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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 16/773,641   | 01/27/2020  | John Maloney         | 066859/543316       | 3992             |
| 826  | 7590        | 12/23/2020           | EXAMINER            |                  |
| ALSTON & BIRD LLP<br>BANK OF AMERICA PLAZA<br>101 SOUTH TRYON STREET<br>SUITE 4000<br>CHARLOTTE, NC 28280-4000 |             |                      | PACKARD, BENJAMIN J |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1612                |                  |
|  |             |                      | NOTIFICATION DATE   | DELIVERY MODE    |
|  |             |                      | 12/23/2020          | ELECTRONIC       |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

[usptomail@alston.com](mailto:usptomail@alston.com)

|   |                                       |                                       |                                 |
|---|---------------------------------------|---------------------------------------|---------------------------------|
| <b>Corrected<br/>Notice of Allowability</b> | <b>Application No.</b><br>16/773,641  | <b>Applicant(s)</b><br>Maloney et al. |                                 |
|   | <b>Examiner</b><br>BENJAMIN J PACKARD | <b>Art Unit</b><br>1612               | <b>AIA (FITF) Status</b><br>Yes |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--*

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to IDS filed 12/16/20.  
 A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on \_\_\_\_\_.
2.  An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_\_; the restriction requirement and election have been incorporated into this action.
3.  The allowed claim(s) is/are 1-27. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see [http://www.uspto.gov/patents/init\\_events/pph/index.jsp](http://www.uspto.gov/patents/init_events/pph/index.jsp) or send an inquiry to [PPHfeedback@uspto.gov](mailto:PPHfeedback@uspto.gov).
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

**Certified copies:**

- a)  All    b)  Some    \*c)  None of the:
1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5.  CORRECTED DRAWINGS (as "replacement sheets") must be submitted.  
 including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.  
**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Examiner's Amendment/Comment                  |
| 2. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date <u>1pg (12/16/20)</u> . | 6. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material _____.                    | 7. <input type="checkbox"/> Other _____.                                  |
| 4. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date. _____.  |   |

/BENJAMIN J PACKARD/  
Primary Examiner, Art Unit 1612

|  |   |    |                          |                     |
|--|---|----|--------------------------|---------------------|
| Substitute for form 1449B/PTO                            |   |    | <b>Complete if Known</b> |                     |
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b> |   |    | Application Number       | 16/773,641          |
|  |   |    | Filing Date              | January 27, 2020    |
|  |   |    | First Named Inventor     | John Maloney        |
|  |   |    | Art Unit                 | 1612                |
|  |   |    | Examiner Name            | Benjamin J. Packard |
|  |   |    | Attorney Docket Number   | 066859/543316       |
| Sheet  | 1 | of | 2                        |                     |
| (Use as many sheets as necessary)                        |   |    |                          |                     |

| NON PATENT LITERATURE DOCUMENTS |                          |   |                |
|---------------------------------|--------------------------|---|----------------|
| Examiner<br>Initials *          | Cite<br>No. <sup>1</sup> | 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 <sup>2</sup> |
|                                 | 327                      | "ELCYS (cysteine hydrochloride injection), for intravenous use [Label and Highlights of Prescribing Information]," Exela Pharma Sciences, LLC, 9 pages, (2019).   |                |
|                                 | 349                      | "Guidance for Industry: Q1A(R2) Stability Testing of New Drug Substances and Products," U.S. Dept. of Health and Human Services, FDA, CDER, CBER, 25 pages, (2003).   |                |
|                                 | 345                      | "International Conference on Harmonisation; Guidance on Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances," Federal Register, 65(251):83041-83063, (2000).                         |                |
|                                 | 341                      | AKERS, MICHAEL J., <i>Sterile Drug Products: Formulation, Packaging, Manufacturing, and Quality</i> , New York: Informa Healthcare, (2010).   |                |
|                                 | 328                      | Amended Complaint [redacted], <i>Exela Pharma Sciences, LLC v. Sandoz, Inc.</i> , Civil Action No. 1:20-cv-645-MN, (D. Del., June 1, 2020), ECF No. 12.   |                |
|                                 | 329                      | Amended Complaint, <i>Exela Pharma Sciences, LLC v. Eton Pharmaceuticals, Inc.</i> , Civil Action No. 20-00365-MN, (D. Del., July 28, 2020), ECF No. 14.  |                |
|                                 | 347                      | CHA et al., "Stability Studies," <i>Handbook of Modern Pharmaceutical Analysis</i> , Ed. Satinder Ahuja and Stephen Scypinski, 2nd ed., Vol. 10, Amsterdam: Elsevier, 459-467 and 485-486, (2011).  |                |
|                                 | 325                      | Declaration of Dr. Robert J. Kuhn, Exhibit 2001, Patent Owner's Preliminary Response, <i>Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC</i> , PGR2020-00064, U.S. Patent No. 10,478,453, (August 28, 2020).   |                |
|                                 | 351                      | Declaration of Dr. Robert J. Kuhn, Exhibit 2001, Patent Owner's Preliminary Response, <i>Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC</i> , PGR2020-00068, U.S. Patent No. 10,583,155, (September 18, 2020).  |                |
|                                 | 338                      | Declaration of Barrett Rabinow, Exhibit 1003, Petition for Post Grant Review of U.S. Patent No. 10,653,719, <i>Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC</i> , PGR2020-00086, (PTAB September 21, 2020).   |                |
|                                 | 339                      | Declaration of Daniel Ingles, Exhibit 1078, Petition for Post Grant Review of U.S. Patent No. 10,653,719, <i>Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC</i> , PGR2020-00086, (PTAB September 21, 2020).   |                |
|                                 | 348                      | Declaration of Harry "Warren" Johnson, dated August 24, 2020, Exhibit 1116, Petition for Post Grant Review of U.S. Patent No. 10,653,719, <i>Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC</i> , PGR2020-00086, (PTAB September 21, 2020).           |                |
|                                 | 330                      | Declaration of Mark Hartman [redacted], <i>Exela Pharma Sciences, LLC v. Sandoz, Inc.</i> , No. 19-cv-00318-MR (W.D.N.C. December 6, 2019), ECF No. 26-1.   |                |
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| Examiner<br>Signature |  | Date<br>Considered |  |
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| Substitute for form 1449B/PTO                            |   |    |   | <b>Complete if Known</b> |                     |
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|  |   |    |   | Examiner Name            | Benjamin J. Packard |
|  |   |    |   | Attorney Docket Number   | 066859/543316       |
| Sheet  | 2 | of | 2 |                          |                     |
| <i>(Use as many sheets as necessary)</i>                 |   |    |   |                          |                     |

|  |     |  |  |
|--|-----|--|--|
|  | 324 | Patent Owner's Preliminary Response, <i>Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC</i> , PGR2020-00064, U.S. Patent No. 10,478,453, (August 28, 2020).   |  |
|  | 334 | Patent Owner's Preliminary Response, <i>Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC</i> , PGR2020-00068, U.S. Patent No. 10,583,155, (September 18, 2020).  |  |
|  | 333 | Patent Owner's Sur-Reply to Petitioner's Reply to Patent Owner's Preliminary Response, <i>Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC</i> , PGR2020-00064, U.S. Patent No. 10,478,453, (October 5, 2020).   |  |
|  | 336 | Patent Owner's Sur-Reply to Petitioner's Reply to Patent Owner's Preliminary Response, <i>Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC</i> , PGR2020-00068, U.S. Patent No. 10,583,155, (October 26, 2020).  |  |
|  | 337 | Petition for Post Grant Review of U.S. Patent No. 10,653,719, <i>Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC</i> , PGR2020-00086, (PTAB September 21, 2020).  |  |
|  | 332 | Petitioner's Reply to Patent Owner's Preliminary Response, <i>Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC</i> , PGR2020-00064, U.S. Patent No. 10,478,453, (September 28, 2020).  |  |
|  | 335 | Petitioner's Reply to Patent Owner's Preliminary Response, <i>Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC</i> , PGR2020-00068, U.S. Patent No. 10,583,155, (October 19, 2020).  |  |
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|  | 326 | SEDMAN et al., "Evidence of Aluminum Loading in Infants Receiving Intravenous Therapy," <i>The New England Journal of Medicine</i> , 312(21):1337-1343, (1985).  |  |
|  | 350 | <i>The Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals</i> , Ed. Maryadele J. O'Neil et al., 14th ed., Whitehouse Station: Merck & Co., Inc, pp. 2782-2783, (2006).  |  |
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| Examiner Signature |  | Date Considered |  |
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|                                 | 305                      | Petition for Post Grant Review of U.S. Patent No. 10,583,155, Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC, PGR2020-00068, (PTAB June 8, 2020).  |                |
|                                 | 306                      | VAN GOUDOEVER et al., "ESPGHAN/ESPEN/ESPR/CSPEN guidelines on pediatric parenteral nutrition: Amino acids," Clinical Nutrition, 37:2315-2323, (2018).  |                |
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|                                 | 311                      | Citizen Petition, Lachman Consultant Services, Inc., 12 pages, (2018), retrieved from Exhibit 1092, Petition for Post Grant Review of U.S. Patent No. 10,583,155, Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC, PGR2020-00068, (PTAB June 8, 2020).  |                |
|                                 | 312                      | Declaration of Madan Chilakuri, (2020), Exhibit 1093, Petition for Post Grant Review of U.S. Patent No. 10,583,155, Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC, PGR2020-00068, (PTAB June 8, 2020).  |                |
|                                 | 313                      | Excerpt from "Parenteral Formulations [Chapter 30]", Bentley's Textbook of Pharmaceutics: An Adaptation, Eds. Sanjay K. Jain et al., pp. 410-415, (2012).  |                |
|                                 | 314                      | AHOLA et al., "N-Acetylcysteine does not Prevent Bronchopulmonary Dysplasia in Immature Infants: A Randomized Controlled Trial," J Pediatr, 143:713-719, (2003).   |                |
|                                 | 315                      | "Guidance for Industry: E11 Clinical Investigation of Medicinal Products in the Pediatric Population," U.S. Dept. of Health and Human Services, FDA, CDER, CBER, 17 pages, (2000).   |                |
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|                                 | 318                      | YESIL et al., "Evaluation of the Children with Acute Acetaminophen Overdose and Intravenous N-Acetylcysteine Treatment," Pak J Med Sci., 34(3):590-594, (2018).  |                |
|                                 | 319                      | LEE et al., "Intravenous N-Acetylcysteine Improves Transplant Free Survival in Early Stage Non-Acetaminophen Acute Liver Failure," Gastroenterology, 137(3):856-864, (2009).   |                |
|                                 | 320                      | Declaration of Judy K. He, (2020), Exhibit 1105, Petition for Post Grant Review of U.S. Patent No. 10,583,155, Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC, PGR2020-00068, (PTAB June 8, 2020).   |                |

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