

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ETON PHARMACEUTICALS, INC.,

Petitioner

v.

EXELA PHARMA SCIENCES, LLC,

Patent Owner

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**U.S. PATENT NO. 10,583,155**

**PGR2020-00068**

PETITIONER'S UPDATED INDEX OF EXHIBITS

**PETITIONER'S INDEX OF EXHIBITS**

Exhibit	Description
1001	U.S. Patent No. 10,583,155 (“155 patent”)
1002	U.S. Patent No. 10,478,453 File History
1003	Declaration of Barrett Rabinow, Ph.D.
1004	Affidavit of Christopher Butler
1005	<p>Way Back Machine Screenshots of</p> <p><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/20170403170533/http://drugsdb.eu/drug.php?d=L-cysteine%20Hydrochloride&amp;m=Sandoz%20Inc&amp;id=083366d6-0437-4ee0-90d4-440a5b5d03b5.xml</a> and</p> <p><a href="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">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></p>
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., <i>Aluminum in Pediatric Parenteral Nutrition Products: Measured Versus Labeled Content</i> , 16 J. PEDIATRIC PHARMACOLOGY & THERAPEUTICS 92 (2011)
1008	Denise Bohrer et al., <i>Influence of the Glass Packing on the Contamination of Pharmaceutical Products by Aluminum. Part II: Amino Acids for Parenteral Nutrition</i> , 15 J. TRACE ELEMENTS MED. & BIOLOGY 103 (2001) (“Bohrer II”)

1009	Way Back Machine Screenshots of  <a href="https://web.archive.org/web/20130831172706/http://www.drugsdb.eu/drug.php?d=Aminosyn&amp;m=Hospira,%20Inc.&amp;id=2A72A8B8-A77C-49C6-3C8D-43B03672D802.xml">https://web.archive.org/web/20130831172706/http://www.drugsdb.eu/drug.php?d=Aminosyn&amp;m=Hospira,%20Inc.&amp;id=2A72A8B8-A77C-49C6-3C8D-43B03672D802.xml</a>
1010	Affidavit of Christopher Butler
1011	Kavita Pilaniya et al., <i>Recent Trends in the Impurity Profile of Pharmaceuticals</i> , 3 J. ADVANCED PHARMACEUTICAL TECH. & RES. 302 (2010)
1012	Denise Bohrer et al., <i>Influence of the Glass Packing on the Contamination of Pharmaceutical Products by Aluminum. Part III: Interaction Container-Chemicals During the Heating for Sterilisation</i> , 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 Solution— Sources and Possible Alternatives</i> , 10 J. PARENTERAL & ENTERAL NUTRITION 591 (1986)
1016	<i>Cysteine</i> , DRUGBANK, <a href="https://www.drugbank.ca/drugs/DB00151">https://www.drugbank.ca/drugs/DB00151</a> (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
1020	Loyd V. Allen, <i>L-Cysteine Hydrochloride 50 mg/mL Injection</i> , 36 U.S. PHARMACIST 41 (Sept. 20, 2011)
1021	ESSENTIALS OF PHARMACEUTICAL CHEMISTRY (Donald Cairns ed., 4th ed. 2012)
1022	Declaration of Harry "Warren" Johnson
1023	M.X. Sullivan et al., <i>The Effect of Pyruvic Acid on the Estimation of Cystine and Cysteine</i> , 122 J. BIOL. CHEM. 11 (1937)
1024	R.S. Asquith et al., <i>The Photochemical Degradation of Cystine in Aqueous Solution in the Presence of Air</i> , 184 BIOCHIMICA ET BIOPHYSICA ACTA (BBA) – GENERAL SUBJECTS 345 (1969)
1025	Soji Rokushika et al., <i>Radiolysis of Cystine in Aqueous Solution by Gamma Irradiation</i> , 7-2 J. RADIATION RES. 47 (1966)
1026	Ben H. Nicolet, <i>Biochemistry by Analogy: The Sulfur of Cystine</i> , 28 J. WASH. ACADS. SCI. 84 (1938)
1027	Kenneth C. Waterman et al., <i>Stabilization of Pharmaceuticals to Oxidative Degradation</i> , 7 PHARMACEUTICAL DEV. & TECH. 1 (2002).
1028	Henri J. R. Maget, <i>Use of an Oxygen Extractor to Minimize Oxidation of Compounded Preparations</i> , 3 INT'L J. PHARM. COMPOUNDING 493 (1999)
1029	Alpaslan Yaman, <i>Engineering Considerations in Sterile Powder Processes</i> , in STERILE PHARMACEUTICAL PRODUCTS: PROCESS

	ENGINEERING APPLICATIONS 297 (Kenneth E. Avis ed. 1995)
1030	Copyright Registration Number for Alpaslan Yaman, <i>Engineering Considerations in Sterile Powder Processes</i> , in STERILE PHARMACEUTICAL PRODUCTS: PROCESS ENGINEERING APPLICATIONS 297 (Kenneth E. Avis ed. 1995)
1031	Jalpa Patel et al., <i>Stability Considerations for Biopharmaceuticals, Part 1: Overview of Protein and Peptide Degradation Pathways</i> , 2011 BIOPROCESS INT'L 20
1032	Henry L. Avallone et al., <i>Food and Drug Administration Inspection and Licensing of Manufacturing Facilities</i> , in DRUG BIOTECHNOLOGY REGULATION: SCIENTIFIC BASIS AND PRACTICES 322-23 (Yuan-yuan H. Chiu et al. eds. 1991)
1033	Gaozhong Zhu et al., <i>Formulation of Protein- and Peptide-Based Parental Products</i> , in PHARMACEUTICAL DOSAGE FORMS (Sandeep Nema et al. eds. 2010)
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> , in ICH QUALITY GUIDELINES: AN IMPLEMENTATION GUIDE (Andrew Teasdale et al. eds. 2018)
1035	<i>Aluminum in Large and Small Volume Parenterals Used in Total Parenteral Nutrition</i> , 65 Fed. Reg. 4103 (Jan. 26, 2000) (codified at 21 C.F.R. pt. 201)
1036	G.J. Schuringa et al., <i>The Reaction of Combined Cystine of Wool with Sodium Bisulfite</i> , 21 TEXTILE RES. J. 281 (1951)
1037	Lawrence X. Yu et al., <i>Understanding Pharmaceutical Quality by Design</i> , 16 AM. ASSOC. PHARM. SCIENTISTS J. 771 (2014)
1038	Victoria Lima-Rogel et al., <i>Aluminum Contamination in Parenteral Nutrition Admixtures for Low-Birth-Weight Preterm Infants in Mexico</i> ,

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