UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ALTAIRE PHARMACEUTICALS, INC.,
Petitioner,

v.

PARAGON BIOTECK, INC.,
Patent Owner.

Case PGR2015-00011
Patent No. 8,859,623

DECLARATION OF SAILAJA MACHIRAJU

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I, Sailaja Machiraju, declare as follows:

I. QUALIFICATIONS

1. My name is Sailaja Machiraju. I am a Senior Research Associate at Paragon BioTeck, Inc ("Paragon"). I have been employed by Paragon since June, 2013.

2. I am a named inventor on U.S. Patent No. 8,859,623 ("the '623 patent," Ex. 1001).

3. I have a Master of Science degree in Organic Chemistry from BAM University in India.

4. I have about eight and a half years of experience in the pharmaceutical industry.

5. My primary duties at Paragon include leading research on ophthalmic pharmacology, clinical biology, organic and analytical chemistry.

6. A major focus of my current and past research is synthesis, characterization, and separation of chiral molecules. As a result, I am familiar with a variety of analytical techniques for confirming chiral purity including high-performance liquid chromatography (HPLC).

7. I am the lead scientist with respect to research and development performed in-house at Paragon. I also direct experiments performed by contract research organizations on Paragon's behalf.

II. HPLC EXPERIMENTS

8. I was responsible for overseeing the performance of the HPLC experiments, described herein, by Encompass Pharmaceutical Services, Inc. ("Encompass").

9. Encompass provides analytical chemistry services to the pharmaceutical industry, as such, the analytical methods performed in their laboratories conform to Good Manufacturing Practice (GMP), International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), and United States Pharmacopeial Convention (USP) guidelines. We have used Encompass in the past and are confident in the quality of analytical chemistry services they provide.

10. The purpose of the experiment was to determine whether the HPLC method described in the USP Monograph for identification of R-form phenylephrine was capable of separating phenylephrine enantiomers.

11. I directed Encompass to perform certain HPLC experiments on phenylephrine using the experimental conditions described in the USP Monograph. (Ex. 2009; Ex. 2010). These experiments were performed using a L1 HPLC column which contains octyl decyl silane ("C-18") solid packing material. The specific HPLC column used was a Zorbax C18 (2) 250 x 4.6mm HPLC column, 5 µm, part number 880975-902.

12. The mobile phase was methanol and water (1:1) containing 1.1 g of sodium 1-octanesulfonate per liter, adjusted with phosphoric acid to a pH of 3.0,

filter, and de-gassed. The diluent for all samples was a mixture of methanol and water (1:1), adjusted with phosphoric acid to a pH of 3.0.

13. The flow rate for all HPLC runs was 1 mL per minute and the injection volume was 20 µL. Peaks were detected at 270 nm.

14. I directed the following samples to be injected onto the C-18 column:

- A blank, which comprises injection of the diluent for the samples;
- A resolution control, which comprises a mixture of epinephrine bitartrate and R-form phenylephrine;
- 2.5% w/v enantiomerically enriched R-form phenylephrine;
- 2.5% w/v enantiomerically enriched S-form phenylephrine; and
- A racemic mixture (2.5% w/v with respect to each enantiomer) of phenylephrine.

15. The R-form of phenylephrine was purchased from USP and is from Lot M0L504. The S-form of phenylephrine was purchased from Toronto Research Chemicals and is from Lot 10-XAL-77-1. Epinephrine bitartrate was purchased from USP and is from Lot PIL 152.

16. Encompass confirmed that they ran the three phenylephrine samples according to the method I directed.

17. I have reviewed the data acquired by Encompass and I include it as Exhibit 2040.

18. Page 1 of Exhibit 2040 shows the HPLC chromatogram for the diluent-only injection in which no peaks are visible. This is the expected result

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