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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

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EXAMINER
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

Corrected ***Notice of Allowability***	**Application No.** 16/773,641	**Applicant(s)** Maloney et al.	
	Examiner BENJAMIN J PACKARD	**Art Unit** 1612	**AIA (FITF) Status** 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** or send an inquiry to **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. ☐ Notice of References Cited (PTO-892)
2. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 1pg (12/16/20).
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☐ Examiner's Amendment/Comment
6. ☐ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/BENJAMIN J PACKARD/
Primary Examiner, Art Unit 1612

Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	16/773,641
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(Use as many sheets as necessary)				Examiner Name	Benjamin J. Packard
Sheet	1	of	2	Attorney Docket Number	066859/543316

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]
	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., *Sterile Drug Products: Formulation, Packaging, Manufacturing, and Quality*, New York: Informa Healthcare, (2010).	
	328	Amended Complaint [redacted], *Exela Pharma Sciences, LLC v. Sandoz, Inc.,* Civil Action No. 1:20-cv-645-MN, (D. Del., June 1, 2020), ECF No. 12.	
	329	Amended Complaint, *Exela Pharma Sciences, LLC v. Eton Pharmaceuticals, Inc.*, Civil Action No. 20-00365-MN, (D. Del., July 28, 2020), ECF No. 14.	
	347	CHA et al., "Stability Studies," *Handbook of Modern Pharmaceutical Analysis*, 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, *Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC*, 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, *Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC*, 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, *Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC*, 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, *Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC*, 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, *Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC*, PGR2020-00086, (PTAB September 21, 2020).	
	330	Declaration of Mark Hartman [redacted], *Exela Pharma Sciences, LLC v. Sandoz, Inc.,* No. 19-cv-00318-MR (W.D.N.C. December 6, 2019), ECF No. 26-1.	
	340	LANGILLE, STEPHEN E., "Particulate Matter in Injectable Drug Products," PDA Journal of Pharmaceutical Science and Technology, 67(3):186–200, (2013).	
	323	MIRTALLO, JAY M., "Aluminum Contamination of Parenteral Nutrition Fluids," Journal of Parenteral and Enteral Nutrition, 34(3):346-347, (2010).	

Examiner Signature		Date Considered	

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	324	Patent Owner's Preliminary Response, *Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC*, PGR2020-00064, U.S. Patent No. 10,478,453, (August 28, 2020).	
	334	Patent Owner's Preliminary Response, *Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC*, 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, *Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC*, 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, *Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC,* 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, *Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC*, PGR2020-00086, (PTAB September 21, 2020).	
	332	Petitioner's Reply to Patent Owner's Preliminary Response, *Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC,* PGR2020-00064, U.S. Patent No. 10,478,453, (September 28, 2020).	
	335	Petitioner's Reply to Patent Owner's Preliminary Response, *Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC*, PGR2020-00068, U.S. Patent No. 10,583,155, (October 19, 2020).	
	344	RIGNALL, ANDY, "ICHQ1A(R2) Stability Testing of New Drug Substance and Product and ICHQ1C Stability Testing of New Dosage Forms," *ICH Quality: An Implementation Guide*, Ed. Andrew Teasdale et al., Hoboken, NJ: John Wiley & Sons, Inc., pp. 3-14, 26-31 and 37-38, (2018).	
	326	SEDMAN et al., "Evidence of Aluminum Loading in Infants Receiving Intravenous Therapy," The New England Journal of Medicine, 312(21):1337-1343, (1985).	
	350	*The Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals*, Ed. Maryadele J. O'Neil et al., 14th ed., Whitehouse Station: Merck & Co., Inc, pp. 2782-2783, (2006).	
	331	Transcript of Telephone Conference, Exhibit 1083*, Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC*, PGR2020-00064, U.S. Patent No. 10,478,453, (September 21, 2020).	
	343	TURCO, SALVATORE J., "Intravenous Admixtures," *Remington: The Science and Practice*, 21 ed., Philadelphia: Lippincott Williams & Wilkins, pp. 837-846, (2006).	
	342	USP 23/NF 27, The U.S. Pharmacopeial Convention, The National Formulary, pp. 1-12, (2009).	
	346	Warning Letter from U.S. Food and Drug Administration to Mr. Ian Reed, Pfizer, Hospira Inc, dated February 14, 2017.	

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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 nutrion: Amino acids," Clinical Nutrition, 37:2315-2323, (2018).	
	307	Healthcare Professional Letter from Baxter Healthcare Corporation, "Temporary importation of intravenous drug products to address drug shortages," 8 pages, (2017), retrieved from Exhibit 1087, 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).	
	308	ZIEGLER, EKHARD E., "Parenteral Nutrition," Iowa Neonatology Handbook: Feeding, (2006).	
	309	WORTHINGTON et al., "When is Parenteral Nutrition Appropriate?," Journal of Parenteral and Enteral Nutrition, 41(3):324-377, (2017).	
	310	GASSER et al., "Parenteral Nutrition: Macronutrient Composition and Requirements," Support Line, 27(6):6-12, (2005).	
	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).	
	316	USP XXI, The United States Pharmacopeia, Twenty-First Revision,The U.S. Pharmacopeial Convention, Inc., pp. 19-20, 268-269, and 1375, (1985).	
	317	BOULLATA, JOSEPH I., "Nutrients and Associated Substances," Remington: The Science and Practice of Pharmacy, 21 Ed., Ed. David B. Troy, Philadelphia: Lippincott Williams & Wilkins, pp. 1688-1693, (2005).	
	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).	

Examiner Signature		Date Considered	

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