# UNITED STATES PATENT AND TRADEMARK OFFICE ————— BEFORE THE PATENT TRIAL AND APPEAL BOARD ————— ETON PHARMACEUTICALS, INC., Petitioner

v.

EXELA PHARMA SCIENCES, LLC,

Patent Owner

U.S. PATENT NO. 10,653,719

PGR2020-00086

PETITIONER'S UPDATED INDEX OF EXHIBITS



# **PETITIONER'S EXHIBIT LIST**

Exhibit	Description
1001	U.S. Patent No. 10,583,155
1002	U.S. Patent No. 10,478,453 File History
1003	Declaration of Barrett Rabinow, Ph.D.
1004	Affidavit of Christopher Butler
1005	Way Back Machine Screenshots of <a href="https://web.archive.org/web/20170403170533/http://drugsdb.eu/drug.php?d=L-cysteine%20Hydrochloride&amp;m=Sandoz%20Inc&amp;id=083366d6-0437-4ee0-90d4-440a5b5d03b5.xml">https://web.archive.org/web/20160824090050/http://drugsdb.eu/drug.php?d=L-cysteine%20Hydrochloride&amp;m=Sandoz%20Inc&amp;id=083366d6-0437-4ee0-90d4-440a5b5d03b5.xml</a>
1006	A Hernández-Sánchez et al., <i>Aluminum in Parenteral Nutrition: A Systematic Review</i> , 67 Eur. J. CLINICAL NUTRITION 230 (2013)
1007	Robert L. Poole et al., Aluminum in Pediatric Parenteral Nutrition Products: Measured Versus Labeled Content, 16 J. Pediatric Pharmacology & Therapeutics 92 (2011)
1008	Denise Bohrer et al., Influence of the Glass Packing on the Contamination of Pharmaceutical Products by Aluminum. Part II: Amino Acids for Parenteral Nutrition, 15 J. TRACE ELEMENTS MED. & BIOLOGY 103 (2001) ("Bohrer II")
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1011	Kavita Pilaniya et al., Recent Trends in the Impurity Profile of Pharmaceuticals, 3 J. Advanced Pharmaceutical Tech. & Res. 302



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1012	Denise Bohrer et al., Influence of the Glass Packing on the Contamination of Pharmaceutical Products by Aluminum. Part III: Interaction Container-Chemicals During the Heating for Sterilisation, 17 J. Trace Elements Med. & Biology 107 (2003) ("Bohrer III")
1013	Q3D ELEMENTAL IMPURITIES: GUIDANCE FOR INDUSTRY (Sept. 2015)
1014	Michael J Akers, <i>Parenteral Preparations</i> , in Remington: The Science and Practice of Pharmacy 810 (David B. Troy et al. eds., 21st ed. 2006)
1015	Winston W.K. Koo et al., <i>Aluminum in Parenteral Nutrition</i> Solution—Sources and Possible Alternatives, 10 J. PARENTERAL & ENTERAL NUTRITION 591 (1986)
1016	Cysteine, DRUGBANK, https://www.drugbank.ca/drugs/DB00151 (last visited May 7, 2020)
1017	Barrett E. Rabinow et al., <i>Plastic Packaging Materials</i> , in REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY 1047 (David B. Troy et al. eds., 21st ed. 2006)
1018	FDA GUIDANCE FOR INDUSTRY Q8(R2) PHARMACEUTICAL DEVELOPMENT, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CENTER FOR DRUG EVALUATION AND RESEARCH (CDER) CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER) (Nov. 2009)
1019	August 4, 2017 Letter from Donna Griebel, M.D., Director of Division of Gastroenterology and Inborn Errors Products, CDER, to Patent Owner
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1021	ESSENTIALS OF PHARMACEUTICAL CHEMISTRY (Donald Cairns ed., 4th ed. 2012)



1022	Declaration of Harry "Warren" Johnson, dated May 15, 2020
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1034	Andrew Teasdale et al., <i>Impurities in New Drug Substances and New Drug Products: ICH Q3A/B: Key Guidelines in the General Impurity Management Process</i> , <i>in</i> ICH QUALITY GUIDELINES: AN IMPLEMENTATION GUIDE (Andrew Teasdale et al. eds. 2018)
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1037	Lawrence X. Yu et al., <i>Understanding Pharmaceutical Quality by Design</i> , 16 Am. ASSOC. PHARM. SCIENTISTS J. 771 (2014
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1042	Prescribing Information for Selenious Acid Injection (revised 04/2019)
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1044	Prescribing Information for Zinc Sulfate Injection (revised 07/2019)
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