

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 GOJKO LALIC, PH.D.

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I, Gojko Lalic, declare as follows:

I. QUALIFICATIONS

1. My name is Gojko Lalic. I am an Assistant Professor at the University of Washington (“UW”). I received my B.S. in Chemistry from the University of Belgrade in 1998 and my Ph.D. in Organic Chemistry from Harvard University in 2004.

2. Following completion of my Ph.D. thesis, I was a post-doctoral research fellow for two years at the University of California, Berkeley and an additional two years at Harvard University. During this time, I was heavily involved in the development of enantioselective synthetic methods.

3. In 1998 I joined UW as an Assistant Professor. At UW I lead a research group devoted to the development of new methods for the synthesis of organic molecules, including the synthesis of enantioenriched chiral molecules. I have supervised numerous Ph.D. and post-doctoral research fellows in my laboratory.

4. I am the author or co-author of 30 peer-reviewed publications in synthetic organic chemistry and enantioselective synthesis. I have presented lectures on the development of new reactions for the synthesis of organic molecules at academic conferences and been an invited lecturer at universities and pharmaceutical companies.

5. I have received awards based on the high quality of my scientific research, including a Career Award from the National Science Foundation.

6. A copy of my curriculum vitae is attached as Exhibit 2017.

II. SCOPE OF WORK

7. I understand that a petition was filed with the United States Patent and Trademark Office for post-grant review of U.S. Patent No. 8,859,623 (“the ’623 patent,” Ex. 1001).

8. I further understand that the Patent Trial and Appeal Board (“PTAB” or the “Board”) has decided to institute post-grant review of claims 1-13 of the ’623 patent under 35 U.S.C. § 103 based on Lot #11578 and #11581 of phenylephrine hydrochloride ophthalmic solution allegedly produced and sold by Altaire (“the Altaire Product”).

9. I have been specifically asked to provide my expert opinion on the experiments that purport to establish the chiral purity of the Altaire Product. (Exs. 1012, 1015-1017, 1019, 1020). I have further been asked to provide my opinion on the HPLC experiments presented by Paragon in support of their Patent Owner Response. In connection with this analysis, I have also been asked to review the ’623 patent as well as the declaration of Altaire’s President, Mr. Sawaya. (Ex. 1001, 1003).

III. SUMMARY OF OPINIONS

10. In my opinion the HPLC data submitted by Altaire in the Petition (including what is shown in Ex. 1016) is insufficient to establish the chiral purity of the Altaire Product in terms of both initial purity and purity following storage. Exhibit 1016 is the only exhibit that presents chromatograms for samples of the Altaire Product.

11. There are numerous deficiencies with the HPLC data presented, including a lack of any accompanying experimental and methodological detail; however, in my analysis I have focused primarily on the lack of controls. The lack of experimental controls presented with the HPLC data regarding the purity of the Altaire Product renders the submitted experiments incapable of supporting an assertion of at least 95% optical purity of the tested Altaire Product.

12. I have also reviewed the optical rotation analysis provided by Altaire and the corresponding exhibits. In my opinion, those materials provided by Altaire fail to establish the chiral purity of the Altaire Product in terms of both initial purity and purity following storage.

13. In my experience and opinion, optical rotation measurements are highly variable, and as a result, are generally not used to accurately determine chiral purity of a sample. In agreement with this general limitation of the optical rotation measurement is the stated accuracy limitation of the optical rotation assay reported in Exhibit 1012. According to Altaire's statement this assay only allows estimation of optical purity within $\pm 6\%$. Thus, Altaire's optical rotation measurements cannot establish that the chiral purity of the Altaire Product is at least 95%. The second problem with the polarimetry data submitted by Altaire is the purity of the phenylephrine control used in calculating optical purity of the Altaire Product. The optical purity of the control sample is either unknown or not specified. The basis for my opinions is discussed in detail below.

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