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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 ALSTON & B	7590 12/23/202 IRD LLP	0	EXAM	IINER
BANK OF AM	IERICA PLAZA	PACKARD, BENJAMIN J		
SUITE 4000	RYON STREET		ART UNIT	PAPER NUMBER
CHARLOTTE	, NC 28280-4000		1612	
			NOTIFICATION DATE	DELIVERY MODE
			12/23/2020	FLECTRONIC

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

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Corrected	16/773,641	1 ,	Maloney et al.	
Notice of Allowability	Examiner BENJAMIN J PACKARD	Art Unit	AIA (FITF) Status	
The MAILING DATE of this communication appears and all claims being allowable, PROSECUTION ON THE MERITS I herewith (or previously mailed), a Notice of Allowance (PTOL-8 NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT of the Office or upon petition by the applicant. See 37 CFR 1.31  1. ✓ This communication is responsive to IDS filed 12/16/20.	S (OR REMAINS) CLOSED 5) or other appropriate comn <b>RIGHTS.</b> This application is 3 and MPEP 1308.	with the correspondent in this application. If not nunication will be mailed	included In due course. <b>THIS</b>	
☐ A declaration(s)/affidavit(s) under <b>37 CFR 1.130(b)</b> w  2.☐ An election was made by the applicant in response to a restriction requirement and election have been incorporation.	estriction requirement set for	th during the interview c	on; the	
3. The allowed claim(s) is/are 1-27. As a result of the allow Highway program at a participating intellectual property http://www.uspto.gov/patents/init_events/pph/index.j	ed claim(s), you may be eligi office for the corresponding a	application. For more infe	ormation, please see	
4.☐ Acknowledgment is made of a claim for foreign priority ur	nder 35 U.S.C. § 119(a)-(d) o	or (f).		
Certified copies:				
a) \[ \text{All} \] b) \[ \text{Some} \] *c) \[ \text{None of the:} \]  1. \[ \text{Certified copies of the priority documents h} \]  2. \[ \text{Certified copies of the priority documents h} \]  3. \[ \text{Copies of the certified copies of the priority} \]  International Bureau (PCT Rule 17.2(a)).	ave been received in Applica		e application from the	
* Certified copies not received:				
Applicant has THREE MONTHS FROM THE "MAILING DAT noted below. Failure to timely comply will result in ABANDOI THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.  5. CORRECTED DRAWINGS (as "replacement sheets") middling changes required by the attached Examine Paper No./Mail Date	NMENT of this application.  ust be submitted.		·	
Identifying indicia such as the application number (see 37 CFI sheet. Replacement sheet(s) should be labeled as such in the			t (not the back) of each	
6. DEPOSIT OF and/or INFORMATION about the deposit of attached Examiner's comment regarding REQUIREMEN				
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 Deposition of Biological Material  4.  Interview Summary (PTO-413),         Paper No./Mail Date.  /BENJAMIN J PACKARD/ Primary Examiner, Art Unit 1612	6. 🗌 Examine	er's Amendment/Comme er's Statement of Reason 		
U.S. Patent and Trademark Office PTOL-37 (Rev. 08-13)  Noti	ce of Allowability	Part of Paper No./	Mail Date 20201219	

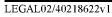
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Modified PTO/SB/08 Form

Substitute for form 1449B/PTO				Complete if Known		
				Application Number	16/773,641	
INFO	RMATION DIS	CLOS	URE	Filing Date	January 27, 2020	
STAT	<b>EMENT BY A</b>	<b>PPLIC</b>	ANT	First Named Inventor	John Maloney	
				Art Unit	1612	
(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.	Т				
	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], <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 Scienc</i> es, <i>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</i> <i>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.					
	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 Date			
	Examiner	Date	ate
Signature Considered	Signature	Con	onsidered



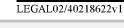


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				Art Unit	1612				
(Use as many sheets as necessary)				Examiner Name	Benjamin J. Packard				
Sheet	2	of	2	Attorney Docket Number 066859/543316					

324	Patent Owner's Preliminary Response, <i>Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences,</i> LLC, 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,</i> 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, <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).
344	RIGNALL, ANDY, "ICHQ1A(R2) Stability Testing of New Drug Substance and Product and ICHQ1C Stability Testing of New Dosage Forms," <i>ICH Quality: An Implementation Guide</i> , 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, <i>Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC</i> , PGR2020-00064, U.S. Patent No. 10,478,453, (September 21, 2020).
343	TURCO, SALVATORE J., "Intravenous Admixtures," <i>Remington: The Science and Practice</i> , 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.

Examiner	Date	
Signature	Considered	



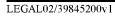


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Sheet	1	of	2	Attorney Docket Number	066859/543316	

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Examiner Initials *	Cite 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>					
	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).						
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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).						
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	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).						
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	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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