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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/015,237	05/22/2023	11634781	EXCTD-35239.559	8678
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CASIMIR JONES, S.C. 2275 DEMING WAY, SUITE 310 MIDDLETON, WI 53562			EXAMINER JASTRZAB, KRISANNE MARIE	
			ART UNIT	PAPER NUMBER
			3991	
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			06/29/2023	PAPER

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.



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***EX PARTE* REEXAMINATION COMMUNICATION TRANSMITTAL FORM**

REEXAMINATION CONTROL NO. 90/015,237 .

PATENT UNDER REEXAMINATION 11634781 .

ART UNIT 3991 .

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Order Granting Request For Ex Parte Reexamination	Control No. 90/015,237	Patent Under Reexamination 11634781	
	Examiner KRISANNE M JASTRZAB	Art Unit 3991	AIA (FITF) Status No

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

The request for *ex parte* reexamination filed 05/22/2023 has been considered and a determination has been made. An identification of the claims, the references relied upon, and the rationale supporting the determination are attached.

Attachments: a) ☐ PTO-892, b) ☒ PTO/SB/08, c) ☐ Other: _____

1. ☒ The request for *ex parte* reexamination is GRANTED.

RESPONSE TIMES ARE SET AS FOLLOWS:

For Patent Owner's Statement (Optional): TWO MONTHS from the mailing date of this communication (37 CFR 1.530 (b)). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).**

For Requester's Reply (optional): TWO MONTHS from the **date of service** of any timely filed Patent Owner's Statement (37 CFR 1.535). **NO EXTENSION OF THIS TIME PERIOD IS PERMITTED.** If Patent Owner does not file a timely statement under 37 CFR 1.530(b), then no reply by requester is permitted.

/KRISANNE M JASTRZAB/
Patent Reexamination Spec., Art Unit

cc:Requester (if third party requester)

Notice of Pre-AIA or AIA Status

The present application is being examined under the pre-AIA first to invent provisions.

Reexamination

A substantial new question of patentability affecting claims 1-20 of United States Patent Number 11,634,781 (hereinafter “the ‘781 patent”) is raised by the request for *ex parte* reexamination.

Extensions of time under 37 CFR 1.136(a) will not be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 305 requires that *ex parte* reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.550(a)). Extensions of time in *ex parte* reexamination proceedings are provided for in 37 CFR 1.550(c).

35 USC 325(d)

A review of the post grant history for the '781 patent indicates that there have been no other Office post grant challenges involving the patent (Reexamination Proceedings or *Inter Partes* Review, Post Grant Review, Covered Business Method trials). Accordingly, a determination of whether to exercise discretion to reject the request pursuant to 35 USC 325(d) is not applicable.

Substantial New Question of Patentability (SNQ)

SNQ A: The request indicates that Requester considers U.S. Patent No. 5,952,178 to Lapidus et al., (hereinafter “Lapidus ‘178”) as raising a substantial new question of patentability as to claims 1-4 and 12 of the ‘781 patent.

It is agreed that consideration of Lapidus ‘178 raises an SNQ as to claims 1-4 and 12 of the ‘781 patent.

Lapidus ‘178 teaches methods for disease diagnosis of fecal stool samples. A stool is voided into a receptacle configured to fit a conventional toilet and accept stool voided in a conventional manner. The receptacle is sized for transportation to a testing facility. The receptacle further includes means to remove a sample portion of the stool. A sealing means is provided for the receptacle. See Example 1, column 7, line 60 through column 8, line 45. Once obtained the sample portion of the stool is homogenized in an appropriate buffer. The buffer may contain inhibitors of DNA and RNA degrading enzymes or chemical compounds which react with blood for detecting the presence of fecal occult blood. DNA or RNA may be isolated from the homogenate and subsequent tests may be performed thereon. See column 9, lines 30-50.

The teachings regarding the collection and processing of a fecal sample of Lapidus ‘178 were not previously considered in the prosecution that became the ‘781 patent. Further there is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not the claims are patentable. Accordingly, Lapidus ‘178 raises a substantial new question of patentability as to claims

1-4 and 12 of the '781 patent, which question has not been decided in a previous examination of the '781 patent.

SNQ B: The request indicates that Requester considers U.S. Patent No. 5,741,650 to Lapidus et al., (hereinafter "Lapidus '650") as raising a substantial new question of patentability as to claims 1-4 and 12 of the '781 patent.

It is agreed that consideration of Lapidus '650 raises an SNQ as to claims 1-4 and 12 of the '781 patent.

Lapidus '650 teaches methods for disease diagnosis of fecal stool samples. A stool is voided into a receptacle configured to fit a conventional toilet and accept stool voided in a conventional manner. The receptacle is sized for transportation to a testing facility. The receptacle further includes means to remove a sample portion of the stool. A sealing means is provided for the receptacle. See Example 1, column 7, line 15 through column 8, line 25. Once obtained the sample portion of the stool is homogenized in an appropriate buffer. The buffer may contain inhibitors of DNA and RNA degrading enzymes or chemical compounds which react with blood for detecting the presence of fecal occult blood. DNA or RNA may be isolated from the homogenate and subsequent tests may be performed thereon. See column 8, lines 5-25.

The teachings regarding the collection and processing of a fecal sample of Lapidus '650 were not previously considered in the prosecution that became the '781 patent. Further there is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not the claims are patentable. Accordingly, Lapidus '650 raises a substantial new question of patentability as to claims

1-4 and 12 of the '781 patent, which question has not been decided in a previous examination of the '781 patent.

SNQs C & D: The request indicates that Requester considers either of Lapidus '178 and '650 together with EP 1,366,715 to DeLuca et al., (hereinafter "DeLuca") and Olson et al., "*DNA Stabilization Is Critical for Maximizing Performance of Fecal DNA-Based Colorectal Cancer Tests*", Diagnostic Molecular Pathology, 2005, Vol: 14, Issue 3, pages 183-191 (hereinafter "Olson") as raising a substantial new question of patentability as to claims 1-6 and 14-15 of the '781 patent.

It is agreed that consideration of each Lapidus '178 and '650 with DeLuca and Olson raises an SNQ as to claims 1-6 and 15 of the '781 patent.

Each of Lapidus '178 and '650 are considered as set forth above.

DeLuca teaches an extraction tube 1 for separating a test portion from a fecal sample. The tube is sealable. Once a test portion is obtained and contained, a buffer is introduced into the tube. The buffer may be a solution having a pH between 7 and 9 and contain specific stabilizers. See paragraphs 26, 41-43, 46 and 49.

Olson investigates how fecal sample handling conditions affect the stability of DNA in stool. The use of EDTA stabilization buffers for samples stored at room temperature were shown to counteract potential sample compromise and degradation when comparing quantitative PCR data. See the abstract and Results.

The teachings regarding the collection and processing of a fecal sample of each of Lapidus '178 and '650 along with the teachings of a test portion container of DeLuca

and temperature and buffer conditions of Olson, were not previously considered in the prosecution that became the '781 patent. Further there is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not the claims are patentable. Accordingly, either of Lapidus '178 and '650 together with DeLuca and Olson raises a substantial new question of patentability as to claims 1-6 and 14-15 of the '781 patent, which question has not been decided in a previous examination of the '781 patent.

SNQ E: The request indicates that Requester considers Ahlquist et al., "*Stool DNA and Occult Blood Testing for Screen Detection of Colorectal Neoplasia*", *Annals of Internal Medicine*, 2008, Vol. 149, Issue 7, pages 441-450 (hereinafter "Ahlquist") together with DeLuca and Olson as raising a substantial new question of patentability as to claims 1-6 and 15 of the '781 patent.

It is agreed that consideration of Ahlquist with DeLuca and Olson raises an SNQ as to claims 1-6 and 15 of the '781 patent.

Ahlquist teaches at home collection of a fecal sample and same-day shipment of the collected sample to a central testing facility. See "Measurements". Stools were collected using plastic buckets mounted to the toilet seat. After collection, the patients smeared stool onto windows of Hemoccult and HemoccultSensa cards. The patient then shipped the smeared cards and sealed bucket containing the remaining portion of the stool sample to the Mayo clinic for testing. See Stool Collection and Processing.

Each of DeLuca and Olson are considered as set forth above.

The teachings regarding the collection and processing of a fecal sample of Ahlquist along with the teachings of a test portion container of DeLuca and temperature and buffer conditions of Olson, were not previously considered in the prosecution that became the '781 patent. Further there is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not the claims are patentable. Accordingly, Ahlquist together with DeLuca and Olson raises a substantial new question of patentability as to claims 1-6 and 15 of the '781 patent, which question has not been decided in a previous examination of the '781 patent.

SNQ F: The request indicates that Requester considers WO 2005/014154 to O'Neill (hereinafter "O'Neill") together with DeLuca and Olson as raising a substantial new question of patentability as to claims 1-4 and 14-15 of the '781 patent.

It is agreed that consideration of each O'Neill with DeLuca and Olson raises an SNQ as to claims 1-4 and 14-15 of the '781 patent.

O'Neill teaches a method and apparatus for removing cellular material from stools and a container for collecting them. The stool is collected in a container at home, which may be removably installed on a toilet, and transported to a facility for handling and testing. See page 8, lines 7-12 and 24-30. The container is hermetically sealable to prevent the growth of aerobic bacteria and preserve the stool. See page 9, lines 27-35. A specimen of the stool is removed for testing for a variety of conditions such as colorectal cancer, polyps or ulcerative colitis by qualitative and quantitative analysis of DNA alterations, gene expression and enzyme activity. See page 10, line 24-page, 11,

line 10 and page 1, lines 15-30. O'Neill was cited during the prosecution of the application that became the '781 patent, however, it was not applied in a rejection nor was it considered in light of DeLuca and Olson.

Each of DeLuca and Olson are considered as set forth above.

The teachings regarding the collection and processing of a fecal sample of O'Neill along with the teachings of a test portion container of DeLuca and temperature and buffer conditions of Olson, were not previously considered together in the prosecution that became the '781 patent. Further there is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not the claims are patentable. Accordingly, O'Neill together with DeLuca and Olson raises a substantial new question of patentability as to claims 1-4 and 14-15 of the '781 patent, which question has not been decided in a previous examination of the '781 patent.

SNQs G & H: The request indicates that Requester considers either of Lapidus '178 and '650 together with DeLuca and Olson as well as Leung et al., "*Detection of Hypermethylated DNA or Cyclooxygenase-2 Messenger RNA in Fecal Samples of Patients With Colorectal Cancer or Polyps*," American Journal of Gastroenterology, 2007, Vol. 102, Issue 5, pages 1070-1076 (hereinafter "Leung") as raising a substantial new question of patentability as to claims 5-13 of the '781 patent.

It is agreed that consideration of each Lapidus '178 and '650 with DeLuca and Olson and Leung raises an SNQ as to claims 5-13 of the '781 patent.

Each of Lapidus '178 and '650, DeLuca and Olson are considered as set forth above.

Leung teaches detection of epigenetic changes such as hypermethylated DNA or Cyclooxygenase-2 Messenger RNA in fecal samples as a method of screening for colorectal cancer or polyps. See page 1070, last paragraph through the first full paragraph of page 1071. Stool samples were collected by patients at home and brought to a laboratory for testing. See Methods. Methylation-specific PCR was performed to examine seven tumor-related genes. See DNA Isolation and Methylation-Specific PCR. COX-2 expression was detected by RT-PCR. See RNA Isolation and RT-PCR.

The teachings regarding the collection and processing of a fecal sample of each of Lapidus '178 and '650 along with the teachings of a test portion container of DeLuca, temperature and buffer conditions of Olson and the detection testing taught in Leung, were not previously considered in the prosecution that became the '781 patent. Further there is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not the claims are patentable. Accordingly, either of Lapidus '178 and '650 together with DeLuca, Olson and Leung raises a substantial new question of patentability as to claims 5-13 of the '781 patent, which question has not been decided in a previous examination of the '781 patent.

SNQ I: The request indicates that Requester considers Ahlquist together with DeLuca, Olson and Leung as raising a substantial new question of patentability as to claims 7-14 of the '781 patent.

It is agreed that consideration of Ahlquist with DeLuca, Olson and Leung raises an SNQ as to claims 7-14 of the '781 patent.

Each of Ahlquist, DeLuca, Olson and Leung are considered as set forth above.

The teachings regarding the collection and processing of a fecal sample of Ahlquist along with the teachings of a test portion container of DeLuca, temperature and buffer conditions of Olson and detection testing taught by Leung, were not previously considered in the prosecution that became the '781 patent. Further there is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not the claims are patentable. Accordingly, Ahlquist together with DeLuca, Olson and Leung raises a substantial new question of patentability as to claims 7-14 of the '781 patent, which question has not been decided in a previous examination of the '781 patent.

SNQ J: The request indicates that Requester considers O'Neill together with DeLuca, Olson and Leung as raising a substantial new question of patentability as to claims 5-13 of the '781 patent.

It is agreed that consideration of O'Neill with DeLuca, Olson and Leung raises an SNQ as to claims 5-13 of the '781 patent.

Each of O'Neill, DeLuca, Olson and Leung are considered as set forth above.

The teachings regarding the collection and processing of a fecal sample of O'Neill along with the teachings of a test portion container of DeLuca, temperature and buffer conditions of Olson and detection testing taught by Leung, were not previously considered in the prosecution that became the '781 patent. Further there is a

substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not the claims are patentable. Accordingly, O'Neill together with DeLuca, Olson and Leung raises a substantial new question of patentability as to claims 5-13 of the '781 patent, which question has not been decided in a previous examination of the '781 patent.

SNQs K & L: The request indicates that Requester considers either of Lapidus '178 and '650 together with DeLuca and Olson as well as Hoepffner et al., "*Comparative Evaluation of a New Bedside Faecal Occult Blood Test in a Prospective Multicentre Study*," *Alimentary Pharmacology & Therapeutics*, 2006, Vol. 23, Issue 1, pages 145-154 (hereinafter "Hoepffner") as raising a substantial new question of patentability as to claims 16-20 of the '781 patent.

It is agreed that consideration of each Lapidus '178 and '650 with DeLuca and Olson and Hoepffner raises an SNQ as to claims 16-20 of the '781 patent.

Each of Lapidus '178 and '650, DeLuca and Olson are considered as set forth above.

Hoepffner teaches a bedside immunological test strip device for detection of fecal occult blood in patents. A stick of the sample collection device (see Fig. 1) was inserted into the feces and then into the collection device which contained extraction buffer solution. The test strip included a sandwich immunoassay in which gold-labelled anti-Hb antibodies bind to Hb if present generating a violet band within 10 minutes. See page 148, second full paragraph and Fig. 2.

The teachings regarding the collection and processing of a fecal sample of each of Lapidus '178 and '650 along with the teachings of a test portion container of DeLuca, temperature and buffer conditions of Olson and the sample collection and detection testing taught in Hoepffner, were not previously considered in the prosecution that became the '781 patent. Further there is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not the claims are patentable. Accordingly, either of Lapidus '178 and '650 together with DeLuca, Olson and Hoepffner raises a substantial new question of patentability as to claims 16-20 of the '781 patent, which question has not been decided in a previous examination of the '781 patent.

SNQ M: The request indicates that Requester considers Ahlquist together with DeLuca, Olson and Hoepffner as raising a substantial new question of patentability as to claims 16-20 of the '781 patent.

It is agreed that consideration of Ahlquist with DeLuca, Olson and Hoepffner raises an SNQ as to claims 16-20 of the '781 patent.

Each of Ahlquist, DeLuca, Olson and Hoepffner are considered as set forth above.

The teachings regarding the collection and processing of a fecal sample of Ahlquist along with the teachings of a test portion container of DeLuca, temperature and buffer conditions of Olson and the sample collection and detection testing taught by Hoepffner, were not previously considered in the prosecution that became the '781 patent. Further there is a substantial likelihood that a reasonable examiner would

consider these teachings important in deciding whether or not the claims are patentable. Accordingly, Ahlquist together with DeLuca, Olson and Hoepffner raises a substantial new question of patentability as to claims 16-20 of the '781 patent, which question has not been decided in a previous examination of the '781 patent.

SNQ N: The request indicates that Requester considers O'Neill together with DeLuca, Olson and Hoepffner as raising a substantial new question of patentability as to claims 16-20 of the '781 patent.

It is agreed that consideration of O'Neill with DeLuca, Olson and Hoepffner raises an SNQ as to claims 16-20 of the '781 patent.

Each of O'Neill, DeLuca, Olson and Hoepffner are considered as set forth above.

The teachings regarding the collection and processing of a fecal sample of O'Neill along with the teachings of a test portion container of DeLuca, temperature and buffer conditions of Olson and the sample collection and detection testing taught by Hoepffner, were not previously considered in the prosecution that became the '781 patent. Further there is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not the claims are patentable. Accordingly, O'Neill together with DeLuca, Olson and Hoepffner raises a substantial new question of patentability as to claims 16-20 of the '781 patent, which question has not been decided in a previous examination of the '781 patent.

Declaration

The declaration of Mr. Anthony P. Shuber, MS filed with the Request has been entered and fully considered.

Duty of Disclosure

The patent owner is reminded of the continuing responsibility under 37 CFR 1.565(a) to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. 11,634,781 throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282 and 2286.

Service of Papers

After the filing of a request for reexamination by a third party requester, any document filed by either the patent owner or the third party requester must be served on the other party (or parties where two or more third party requester proceedings are merged) in the reexamination proceeding in the manner provided in 37 CFR 1.248. See 37 CFR 1.550(f).

Correspondence

Any inquiry concerning this communication or earlier communications from the specialist should be directed to Krisanne Jastrzab whose telephone number is 571-272-1279. The specialist can normally be reached on Mon.-Thurs. 8:30 am-7:00 pm.

If attempts to reach the specialist by telephone are unsuccessful, either of the specialist's supervisors, Timothy Speer or Jean Witz, can be reached on 313-446-4825 and 571-272-0927, respectively.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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