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| Substitute for form 1449B/PTO | | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i> | | | | Application Number | 16/746,028 |
| | | | | Filing Date | January 17, 2020 |
| | | | | First Named Inventor | John Maloney |
| | | | | Art Unit | 1612 |
| | | | | Examiner Name | Benjamin J. Packard |
| Sheet | 1 | of | 1 | Attorney Docket Number | 066859/542422 |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|-----------------------|---|----------------|
| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| | 235 | Declaration of John Geissler, Exhibit 1, Response in Opposition to Plaintiff's Motion for Preliminary Injunction, Exela Pharma Sciences, LLC v.Sandoz, Inc., No. 1:19-cv-318, (W.D.N.C., December 6, 2019). | |

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| Examiner Signature | | Date Considered | |
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Electronic Acknowledgement Receipt

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| EFS ID: | 39189729 |
| Application Number: | 16746028 |
| International Application Number: | |
| Confirmation Number: | 4075 |
| Title of Invention: | STABLE, HIGHLY PURE L-CYSTEINE COMPOSITIONS FOR INJECTION AND METHODS OF USE |
| First Named Inventor/Applicant Name: | JOHN MALONEY |
| Customer Number: | 826 |
| Filer: | Bryan Lee Skelton/Laura Tremont |
| Filer Authorized By: | Bryan Lee Skelton |
| Attorney Docket Number: | 066859/542422 |
| Receipt Date: | 17-APR-2020 |
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| Time Stamp: | 12:57:13 |
| Application Type: | Utility under 35 USC 111(a) |

Payment information:

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| Submitted with Payment | no |
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File Listing:

| Document Number | Document Description | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl.) |
|-----------------|----------------------|----------------------------|--|------------------|------------------|
| 1 | Transmittal Letter | 542422_IDS_Transmittal.pdf | 138270 857533cc0fa2b21de31a68d05805a1f26408c7f8 | no | 1 |

Warnings:

| Information: | | | | | |
|---|--|--------------------------------------|--|----------|----|
| 2 | Information Disclosure Statement (IDS) Form (SB08) | 542422_IDS_SB08.pdf | 160689 094a989d26b3df989741f6c85526ec3090fa1177 | no | 1 |
| Warnings: | | | | | |
| Information: | | | | | |
| This is not an USPTO supplied IDS fillable form | | | | | |
| 3 | Non Patent Literature | 235-Declaration_of_John_Geissler.pdf | 11773346 a67540046560cc46bc60cb397161350d9b405938 | no | 53 |
| Warnings: | | | | | |
| Information: | | | | | |
| | | | Total Files Size (in bytes): | 12072305 | |
| <p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p> | | | | | |

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: John Maloney et al. Confirmation No.: 4075
Appl. No.: 16/746,028 Group Art Unit: 1612
Filed: January 17, 2020 Examiner: Benjamin J. Packard
For: STABLE, HIGHLY PURE L-CYSTEINE COMPOSITIONS FOR INJECTION
AND METHODS OF USE

Submitted via EFS-Web
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT
CITATION UNDER 37 C.F.R. § 1.97**

Attached is a list of documents on form PTO-SB08.

Submitted herewith is the Declaration of John Geissler and its Exhibits A-F, submitted in concurrent litigation, *Exela Pharma Sciences, LLC v. Sandoz, Inc.*, No. 1:19-cv-318, (W.D.N.C., November 6, 2019), which was referred to in Applicant's previous Information Disclosure Statement. Applicant points the Examiner's attention to the batch data on page 45 of 53.

It is requested that the Examiner consider these documents and officially make them of record in accordance with the provisions of 37 C.F.R. § 1.97 and Section 609 of the MPEP. By identifying the listed documents, Applicant in no way makes any admission as to the prior art status of the listed documents, but is instead identifying the listed documents for the sake of full disclosure.

Respectfully submitted,

/bryan l. skelton/

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