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. IPR2020-00770 –
Patent No. 9,604,901

**DECLARATION OF RODOLFO PINAL, PH.D.
SUPPORTING UNITED THERAPEUTIC CORPORATION'S
PATENT OWNER RESPONSE**

TABLE OF CONTENTS

Page

I, Rodolfo Pinal, declare as follows:

1. I am the same Rodolfo Pinal that submitted the declaration marked as Exhibit 2002 in this proceeding.

I. QUALIFICATIONS

2. 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.

3. I received my Ph.D. from the University of Arizona in Pharmaceutical Sciences with a concentration in Physical Chemistry and have over 30 years of experience studying formulation science, specifically on aspects pertaining to formulations for pharmaceutical composition and pharmaceutical product development.

4. 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.

5. From 1993-1997, I served as a Principal Scientist in the Sterile Dosage Forms group at Roche. In this role, I developed injectable formulations for new and investigational drug products. I was responsible for developing formulations for use in clinical trials, development of HPLC methods for assaying potency and stability of the active compound as well as pharmaceutical compositions intended for injection. I was also responsible for writing the directions for manufacturing clinical batches in the cGMP suite and for supervising the sterile suite operators during the manufacture of the resulting pharmaceutical products.

6. From 1997-2003, I served as Principal Scientist and then a Research Leader in the Solid-State Pharmaceutics group at Roche, which was part of the oral dosage forms development group. In this role, I was responsible for identifying and devising methods for the measurement and monitoring of physical properties/parameters critical for the development of a given specific pharmaceutical product or process. I also worked extensively with process chemists from the Chemical Synthesis Department "Kilo Lab" at the company's

site in New Jersey, as well as with process chemists from the industrial production site located in South Carolina.

7. I have first-hand industrial experience in the scale-up process for making APIs (active pharmaceutical ingredients). The laboratory under my supervision was responsible for the solid-state characterization of every batch of API generated at the New Jersey facility during the scale up of the synthesis. This responsibility extended to API batches produced at other sites but utilized during research and development at the New Jersey plant. The solid-state characterization work performed in my laboratory included crystal form and polymorphism, covering thermodynamic *vs.* kinetic stability, hygroscopicity, crystal morphology, particle size, solvates, hydrates, etc. A quick description of part of my responsibilities is as follows. As process (Kilo Lab) chemists began to work on replacing the synthetic process of APIs originally used by (drug discovery) medicinal chemists, toward one suitable for large scale production, they sent samples of their produced batches to me. My laboratory performed the solid-state characterization work required and convey the information to the Kilo Lab. Through an iterative process, the two groups would find the different polymorphs of the API, establish the stability relationship among them, and also establish the specifications for crystal morphology, particle size among the relevant attributes necessary for downstream processing. I was responsible for writing the sections

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.