UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ETON PHARMACEUTICALS, INC.,

Petitioner

v.

EXELA PHARMA SCIENCES, LLC,

Patent Owner

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U.S. PATENT NO. 10,653,719

DECLARATION OF HARRY "WARREN" JOHNSON

1. My name is Harry "Warren" Johnson. I am over 21 years of age. I submit this declaration on behalf of Eton Pharmaceuticals, Inc. (hereinafter "Eton") in connection with the above-captioned matter, which I understand concerns U.S. Patent No. 10,653,719 ("the '719 patent"). I am not being compensated for my time, although, as noted below, I have an indirect, potential financial interest in this matter.

2. I previously submitted a declaration dated May 15, 2020, in connection with a PGR concerning U.S. Patent No. 10,478,453 ("the '453 patent"), which I understand is related to the '719 patent.

3. In connection with this Declaration, I reviewed certain business records of Allergy Laboratories, Inc. (hereinafter "Allergy Labs") and AL Pharma, Inc. (hereinafter "AL Pharma"). These records were created and maintained in the ordinary course of Allergy's and AL Pharma's business.

4. I also held discussions with individuals who provided information that I also relied upon in preparing this declaration.

5. Based on my personal knowledge and the results of my investigation, I am informed and understand that the facts stated in this Declaration are true.

Background

6. From January 2001 to approximately January 2017, I served as Vice President and was a 49% owner of Allergy Labs. My wife owned the remaining shares. In or around January 2017, Allergy Labs sold some of its assets and business

activities, including the Allergy Laboratories name, to ALK. Allergy Labs (which changed its name to AL Pharma, Inc. ("AL Pharma") following the sale) retained the real estate, including its Oklahoma City plant, and the cysteine products, which, as discussed below, Allergy Labs previously manufactured for Sandoz Inc. ("Sandoz"). ALK currently leases AL Pharma's Oklahoma City plant. My wife and I own all outstanding shares of AL Pharma. I have served as Vice President of AL Pharma since January 2017.

7. AL Pharma has a profit sharing arrangement with Eton in connection with Eton's proposed L-Cysteine Hydrochloride Injection drug product that is the subject of Eton's Abbreviated New Drug Application (ANDA). I understand that Eton's ANDA has prompted a suit for alleged patent infringement by Exela Pharma Sciences, LLC ("Exela"). I am advised that Exela contends the manufacture, use and/or sale of Eton's proposed ANDA product would infringe one or more claims of the '453 patent, the '719 patent, and U.S. Patent No 10,583,155 ("the '155 patent"), which I understand is related to the '453 and '719 patents.

The Sandoz L-Cysteine Product

8. In addition to serving as Vice President, my job responsibilities at Allergy Labs during the time frame of January 2001 through January 2017 included manufacturing, sales, accounting, inventory and purchasing. My wife, a chemist and pharmacist, was primarily responsible for quality assurance and quality control.

9. Prior to approximately 2008, Allergy Labs contract-manufactured an L-Cysteine Hydrochloride Injection, USP drug product for Parenta Pharmaceuticals ("Parenta"). Allergy Labs manufactured the Parenta L-Cysteine Product at Allergy's manufacturing plant in Oklahoma City, Oklahoma. In or about 2008, I understand that Parenta was acquired by Sandoz. From that time until 2016, Allergy Labs contract-manufactured the L-Cysteine Hydrochloride Injection Product (50 mg/mL product and available in both single dose vials and pharmacy bulk package) for Sandoz (the "Sandoz L-Cysteine Product" or "Sandoz product").

10. Allergy Labs contract-manufactured the Sandoz L-Cysteine Product pursuant to Sandoz's specifications and sold the finished product to Sandoz pursuant to purchase orders. Among other things, the specifications for the Sandoz product required that the finished product was a clear colorless solution free of visible particulate matter from the time of manufacture until the product's expiration date, which was two years after manufacture.

11. Compliance with the above-referenced free of visible particulate matter specification was evaluated by visually inspecting the product shortly after manufacture and by storing samples for each lot of Sandoz product at approximately 25 °C and approximately 60% relative humidity and visually inspecting the samples at 3, 6, 9, 12, 18 and 24-month time intervals. Allergy Labs contracted a third-party, KABS Pharmaceutical Services ("KABS"), to assist in evaluating the Sandoz

product samples for compliance with the free of visible particulate matter specification.

12. The Sandoz product consistently met the free of visible particulate matter specification, remaining free of visually detectable particulate matter for at least 24 months after manufacture.

13. Pursuant to its agreement with Sandoz, various regulatory obligations, and as part of its ordinary business practices, Allergy Labs made, received and kept records associated with its manufacture of the Sandoz L-Cysteine Product and compliance with product specifications. These records included, but were not limited to, maintaining records demonstrating compliance with the free of visible particulate matter specification for each lot of Sandoz L-Cysteine Product.

14. Attached as Exhibit A is a true and correct copy of a record relating to Sandoz product lot #2081915, which was manufactured on August 19, 2015. As was Allergy's practice at the time, the date on which the product was manufactured is reflected by the lot number assigned to the product. Consistent with that practice, the numbers in the lot # that I have shown in bold represent the manufacture date (#2**081915**) of 08/19/15 and the "2" stands for manufacturing line 2 at the Oklahoma City plant. It is my understanding and belief that this record was made by KABS at or near the time of the events recorded therein by technicians who had knowledge and were responsible for making records of the testing of the Sandoz product

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