

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ALTAIRE PHARMACEUTICALS, INC.,  
Petitioner,

v.

PARAGON BIOTECK, INC.,  
Patent Owner.

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Case PGR2015-00011  
Patent 8,859,623 B1

**DECLARATION # 3 OF ASSAD SAWAYA**

I, **Assad Sawaya**, do hereby declare as follows:

1. As shown in my curricula vitae, a true copy attached herein as Exhibit A, I have over 50 years of experience in the pharmaceutical industry.
2. Since 1997, I have been the president of Altaire Pharmaceuticals, Inc. (“Altaire”). My responsibilities at Altaire include managing and directing a research and development laboratory including numerous chemist,

microbiologists, and pharmacists focusing in developing, among other things, ophthalmic, otic, dermatological and oral pharmaceutical products. I also manage employees having experience in analytical chemistry, method development, and method validation to meet the Food & Drug Administration's requirements for "Quality Control and Quality Assurance." The employees I manage employ state of the art methodologies, such as gas chromatography, high performance liquid chromatography, and ultra performance liquid chromatography. I am very familiar with and have personal knowledge of analyzing and interpreting the underlying testing methodologies and the results generated by such methodologies.

3. Prior to founding Altaire, I was the president of Pharmafair Laboratories, Inc. ("Pharmafair"), which was later acquired by Bausch and Lomb Laboratories. At Pharmafair, I facilitated the development of formulations and processing controls for ophthalmic, otic, and dermatological products, and obtained more than 25 ANDA approvals. I additionally, directed and managed research and development laboratories, including analytical testing laboratories. I also oversaw chemical and microbiological testing conducted by a staff including a PhD chemist, a microbiologist, and a pharmacist.

4. Prior to Pharmafair, I was the owner/operator of GMP Laboratories, a company that provided consulting services specifically directed to the pharmaceutical industry. In my role, I managed and trained the quality control laboratory staff that performed analytical and microbiological testing. Accordingly, in my role, I routinely analyzed quality control testing data relating to analytical and microbiological testing.
5. Prior to GMP Laborites, I was a supervisor of microbiology for a quality control lab at Dome Laboratories and a manager of the same at Burroughs Wellcome Laboratory. As demonstrated in my resume, these roles intimately involved the active management of teams analyzing and testing pharmaceutical products, including developing a sterilization system for sterile pharmaceutical products. My role also required supervising and training microbiology analysts.
6. In addition to my extensive work experience, I also attended Long Island University from 1957-1961 wherein I took courses for a Premed B.S. program.
7. Explained herein is only a subset of my comprehensive work experience in the pharmaceutical industry. Please see my resume, Exhibit A, for a more complete recitation.

8. As demonstrated, I have been testing, reviewing, analyzing, or supervising the testing of pharmaceutical compositions since 1957 and have developed significant experience in the pharmaceutical industry. From this experience, I have obtained extensive experience testing and analyzing results for a variety of testing methodologies relevant to the pharmaceutical field, including validation reports, high performance liquid chromatography reports, and optical rotation reports. As such, I am more than competent to review, analyze, and opine on such reports.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.



**Assad Sawaya**

Date: 5/4/16

# **EXHIBIT A**

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