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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		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 RIGHTS. This application is 3 and MPEP 1308.	with the correspondent in this application. If not nunication will be mailed	included In due course. THIS	
☐ A declaration(s)/affidavit(s) under 37 CFR 1.130(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).		
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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	
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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 		
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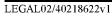
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Substitute for form 1449B/PTO				Complete if Known		
				Application Number	16/773,641	
INFO	RMATION DIS	CLOS	URE	Filing Date	January 27, 2020	
STAT	EMENT BY A	PPLIC	ANT	First Named Inventor	John Maloney	
				Art Unit	1612	
(Use as many sheets as necessary)				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).					
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	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).					
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	340	LANGILLE, STEPHEN E., "Particulate Matter in Injectable Drug Products," PDA Journal of Pharmaceutical Science and Technology, 67(3):186–200, (2013).					
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Examiner Date			
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Signature Considered	Signature	Con	onsidered



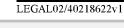


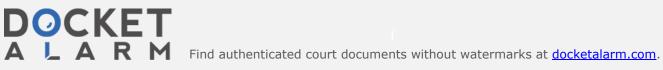
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Sheet	2	of	2	Attorney Docket Number 066859/543316		

324	Patent Owner's Preliminary Response, <i>Eton Pharmaceuticals, Inc. v. Exela Pharma Scienc</i> es, <i>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</i> 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, <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).
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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	



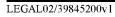


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	305	Petition for Post Grant Review of U.S. Patent No. 10,583,155, Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC, PGR2020-00068, (PTAB June 8, 2020).						
	306	VAN GOUDOEVER et al., "ESPGHAN/ESPEN/ESPR/CSPEN guidelines on pediatric parenteral nutrion: Amino acids," Clinical Nutrition, 37:2315-2323, (2018).						
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