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 PGR2020-00064
Patent No. 10,478,453

PATENT OWNER'S
PRELIMINARY RESPONSE

TABLE OF CONTENTS

EXHIBIT LIST

Exhibit No.	Description
2001	Declaration of Dr. Robert J. Kuhn
2002	Aileen B. Sedman et al., *Evidence of Aluminum Loading in Infants Receiving Intravenous Therapy*, 312 NEW ENG. J. MED. 1337 (1985)
2003	Nicholas J. Bishop et al., *Aluminum Neurotoxicity in Preterm Infants Receiving Intravenous-Feeding Solutions*, 336 NEW ENG. J. MED. 1557 (1997)
2004	ELCYS® Label, Exela Pharma Sciences, LLC
2005	Amended Complaint (Redacted), *Exela Pharma Sciences, LLC v. Sandoz, Inc.*, No. 1:20-cv-00645-MN (D. Del. June 1, 2020), ECF No. 12
2006	Amended Complaint, *Exela Pharma Sciences, LLC v. Eton Pharmaceuticals, Inc.*, No. 20-365-MN (D. Del. July 28, 2020), ECF No. 14
2007	Declaration of Mark Hartman (Redacted), *Exela Pharma Sciences, LLC v. Sandoz Inc.*, No. 19-cv-00318-MR (W.D.N.C. Dec. 6, 2019), ECF No. 26-1
2008	Megan Fortenberry et al., *Evaluating Differences in Aluminum Exposure Through Parenteral Nutrition in Neonatal Morbidities*, 9 NUTRIENTS 1249 (2017)
2009	Kathleen M. Gura, *Aluminum Contamination in Parenteral Products*, 17 CURR. OPIN. CLIN. NUTR. & METAB. CARE 551 (2014)
2010	Gordon L. Klein et al., *Hypocalcemia Complicating Deferoxamine Therapy in an Infant with Parenteral Nutrition-Associated Aluminum Overload: Evidence for a Role of Aluminum in the Bone Disease of Infants*, 9 J. PED. GASTR. & NUTR. 400 (1989)
2011	Jay M. Mirtallo, *Aluminum Contamination of Parenteral Nutrition Fluids*, 34 J. PARENTERAL & ENTERAL NUTR. 346 (2010)
2012	Robert L. Poole et al., *Aluminum Exposure From Pediatric Parenteral Nutrition: Meeting the New FDA Regulation*, 32 J. PARENTERAL & ENTERAL NUTR. 242 (2008)

I. INTRODUCTION

Exela's U.S. Patent No. 10,478,453 ("the '453 patent;" Ex. 1001) relates to inventions for stable, highly pure L-cysteine compositions for parenteral administration to, primarily, preterm and underweight infants to nourish them during their fragile first days, weeks, or sometimes months of life. While prior L-cysteine formulations contained up to 5,000 ppb[1] of toxic aluminum, the inventive compositions contain no more than 250 ppb of aluminum, and in certain claims even less.[2] Unlike prior L-cysteine compositions which, as Eton acknowledges, had aluminum levels that were known to increase over time,[3] the aluminum and other impurity levels in the claimed compositions are stable over time so as to remain safe for administration to infants throughout the product's shelf life.[4] Exela's invention solved what was by 2013 already a "decades old and still

---

[1] "ppb" is also referred to as "mcg/L" or "µg/L" ("micrograms per Liter").

[2] *See, e.g.,* Ex. 1001 ('453 Patent) at 59:8–9; *id.* at 59:38–39; Ex. 1005 (Sandoz Label) at 10.

[3] Paper 1 at 34, 41, 45; *see also* Ex. 1008 (Bohrer 2001) at 1, 4, Table 2 and Fig. 2.

[4] *See, e.g.,* Ex. 1001 ('453 Patent) at 16:44–47, 59:2.

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.