

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

KVK-TECH, INC.,

Petitioner,

v.

SHIRE LLC,

Patent Owner.

Case IPR2018-00293
US Patent No. 9,173,857

DECLARATION OF BERNHARDT L. TROUT, Ph.D.

SHIRE EX. 2001
KVK v. SHIRE
IPR2018-00293

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DECLARATION OF BERNHARDT L. TROUT, Ph.D.

I, Bernhardt L. Trout, Ph.D., do hereby declare and say as follows:

I. INTRODUCTION

1. I am a citizen of the United States of America and am more than twenty-one (21) years of age. I have been retained by counsel for Patent Owner Shire LLC as an expert in drug delivery and pharmaceutical formulation to address topics relevant to the subject matter of *KVK-Tech, Inc. v. Shire LLC*, IPR2018-00293, involving the claims of U.S. Patent No. 9,173,857 (the “857 patent”). EX. 1001. I am being compensated at my usual rate for consultation on patent matters, and I am being provided with, or reimbursed for, my expenses. My compensation is in no way dependent on the outcome of this case.

II. EXPERIENCE AND QUALIFICATIONS**A. Professional Background**

2. I am currently a Professor of Chemical Engineering at the Massachusetts Institute of Technology (MIT) and the Director of the Novartis-MIT Center for Continuous Manufacturing. I am also Director of the MIT Benjamin Franklin Project of the Advancement of the Arts and Sciences, which is also known as Engineering, Ethics, and Entrepreneurship.

3. I received my S.B. and S.M. degrees from MIT (1990) and my Ph.D. from the University of California at Berkeley (1996), all in chemical engineering. I

performed post-doctoral research at the Max-Planck Institute, Stuttgart, in solid-state physics. In 1998, I became an Assistant Professor of Chemical Engineering at MIT. I was promoted to Associate Professor of Chemical Engineering in 2003, and I was promoted to full Professor of Chemical Engineering at MIT in 2008. I hold the Raymond F. Baddour, ScD, (1949) Chair as Professor of Chemical Engineering.

4. I am a member of various scientific societies including the American Institute of Chemical Engineering, the American Association of Pharmaceutical Scientists, and the American Chemical Society.

5. I have been a reviewer for several journals including Proceedings of the National Academy of Sciences, The Journal of Physical Chemistry, Chemical Physics Letters, Pharmaceutical Research, Journal of the American Chemical Society, Biochemistry, Journal of Pharmaceutical Sciences, Biophysical Journal, The Journal of Organic Chemistry, Analytical Biochemistry, Research Letters in Physical Chemistry, Nature Materials, Molecular Pharmaceutics, Chemical Physics Letters, Angewandte Chemie, Crystal Growth & Design, The Journal of Chromatography A, and Crystal Engineering Communications.

6. I have given more than 100 invited talks on pharmaceuticals and pharmaceutical processing, including at the FDA, the American Association of

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