

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Nexus Pharmaceuticals, Inc.,
Petitioner

v.

Exela Pharma Sciences LLC,
Patent Owner

Case No.: Unassigned
Patent No. 11,642,370

DECLARATION OF PASQUALE N. CONFALONE, Ph.D.

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1.	“A solution of L-cysteine for use in total parenteral nutrition (TPN) comprising”	63
2.	“about 10 mg/L to about 100 mg/mL of L-cysteine or a pharmaceutically acceptable salt of hydrate thereof, in a pharmaceutically acceptable carrier; wherein:”	63
3.	“after 12 months of storage in a sealed vial at room temperature:”	64
4.	“the total amount of oxygen within the sealed vial is no more than about 5%; and”	64
5.	“the solution: contains no more than 250 ppb aluminum”	66
6.	“is substantially free of visually detectable particulate matter, and”	68
7.	“has a pH form 1.0 to 2.5”	69
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PETITIONER'S EXHIBIT LIST

<u>Exhibit No.</u>	<u>Description</u>
Exhibit 1001	U.S. Patent No. 11,642,370 (“the ’370 patent”)
Exhibit 1002	’370 Patent File History
Exhibit 1003	Declaration of Pasquale N. Confalone Ph.D.
Exhibit 1004	Affidavit of Christopher Butler
Exhibit 1005	Sandoz Label Way Back Machine Screenshots of https://web.archive.org/web/20170403170533/http://drugsdb.eu/drug.php?d=L-cysteine%20Hydrochloride&m=Sandoz%20Inc&id=083366d6-0437-4ee0-90d4-440a5b5d03b5.xml and https://web.archive.org/web/20160824090050/http://drugsdb.eu/drug.php?d=L-cysteine%20Hydrochloride&m=Sandoz%20Inc&id=083366d6-0437-4ee0-90d4-440a5b5d03b5.xml
Exhibit 1006	A. Hernandez-Sanchez et al., <i>Aluminum in Parenteral Nutrition: A Systematic Review</i> , 67 Eur. J. Clinical Nutrition 230 (2013)
Exhibit 1007	<i>Exela Pharma Sciences, LLC v. Eton Pharmaceuticals, Inc.</i> , 620 F.Supp.3d 108 (D. Del. 2022)
Exhibit 1008	D. 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”)
Exhibit 1009	P. Nasa, <i>A Review on Pharmaceutical Packaging Material</i> , World J. of Pharm. Res., vol. 3, Issue 5, 344-368 (2015)
Exhibit 1010	Reserved
Exhibit 1011	D. Bohrer et al., <i>Ion-exchange and potentiometric characterization of Al-cystine and Al-cysteine complexes</i> , J. Biol Inorg. Chem. 11, 991-991 (2006)
Exhibit 1012	D. 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”)

<u>Exhibit No.</u>	<u>Description</u>
Exhibit 1013	Reserved
Exhibit 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)
Exhibit 1015	United States Patent No. 10,583,155 (“the ’155 patent”)
Exhibit 1016	United States Patent No. 10,905,713 (“the ’713 patent”)
Exhibit 1017	Reserved
Exhibit 1018	United States Patent No. 10,912,795 (“the ’795 patent”)
Exhibit 1019	United States Patent No. 10,478,453 (“the ’453 patent”)
Exhibit 1020	Lloyd V. Allen, <i>L-Cysteine Hydrochloride 50 mg/mL Injection</i> , 36 U.S. Pharmacist 41 (Sept. 20, 2011)
Exhibit 1021	Essential of Pharmaceutical Chemistry (Donald Cairns ed., 4 th ed. 2012).
Exhibit 1022	United States Patent No. 10,933,089 (“the ’089 patent”)
Exhibit 1023	’089 patent file history
Exhibit 1024	’453 patent file history
Exhibit 1025	Drug Facts and Comparison (2015)
Exhibit 1026	Copyright Registration Number for Drug Facts and Comparisons (2015)
Exhibit 1027	Kenneth C. Waterman et al., <i>Stabilization of Pharmaceuticals to Oxidative Degradation</i> , 7 Pharmaceutical Dev. & Tech. 1 (2002)
Exhibit 1028	Reserved
Exhibit 1029	Alpaslan Yaman, <i>Engineering Considerations in Sterile Powder Processes</i> , in <i>Sterile Pharmaceutical Products: Process Engineering Applications</i> 297 (Kenneth E. Avis ed. 1995)
Exhibit 1030	Reserved
Exhibit 1031	Jalpa Patel et al., <i>Stability Considerations for Biopharmaceuticals, Part I: Overview of Protein and Peptide Degradation Pathways</i> , 2011 BioProcess Int’l 20
Exhibit 1032	R.C. Whiting et al., <i>Effect of Headspace Oxygen Concentration on Growth and Toxin Production by Proteolytic Strains of Clostridium Botulinum</i> , 55 J. Food Protection 23 (1992)
Exhibit 1033	Gaozhong Zhu et al., <i>Formulation of Protein- and Peptide-Based Parental Products</i> , in <i>Pharmaceutical Dosage Forms</i> (Sandeep Nema et al. eds. 2010)
Exhibit 1034	Farideh Jalilehvand et al., <i>Lead(II) Complex Formation with LCysteine in Aqueous Solution</i> , 54 Inorg. Chem. 2160 (2015)

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