

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 Biotech, Inc.*

Patent Owner

U.S. Patent No. 8,859,623

Issue Date: October 14, 2014

Entitled: METHODS AND COMPOSITIONS OF STABLE PHENYLEPHRINE  
FORMULATIONS

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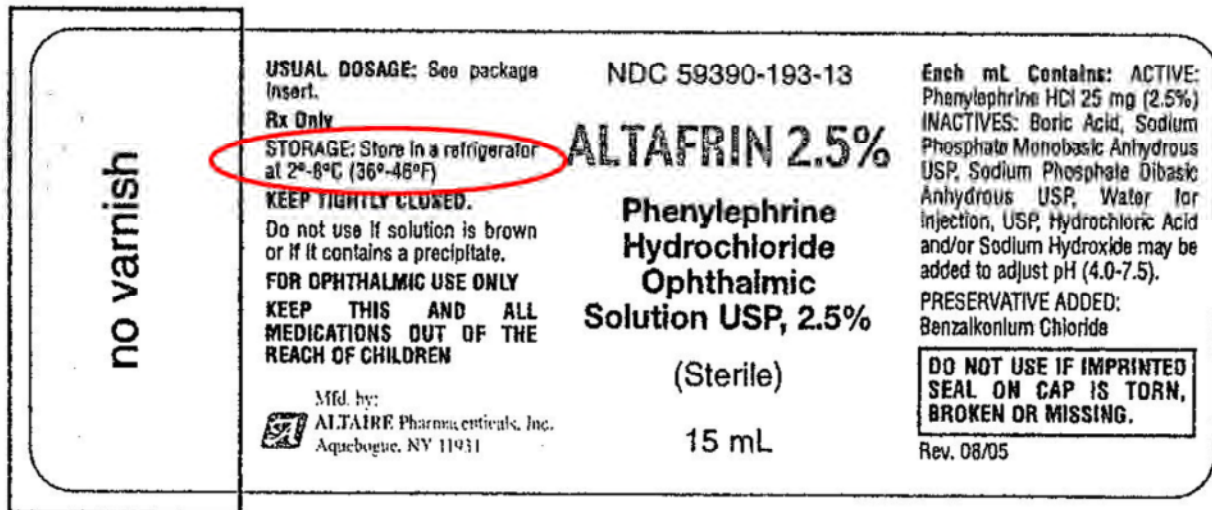
Post-Grant Review No.: Unassigned

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**DECLARATION OF ASSAD SAWAYA**

I, Assad Sawaya, declare as follows:

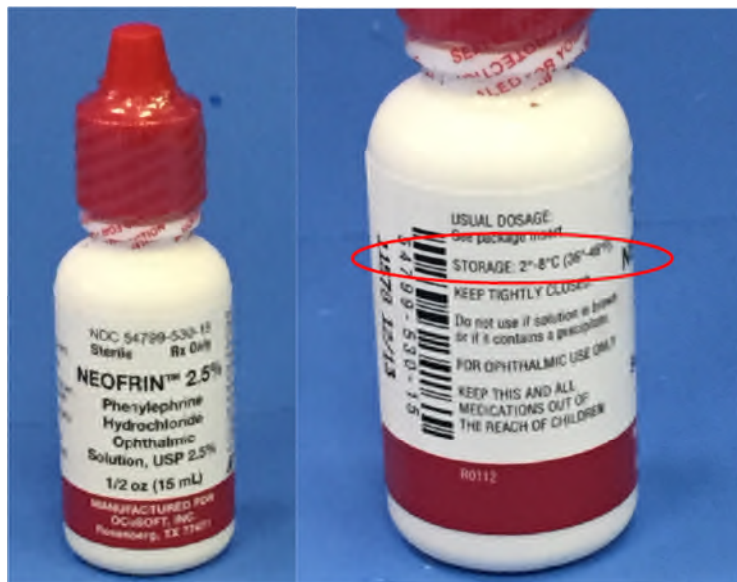
1. I am President of Altaire Pharmaceutical, Inc. I make this declaration based upon my personal knowledge of the facts stated herein.
2. Altaire manufactured the products that are the subject of the '623 patent (Phenylephrine HCl Ophthalmic Solution 2.5% and Phenylephrine HCl Ophthalmic Solution 10%) for various customers, for at least 8 years prior to the '623 patent's filing date. Altaire's products have consistently had a label instructing storage in a refrigerator "at 2°-8° C (36°-46° F)." (See, *e.g.*, Exhibits 1004 and 1005 (excerpts reproduced and annotated below)).<sup>1</sup>



<sup>1</sup> Exhibits 1004 and 1005 are dated as approved for print in September 2005 and December 2004, respectively.



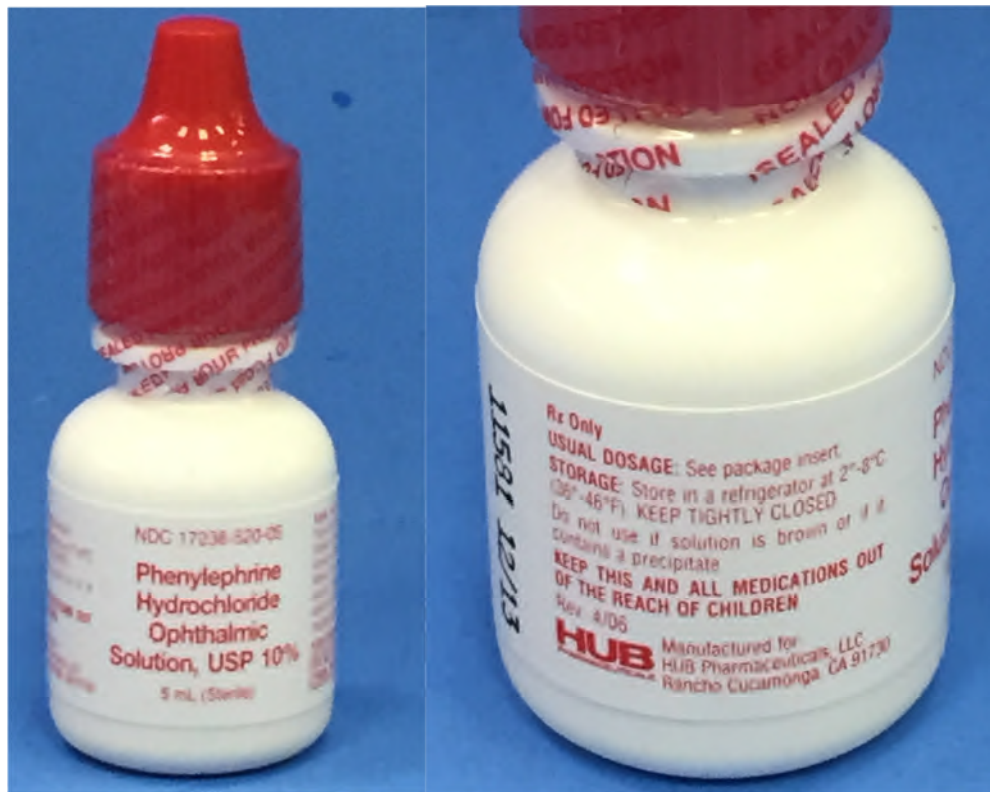
3. Labels like those depicted above were provided on Altaire's Phenylephrine Hydrochloride Ophthalmic Solution sold and distributed over one year prior to the '623 patent's filing. (*See, e.g.*, Exhibit 1006 at 1 of 3 and 3 of 3 (reproduced and annotated below).



4. The above depicted product (Lot # 11578 (*see id.* at 2 of 3)) was sold and distributed over a year prior to the '623 patent's earliest filing date. (*See* Exhibit 1007). Lot # 11578 was manufactured in December 2011 as a 2.5% Phenylephrine Hydrochloride Ophthalmic Solution. Lot #11578 had an expiration

date of December 2013, which means that it would maintain its chirality for application to the eye when stored at 2°-8° C low temperature storage until that date. (See Exhibit 1006 at 2 of 3 (noting a date of “12/13” indicating its expiration date)).

5. Altaire also sold and distributed a 10% Phenylephrine Hydrochloride Ophthalmic Solution. (See, e.g., Exhibit 1008 at 1 of 3 and 3 of 3 (reproduced below)).



6. Lot # 11581 (see *id.* at 2 of 3)) was sold and distributed over a year prior to the '623 patent's earliest filing date. (See Exhibit 1009). Lot # 11581 was manufactured in January 2012 and had an expiration date of December

2013, which means that it would maintain its chirality for application to the eye when stored at 2°-8° C low temperature storage until that date. (See Exhibit 1008 at 2 of 3 (noting a date of “12/13” indicating its expiration date)).

7. After years of selling its Phenylephrine Hydrochloride Ophthalmic Solution, Altaire was approached by Paragon’s CEO, Mr. Patrick Witham, to enter into an agreement dated May 15, 2011 (“Agreement”) whereby Altaire would provide the Chemistry, Manufacturing and Controls (or CMC) sections regarding Altaire’s Phenylephrine HCl Ophthalmic Solution product for the limited purposes of supporting a New Drug Application (or NDA) to be submitted by Paragon to the Federal Food & Drug Administration (“FDA”).

8. The Agreement specified that:
- a. Altaire’s CMC sections are provided for the limited purposes of obtaining the NDAs contemplated by the Agreement;
  - b. the Altaire information may not be used for any other purpose; and
  - c. it is the specific intent of the parties that the Altaire information is the *proprietary and confidential information of Altaire*,

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