

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT TRIAL AND APPEAL BOARD

ADAMIS PHARMACEUTICALS CORPORATION
Petitioner

v.

BELCHER PHARMACEUTICALS, LLC
Patent Owner

CASE: IPR2019-01021
U.S. PATENT NO. 9,283,197

**DECLARATION OF JAMES KIPP, PH.D. IN SUPPORT OF PETITION
FOR *INTER PARTES* REVIEW OF U.S. PATENT 9,283,197**

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I, James Kipp, Ph.D., do hereby declare and say:

I. INTRODUCTION

1. I am over the age of twenty-one (21) and competent to make this declaration. I am also qualified to give testimony under oath. The facts and opinions listed below are within my personal knowledge.

2. I have been engaged in this matter to provide my independent analysis of certain issues I understand arise in connection with the *Inter Partes* Review of U.S. Patent No. 9,283,197 (which I refer to as the ‘197 Patent). (Ex. 1001). I am being compensated for my time in connection with this IPR at my standard consulting rates. I have received no compensation for this declaration beyond my normal hourly rate for time spent on this matter, and I will not receive any added compensation based on the outcome of any proceeding related to the ‘197 Patent.

3. I have been asked to review certain documents, including the ‘197 Patent (Ex. 1001), and to provide my opinions on how those of skill in the art (as defined herein) would understand those documents. For purposes of this declaration, the documents I was asked to review include:

Ex. 1001	U.S. Patent No. 9,283,197 (“‘197 Patent”)
Ex. 1004	File History of U.S. Patent No. 9,283,197
Ex. 1005	Stepensky, D., <i>Long-Term Stability Study of L-Adrenaline Injections: Kinetics of Sulfonation and Racemization Pathways of Drug Degradation</i> , Journal of Pharmaceutical Sciences, Vol. 93 No. 4, published in April 2004 (“Stepensky”)

Ex. 1006	U.S. Patent Application Publication No. 2008/0269347 to Bruss et al. (“ <i>Bruss</i> ”)
Ex. 1007	Fyllingen, G., <i>Racemisation and oxidation in adrenaline injections</i> , Acta Pharm. Nord. 2(5) 1990 (“ <i>Fyllingen</i> ”)
Ex. 1008	Vidal-Ollivier, E., <i>Assay for epinephrine and its impurities using reversed-phase high-performance liquid chromatography</i> , Journal of Chromatography 1987 (“ <i>Vidal</i> ”)
Ex. 1009	Kerddonfak, S., <i>The Stability and Sterility of Epinephrine Prefilled Syringe</i> , Asian Pacific Journal of Allergy and Immunology, 2010 (“ <i>Kerddonfak</i> ”)
Ex. 1010	U.S. Patent No. 5,002,973 to Zeleznick et al. (“ <i>Zeleznick</i> ”)
Ex. 1011	International Patent Publication No. WO 2014/127015 to Gupta et al. (“ <i>Gupta</i> ”)
Ex. 1012	Connors, K.A. <i>Chemical Stability of Pharmaceuticals: A Handbook for Pharmacists</i> , 2nd Edition, published in 1986 (“ <i>Connors</i> ”)
Ex. 1013	2004 United States Pharmacopeia Monograph for Epinephrine
Ex. 1014	2009 United States Pharmacopeia Monograph for Epinephrine (“ <i>USP</i> ”)
Ex. 1015	2014 United States Pharmacopeia Monograph for Epinephrine
Ex. 1016	Analytical Profiles of Drug Substances, 7, Epinephrine by Dale H. Szulczewski et al., published in 1978 (“ <i>Szulczewski</i> ”)
Ex. 1017	Moed H.D. et al., <i>Synthesis of beta-phenyl-ethylamine derivatives III Bronchodilators</i> , Rec. Trav. Chim. 74, 1955 (“ <i>Moed</i> ”)
Ex. 1018	IMS Product Information
Ex. 1019	Claim Construction Order in Case No. 17-775-LPS, <i>Belcher Pharmaceuticals, LLC v. Hospira, Inc</i>
Ex. 1020	Belcher Initial Infringement Contentions in Case No. 8:18-cv-02379-WFJ-AAS, <i>Adamis Pharmaceuticals Corp. v. Belcher Pharmaceuticals, LLC</i>
Ex. 1022	Goodman, L.S., <i>The Pharmacological Basis of Therapeutics</i> , 5 th Edition, (“ <i>Goodman</i> ”) published in 1975
Ex. 1023	Belcher Expert Report in Case No. 17-775-LPS

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