Doc code: RCEX
Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (02-18)
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REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	16/746,028	Filing Date	2020-01-17	Docket Number (if applicable)	066859/542422	Art Unit	1612
First Named Inventor	John Maloney			Examiner Name	Benjamin J. Packard		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☒ Enclosed

- ☐ Amendment/Reply
- ☒ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____ (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

☒ **The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**
The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 160605

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

Applicant Signature

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Signature of Registered U.S. Patent Practitioner			
Signature	/bryan l. skelton/	Date (YYYY-MM-DD)	2020-05-28
Name	Bryan L. Skelton	Registration Number	50893

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

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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.

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/

Bryan L. Skelton
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ELECTRONICALLY FILED USING THE EFS-WEB ELECTRONIC FILING SYSTEM OF THE UNITED STATES PATENT & TRADEMARK OFFICE ON May 28, 2020.

Modified PTO/SB/08 Form

Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	16/746,028
				Filing Date	January 17, 2020
				First Named Inventor	John Maloney
				Art Unit	1612
(Use as many sheets as necessary)				Examiner Name	Benjamin J. Packard
Sheet	1	of	4	Attorney Docket Number	066859/542422

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	292	US 6,382,442 B1	05-07-2002	Thibault et al.	
	276	US 8,415,337 B1	04-09-2013	Krishna	

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]
	293	"Aluminum in large and small volume parenterals used in total parenteral nutrition," Food and Drug Administration, 21 C.F.R. § 201.323, 89-90, (2003).	
	272	"American Regent Announces the Launch and Availability of Selenious Acid Injection, USP," Press Release, American Regent, Inc., 6 pages, (2019).	
	251	"Cysteine," DrugBank, 23 pages, Exhibit 1016, Petition for Post Grant Review of U.S. Patent No. 10,478,453, Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC, PGR2020-00064, (PTAB May 19, 2020).	
	298	"ELCYS (Cysteine Hydrochloride)," NDA 210660, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, 3 pages, (2019).	
	274	"Neonatal Parenteral Nutrition," Intensive Care Nursery House Staff Manual, UCSF Children's Hospital, pp. 136-142, (2004-2006).	
	280	"Aluminum in Large and Small Volume Parenterals Used in Total Parenteral Nutrition," Federal Register, 63(2):176-185, (1998).	
	246	"AMINOSYN [label information]", Hospira, Inc., 11 pages, Exhibit 1009, Petition for Post Grant Review of U.S. Patent No. 10,478,453, Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC, PGR2020-00064, (PTAB May 19, 2020).	
	278	"Aminosyn Sulfite Free [drug information]," RX List, 15 pages, Exhibit 1052, Petition for Post Grant Review of U.S. Patent No. 10,478,453, Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC, PGR2020-00064, (PTAB May 19, 2020).	
	253	"Guidance for Industry: Q8(R2) Pharmaceutical Development," U.S. Dept. of Health and Human Services, FDA, CDER, CBER, 29 pages, (2009).	
	244	"L-CYSTEINE HYDROCHLORIDE - cysteine hydrochloride injection, solution [label information]", Sandoz Inc., 11 pages, Exhibit 1005, Petition for Post Grant Review of U.S. Patent No. 10,478,453, Eton Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC, PGR2020-00064, (PTAB May 19, 2020).	
	248	"Q3D Elemental Impurities: Guidance for Industry," U.S. Dept. of Health and Human Services, FDA, CDER, CBER, 85 pages, (2015).	
	271	"Selenious Acid Injection [prescribing information]," American Regent, Inc., 8 pages, (2019).	
	273	"Zinc sulfate injection [prescribing information]," American Regent, Inc., 9 pages, (2019).	

Examiner Signature		Date Considered	

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