

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIQUIDIA TECHNOLOGIES, INC.,
Petitioner,

v.

UNITED THERAPEUTICS CORPORATION,
Patent Owner.

Case No. IPR2020-00769 - Patent No. 9,593,066
Case No. IPR2020-00770 - Patent No. 9,604,901

DECLARATION OF RODOLFO PINAL, PH.D.

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I, Rodolfo Pinal, declare as follows:

I. QUALIFICATIONS

1. I am currently Associate Professor in the Department of Industrial and Physical Pharmacy at Purdue University, in West Lafayette, Indiana, where I have been teaching since 2003. I also serve as Director of the NSF-I/UCRC Purdue Dane O. Kildsig Center for Pharmaceutical Processing Research (CPPR), a position I have held since 2005. Since 2016, I have served as Director of Graduate Studies in the Department of Industrial and Physical Pharmacy at Purdue. I am also a member of the Faculty Senate at Purdue.

2. I received my Ph.D. from the University of Arizona in Pharmaceutical Sciences with a concentration in Physical Chemistry.

3. I have over 30 years of experience studying formulation science, specifically on aspects pertaining to formulations for pharmaceutical composition and pharmaceutical product development. My professional experience includes over thirteen years working in the pharmaceutical industry.

4. At Purdue, I teach at both the graduate and undergraduate levels, including courses in pharmaceutical sciences, pharmaceutical formulation, pharmaceutical excipients, pharmaceutical processing and manufacturing, as well as performance testing and methods of analysis in pharmaceutical systems.

5. My research at Purdue focuses on three main areas. One has to do with the characterization of pharmaceutical solids, including crystal polymorphs, solvates, hydrates, and amorphous systems. A second area consists of utilizing the findings from this first area to elucidate the effect of solid-state properties on the performance attributes of pharmaceutical dosage forms. The third area combines the findings from the other two areas with the focus of developing novel technologies and processes for the production of dosage forms. My research on practical applications applies the findings from the theoretical part of my research, in order to develop formulation approaches and processing/manufacturing methods for drugs deemed problematic due to their solid-state, as well as solution/dissolution properties.

6. Prior to joining academia, I gained over thirteen years of industry experience in pharmaceutical research and development as a scientist with Hoffman-La Roche. From 1990-1993, I served as a Research Associate and then as a Senior Scientist in the pre-formulation group. During this time, my work focused on the physiochemical characterization of new chemical entities (*i.e.*, drug candidates), including developing stability-indicating methods, stability screening of drug candidates, photodegradation and drug-excipient compatibility studies, and solubility/solubilization and partitioning studies.

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