," and naming John Maloney, Aruna Koganti, and Phanesh Koneru as inventors. A copy of the '155 patent is attached to thisComplaint as Exhibit D.

ANSWER: Eton admits that Exhibit D purports to be a copy of the '155 patent and that, on its face, Exhibit D is entitled, "Stable, Highly Pure L-Cysteine Compositions for Injection and Methods of Use." Eton also admits that Exhibit D, on its face, indicates that the "Date of Patent" is "*Mar. 10, 2020" and that the named "Inventors" are John Maloney, Aruna Koganti, and Phanesh Koneru. Eton denies the remaining allegations of Paragraph 34.

35. The '155 patent is assigned to Plaintiff Exela.

ANSWER: Eton admits that Exhibit D indicates on its face that "Exela Pharma Sciences, LLC, Lenoir, NC (US)" is the "Assignee" of the '155 patent. Eton lacks sufficient knowledge and

information to form a belief as to the remaining allegations of Paragraph 35 and therefore denies the same.

36. On March 10, 2020, Exela submitted the '155 patent for listing in the OrangeBook, which provides notice concerning patents covering FDA-approved drugs.

ANSWER: Eton admits that the '155 patent is listed in the Orange Book NDA 210660 and that "03/10/2020" is identified as the "Submission Date" for the '155 patent. Eton lacks sufficient knowledge and information to form a belief as to the remaining allegations of Paragraph 36 and therefore denies the same.

37. On or about March 11, 2020, the FDA published the '155 patent in the Orange Book.

ANSWER: Eton is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 37, and therefore denies all such allegations.

38. Claim 1 of the '155 patent reads as follows:

A method of treating a subject having an adverse health condition that is responsive to L-cysteine administration, said method comprising:
parenterally administering to said subject a parenteral composition comprising amixture of one or more amino acids, intravenous fluid, and a stable L-cysteinecomposition, wherein said stable L-cysteine composition contributes to said parenteral composition:
a therapeutically effective amount of L-cysteine or a pharmaceutically acceptablesalt thereof and/or hydrate thereof;
per Liter of said stable L-cysteine composition, from about 1.0 mcg to about 250mcg of Aluminum;
not more than about 2.0 wt% of cystine relative to L-cysteine; and not more than about 2.0 wt% of pyruvic acid relative to L-cysteine.

ANSWER: Admitted.

39. Claim 3 of the '155 patent reads as follows:

The method of claim 1, wherein said stable L-cysteine composition contributesAluminum in an amount less than 150 mcg/L.

ANSWER: Admitted.

40. Claim 27 of the '155 patent reads as follows:

A method of treating a subject having an adverse health condition that is responsive toL-cysteine administration, said method comprising:

parenterally administering to said subject a parenteral composition comprising amixture comprising a stable L-cysteine composition, wherein said stable L- cysteine composition contributes to said parenteral composition:

a therapeutically effective amount of L-cysteine or a pharmaceutically acceptablesalt thereof and/or hydrate thereof;

per Liter of said stable L-cysteine composition, not more than about 150 mcg ofAluminum;

cystine relative to L-cysteine not more than about 2.0 wt%; and pyruvic acid relative to L-cysteine not more than about 2.0 wt%.

ANSWER: Admitted.

41. Exela's ELCYS® product, and its use according to the directions and instructionson the FDA-approved label, is covered by at least claims 1, 3 and 27 of the '155 patent.

ANSWER: Eton is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 41, and therefore denies all such allegations.

D. The Asserted '719 patent

42. On May 19, 2020, the USPTO issued the '719 patent, entitled "Stable, Highly Pure L-Cysteine Compositions for Injection and Methods of Use," and naming John Maloney, Aruna Koganti, and Phanesh Koneru as inventors. A copy of the '719 patent is attached to thisComplaint as Exhibit E.

ANSWER: Eton admits that Exhibit E purports to be a copy of the '719 patent and that, on its face, Exhibit E is entitled, "Stable, Highly Pure L-Cysteine Compositions for Injection and Methods of Use." Eton also admits that Exhibit E, on its face, indicates that the "Date of Patent" is "*May 19, 2020" and that the named "Inventors" are John Maloney, Aruna Koganti, and Phanesh Koneru. Eton denies the remaining allegations of Paragraph 42.

43. The '719 patent is assigned to Plaintiff Exela.

ANSWER: Eton admits that Exhibit E indicates on its face that "Exela Pharma Sciences, LLC, Lenoir, NC (US)" is the "Assignee" of the '719 patent. Eton lacks sufficient know and

information to form a belief as to the remaining allegations of Paragraph 43 and therefore denies the same.

44. On or about July 1, 2020, Exela submitted the '719 patent for listing in the Orange Book which provides notice concerning patents covering FDA-approved drugs.

ANSWER: Eton admits that the '719 patent is listed in the Orange Book NDA 210660 and that "07/02/2020" is identified as the "Submission Date" for the '719 patent. Eton lacks sufficient knowledge and information to form a belief as to the remaining allegations of Paragraph 44 and therefore denies the same.

45. On or about July 8, 2020, the FDA published the '719 patent in the Orange Book.

ANSWER: Eton is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 45, and therefore denies all such allegations.

46. Claim 12 of the '719 patent reads as follows:

A solution of L-cysteine comprising,
a pharmaceutically acceptable carrier,
about 50 mg/mL of L-cysteine hydrochloride monohydrate, or equivalent amount ofa pharmaceutically acceptable L-cysteine or a salt or hydrate thereof,
less than about 150 ppb of aluminum, anda pH from about 1.0 to about 2.5,
wherein the solution is substantially free of visually detectable particulate matter forat least 6 months from the time of manufacture of the solution and is suitable for use as an additive in a parenteral nutrition composition for administration to a neonate or infant.

ANSWER: Admitted.

47. Claim 13 of the '719 patent reads as follows:

The solution of claim 12, wherein the solution is substantially free of visually detectable particulate matter for at least 9 months from the time of manufacture ofthe solution.

ANSWER: Admitted.

48. Claim 14 of the '719 patent reads as follows:

The solution of claim 12, wherein the solution is substantially free of visually detectable particulate matter for at least 12 months from the time of manufacture ofthe solution.

ANSWER: Admitted.

49. Claim 15 of the ’719 patent reads as follows:

The solution of claim 12, wherein the solution is substantially free of visually detectable particulate matter for at least 24 months from the time of manufacture ofthe solution.

ANSWER: Admitted.

50. Exela’s ELCYS® product, and its use according to the directions and instructionson the FDA-approved label, is covered by at least claims 12-15 of the ’719 patent.

ANSWER: Eton is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 50, and therefore denies all such allegations.

E. The Asserted ’713 Patent

51. On February 2, 2021, the USPTO issued the ’713 patent, entitled “Stable, Highly Pure L-Cysteine Compositions for Injection and Methods of Use,” and naming John Maloney, Aruna Koganti, and Phanesh Koneru as inventors. A copy of the ’713 patent is attached to this Complaint as Exhibit F.

ANSWER: Eton admits that Exhibit F purports to be a copy of the ’713 patent and that, on its face, Exhibit F is entitled, “Stable, Highly Pure L-Cysteine Compositions for Injection and Methods of Use.” Eton also admits that Exhibit F, on its face, indicates that the “Date of Patent” is “*Feb. 2, 2021” and that the named “Inventors” are John Maloney, Aruna Koganti, and Phanesh Koneru. Eton denies the remaining allegations of Paragraph 51.

52. The ’713 patent is assigned to Plaintiff Exela.

ANSWER: Eton admits that Exhibit F indicates on its face that “Exela Pharma Sciences, LLC, Lenoir, NC (US)” is the “Assignee” of the ’713 patent. Eton lacks sufficient know and information to form a belief as to the remaining allegations of Paragraph 52 and therefore denies the same.

53. On or about February 2, 2021, Exela submitted the ’713 patent for listing in the

Orange Book which provides notice concerning patents covering FDA-approved drugs.

ANSWER: Eton admits that the '713 patent is listed in the Orange Book NDA 210660 and that "02/02/2021" is identified as the "Submission Date" for the '713 patent. Eton lacks sufficient knowledge and information to form a belief as to the remaining allegations of Paragraph 53 and therefore denies the same.

54. At least as early as February 15, 2021, the FDA published the '713 patent in the Orange Book.

ANSWER: Eton is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 54, and therefore denies all such allegations.

55. Claim 1 of the '713 patent reads as follows:

A solution of L-cysteine comprising, a pharmaceutically acceptable carrier, about 50 mg/mL of L-cysteine hydrochloride monohydrate, or equivalent amount of a pharmaceutically acceptable L-cysteine or a salt or hydrate thereof, a pharmaceutically acceptable amount of cystine for at least about 12 months from the time of manufacture of the solution, less than about 150 ppb of aluminum for atleast about 12 months from the time of manufacture of the solution, a pH from about 1.0 to about 2.5, and wherein the solution is enclosed in a single-use vial.

ANSWER: Admitted.

56. Exela's ELCYS® product, and its use according to the directions and instructionson the FDA-approved label, is covered by at least claim 1 of the '713 patent.

ANSWER: Eton is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 56, and therefore denies all such allegations.

F. The Asserted '795 Patent

57. On Febraury 9, 2021, the USPTO issued the '795 patent, entitled "Stable, Highly Pure L-Cysteine Compositions for Injection and Methods of Use," and naming John Maloney, Aruna Koganti, and Phanesh Koneru as inventors. A copy of the '795 patent is attached to this Complaint as Exhibit G.

ANSWER: Eton admits that Exhibit G purports to be a copy of the '795 patent and that, on its face, Exhibit G is entitled, "Stable, Highly Pure L-Cysteine Compositions for Injection and Methods of Use." Eton also admits that Exhibit G, on its face, indicates that the "Date of Patent" is "*Feb. 9, 2021" and that the named "Inventors" are John Maloney, Aruna Koganti, and Phanesh Koneru. Eton denies the remaining allegations of Paragraph 57.

58. The '795 patent is assigned to Plaintiff Exela.

ANSWER: Eton admits that Exhibit G indicates on its face that "Exela Pharma Sciences, LLC, Lenoir, NC (US)" is the "Assignee" of the '795 patent. Eton lacks sufficient know and information to form a belief as to the remaining allegations of Paragraph 58 and therefore denies the same..

59. On or about February 9, 2021, Exela submitted the '795 patent for listing in the Orange Book which provides notice concerning patents covering FDA-approved drugs.

ANSWER: Eton admits that the '795 patent is listed in the Orange Book NDA 210660 and that "02/09/2021" is identified as the "Submission Date" for the '795 patent. Eton lacks sufficient knowledge and information to form a belief as to the remaining allegations of Paragraph 59 and therefore denies the same.

60. At least as early as February 15, 2021, the FDA published the '795 patent in the Orange Book.

ANSWER: Eton is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 60, and therefore denies all such allegations.

61. Claim 1 of the '795 patent reads as follows:

A solution of L-cysteine comprising, a pharmaceutically acceptable carrier, and about 50 mg/mL of L-cysteine hydrochloride monohydrate, or equivalent amount of a pharmaceutically acceptable L-cysteine or a salt or hydrate thereof; wherein the solution is stored in a single-use vial; wherein for at least 12 months from the time of manufacture of the solution, the solution will remain: substantially free of visually detectable particulate matter, at a pH from about 1.0 to 2.5,

and containingno more than 150 ppb of aluminum; and wherein the solution is safe for use as an additive in a parenteral nutrition composition for intravenous administration to an individual for at least 12 months from the time of manufacture of the solution.

ANSWER: Admitted.

62. Claim 11 of the '795 patent reads as follows:

A method of preparing the solution of claim 1 comprising, mixing at no more than 30° C. a pharmaceutically acceptable carrier comprising no more than 1 ppm dissolved oxygen with L-cysteine or a pharmaceutically acceptable salt thereof and/or hydratethereof; adjusting the pH of said mixture to from about 1.0 to about 2.5; transferringaseptically an amount of the pH-adjusted mixture into a single-use vial; reducing the headspace oxygen in the single-use vial; and sealing the single-use vial.

ANSWER: Admitted.

63. Exela's ELCYS® product, and its use according to the directions and instructionson the FDA-approved label, is covered by at least claims 1 and 11 of the '795 patent.

ANSWER: Eton is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 63, and therefore denies all such allegations.

G. The Asserted '089 Patent

64. On March 2, 2021, the USPTO issued the '089 patent, entitled "Stable, Highly Pure L-Cysteine Compositions for Injection and Methods of Use," and naming John Maloney, Aruna Koganti, and Phanesh Koneru as inventors. A copy of the '089 patent is attached to thisComplaint as Exhibit H.

ANSWER: Eton admits that Exhibit H purports to be a copy of the '089 patent and that, on its face, Exhibit H is entitled, "Stable, Highly Pure L-Cysteine Compositions for Injection and Methods of Use." Eton also admits that Exhibit H, on its face, indicates that the "Date of Patent" is "*Mar. 2, 2021" and that the named "Inventors" are John Maloney, Aruna Koganti, and Phanesh Koneru. Eton denies the remaining allegations of Paragraph 64.

65. The '089 patent is assigned to Plaintiff Exela.

ANSWER: Eton admits that Exhibit H indicates on its face that "Exela Pharma Sciences, LLC, Lenoir, NC (US)" is the "Assignee" of the '089 patent. Eton lacks sufficient know and information to form a belief as to the remaining allegations of Paragraph 65 and therefore denies the same.

66. On or about March 2, 2021, Exela submitted the '089 patent for listing in the Orange Book which provides notice concerning patents covering FDA-approved drugs.

ANSWER: Eton admits that the '089 patent is listed in the Orange Book NDA 210660 and that "03/02/2021" is identified as the "Submission Date" for the '089 patent. Eton lacks sufficient knowledge and information to form a belief as to the remaining allegations of Paragraph 66 and therefore denies the same.

67. On or about March 3, 2021, the FDA published the '089 patent in the Orange Book.

ANSWER: Eton is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 67, and therefore denies all such allegations.

68. Claim 1 of the '089 patent reads as follows:

A solution of L-cysteine comprising, a pharmaceutically acceptable carrier, about 50 mg/mL of L-cysteine hydrochloride monohydrate, or equivalent amount of a pharmaceutically acceptable L-cysteine or a salt or hydrate thereof, less than about150 ppb of aluminum for at least about 6 months from the time of manufacture of the solution, and a pH from about 1.0 to about 2.5, wherein the solution is suitablefor use as an additive in a parenteral nutrition composition for administration to anindividual.

ANSWER: Admitted.

69. Exela's ELCYS® product, and its use according to the directions and instructionson the FDA-approved label, is covered by at least claim 1 of the '089 patent.

ANSWER: Eton is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 69, and therefore denies all such allegations.

ACTS GIVING RISE TO THIS ACTION FOR DEFENDANT'S INFRINGEMENT OF THE PATENTS-IN-SUIT

70. On or about February 3, 2020, Plaintiff received a letter, dated January 31, 2020, signed on behalf of Eton by Jeffrey Wolfson of the law firm Haynes Boone ("Eton's Paragraph IV Letter").

ANSWER: Eton admits that a letter dated January 31, 2020 ("Notice Letter") was sent on its behalf by Jeffrey Wolfson of the law firm of Haynes and Boone, LLP to Plaintiff, providing written notification pursuant to 21 U.S.C. § 355(j)(2)(B) that Eton filed Abbreviated New Drug Application ("ANDA") 214082 to the FDA and that ANDA 214082 contains a Paragraph IV Certification for the '453 Patent. Eton lacks sufficient knowledge and information to form a belief as to the remaining allegations of Paragraph 70 and therefore denies the same.

71. Eton's Paragraph IV Letter states that Eton had filed Abbreviated New Drug Application ("ANDA") No. 214082 with the FDA seeking approval for Cysteine Hydrochloride Injection, USP, 500 mg/50 mL (50 mg/mL), 10 mL Fill ("Eton's Proposed Generic CysteineHydrochloride Product"), which is a generic version of Exela's ELCYS® product.

ANSWER: Eton admits that the Notice Letter provided written notification pursuant to 21 U.S.C. § 355(j)(2)(B) that Eton filed ANDA 214082 to the FDA and that ANDA 214082 contains a Paragraph IV Certification for the '453 Patent. Eton also admits that it is seeking FDA approval for the commercial manufacture, use, or sale of Eton's Cysteine Hydrochloride Injection, USP, 50 mg/mL, 10 mL Fill, Single Dose Vial ("Eton's ANDA Product") before the expiration of the '453 Patent. Eton denies the remaining allegations of Paragraph 71.

72. This action is being commenced before the expiration of 45 days from the date Exela received Eton's Paragraph IV Letter, which triggers a stay of FDA approval of Eton's ANDA No. 214082 pursuant to 21 U.S.C § 355(j)(5)(B)(iii).

ANSWER: Eton is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 69, and/or the allegations contain conclusions of law to which

no answer is required. To the extent an answer is required, Eton denies the allegations in Paragraph 72.

73. Eton's Paragraph IV Letter states that "[t]he basis of [its] proposed abbreviated new drug application (ANDA) for Cysteine Hydrochloride Injection, USP, 500 mg/10 mL (50 mg/mL), 10 mL Fill, is the reference listed drug (RLD) and Reference Standard (RS), ELCYS® (Cysteine Hydrochloride) Injection, USP, 50 mg/mL, NDA 210660, approved on April 16, 2019, held by Exela Pharma Sciences, LLC, which is listed as the RLD and RS" in the Orange Book.

ANSWER: Eton admits that the reference listed drug that is the basis for ANDA 214082 is ELCYS® (Cysteine Hydrochloride) Injection, USP, 50 mg/mL. Eton also admits the electronic version of 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" and "Apr 16, 2019" as the "Approval Date" for this product. Eton denies the remaining allegations of Paragraph 73.

74. Eton's Paragraph IV Letter also states that ANDA No. 214082 contains any required bioavailability or bioequivalence data and a Paragraph IV certification for the '453 patent.

ANSWER: Eton admits that the Notice Letter to Plaintiff, providing written notification pursuant to 21 U.S.C. § 355(j)(2)(B) that Eton filed ANDA 214082 to the FDA and that ANDA 214082 contains Paragraph IV Certifications for the '453 Patent and that Eton's ANDA includes any required bioavailability and bioequivalence data. Eton denies the remaining allegations of Paragraph 74.

75. Eton submitted to the FDA ANDA No. 214082 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking FDA's approval to engage inthe commercial manufacture, use, importation, offer for sale, and/or sale of Eton's Proposed Generic

Cysteine Hydrochloride Product before the expiration of the '453 patent.

ANSWER: Eton admits that it is seeking FDA approval for the commercial manufacture, use, or sale of Eton's ANDA Product before the expiration of the '453 Patent. Eton denies the remaining allegations of Paragraph 75.

76. Attached to Eton's Paragraph IV Letter is a statement of the factual and legal bases for Eton's position that the '453 patent is invalid and/or will not be infringed by the commercial manufacture, use, or sale of Eton's Proposed Generic Cysteine Hydrochloride Product described in ANDA No. 214082.

ANSWER: Eton admits that Eton's Notice Letter includes a statement of the factual and legal bases of its Paragraph IV Certification that the '453 Patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Eton's ANDA Product before the expiration of the '453 Patent. Eton denies the remaining allegations of Paragraph 76, and avers that the asserted claims are not infringed and/or invalid for additional reasons.

77. In particular, Eton's Paragraph IV letter alleges that claims 1-21 of the '453 patent are not infringed and claim 22 of the '453 patent is invalid.

ANSWER: Eton admits that Eton's Notice Letter includes a statement of the factual and legal bases of its Paragraph IV Certification that the '453 Patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Eton's ANDA Product before the expiration of the '453 Patent, including bases for alleging claims 1-21 are not infringed and claim 22 is invalid. Eton denies the remaining allegations of Paragraph 77, and avers that the asserted claims are not infringed and/or invalid for additional reasons.

78. Eton's Paragraph IV Letter does not allege invalidity of claims 1-21 of the '453 patent or non-infringement of claim 22 of the '453 patent.

ANSWER: Eton admits that Eton's Notice Letter includes a statement of the factual and

legal bases of its Paragraph IV Certification that the '453 Patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Eton's ANDA Product before the expiration of the '453 Patent. Eton denies the remaining allegations of Paragraph 78, and avers that the asserted claims are not infringed and/or invalid for additional reasons.

79. Eton's Paragraph IV Letter is not marked confidential.

ANSWER: Admitted.

80. Attached to Eton's Paragraph IV Letter is an Offer of Confidential Access to ANDA No. 214082. The terms of the proposed Offer would not allow Plaintiff to conduct a complete and full investigation of the information contained in the ANDA and of the representations about Eton's Proposed Generic Cysteine Hydrochloride Product that appear in Eton's Paragraph IV Letter. For example, the Offer would not allow in-house counsel for Plaintiff to review the ANDA and only obligates Eton to produce the portions of the ANDA that Eton unilaterally deems "pertinent" to patent infringement rather the producing the entire ANDA. Thus, Plaintiff could not agree to the terms of the original Offer of Confidential Access.

ANSWER: Eton admits that Eton's Notice Letter included an Offer of Confidential Access ("OCA") to ANDA 214082, and that, to date, the parties have not reached an agreement regarding the OCA. Answering further, the terms of Eton's OCA are no more restrictive than those typically found in a Protective Order, and, upon information and belief, the terms in Eton's OCA are similar to those proposed by Exela when similarly situated as Eton. Eton denies the remaining allegations of Paragraph 80.

81. On February 13, 2020, counsel for Plaintiff sent a letter to counsel for Eton in an attempt to negotiate the terms of Plaintiff's access to ANDA No. 214082. After counsel for Eton responded, counsel for Plaintiff followed up by providing a redlined version of the Offer of Confidential Access, setting forth terms for access that would be acceptable to Plaintiff. The parties

were not able to reach an agreement regarding access to ANDA No. 214082 prior to the expiry of the time period set forth in 21 U.S.C. § 355(j)(5)(B)(iii).

ANSWER: Eton admits that the parties have attempted to reach an agreement on an OCA, and that, to date, the parties have not reached an agreement regarding the OCA. Eton denies the remaining allegations of Paragraph 81.

82. On March 16, 2020, Exela filed a Complaint in Civil Action No. 1:20-cv-00365-MN asserting the '453 and '155 patents. [D.I. 1]

ANSWER: Admitted.

83. On or about May 7, 2020, Plaintiff received a second letter, dated May 6, 2020, signed on behalf of Eton by Jeffrey Wolfson of the law firm Haynes Boone, reiterating Eton's prior filing of ANDA No. 214082 with FDA ("Eton's Second Paragraph IV Letter"). Eton's Second Paragraph IV Letter alleges that claims 1-30 of U.S. Patent No. 10,586,155 are invalid. Eton's Second Paragraph IV Letter does not allege that any of claims 1-30 of the '155 patent isnot infringed by Eton's manufacture, sale, offer for sale, and/or importation of Eton's ProposedGeneric Cysteine Hydrochloride Product.

ANSWER: Eton admits that a letter dated May 6, 2020 ("Second Notice Letter") was sent on its behalf by Jeffrey Wolfson of the law firm Haynes and Boone, LLP to Plaintiff, providing written notification pursuant to 21 U.S.C. § 355(j)(2)(B) that Eton's ANDA 214082 contains a Paragraph IV certification for the '155 Patent and that Eton's ANDA includes any required bioavailability and bioequivalence data. Eton further admits that Eton's Second Notice Letter includes a statement of the factual and legal bases of its Paragraph IV Certification that the '155 Patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Eton's ANDA Product before the expiration of the '155 Patent. Eton denies the remaining allegations of Paragraph 83.

84. On July 28, 2020, Exela filed a First Amended Complaint, asserting the '719 patent in addition to the '453 and '155 patents. [D.I. 14]

ANSWER: Admitted.

85. Pursuant to the Scheduling Order [D.I. 22], Eton produced ANDA No. 214082 to Exela on September 4, 2020. Exela has repeatedly requested that Eton produce all subsequent submissions and correspondence to or from FDA related to ANDA No. 214082, as well as all stability and other testing data related to the ANDA product, but to date Eton has failed to produce such submissions, correspondence and data.

ANSWER: Denied.

86. On December 22, 2020, Exela informed Eton that it intended to assert three additional patents recently allowed by the USPTO, and on January 5, 2020, Exela provided Eton with the application numbers and claims of the '713, '795, and '089 patents. On February 5, 2020, Exela updated Eton regarding the issuance status of three patent applications.

ANSWER: Eton admits that on or about December 22, 2020, during an initial meeting and confer, Exela stated that it has additional patents that it may add to the case. Eton also admits that on January 5, 2021, Exela claimed to be provided the allowed claims for U.S. Patent Application Nos. 16/746,028, 16/773,641 and 16/850,726, but provided the allowed claims in a separate correspondence. Eton also admits that on February 5, 2020, Exela informed Eton for the first time that not all of the patents had yet issued. Eton denies all remaining allegations in paragraph 86.

87. In filing and maintaining ANDA No. 214082, Eton has requested and continues to request FDA's approval to market a generic version of Exela's ELCYS® product throughout the United States, including in Delaware.

ANSWER: Eton admits that it filed ANDA 214082 to seek FDA approval to market Eton's ANDA Product. Eton denies the remaining allegations of Paragraph 87.

88. On information and belief, following FDA approval of ANDA No. 214082, Eton will offer for sale and sell the approved generic version of ELCYS® throughout the United States, including in Delaware.

ANSWER: Eton admits that it filed ANDA 214082 to seek FDA approval to market Eton's ANDA Product. Eton denies the remaining allegations of Paragraph 88.

89. Eton's effort to seek FDA approval to market a generic version of ELCYS® prior to the expiration of the '453, '155, '719, '713, '795, and '089 patents constitutes an act of infringement pursuant to 35 U.S.C. § 271(e)(2). It also creates a justiciable controversy between the parties with respect to the subject matter of ANDA No. 214082, the '155 patent, the '453 patent, the '719 patent, the '713 patent, the '795 patent, and the '089 patent as further evidencedby Eton's Paragraph IV Letters.

ANSWER: Paragraph 89 contains conclusions of law to which no answer is required. To the extent an answer is required, Eton denies the allegations in Paragraph 89.

90. Eton's Proposed Generic Cysteine Hydrochloride Product will be sold and distributed with labeling that contains substantially the same instructions for use as those in the label for Exela's ELCYS® product, including instructions that are substantially the same as those described above in paragraphs 14-25. [Exhibit I (Eton Label)]

ANSWER: Eton admits that ANDA 214082 contains labeling as required by applicable FDA statutes and regulations and states that the proposed labeling speaks for itself. Eton denies the remaining allegations of Paragraph 90.

91. For example, the labeling for Eton's Proposed Generic Cysteine Hydrochloride Product, like the labeling for ELCYS®, instructs healthcare providers that the product is indicated for use as an additive to amino acid solutions to meet nutritional requirements of newborn infants requiring total parenteral nutrition and adult and pediatric patients who may have impaired

enzymatic processes and require TPN. [*Id.* at §§ 2.2-2.5.]

ANSWER: Eton admits that ANDA 214082 contains labeling as required by applicable FDA statutes and regulations and states that the proposed labeling speaks for itself. Eton denies the remaining allegations of Paragraph 91.

92. Based on that instruction, which appears in the indications and usage section of the label for Eton's Proposed Generic Cysteine Hydrochloride Product, the product will be used to treat patients who have adverse health conditions that are responsive to L-cysteine administration. [*Id.* at § 1.]

ANSWER: Eton admits that ANDA 214082 contains labeling as required by applicable FDA statutes and regulations and states that the proposed labeling speaks for itself. Eton denies the remaining allegations of Paragraph 92.

93. The labeling for Eton's Proposed Generic Cysteine Hydrochloride Product, like the labeling for ELCYS®, contains recommended dosage and volume for pediatric patients frombirth to less than 12 years of age, including for neonates and infants, e.g., preterm and term infants less than 1 month of age, and pediatric patients 1 month to less than 1 year of age. [*Id.* At §§ 2.4-2.5 and Tbl. 1.]

ANSWER: Eton admits that ANDA 214082 contains labeling as required by applicable FDA statutes and regulations and states that the proposed labeling speaks for itself. Eton denies the remaining allegations of Paragraph 93.

94. Based on that information, which appears in the dosage and administration section of the label for Eton's Proposed Generic Cysteine Hydrochloride Product, the product will be used to treat neonates and infants. [*Id.*]

ANSWER: Eton admits that ANDA 214082 contains labeling as required by applicable FDA statutes and regulations and states that the proposed labeling speaks for itself. Eton denies the

remaining allegations of Paragraph 94.

95. Eton's Proposed Generic Cysteine Hydrochloride Product contains L-cysteine hydrochloride monohydrate in an amount from 10-100 mg/mL. Specifically, Eton's Proposed Generic Cysteine Hydrochloride Product contains 50 mg/mL of L-cysteine hydrochloride monohydrate. [*Id.* at §§ 3, 11.] Additionally, Eton's Paragraph IV Letter states that its Proposed Generic Cysteine Hydrochloride Product is an injection containing 500 mg/10mL (50 mg/mL) cysteine hydrochloride, USP in a 10 mL single-dose vial. Like ELCYS®, Eton's Proposed Generic Cysteine Hydrochloride Product comprises water as the carrier for L-cysteine. [*Id.* at § 11.]

ANSWER: Paragraph 95 contains legal conclusions to which no response is required. To the extent a response is required, Eton admits that the subject of Eton's ANDA 214082 is an L-Cysteine Hydrochloride Injection Product for injection containing 500 mg/10 mL (50 mg/mL). Eton denies the remaining allegations of Paragraph 95.

96. Eton's Proposed Generic Cysteine Hydrochloride Product is packaged in a 10mL single-use vial. [*Id.* at § 16.]

ANSWER: Eton admits that ANDA 214082 contains labeling as required by applicable FDA statutes and regulations and states that the proposed labeling speaks for itself. Eton denies the remaining allegations of Paragraph 96.

97. On information and belief, Eton's Proposed Generic Cysteine Hydrochloride Product is safe for use as an additive in a parenteral nutrition composition for intravenous administration.

ANSWER: Eton admits that FDA will only approve pharmaceutical products that are deemed safe for the intended use. Paragraph 97 contains conclusions of law to which no answer is required. To the extent an answer is required, Eton denies the allegations in Paragraph 97.

98. Eton's Proposed Generic Cysteine Hydrochloride Product has a pH range from

about 1.0 to about 2.5. [*Id.* at § 11.]

ANSWER: Eton admits that ANDA 214082 contains labeling as required by applicable FDA statutes and regulations and states that the proposed labeling speaks for itself. Paragraph 98 contains conclusions of law to which no answer is required. To the extent an answer is required, Eton denies the allegations in Paragraph 98.

99. Eton's Proposed Generic Cysteine Hydrochloride Product is stable, and will not be approved by FDA if it is not stable.

ANSWER: Eton is without knowledge or information sufficient to form a belief as to what FDA will approve. Further, Paragraph 99 contains conclusions of law to which no answer is required. To the extent an answer is required, Eton denies the allegations in Paragraph 99.

100. Eton's Proposed Generic Cysteine Hydrochloride Product is substantially free of visually detectable particulate matter.

ANSWER: Paragraph 100 contains conclusions of law to which no answer is required. To the extent an answer is required, Eton denies the allegations in Paragraph 100.

101. On information and belief, and especially in view of the FDA-approved shelf life for ELCYS® and supporting 24-month stability data, Eton's Proposed Generic Cysteine Hydrochloride Product will be approved for at least a 24-month shelf life, meaning that it will be substantially free of visually detectable particulate matter for at least 24 months from the time of manufacture of the solution.

ANSWER: Eton is without knowledge or information sufficient to form a belief as to what FDA will approve. Further, Paragraph 101 contains conclusions of law to which no answer is required. To the extent an answer is required, Eton denies the allegations in Paragraph 101.

102. The label for Eton's Proposed Generic Cysteine Hydrochloride Product states that the product contains no more than 350 mcg/L of aluminum. By seeking approval for products

containing no more than 350 mcg/L of aluminum, Eton is seeking approval for products containing aluminum in the amounts recited in Exela's patent claims identified above, through the product's shelf-life. [*Id.* at § 11.]

ANSWER: Eton admits that ANDA 214082 contains labeling as required by applicable FDA statutes and regulations and states that the proposed labeling speaks for itself. Eton denies that it is seeking approval for products containing aluminum in amounts recited in Exela's patent claims.

103. Eton's Proposed Generic Cysteine Hydrochloride Product contains no more than 2.0% total impurities.

ANSWER: Paragraph 103 contains conclusions of law to which no answer is required. To the extent an answer is required, Eton denies the allegations in Paragraph 103.

104. Eton's Proposed Generic Cysteine Hydrochloride Product contains from about 0.001 wt % to about 2.0 wt% cystine (or L-cystine) relative to L-cysteine.

ANSWER: Paragraph 104 contains conclusions of law to which no answer is required. To the extent an answer is required, Eton denies the allegations in Paragraph 104.

105. Eton's Proposed Generic Cysteine Hydrochloride Product contains from about 0.001 wt % to about 2.0 wt % pyruvic acid relative to L-cysteine.

ANSWER: Denied.

106. Eton's Proposed Generic Cysteine Hydrochloride Product contains a pharmaceutically acceptable amount of cystine for at least about 12 months from the time of manufacture of the solution. Eton's Proposed Generic Cysteine Hydrochloride Product contains dissolved oxygen present in the carrier in an amount of less than 2 ppm.

ANSWER: Paragraph 106 contains conclusions of law to which no answer is required. To the extent an answer is required, Eton denies the allegations in Paragraph 106.

107. On information and belief, Eton's Proposed Generic Cysteine Hydrochloride Product contains dissolved oxygen present in the carrier in an amount from about 0.1 ppm to about 5 ppm from the time of manufacture to about 1 month from manufacture when stored at room temperature. Indeed, Eton's Paragraph IV Letter makes no claim that its Proposed GenericCysteine Hydrochloride Product does not have dissolved oxygen levels in this range.

ANSWER: Paragraph 107 contains conclusions of law to which no answer is required. To the extent an answer is required, Eton denies the allegations in Paragraph 107.

108. On information and belief, Eton's Proposed Generic Cysteine Hydrochloride Product contains headspace oxygen that is from about 0.5% v/v to 4.0% v/v from the time of manufacture to about 1 month from manufacture when stored at room temperature. As disclosedin the '453 patent in Example 5, even when a robust process is followed to reduce headspace oxygen—for example, a high-speed filler capable of using vacuum and gas overlay in alternate pulses—the headspace oxygen in at least some vials so treated is present at about 0.5% v/v upon manufacture and from about 0.5% v/v to over 1.5% v/v (but less than 4.0% v/v) at about 1 month from the time of manufacture when stored at room temperature. [Exhibit C at 48:15-49:67; 28:48-58.] In addition, as the '453 patent discloses in Examples 4 and 5, when headspace oxygen is reduced by means of a lyophilization process, the headspace oxygen in vials containing a cysteine solution is present, on average, from about 1.9% v/v to about 2.3% v/v upon manufacture and about 0.9% v/v to about 2.8% v/v at about 1 month after manufacture. [Exhibit C at 44:1-49:67, 28:48-58.] Because Eton's Proposed Generic Cysteine Hydrochloride Product contains, on information and belief, similar components and similar amounts of headspace oxygen and dissolved oxygen at the time of manufacture as the cysteine solutions of Example 5 of the '453 patent, on information and belief Eton's Proposed Generic Cysteine Hydrochloride Product will exhibit similar trends in

headspace oxygen from the time of manufacture to about 1 month from manufacture as the cysteine solutions of Example 5, and thuswill contain headspace oxygen from about 0.5% v/v to 4.0% v/v from the time of manufacture toabout 1 month after manufacture when stored at room temperature.

ANSWER: Paragraph 108 contains conclusions of law to which no answer is required. To the extent an answer is required, Eton denies the allegations in Paragraph 108.

109. Eton's Proposed Generic Hydrochloride Product is prepared by mixing L- Cysteine or a pharmaceutically acceptable salt and/or hydrate with water for injection, a pharmaceutically acceptable carrier comprising no more than 1 ppm dissolved oxygen at atemperature between 15-30°C.

ANSWER: Paragraph 109 contains conclusions of law to which no answer is required. To the extent an answer is required, Eton denies the allegations in Paragraph 109.

110. The preparation of Eton's Proposed Generic Hydrochloride Product involves adjusting its pH to 1.1 to 1.8 during manufacture.

ANSWER: Paragraph 110 contains conclusions of law to which no answer is required. To the extent an answer is required, Eton denies the allegations in Paragraph 110.

111. The labeling for Eton's Proposed Generic Cysteine Hydrochloride Product, like the label for ELCYS®, instructs healthcare providers that, prior to administration, the product must be diluted and used as an admixture in parenteral nutrition solutions. [Exhibit I at §§ 2.1- 2.2.] Like the label for ELCYS®, the label for Eton's Proposed Generic Cysteine HydrochlorideProduct also provides instructions as to how to prepare that admixture for use in a TPN solution.[*Id.* at §§ 2.2-2.3.]

ANSWER: Eton admits that ANDA 214082 contains labeling as required by applicable FDA statutes and regulations and states that the proposed labeling speaks for itself. Paragraph 111 contains conclusions of law to which no answer is required. To the extent an answer is required,

Eton denies the allegations in Paragraph 111.

112. The label for Eton's Proposed Generic Cysteine Hydrochloride Product provides the same instructions as the label for ELCYS® for admixing the product with one or more amino acids [*Id.*]. On information and belief, following those instructions on the label produces a composition comprising L-cysteine along with one or more amino acids (including leucine, isoleucine, lysine, valine, phenylalanine, histidine, threonine, methionine, tryptophan, alanine, arginine, glycine, proline, serine, or tyrosine) and intravenous fluid or water.

ANSWER: Eton admits that ANDA 214082 contains labeling as required by applicable FDA statutes and regulations and states that the proposed labeling speaks for itself. Paragraph 112 contains conclusions of law to which no answer is required. To the extent an answer is required, Eton denies the allegations in Paragraph 112.

113. According to ANDA No. 214082, commercial batches of Eton's Proposed Generic Cysteine Hydrochloride Product will be manufactured and packaged by Grand RiverAseptic Manufacturing ("GRAM").

ANSWER: Admitted.

114. On information and belief, Eton has contracted with or will contract with GRAMto manufacture Eton's Proposed Generic Cysteine Hydrochloride Product according to the manufacturing instructions and specifications in the ANDA, which Eton has provided or will provide to GRAM.

ANSWER: Eton admits that the manufacturing instructions and specifications in the ANDA are identical to the manufacturing instructions and specifications used by Allergy Laboratories to manufacture the same Cystine Hydrochloride Injectable product since at least 2013. To the extent GRAM is contracted to manufacture Eton's Proposed Generic Cysteine Hydrochloride Product, it will be provided with the same manufacturing instructions and specifications as those used by

Allergy Laboratories since at least 2013. Eton denies all remaining allegations in Paragraph 114.

115. The label for Eton's Proposed Generic Cysteine Hydrochloride Product contains the same warning as the label for ELCYS®, described above in Paragraph 25, about patients receiving greater than 4 to 5 mcg/kg/day of parenteral aluminum. [*Id.* at § 5.7.] On informationand belief, following the instructions on the label for Eton's Proposed Generic Cysteine Hydrochloride Product results in a parenteral nutrition regimen with aluminum present in an amount from 1-2 to 4-5 micrograms/kg/day.

ANSWER: Eton admits that ANDA 214082 contains labeling as required by applicable FDA statutes and regulations and states that the proposed labeling speaks for itself. Paragraph 115 contains conclusions of law to which no answer is required. To the extent an answer is required, Eton denies the allegations in Paragraph 115.

116. On information and belief, a composition prepared according to the admixture instructions on the label for Eton's Proposed Generic Cysteine Hydrochloride Product will beused for infusion in a TPN regimen and has a volume of about 100 mL to about 1000 mL.

ANSWER:

117. The labeling for the Eton's Proposed Generic Cysteine Hydrochloride Product, like the label for ELCYS®, instructs healthcare providers that the dosage of the final TPN solution must be based on the concentrations of all the components in the solution and the recommended nutritional requirements. [*Id.* at §§2.4-2.5.] When used as directed on the label,Eton's Proposed Generic Cysteine Hydrochloride Product will be dosed to provide a therapeutically effective amount of L-cysteine to patients. [*Id.* at §§ 1, 2.4, 2.5.]

ANSWER: Eton admits that ANDA 214082 contains labeling as required by applicable FDA statutes and regulations and states that the proposed labeling speaks for itself. Paragraph 117 contains conclusions of law to which no answer is required. To the extent an answer is required,

Eton denies the allegations in Paragraph 117.

118. For the reasons above, Eton is seeking approval for products meeting all the limitations of at least claims 1 and 4 of the '453 patent, claims 12-15 of the '719 patent, claim 1of the '713 patent, claims 1 and 11 of the '795 patent, and claim 1 of the '089 patent, either literally or under the doctrine of equivalents; therefore, the products Eton is likely to sell will infringe Exela's '453, '155, '719, '713, '795, and '089 patents.

ANSWER: Denied.

119. On information and belief, healthcare providers will admix Eton's Proposed Generic Cysteine Hydrochloride Product according to the instructions on Eton's label and administer those compositions to patients who require TPN.

ANSWER: Eton is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 119, and therefore deny all such allegations.

120. On information and belief, when healthcare providers admix Eton's Proposed Generic Cysteine Hydrochloride Product according to the instructions on Eton's label to prepare compositions for a TPN regimen and/or administer those compositions to patients who require TPN, they will satisfy all the limitations of at least claim 22 of the '453 patent and claims 1, 3 and 27 of the '155 patent, either literally or under the doctrine of equivalents.

ANSWER: Eton admits that ANDA 214082 contains labeling as required by applicable FDA statutes and regulations and states that the proposed labeling speaks for itself. Paragraph 120 contains conclusions of law to which no answer is required. To the extent an answer is required, Eton denies the allegations in Paragraph 120.

121. Accordingly, on information and belief, healthcare providers that follow the instructions on the labeling for Eton's Proposed Generic Cysteine Hydrochloride Product will directly infringe at least some claims of the '453 and '155 patents.

ANSWER: Eton admits that ANDA 214082 contains labeling as required by applicable FDA statutes and regulations and states that the proposed labeling speaks for itself. Paragraph 121 contains conclusions of law to which no answer is required. To the extent an answer is required, Eton denies the allegations in Paragraph 121.

COUNT I

(Infringement of the '453 patent Under 35 U.S.C. § 271(e)(2))

122. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

ANSWER: Eton incorporates by reference its answers to Paragraphs 1 through 121 as if set forth herein.

123. Eton submitted ANDA No. 214082 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of Eton's Proposed Generic Cysteine Hydrochloride Product throughout the United States. By submitting the application, Eton has committed an act of infringement of the '453 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Eton admits that it filed ANDA 214082 to seek FDA approval for Eton's ANDA Product. Eton denies the remaining allegations of Paragraph 123.

124. The commercial manufacture, importation, use, sale, or offer for sale of Eton's Proposed Generic Cysteine Hydrochloride Product will constitute an act of direct infringement of the '453 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

125. On information and belief, Eton became aware of the '453 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using ELCYS®, and no later than when it submitted a paragraph IV certification to FDA regarding ANDA No. 214082, in which it identified the '453 patent as a patent covering theapproved product ELCYS®.

ANSWER: Eton admits it became aware of the '453 patent at or about the time the '453

patent was listed in the Orange Book in connection with ELCYS. Eton denies all remaining allegations in paragraph 125.

126. On information and belief, Eton knew or should have known that its commercial making, using, offering to sell, selling, importing or otherwise promoting and/or distributing of Eton's Proposed Generic Cysteine Hydrochloride Product, with its labeling, will actively inducethe direct infringement of the '453 patent.

ANSWER: Denied.

127. On information and belief, Eton knew or should have known that Eton's Proposed Generic Cysteine Hydrochloride Product will be especially made or especially adapted for use inan infringement of the '453 patent, and is not a staple article or commodity of commerce suitablefor substantial non-infringing use, as evidence by, for example, the contents of its proposed labeling. And, on information and belief, Eton knew or should have known that its commercial offering to sell, selling, importing or otherwise distributing of Eton's Proposed Generic Cysteine Hydrochloride Product will actively contribute to the direct infringement of the '453 patent.

ANSWER: Denied.

128. Unless and until Eton is enjoined from infringing the '453 patent, Plaintiff will suffer irreparable injury for which damages are an inadequate remedy.

ANSWER: Denied.

129. Plaintiff is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including anorder of this Court stating that the effective date of approval of Eton's ANDA No. 214082 be adate that is not earlier than the expiration date of the '453 patent.

ANSWER: Denied.

COUNT II

(Declaratory Judgment of Infringement of the '453 patent Under 35 U.S.C. § 271(a))

130. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

ANSWER: Eton incorporates by reference its answers to Paragraphs 1 through 129 as if set forth herein.

131. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER: Eton admits that this claim purports to arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Eton denies that there is subject matter jurisdiction for this claim.

132. There is an actual case or controversy such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

ANSWER: Paragraph 132 contains conclusions of law to which no answer is required. To the extent an answer is required, Eton denies the allegations in Paragraph 132.

133. On information and belief, Eton will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Eton's Proposed Generic Cysteine Hydrochloride Product immediately and imminently upon FDA approval of ANDA No. 214082.

ANSWER: Eton admits that it filed ANDA 214082 to seek FDA approval for Eton's ANDA Product. Eton denies the remaining allegations of Paragraph 133.

134. Eton's actions, including but not limited to, the development of Eton's Proposed Generic Cysteine Hydrochloride Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Eton has made and will continue to make substantial preparation in the United States, including in the District of Delaware, to manufacture, sell, offer to sell, and/or import Eton's Proposed Generic Cysteine Hydrochloride Product.

ANSWER: Eton admits that it filed ANDA 214082 to seek FDA approval for Eton's ANDA Product. Eton denies the remaining allegations of Paragraph 134.

135. On information and belief, Eton's Proposed Generic Cysteine Hydrochloride Product practices all limitations of at least claims 1 and 4 of the '453 patent, either literally or under the doctrine of equivalents, as detailed above, and thus the manufacture, importation, use,sale, and/or offer for sale of Eton's Proposed Generic Cysteine Hydrochloride Product will constitute an act of infringement of the '453 patent.

ANSWER: Denied.

136. The commercial manufacture, importation, use, sale, or offer for sale of Eton's Proposed Generic Cysteine Hydrochloride Product in violation of Plaintiff's patent rights willcause harm to Plaintiff, for which damages are inadequate.

ANSWER: Denied.

137. Plaintiff is entitled to a declaratory judgment that the future manufacture, use, offer for sale, sale and/or importation of Eton's Proposed Generic Cysteine Hydrochloride Product before patent expiration will constitute direct infringement of at least claims 1 and 4 ofthe '453 patent under 35 U.S.C. § 271(a).

ANSWER: Denied.

138. Unless and until Eton is enjoined from infringing the '453 patent, Plaintiff will suffer irreparable injury for which damages are an inadequate remedy.

ANSWER: Denied.

COUNT III

(Declaratory Judgment of Infringement of the '453 patent Under 35 U.S.C. § 271(b))

139. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

ANSWER: Eton incorporates by reference its answers to Paragraphs 1 through 138 as if set forth herein.

140. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER: Eton admits that this claim purports to arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Eton denies that there is subject matter jurisdiction for this claim.

141. There is an actual case or controversy such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

ANSWER: Paragraph 141 contains conclusions of law to which no answer is required. To the extent an answer is required, Eton denies the allegations in Paragraph 141.

142. Eton has actual knowledge of the '453 patent.

ANSWER: Admitted.

143. On information and belief, Eton became aware of the '453 patent no later than when it was when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using ELCYS®, and no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 214082, in which it identified the '453 patent as one of the patents covering ELCYS®.

ANSWER: Eton admits it became aware of the '453 patent at or about the time the '453 patent was listed in the Orange Book in connection with ELCYS. Eton denies all remaining allegations in paragraph 143.

144. On information and belief, Eton will engage in the commercial manufacture, use, offer for sale, sale, importation or other promotion and/or distribution of Eton's Proposed Generic Cysteine Hydrochloride Product immediately and imminently upon FDA approval of ANDA No. 214082.

ANSWER: Eton admits that it filed ANDA 214082 to seek FDA approval for Eton's

ANDA Product. Eton denies the remaining allegations of Paragraph 144.

145. Eton's actions, including but not limited to, the development of Eton's Proposed Generic Cysteine Hydrochloride Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Eton has made and will continue to make substantial preparation in the United States, including in the District of Delaware, to manufacture, sell, offer to sell, import or otherwise promote and/or distribute Eton's Proposed Generic CysteineHydrochloride Product.

ANSWER: Eton admits that it filed ANDA 214082 to seek FDA approval for Eton's ANDA Product. Eton denies the remaining allegations of Paragraph 145.

146. On information and belief, Eton will include within the packaging of its Proposed Generic Cysteine Hydrochloride Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 22 of the '453 patent.

ANSWER: Denied.

147. On information and belief, healthcare providers preparing a total parenteral nutrition regimen using Eton's Proposed Generic Cysteine Hydrochloride Product within the United States according to the instructions in the product's labeling will directly infringe at least claim 22 of the '453 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

148. On information and belief, Eton possesses specific intent to encourage direct infringement of at least claim 22 of the '453 patent, including because Eton's labeling for its Proposed Generic Cysteine Hydrochloride Product instructs users to perform the patented method, providing evidence of an affirmative intent to induce infringement. Furthermore, because ELCYS® and Eton's Proposed Generic Cysteine Hydrochloride Product have no substantial non-infringing uses, Eton intends for the use of its generic version of ELCYS® todirectly infringe at least claim 22

the ’453 patent.

ANSWER: Denied.

149. On information and belief, upon awareness of the ’453 patent, Eton either actually knew of the potential for infringement of at least claim 22 of the ’453 patent, or was willfully blind as to the potential for that infringement at least because Eton provides instructions for infringement of at least claim 22 of the ’453 patent in its proposed product labeling.

ANSWER: Denied.

150. The commercial making, using, offering to sell, selling, importing, or otherwise promoting and/or distributing of Eton’s Proposed Generic Cysteine Hydrochloride Product, with its labeling, will constitute an act of active inducement of infringement of at least claim 22 of the’453 patent.

ANSWER: Denied.

151. Eton’s Paragraph IV letter makes no allegations of non-infringement for claim 22 of the ’453 patent.

ANSWER: Denied.

152. The commercial making, using, offering to sell, selling, importing, or otherwise promoting and/or distributing of Eton’s Proposed Generic Cysteine Hydrochloride Product in violation of Plaintiff’s patent rights will cause harm to Plaintiff, for which damages are inadequate.

ANSWER: Denied.

153. Plaintiff is entitled to a declaratory judgment that the future making, using, offering to sell, selling, importing, or otherwise promoting and/or distributing of Eton’s ProposedGeneric Cysteine Hydrochloride Product before patent expiration will constitute active inducement of infringement of at least claim 22 of the ’453 patent under 35 U.S.C. § 271(b).

ANSWER: Denied.

154. Unless and until Eton is enjoined from infringing the '453 patent, Plaintiff will suffer irreparable injury for which damages are an inadequate remedy.

ANSWER: Denied.

COUNT IV

(Declaratory Judgment of Infringement of the '453 patent Under 35 U.S.C. § 271(c))

155. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

ANSWER: Eton incorporates by reference its answers to Paragraphs 1 through 154 as if set forth herein.

156. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER:

157. There is an actual case or controversy such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

ANSWER: Eton admits that this claim purports to arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Eton denies that there is subject matter jurisdiction for this claim.

158. Eton has actual knowledge of the '453 patent.

ANSWER: Admitted.

159. On information and belief, Eton became aware of the '453 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering ELCYS ®,and no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 214082, in which it identified the '453 patent as one of the patents covering ELCYS®.

ANSWER: Eton admits it became aware of the '453 patent at or about the time the '453 patent was listed in the Orange Book in connection with ELCYS. Eton denies all remaining

allegations in paragraph 159.

160. On information and belief, Eton will engage in the commercial manufacture, use, offer for sale, sale, importation and/or other distribution of Eton's Proposed Generic Cysteine Hydrochloride Product immediately and imminently upon FDA approval of ANDA No. 214082.

ANSWER: Eton admits that it filed ANDA 214082 to seek FDA approval for Eton's ANDA Product. Eton denies the remaining allegations of Paragraph 160.

161. Eton's actions, including but not limited to, the development of Eton's Proposed Generic Cysteine Hydrochloride Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Eton has made and will continue to make substantial preparation in the United States, including in the District of Delaware, to sell, offer to sell, import and/or otherwise distribute Eton's Proposed Generic Cysteine Hydrochloride Product.

ANSWER: Eton admits that it filed ANDA 214082 to seek FDA approval for Eton's ANDA Product. Eton denies the remaining allegations of Paragraph 161.

162. On information and belief, Eton will include within the packaging of its Proposed Generic Cysteine Hydrochloride Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 22 of the '453 patent.

ANSWER: Denied.

163. On information and belief, healthcare providers preparing a total parenteral nutrition regimen using Eton's Proposed Generic Cysteine Hydrochloride Product within the United States according to the instructions in the product's labeling will directly infringe at least claim 22 of the '453 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

164. On information and belief, Eton knows that its Proposed Generic Cysteine

Hydrochloride Product is a material part of the method of at least claim 22 of the '453 patent, including as evidenced in the contents of its proposed label. On information and belief, Eton's Proposed Generic Cysteine Hydrochloride Product was especially made or especially adapted for use by a healthcare provider in a manner that will directly infringe at least claim 22 of the '453 patent, as evidenced in the contents of its proposed labeling. On information and belief, Eton's Proposed Generic Cysteine Hydrochloride Product is not a staple article of commerce suitable for substantial non-infringing use, as evidenced by the contents of its proposed labeling and the fact that it seeks FDA approval for a particular use. There are no suitable uses for cysteine hydrochloride injections other than treating patients pursuant to FDA's approval for such products.

ANSWER: Denied.

165. Thus, on information and belief, Eton will contribute to the infringement of at least claim 22 of the '453 patent in this District and elsewhere in the United States by offering tosell, selling, importing, or otherwise distributing Eton's Proposed Generic Cysteine Hydrochloride Product, which is a material for use in practicing the method of at least claim 22 of the '453 patent.

ANSWER: Denied.

166. Eton's Paragraph IV Letter makes no allegations of non-infringement for claim 22 of the '453 patent.

ANSWER: Eton admits that Eton's Notice Letter includes a statement of factual and legal basis of its Paragraph IV Certification that the '453 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of Eton's ANDA Production before the expiration of the '453 patent. Eton's Infringement Contentions contain allegations of non-infringement for Claim 22 of the '453 patent.

167. The commercial offering to sell, selling, importing and/or other distribution of Eton's Proposed Generic Cysteine Hydrochloride Product for use in practicing the patented method

in violation of Plaintiff's patent rights will cause harm to Plaintiff, for which damagesare inadequate.

ANSWER: Denied.

168. Plaintiff is entitled to a declaratory judgment that the future offer for sale, sale, importation and/or other distribution of Eton's Proposed Generic Cysteine Hydrochloride Product before patent expiration will constitute contributory infringement of the claims of the'453 patent under 35 U.S.C. § 271(c).

ANSWER: Denied.

169. Unless and until Eton is enjoined from infringing the '453 patent, Plaintiff will suffer irreparable injury for which damages are an inadequate remedy.

ANSWER: Denied.

COUNT V

(Infringement of the '155 patent Under 35 U.S.C. § 271(e)(2))

170. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

ANSWER: Eton incorporates by reference its answers to Paragraphs 1 through 169 as if set forth herein.

171. Eton submitted ANDA No. 214082 to the FDA under section 505(j) of the FDCAto obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of Eton's Proposed Generic Cysteine Hydrochloride Product throughout the United States. By submitting the application, Eton has committed an act of infringement of the '155 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Eton admits that it filed ANDA 214082 to seek FDA approval for Eton's ANDA Product. Eton denies the remaining allegations of Paragraph 123.

172. The use of Eton's Proposed Generic Cysteine Hydrochloride Product according to

the instructions in the product's label will constitute an act of direct infringement of the '155 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

173. On information and belief, Eton monitors the status of patent applications filed by Exela that relate to L-Cysteine drug products and the contents of the Orange Book for the RLDs serving as the basis for its ANDA submissions, including ELCYS®.

ANSWER: Eton admits it became aware of the '155 patent at or about the time the '155 patent was listed in the Orange Book in connection with ELCYS. Eton denies all remaining allegations in paragraph 173.

174. On information and belief, Eton became aware of the '155 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using ELCYS®.

ANSWER: Eton admits it became aware of the '155 patent at or about the time the '453 patent was listed in the Orange Book in connection with ELCYS. Eton denies all remaining allegations in paragraph 174.

175. On information and belief, Eton knew or should have known that its commercial making, offering to sell, selling, importing, or otherwise promoting and/or distributing of Eton's Proposed Generic Cysteine Hydrochloride Product, with its labeling, will actively induce the direct infringement of the '155 patent.

ANSWER: Denied.

176. On information and belief, Eton knew or should have known that Eton's Proposed Generic Cysteine Hydrochloride Product will be especially made or especially adapted for use inan infringement of the '155 patent, and is not a staple article or commodity of commerce suitablefor substantial non-infringing use, as evidenced by, for example, the contents of its proposed labeling.

And, on information and belief, Eton knew or should have known that its commercial offering to sell, selling, importing or otherwise distributing of Eton's Proposed Generic Cysteine Hydrochloride Product with its labeling will actively contribute to the direct infringement of the '155 patent.

ANSWER: Denied.

177. Unless and until Eton is enjoined from infringing the '155 patent, Plaintiff will suffer irreparable injury for which damages are an inadequate remedy.

ANSWER: Denied.

178. Plaintiff is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including anorder of this Court stating that the effective date of approval of Eton's ANDA No. 214082 be adate that is not earlier than the expiration date of the '155 patent.

ANSWER: Denied.

COUNT VI

(Declaratory Judgment of Infringement of the '155 patent Under 35 U.S.C. § 271(b))

179. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

ANSWER: Eton incorporates by reference its answers to Paragraphs 1 through 178 as if set forth herein.

180. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER: Eton admits that this claim purports to arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Eton denies that there is subject matter jurisdiction for this claim.

181. There is an actual case or controversy such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

ANSWER: Paragraph 181 contains conclusions of law to which no answer is required. To

the extent an answer is required, Eton denies the allegations in Paragraph 181.

182. Eton has actual knowledge of the '155 patent.

ANSWER: Admitted.

183. On information and belief, Eton monitors the status of patent applications filed by Exela that relate to L-cysteine drug products and the contents of the Orange Book for the RLDs serving as the basis for its ANDA submissions, including ELCYS®.

ANSWER: Eton admits it became aware of the '155 patent at or about the time the '155 patent was listed in the Orange Book in connection with ELCYS. Eton denies all remaining allegations in paragraph 183.

184. On information and belief, Eton became aware of the '155 patent no later than when it when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using ELCYS®.

ANSWER: Eton admits it became aware of the '155 patent at or about the time the '155 patent was listed in the Orange Book in connection with ELCYS. Eton denies all remaining allegations in paragraph 184.

185. On information and belief, Eton will engage in the commercial manufacture, use, offer for sale, sale, importation or other promotion and/or distribution of Eton's Proposed Generic Cysteine Hydrochloride Product immediately and imminently upon FDA approval of ANDA No. 214082.

ANSWER: Eton admits that it filed ANDA 214082 to seek FDA approval for Eton's ANDA Product. Eton denies the remaining allegations of Paragraph 185.

186. Eton's actions, including but not limited to, the development of Eton's Proposed Generic Cysteine Hydrochloride Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Eton has made and will continue to make substantial preparation

in the United States, including in the District of Delaware, to manufacture, sell, offer to sell, import or otherwise promote and/or distribute Eton's Proposed Generic Cysteine Hydrochloride Product.

ANSWER: Eton admits that it filed ANDA 214082 to seek FDA approval for Eton's ANDA Product. Eton denies the remaining allegations of Paragraph 134.

187. On information and belief, Eton will include within the packaging of its Proposed Generic Cysteine Hydrochloride Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claims 1, 3 and 27 of the '155 patent.

ANSWER: Denied.

188. On information and belief, healthcare providers administering a parenteral nutrition regimen including Eton's Proposed Generic Cysteine Hydrochloride Product within the United States according to the instructions in the product's labeling will directly infringe at leastclaim 1, 3 and 27 of the '155 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

189. On information and belief, Eton possesses specific intent to encourage direct infringement of at least claims 1, 3 and 27 of the '155 patent, including because Eton's labeling for its Proposed Generic Cysteine Hydrochloride Product instructs users to perform the patented methods, providing evidence of an affirmative intent to induce infringement. Furthermore, because ELCYS® and Eton's Proposed Generic Cysteine Hydrochloride Product have no substantial non-infringing uses, Eton intends for the administration of its generic version of ELCYS® to directly infringe at least claims 1, 3 and 27 of the '155 patent.

ANSWER: Denied.

190. On information and belief, upon awareness of the '155 patent, Eton either actually knew of the potential for infringement of at least claims 1, 3 and 27 of the '155 patent, or was

willfully blind as to the potential for that infringement at least because Eton provides instructions for infringement of at least claims 1, 3 and 27 of the '155 patent in its proposed product labeling.

ANSWER: Denied.

191. The commercial making, using, offering to sell, importing, or otherwise promoting and/or distributing of Eton's Proposed Generic Cysteine Hydrochloride Product, withits labeling, will constitute an act of active inducement of infringement of at least claims 1, 3 and27 of the '155 patent.

ANSWER: Denied.

192. The commercial making, using, offering to sell, importing, or otherwise promoting and/or distributing of Eton's Proposed Generic Cysteine Hydrochloride Product inviolation of Plaintiff's patent rights will cause harm to Plaintiff, for which damages are inadequate.

ANSWER: Denied.

193. Plaintiff is entitled to a declaratory judgment that the future making, using,offering to sell, importing, or otherwise promoting and/or distributing of Eton's Proposed Generic Cysteine Hydrochloride Product before patent expiration will constitute active inducement of infringement of at least claims 1, 3 and 27 of the '155 patent under 35 U.S.C. §271(b).

ANSWER: Denied.

194. Unless and until Eton is enjoined from infringing the '155 patent, Plaintiff will suffer irreparable injury for which damages are an inadequate remedy.

ANSWER: Denied.

COUNT VII

(Declaratory Judgment of Infringement of the '155 patent Under 35 U.S.C. § 271(c))

195. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

ANSWER: Eton incorporates by reference its answers to Paragraphs 1 through 194 as if set

forth herein.

196. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER: Eton admits that this claim purports to arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Eton denies that there is subject matter jurisdiction for this claim.

197. There is an actual case or controversy such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

ANSWER: Paragraph 197 contains conclusions of law to which no answer is required. To the extent an answer is required, Eton denies the allegations in Paragraph 197.

198. Eton has actual knowledge of the '155 patent.

ANSWER: Admitted.

199. On information and belief, Eton monitors the status of patent applications filed by Exela that relate to L-cysteine drug products and the contents of the Orange Book for the RLDs serving as the basis for its ANDA submissions, including ELCYS®.

ANSWER:

200. On information and belief, Eton became aware of the '155 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using ELCYS®.

ANSWER: Eton admits it became aware of the '453 patent at or about the time the '453 patent was listed in the Orange Book in connection with ELCYS. Eton denies all remaining allegations in paragraph 200.

201. On information and belief, Eton will engage in the commercial offer for sale, sale, importation and/or other distribution of Eton's Proposed Generic Cysteine Hydrochloride Product

immediately and imminently upon FDA approval of ANDA No. 214082.

ANSWER: Eton admits that it filed ANDA 214082 to seek FDA approval for Eton's ANDA Product. Eton denies the remaining allegations of Paragraph 144.

202. Eton's actions, including but not limited to, the development of Eton's Proposed Generic Cysteine Hydrochloride Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Eton has made and will continue to make substantial preparation in the United States, including in the District of Delaware, to sell, offer to sell, import and/or otherwise distribute Eton's Proposed Generic Cysteine Hydrochloride Product.

ANSWER: Eton admits that it filed ANDA 214082 to seek FDA approval for Eton's ANDA Product. Eton denies the remaining allegations of Paragraph 202.

203. On information and belief, Eton will include within the packaging of its Proposed Generic Cysteine Hydrochloride Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claims 1, 3 and 27 of the '155 patent.

ANSWER: Denied.

204. On information and belief, healthcare providers administering a parenteral nutrition regimen including Eton's Proposed Generic Cysteine Hydrochloride Product within theUnited States according to the instructions in the product's labeling will directly infringe at leastclaims 1, 3 and 27 of the '155 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

205. On information and belief, Eton knows that its Proposed Generic Cysteine Hydrochloride Product is a material part of the method of at least claims 1, 3 and 27 of the '155 patent, including as evidenced in the contents of its proposed label. On information and belief, Eton's Proposed Generic Cysteine Hydrochloride Product was especially made or especially

adapted for use by a healthcare provider in a manner that will directly infringe at least claims 1, 3 and 27 of the '155 patent, as evidenced by the contents of its proposed labeling. On information and belief, Eton's Proposed Generic Cysteine Hydrochloride Product is not a staple article of commerce suitable for substantial non-infringing use, as evidenced by the contents of its proposed labeling and the fact that it seeks FDA approval for a particular use. There are not suitable uses for cysteine hydrochloride injections other than treating patients pursuant to FDA'sapproval for such products.

ANSWER: Denied.

206. Thus, on information and belief, Eton will contribute to the infringement of the claims of the '155 patent in this District and elsewhere in the United States by offering to sell, selling, importing, or otherwise distributing Eton's Proposed Generic Cysteine Hydrochloride Product, which is a material for use in practicing the method of at least claims 1, 3 and 27 of the '155 patent.

ANSWER: Denied.

207. The commercial offering to sell, selling, importing and/or other distribution of Eton's Proposed Generic Cysteine Hydrochloride Product for use in practicing the patented methods in violation of Plaintiff's patent rights will cause harm to Plaintiff, for which damagesare inadequate.

ANSWER: Denied.

208. Plaintiff is entitled to a declaratory judgment that the future offer for sale, sale, importation and/or other distribution of Eton's Proposed Generic Cysteine Hydrochloride Product before patent expiration will constitute contributory infringement of at least claims 1, 3and 27 of the '155 patent under 35 U.S.C. § 271(c).

ANSWER: Denied.

209. Unless and until Eton is enjoined from infringing the ’155 patent, Plaintiff will suffer irreparable injury for which damages are an inadequate remedy.

ANSWER: Denied.

COUNT VIII

(Infringement of the ’719 patent Under 35 U.S.C. § 271(e)(2))

210. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

ANSWER: Eton incorporates by reference its answers to Paragraphs 1 through 210 as if set forth herein.

211. Eton submitted ANDA No. 214082 to the FDA under section 505(j) of the FDCAto obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of Eton’s Proposed Generic Cysteine Hydrochloride Product throughout the United States. By submitting the application, Eton has committed an act of infringement of the ’719 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Eton admits that it filed ANDA 214082 to seek FDA approval for Eton’s ANDA Product. Eton denies the remaining allegations of Paragraph 211.

212. The commercial manufacture, importation, use, sale, or offer for sale of Eton’s Proposed Generic Cysteine Hydrochloride Product will constitute an act of direct infringement of the ’719 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

213. Unless and until Eton is enjoined from infringing the ’719 patent, Plaintiff will suffer irreparable injury for which damages are an inadequate remedy.

ANSWER: Denied.

214. Plaintiff is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including anorder of this Court stating that the effective date of approval of Eton’s ANDA No. 214082 be adate that is

not earlier than the expiration date of the '719 patent.

ANSWER: Denied.

COUNT IX

(Declaratory Judgment of Infringement of the '719 patent Under 35 U.S.C. § 271(a))

215. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

ANSWER: Eton incorporates by reference its answers to Paragraphs 1 through 214 as if set forth herein.

216. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER: Eton admits that this claim purports to arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Eton denies that there is subject matter jurisdiction for this claim.

217. There is an actual case or controversy such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

ANSWER: Paragraph 217 contains conclusions of law to which no answer is required. To the extent an answer is required, Eton denies the allegations in Paragraph 217.

218. On information and belief, Eton will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Eton's Proposed Generic Cysteine Hydrochloride Product immediately and imminently upon FDA approval of ANDA No. 214082.

ANSWER: Eton admits that it filed ANDA 214082 to seek FDA approval for Eton's ANDA Product. Eton denies the remaining allegations of Paragraph 218.

219. Eton's actions, including but not limited to, the development of Eton's Proposed Generic Cysteine Hydrochloride Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Eton has made and will continue to make substantial preparation

in the United States, including in the District of Delaware, to manufacture, sell, offerto sell, and/or import Eton's Proposed Generic Cysteine Hydrochloride Product.

ANSWER: Eton admits that it filed ANDA 214082 to seek FDA approval for Eton's ANDA Product. Eton denies the remaining allegations of Paragraph 219.

220. On information and belief, Eton's Proposed Generic Cysteine Hydrochloride Product practices all limitations of at least claims 12-15 of the '719 patent, either literally or under the doctrine of equivalents, as detailed above, and thus the manufacture, importation, use,sale, and/or offer for sale of Eton's Proposed Generic Cysteine Hydrochloride Product will constitute an act of infringement of the '719 patent.

ANSWER: Denied.

221. The commercial manufacture, importation, use, sale, or offer for sale of Eton's Proposed Generic Cysteine Hydrochloride Product in violation of Plaintiff's patent rights willcause harm to Plaintiff, for which damages are inadequate.

ANSWER: Denied.

222. Plaintiff is entitled to a declaratory judgment that the future manufacture, use, offer for sale, sale and/or importation of Eton's Proposed Generic Cysteine Hydrochloride Product before patent expiration will constitute direct infringement of at least claims 12-15 of the '719 patent under 35 U.S.C. § 271(a).

ANSWER: Denied.

223. Unless and until Eton is enjoined from infringing the '719 patent, Plaintiff will suffer irreparable injury for which damages are an inadequate remedy.

ANSWER: Denied.

COUNT VIII

(Infringement of the '713 Patent Under 35 U.S.C. § 271(e)(2))

224. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

ANSWER: Eton incorporates by reference its answers to Paragraphs 1 through 223 as if set forth herein.

225. Eton submitted ANDA No. 214082 to the FDA under section 505(j) of the FDCAto obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of Eton's Proposed Generic Cysteine Hydrochloride Product throughout the United States. By submitting the application, Eton has committed an act of infringement of the '713 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Eton admits that it filed ANDA 214082 to seek FDA approval for Eton's ANDA Product. Eton denies the remaining allegations of Paragraph 225.

226. The commercial manufacture, importation, use, sale, or offer for sale of Eton's Proposed Generic Cysteine Hydrochloride Product will constitute an act of direct infringement of the '713 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

227. Unless and until Eton is enjoined from infringing the '713 patent, Plaintiff will suffer irreparable injury for which damages are an inadequate remedy.

ANSWER: Denied.

228. Plaintiff is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court stating that the effective date of approval of Eton's ANDA No. 214082 be a date that is not earlier than the expiration date of the '713 patent.

ANSWER: Denied.

COUNT IX

(Declaratory Judgment of Infringement of the '713 Patent Under 35 U.S.C. § 271(a))

229. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

ANSWER: Eton incorporates by reference its answers to Paragraphs 1 through 228 as if set forth herein.

230. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER: Eton admits that this claim purports to arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Eton denies that there is subject matter jurisdiction for this claim.

231. There is an actual case or controversy such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

ANSWER: Paragraph 231 contains conclusions of law to which no answer is required. To the extent an answer is required, Eton denies the allegations in Paragraph 231.

232. On information and belief, Eton will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Eton's Proposed Generic Cysteine Hydrochloride Product immediately and imminently upon FDA approval of ANDA No. 214082.

ANSWER: Eton admits that it filed ANDA 214082 to seek FDA approval for Eton's ANDA Product. Eton denies the remaining allegations of Paragraph 144.

233. Eton's actions, including but not limited to, the development of Eton's Proposed Generic Cysteine Hydrochloride Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Eton has made and will continue to make substantial preparation in the United States, including in the District of Delaware, to manufacture, sell, offerto sell, and/or import Eton's Proposed Generic Cysteine Hydrochloride Product.

ANSWER: Denied.

234. On information and belief, Eton's Proposed Generic Cysteine Hydrochloride Product practices all limitations of at least claim 1 of the '713 patent, either literally or under the

doctrine of equivalents, as detailed above, and thus the manufacture, importation, use, sale, and/or offer for sale of Eton's Proposed Generic Cysteine Hydrochloride Product will constitute an act of infringement of the '713 patent.

ANSWER: Denied.

235. The commercial manufacture, importation, use, sale, or offer for sale of Eton's Proposed Generic Cysteine Hydrochloride Product in violation of Plaintiff's patent rights willcause harm to Plaintiff, for which damages are inadequate.

ANSWER: Denied.

236. Plaintiff is entitled to a declaratory judgment that the future manufacture, use, offer for sale, sale and/or importation of Eton's Proposed Generic Cysteine Hydrochloride Product before patent expiration will constitute direct infringement of at least claim 1 of the '713 patent under 35 U.S.C. § 271(a).

ANSWER: Denied.

237. Unless and until Eton is enjoined from infringing the '713 patent, Plaintiff will suffer irreparable injury for which damages are an inadequate remedy.

ANSWER: Denied.

COUNT X

(Infringement of the '795 Patent Under 35 U.S.C. § 271(e)(2))

238. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

ANSWER: Eton incorporates by reference its answers to Paragraphs 1 through 237 as if set forth herein.

239. Eton submitted ANDA No. 214082 to the FDA under section 505(j) of the FDCAto obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of

Eton's Proposed Generic Cysteine Hydrochloride Product throughout the United States. By submitting the application, Eton has committed an act of infringement of the '795 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Eton admits that it filed ANDA 214082 to seek FDA approval for Eton's ANDA Product. Eton denies the remaining allegations of Paragraph 239.

240. The commercial manufacture, importation, use, sale, or offer for sale of Eton's Proposed Generic Cysteine Hydrochloride Product will constitute an act of direct infringement of the '795 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

241. Unless and until Eton is enjoined from infringing the '795 patent, Plaintiff will suffer irreparable injury for which damages are an inadequate remedy.

ANSWER: Denied.

242. Plaintiff is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including anorder of this Court stating that the effective date of approval of Eton's ANDA No. 214082 be a date that is not earlier than the expiration date of the '795 patent.

ANSWER: Denied.

COUNT XI

(Declaratory Judgment of Infringement of the '795 Patent Under 35 U.S.C. § 271(a))

243. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

ANSWER: Eton incorporates by reference its answers to Paragraphs 1 through 242 as if set forth herein.

244. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER: Eton admits that this claim purports to arise under the Declaratory Judgment

Act, 28 U.S.C. §§ 2201 and 2202. Eton denies that there is subject matter jurisdiction for this claim.

245. There is an actual case or controversy such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

ANSWER: Paragraph 245 contains conclusions of law to which no answer is required. To the extent an answer is required, Eton denies the allegations in Paragraph 245.

246. On information and belief, Eton will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Eton's Proposed Generic Cysteine Hydrochloride Product immediately and imminently upon FDA approval of ANDA No. 214082.

ANSWER: Eton admits that it filed ANDA 214082 to seek FDA approval for Eton's ANDA Product. Eton denies the remaining allegations of Paragraph 246.

247. Eton's actions, including but not limited to, the development of Eton's Proposed Generic Cysteine Hydrochloride Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Eton has made and will continue to make substantial preparation in the United States, including in the District of Delaware, to manufacture, sell, offerto sell, and/or import Eton's Proposed Generic Cysteine Hydrochloride Product.

ANSWER: Denied.

248. On information and belief, Eton's Proposed Generic Cysteine Hydrochloride Product practices all limitations of at least claims 1 and 11 of the '795 patent, either literally or under the doctrine of equivalents, as detailed above, and thus the manufacture, importation, use, sale, and/or offer for sale of Eton's Proposed Generic Cysteine Hydrochloride Product will constitute an act of infringement of the '795 patent.

ANSWER: Denied.

249. The commercial manufacture, importation, use, sale, or offer for sale of Eton's

Proposed Generic Cysteine Hydrochloride Product in violation of Plaintiff's patent rights will cause harm to Plaintiff, for which damages are inadequate.

ANSWER: Denied.

250. Plaintiff is entitled to a declaratory judgment that the future manufacture, use, offer for sale, sale and/or importation of Eton's Proposed Generic Cysteine Hydrochloride Product before patent expiration will constitute direct infringement of at least claim 1 and 11 of the '795 patent under 35 U.S.C. § 271(a).

ANSWER: Denied.

251. Unless and until Eton is enjoined from infringing the '795 patent, Plaintiff will suffer irreparable injury for which damages are an inadequate remedy.

ANSWER: Denied.

COUNT XIV

(Declaratory Judgment of Infringement of the '795 Patent Under 35 U.S.C. § 271(b))

252. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

ANSWER: Eton incorporates by reference its answers to Paragraphs 1 through 251 as if set forth herein.

253. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER: Eton admits that this claim purports to arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Eton denies that there is subject matter jurisdiction for this claim.

254. There is an actual case or controversy such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

ANSWER: Paragraph 254 contains conclusions of law to which no answer is required. To

the extent an answer is required, Eton denies the allegations in Paragraph 254.

255. Eton has actual knowledge of the '795 patent.

ANSWER: Admitted.

256. On information and belief, Eton became aware of the '795 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering ELCYS®.

ANSWER: Eton admits it became aware of the '453 patent at or about the time the '453 patent was listed in the Orange Book in connection with ELCYS. Eton denies all remaining allegations in paragraph 256.

257. On information and belief, Eton will engage in the commercial manufacture, use, offer for sale, sale, importation or other promotion and/or distribution of Eton's Proposed Generic Cysteine Hydrochloride Product immediately and imminently upon FDA approval of ANDA No. 214082.

ANSWER: Eton admits that it filed ANDA 214082 to seek FDA approval for Eton's ANDA Product. Eton denies the remaining allegations of Paragraph 257.

258. Eton's actions, including but not limited to, the development of Eton's Proposed Generic Cysteine Hydrochloride Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Eton has made and will continue to make substantial preparation in the United States, including in the District of Delaware, to manufacture and/or cause to be manufactured, and to sell, offer to sell, import or otherwise promote and/or distributeEton's Proposed Generic Cysteine Hydrochloride Product.

ANSWER: Denied.

259. On information and belief, Eton will provide GRAM with the manufacturing instructions for its Proposed Generic Cysteine Hydrochloride Product that instructs GRAM to perform the method of at least claim 11 of the '795 patent.

ANSWER: Denied.

260. On information and belief, GRAM's manufacturing of Eton's Proposed Generic Cysteine Hydrochloride Product within the United States according to the manufacturing instructions in the ANDA will directly infringe at least claim 11 of the '795 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

261. On information and belief, Eton possesses specific intent to encourage direct infringement of at least claim 11 of the '795 patent, including because Eton's manufacturing instructions for its Proposed Generic Cysteine Hydrochloride Product will instruct manufacturers, including GRAM, to perform the patented method, providing evidence of an affirmative intent to induce infringement. Furthermore, because ELCYS® and Eton's ProposedGeneric Cysteine Hydrochloride Product have no substantial non-infringing uses, Eton intends for the manufacture of its generic version of ELCYS® to directly infringe at least claim 11 the '795 patent.

ANSWER: Denied.

262. On information and belief, upon awareness of the '795 patent, Eton either actually knew of the potential for infringement of at least claim 11 of the '795 patent, or was willfully blind as to the potential for that infringement at least because Eton provides instructions for infringement of at least claim 11 of the '795 patent in its proposed product manufacturinginstructions.

ANSWER: Denied.

263. Eton's procurement of commercial manufacturing of its Proposed Generic Cysteine Hydrochloride Product, according to the manufacturing instructions and specificationsin Eton's ANDA, will constitute an act of active inducement of infringement of at least claim 11of the '795 patent.

ANSWER: Denied.

264. Eton's procurement of commercial manufacturing of its Proposed GenericCysteine Hydrochloride Product in violation of Plaintiff's patent rights will cause harm toPlaintiff, for which damages are inadequate.

ANSWER: Denied.

265. Plaintiff is entitled to a declaratory judgment that the future making, using, offering to sell, selling, importing, or otherwise promoting and/or distributing of Eton's Proposed Generic Cysteine Hydrochloride Product before patent expiration will constitute active inducement of infringement of at least claim 11 of the '795 patent under 35 U.S.C. § 271(b).

ANSWER: Denied.

266. Unless and until Eton is enjoined from infringing the '795 patent, Plaintiff will suffer irreparable injury for which damages are an inadequate remedy.

ANSWER: Denied.

COUNT XV

(Infringement of the '089 Patent Under 35 U.S.C. § 271(e)(2))

267. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

ANSWER: Eton incorporates by reference its answers to Paragraphs 1 through 266 as if set forth herein.

268. Eton submitted ANDA No. 214082 to the FDA under section 505(j) of the FDCAto obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of Eton's Proposed Generic Cysteine Hydrochloride Product throughout the United States. By submitting the application, Eton has committed an act of infringement of the '089 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Eton admits that it filed ANDA 214082 to seek FDA approval for Eton's

ANDA Product. Eton denies the remaining allegations of Paragraph 268.

269. The commercial manufacture, importation, use, sale, or offer for sale of Eton's Proposed Generic Cysteine Hydrochloride Product will constitute an act of direct infringement of the '089 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

270. Unless and until Eton is enjoined from infringing the '089 patent, Plaintiff will suffer irreparable injury for which damages are an inadequate remedy.

ANSWER: Denied.

271. Plaintiff is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including anorder of this Court stating that the effective date of approval of Eton's ANDA No. 214082 be adate that is not earlier than the expiration date of the '089 patent.

ANSWER: Denied.

COUNT XVI

(Declaratory Judgment of Infringement of the '089 Patent Under 35 U.S.C. § 271(a))

272. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

ANSWER: Eton incorporates by reference its answers to Paragraphs 1 through 271 as if set forth herein.

273. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER: Eton admits that this claim purports to arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Eton denies that there is subject matter jurisdiction for this claim.

274. There is an actual case or controversy such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution, and that

actual case or controversy requires a declaration of rights by this Court.

ANSWER: Eton admits that this claim purports to arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Eton denies that there is subject matter jurisdiction for this claim.

275. On information and belief, Eton will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Eton's Proposed Generic Cysteine Hydrochloride Product immediately and imminently upon FDA approval of ANDA No. 214082.

ANSWER: Eton admits that it filed ANDA 214082 to seek FDA approval for Eton's ANDA Product. Eton denies the remaining allegations of Paragraph 160.

276. Eton's actions, including but not limited to, the development of Eton's Proposed Generic Cysteine Hydrochloride Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Eton has made and will continue to make substantial preparation in the United States, including in the District of Delaware, to manufacture, sell, offer to sell, and/or import Eton's Proposed Generic Cysteine Hydrochloride Product.

ANSWER: Denied.

277. On information and belief, Eton's Proposed Generic Cysteine Hydrochloride Product practices all limitations of at least claim 1 of the '089 patent, either literally or under the doctrine of equivalents, as detailed above, and thus the manufacture, importation, use, sale, and/or offer for sale of Eton's Proposed Generic Cysteine Hydrochloride Product will constitute an act of infringement of the '089 patent.

ANSWER: Denied.

278. The commercial manufacture, importation, use, sale, or offer for sale of Eton's Proposed Generic Cysteine Hydrochloride Product in violation of Plaintiff's patent rights will cause harm to Plaintiff, for which damages are inadequate.

ANSWER: Denied.

279. Plaintiff is entitled to a declaratory judgment that the future manufacture, use,offer for sale, sale and/or importation of Eton's Proposed Generic Cysteine Hydrochloride Product before patent expiration will constitute direct infringement of at least claim 1 of the '089patent patent under 35 U.S.C. § 271(a).

ANSWER: Denied.

280. Unless and until Eton is enjoined from infringing the '089 patent, Plaintiff will suffer irreparable injury for which damages are an inadequate remedy.

ANSWER: Denied.

ETON'S AFFIRMATIVE DEFENSES

Eton asserts the following affirmative defenses without prejudice to the responses set forth in its Answer and without making any admission or implication as to the burden of proof for these defenses. Eton reserves the right to assert other defenses and/or counterclaims if discovery merits such action.

FIRST DEFENSE
(Failure to State a Claim)

Plaintiff's Amended Complaint fails to state a claim upon which relief can be granted.

SECOND DEFENSE
(Invalidity)

One or more claims of the Patents-in-Suit are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§102 and 103.

The asserted claims are generally directed to, among other things, an L-cysteine composition having specified amounts of aluminum, L-cystine and pyruvic acid, a method of making a composition for a total parenteral nutrition regime comprising mixing an L-cysteine composition

having specified amounts of aluminum, L-cystine and pyruvic acid with an amino acid solution, and a method of treating a subject having an adverse health condition with an L-cysteine composition having specified amounts of aluminum, L-cystine and pyruvic acid. Eton's proposed ANDA product is identical to the product marketed and sold by Sandoz Inc. in the United States by at least 2010. The asserted claims are obvious and/or anticipated by the L-cysteine product marketed and sold by Sandoz and/or by the Hospira L-cysteine product, which was approved by FDA in the 1980s. The Sandoz L-cysteine product had aluminum levels in the claimed amounts and L-cystine and pyruvic acid in the claimed amounts, to the extent any L-cystine or pyruvic acid existed. The Hospira L-cysteine product, based upon information and belief, had aluminum levels, L-cystine and pyruvic acid in the claimed amounts. The Sandoz L-cysteine product and the Hospira L-cysteine product were indicated for use in an admixture with an amino acid composition for total parenteral nutrition and used to treat a subject having an adverse health condition as claimed. The Sandoz L-cysteine product and the Hospira L-cysteine product also met the claimed pH levels, head space and dissolved oxygen levels. To the extent not anticipated, the asserted claims are the reasonably expected result of optimizing the Sandoz L-cysteine and/or Hospira L-cysteine products using known techniques to minimize and maintain aluminum levels over the product's shelf-life in response to a progressively tightening regulatory environment concerning aluminum levels in parenteral drug products, as well as health and safety concerns associated with aluminum toxicity, while also maintaining the stability of L-cysteine, which was known to be oxygen sensitive and oxidatively degrade to L-cystine and pyruvic acid. Moreover, the claimed head space and dissolved oxygen levels are merely the result of the routine optimization of the Sandoz L-cysteine and/or Hospira L-cysteine product by controlling known parameters (i.e. head space and dissolved oxygen) to achieve the expected result of preventing oxidative degradation of L-cysteine. For at least these reasons, the asserted claims are invalid as anticipated and/or obvious.

THIRD DEFENSE
(Non-Infringement)

The manufacture, use, sale, offer for sale, importation, and/or marketing of Eton's ANDA Product has not infringed, does not infringe, and would not infringe, either directly or indirectly, any valid and unenforceable claim of the Patents-in-Suit, either literally or under the doctrine of equivalents.

FOURTH DEFENSE
(Lack of Subject Matter Jurisdiction)

No case or controversy exists under the Declaratory Judgment Act relating to purported infringement of the '453, '155, '719, '713, '795, and '089 patents independent of 35 U.S.C. § 271(e)(2) as alleged in Plaintiff's Counts II, III, IV, VI, VII, IX, IX (second), XI, XIV and XVI, which are already the subject of Plaintiff's Counts I, V, VIII, VIII (second), X and XV. As such, this Court lacks subject matter jurisdiction over Counts II, III, IV, VI, VII, IX, IX (second), XI, XIV and XVI regarding the alleged infringement of the '453, '155, '719, '713, '795, and '089 patents and these Counts should be dismissed.

RESERVATION OF ALL DEFENSES

Eton hereby reserves any and all defenses that are available under the Federal Rules of Civil Procedure, Local Rules of Civil Practice and Procedure of the United States District Court for the District of Delaware, and U.S. Patent Law, and any other defenses, at law or in equity, including unenforceability, that may exist or become available later as a result of discovery and further factual investigation during this litigation.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Eton hereby demands a trial by jury of all issues so triable.

Dated: August 12, 2021

DEVLIN LAW FIRM LLC

/s/ Timothy Devlin
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CERTIFICATE OF SERVICE

I hereby certify that on August 12, 2021, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

/s/ Timothy Devlin
Timothy Devlin