UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ETON PHARMACEUTICALS, INC.,
Petitioner

v.

EXELA PHARMA SCIENCES, LLC,
Patent Owner

Case PGR2020-00068
Patent No. 10,583,155

DECLARATION OF DR. ROBERT J. KUHN

I, Dr. Robert J. Kuhn, declare as follows:

1. My name is Dr. Robert J. Kuhn. I am over the age of twenty-one (21) years, and I am competent to testify to the matters stated herein.

2. I have been asked by Fish & Richardson P.C. on behalf of Exela Pharma Sciences, LLC ("Exela") to provide this declaration in the matter of the Post Grant Review of U.S. Patent No. 10,583,155 (the "'155 patent").

3. I am being compensated for my work in connection with this IPR proceeding at a rate of $400/hour for preparation of my declaration. My compensation is not in any way contingent on the substance of my opinions or the outcome of these proceedings.

I. ASSIGNMENT

4. I have been asked to review the Sandoz Label (Ex. 1005) and calculate the daily aluminum exposure that would result from use of a product associated with the Sandoz Label, and according to the Dosage and Administration instructions in the Sandoz Label, for patients receiving total parenteral nutrition (TPN) containing that product. I have also been asked to comment on whether it would have been possible to prepare a TPN solution for a patient that provides a maximum daily aluminum exposure of no greater than 5 mcg/kg/day if that TPN solution used as a component a product associated with the Sandoz Label. I have further been asked to comment whether an L-cysteine hydrochloride composition

with no more than 250 mcg/L[1] aluminum could be used in a TPN composition to provide a maximum daily aluminum exposure of no greater than 5 mcg/kg/day.

II. EXPERIENCE AND QUALIFICATIONS

5. I received a Bachelor of Science degree in Pharmacy from the Ohio State University in 1980. I received my Doctorate in Pharmacy from the University of Texas at Austin and University of Texas Health Science Center in 1984. In 1985, I completed an ASHP Pediatric Pharmacotherapy Fellowship at Children's Hospital in Columbus, Ohio. I have worked as a practicing pharmacist since 1981.

6. I am currently the Kentucky Hospital Association Endowed Professor in the Department of Pharmacy Practice and Science at the College of Pharmacy at the University of Kentucky. I am also a professor in the Division of Pediatric Pulmonology in the Department of Pediatrics at the University of Kentucky. In 2017, I became a fellow of both the American Society of Health Systems Pharmacists and the American Association of Clinical Pharmacy.

7. I am also currently a practicing Pediatric Clinical Pharmacist at the Kentucky Children's Hospital at the University of Kentucky, where I also served as the Associate Director of Pharmacy Services from 2008 to 2012. My current duties as Pediatric Clinical Pharmacist include compounding parenteral nutrition

[1] The unit mcg/L is equivalent to the unit ppp or "parts per billion."

(PN) solutions for pediatric and infant patients. I have over 38 years of experience in compounding PN solutions, including for neonatal, pediatric, and adult patients. In my capacity as a Pediatric Clinical Pharmacist, I work directly with the pediatricians responsible for the care of patients in need of PN solutions. In our hospital, pharmacists start the form orders for PN solutions and, in some cases, write the order for the PN solution under the pediatrician's authority. Ultimately, pharmacists are responsible for making sure the components added to the PN solutions are compatible, calculating the risk of toxicity from the components of the PN solution, and ensuring the sterility of the PN solution. I thus have substantial experience and knowledge in the standard PN solutions given to infants in need of PN solutions, including the components used to create a standard PN solution and the historical high levels of aluminum in many of those components, as well as the aluminum content in compounded PN solutions.

8. In addition to my teaching and clinical responsibilities, I have also engaged in pharmacy research relating to aluminum contamination in PN solutions and methods for removing aluminum from such solutions.

9. A more complete recitation of my professional background and expertise is provided in my curriculum vitae, attached here as Exhibit A.

III. OVERVIEW OF PN COMPOSITIONS AND THEIR USE

10. Parenteral nutrition (PN) refers to the intravenous administration of nutrients including amino acids, electrolytes, carbohydrates, and optionally lipids. If a patient receives all of their nutrients intravenously, this is referred to as total parenteral nutrition (TPN). TPN solutions are administered intravenously over a 24 hour period.

11. TPN solutions are compounded daily from multiple components. The process for compounding a TPN solution starts with a prescription for the various nutrients that the infant patient requires. A pediatric pharmacist like myself will then take that prescription, and with the assistance of a computer program, calculate the concentration of the various components needed to provide the prescribed dosages.

12. There are standard components that are included in the majority of TPN solutions for infants. Those standard components include a mixture of amino acids (not including L-cysteine), dextrose, sodium chloride, sodium phosphate, potassium chloride, potassium phosphate, calcium gluconate, magnesium sulfate, zinc chloride, trace elements solution, selenium, pediatric vitamins solution, heparin, levocarnitine, and L-cysteine. Infant patients may also receive lipids as part of a TPN regimen, but those are separated from the other components prior to administration because of a risk of fungal contamination.

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.