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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
16/288,351	**06/01/2021 05:29:35 PM ET**	**N.012.US.10**

Title of Invention

DETECTING MUTATIONS AND PLOIDY IN CHROMOSOMAL SEGMENTS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	1764	FILED BY	Angela McGowan
PATENT CENTER #	60205624	FILING DATE	02/28/2019
CUSTOMER #	110711	FIRST NAMED INVENTOR	Joshua BABIARZ
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Anton Bokal

Documents

TOTAL DOCUMENTS: 0

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C.

371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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ELECTRONIC PAYMENT RECEIPT

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16/288,351	06/01/2021 05:29:35 PM ET	N.012.US.10

Title of Invention

DETECTING MUTATIONS AND PLOIDY IN CHROMOSOMAL SEGMENTS

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APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	1764	FILED BY	Angela McGowan
PATENT CENTER #	60205624	AUTHORIZED BY	Anton Bokal
CUSTOMER #	110711	FILING DATE	02/28/2019
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Joshua BABIARZ

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
DA / 506075	E202161H30002303	Angela McGowan

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
1806	SUBMISSION OF AN INFORMATION DISCLOSURE STATEMENT	260.00	1	260.00
			TOTAL AMOUNT:	$260.00

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Doc Code: DIST.E.FILE **Document Description: Electronic Terminal Disclaimer - Filed**	PTO/SB/25 U.S. Patent and Trademark Office Department of Commerce

Electronic Petition Request	**TERMINAL DISCLAIMER TO OBVIATE A PROVISIONAL DOUBLE PATENTING REJECTION OVER A PENDING "REFERENCE" APPLICATION**
Application Number	16288351
Filing Date	28-Feb-2019
First Named Inventor	Joshua BABIARZ
Attorney Docket Number	N.012.US.10
Title of Invention	DETECTING MUTATIONS AND PLOIDY IN CHROMOSOMAL SEGMENTS

☒ Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action

☒ This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.

Owner	Percent Interest
Natera, Inc.	100%

The owner(s) of percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending reference Application Number(s)

16288416 filed on 02/28/2019

16288462 filed on 02/28/2019

16399941 filed on 04/30/2019

as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the reference application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

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Applicant claims the following fee status: ○ Small Entity ○ Micro Entity ◉ Regular Undiscounted I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.	
THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES I certify, in accordance with 37 CFR 1.4(d)(4) that I am: ◉ An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application Registration Number 51243 ○ A sole inventor ○ A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application ○ A joint inventor; all of whom are signing this request	
Signature	/Anton Bokal/
Name	Anton Bokal

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

Electronic Patent Application Fee Transmittal

Application Number:	16288351
Filing Date:	28-Feb-2019
Title of Invention:	DETECTING MUTATIONS AND PLOIDY IN CHROMOSOMAL SEGMENTS
First Named Inventor/Applicant Name:	Joshua BABIARZ
Filer:	Anton John Bokal/Angela McGowan
Attorney Docket Number:	N.012.US.10

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
STATUTORY OR TERMINAL DISCLAIMER	1814	1	170	170
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**170**

Doc Code: DISQ.E.FILE
Document Description: Electronic Terminal Disclaimer – Approved

Application No.: 16288351

Filing Date: 28-Feb-2019

Applicant/Patent under Reexamination: BABIARZ

Electronic Terminal Disclaimer filed on June 1, 2021

☒ APPROVED

This patent is subject to a terminal disclaimer

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Electronic Acknowledgement Receipt

EFS ID:	42868169
Application Number:	16288351
International Application Number:	
Confirmation Number:	1764
Title of Invention:	DETECTING MUTATIONS AND PLOIDY IN CHROMOSOMAL SEGMENTS
First Named Inventor/Applicant Name:	Joshua BABIARZ
Customer Number:	110711
Filer:	Anton John Bokal/Angela McGowan
Filer Authorized By:	Anton John Bokal
Attorney Docket Number:	N.012.US.10
Receipt Date:	01-JUN-2021
Filing Date:	28-FEB-2019
Time Stamp:	17:15:25
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$170
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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Terminal Disclaimer-Filed (Electronic)	eTerminal-Disclaimer.pdf	35206 0d3b5b089e0adebc039886a97e8322b2c48aa5b3	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30694 58245f727bfffecf77518918819a48da58146931	no	2
Warnings:					
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PTO/SB/06 (09-11)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/288,351	Filing Date 02/28/2019	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $460 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	06/01/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 19	Minus	** 24	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/CHRISTINE V MOORE/
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The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/288,351
	Filing Date	Feb 28, 2019
	First Named Inventor	Joshua BABIARZ
	Art Unit	1637
	Examiner Name	Teresa E. Strzelecka
	Attorney Docket Number	N.012.US.10

U.S. PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

U.S. PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		20030232348	A1	2003-12-18	JONES, K. W., et al.	
		20100273219	A1	2010-10-28	MAY, A. et al.	
		20110045462	A1	2011-02-24	FU, X. D., et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns, Lines where Relevant Passages or Relevant Figures Appear	T[5]
		2007/052006	WO	A1	2007-05-10	GORMLEY, M. A., et al.		

NON-PATENT LITERATURE DOCUMENTS

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Examiner Initials*	Cite No	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[5]
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/288,351
	Filing Date	Feb 28, 2019
	First Named Inventor	Joshua BABIARZ
	Art Unit	1637
	Examiner Name	Teresa E. Strzelecka
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EXAMINER SIGNATURE			

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Field

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CERTIFICATION STATEMENT

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Signature	/Tianran Yan/	Date (YYYY-MM-DD)	2021-04-21
Name/Print	Tianran Yan	Registration Number	67,162

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APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
16/288,351	04/21/2021 03:05:13 PM ET	N.012.US.10

Title of Invention

DETECTING MUTATIONS AND PLOIDY IN CHROMOSOMAL SEGMENTS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	1764	FILED BY	Angela McGowan
PATENT CENTER #	60180549	AUTHORIZED BY	Anton Bokal
CUSTOMER #	110711	FILING DATE	02/28/2019
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Joshua BABIARZ

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
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U.S. PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

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		20110212446	A1	2011-09-01	WANG, D. et al.	

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NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	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[5]
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CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Anton Bokal

Documents

TOTAL DOCUMENTS: 63

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Electronic Patent Application Fee Transmittal

Application Number:	16288351
Filing Date:	28-Feb-2019
Title of Invention:	DETECTING MUTATIONS AND PLOIDY IN CHROMOSOMAL SEGMENTS
First Named Inventor/Applicant Name:	Joshua BABIARZ
Filer:	Anton John Bokal/Angela McGowan
Attorney Docket Number:	N.012.US.10

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	1806	1	260	260
		Total in USD ($)		**260**

Electronic Acknowledgement Receipt	
EFS ID:	42513293
Application Number:	16288351
International Application Number:	
Confirmation Number:	1764
Title of Invention:	DETECTING MUTATIONS AND PLOIDY IN CHROMOSOMAL SEGMENTS
First Named Inventor/Applicant Name:	Joshua BABIARZ
Customer Number:	110711
Filer:	Anton John Bokal/Angela McGowan
Filer Authorized By:	Anton John Bokal
Attorney Docket Number:	N.012.US.10
Receipt Date:	21-APR-2021
Filing Date:	28-FEB-2019
Time Stamp:	15:06:24
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$260
RAM confirmation Number	E20214KF06453800
Deposit Account	
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The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Fee Worksheet (SB06)	fee-info.pdf	30749 6448c7fc39d98b5116d835927581a1cea9e9f374	no	2
Warnings:					
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		Total Files Size (in bytes):	30749		

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PTO/SB/08a (01-10)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/288,351
	Filing Date	Feb 28, 2019
	First Named Inventor	Joshua BABIARZ
	Art Unit	1637
	Examiner Name	Teresa E. Strzelecka
	Attorney Docket Number	N.012.US.10

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Examiner Initial*	Cite No	Patent Number	Kind Code [1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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	Attorney Docket Number	N.012.US.10

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Examiner Initials*	Cite No	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[5]
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Application Number:	16288351
Filing Date:	28-Feb-2019
Title of Invention:	DETECTING MUTATIONS AND PLOIDY IN CHROMOSOMAL SEGMENTS
First Named Inventor/Applicant Name:	Joshua BABIARZ
Filer:	Anton John Bokal/Angela McGowan
Attorney Docket Number:	N.012.US.10

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Filing Fees for Utility under 35 USC 111(a)

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Pages:				
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Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

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		Total in USD ($)		**260**

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Application Number:	16288351
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First Named Inventor/Applicant Name:	Joshua BABIARZ
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37	Non Patent Literature	LAPIERRE_2000_p531_NPL.pdf	3921310 63896196878dbf4fb578e3217391eb6e30b71d02	no	10
Warnings:					
Information:					
38	Non Patent Literature	LASKEN_2003_p531_NPL.pdf	6927006 8c0582e3238c7929369992b5040e7ef562d40464	no	5
Warnings:					
Information:					
39	Non Patent Literature	LI_2005_p843_NPL.pdf	10990204 060c9b87b688cfb51a70c909572ab81d921f6e9f	no	8
Warnings:					
Information:					
40	Non Patent Literature	LO_FetalDNAinMaternalPlasma_2000_p1903_NPL.pdf	5716079 c1075d6c514176dc26e4dd6647d461eaa7b1486b	no	4
Warnings:					
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41	Non Patent Literature	MASUZAKI_2004_p289_NPL.pdf	208877 c55485a383a0d4c437e74741c68835c4b514b68f	no	5
Warnings:					
Information:					

42	Non Patent Literature	MATSUZAKI_2004_p109_NPL.pdf	333716 db9365917c198a2ecd6322b0d6b9dfabf5b99998	no	3
Warnings:					
Information:					
43	Non Patent Literature	NAGALLA_2007_p1245_NPL.pdf	7733226 738c485efed6ff20829cd6533b96b6048545e385	no	13
Warnings:					
Information:					
44	Non Patent Literature	NILSSON_1994_p2085_NPL.pdf	3126445 f2b00ba996b0f158327caf73fc34633ed097aa70	no	4
Warnings:					
Information:					
45	Non Patent Literature	OLIPHANT_2002_pS56_NPL.pdf	5989932 56f7594f32e8b60968a8d0edb251c0bbb89a75f7	no	5
Warnings:					
Information:					
46	Non Patent Literature	PARAMESWARAN_2007_9pgs_NPL.pdf	1432604 5747ff9b9ec27c4d90defa37526a80447df41660	no	9
Warnings:					
Information:					
47	Non Patent Literature	PASK_2004_8pgs_NPL.pdf	3945318 8ba660afb7a64da80a143db4b17d1100b1ca3c31	no	8
Warnings:					
Information:					
48	Non Patent Literature	PATIL_2001_p1719_NPL.pdf	9764016 337f3c9c246e6ee32c0ca254371c60167c4011fe	no	6
Warnings:					
Information:					

49	Non Patent Literature	PAUNIO_1996_p1382_NPL.pdf	13099854 d2df87152672d64d5ec7c1af95803a76a2b4cb40	no	9
Warnings:					
Information:					
50	Non Patent Literature	PHILIP_2004_p1164_NPL.pdf	12176330 64a8c5be6f56d6ac9f3f3fb77e925ecdf08a2975	no	10
Warnings:					
Information:					
51	Non Patent Literature	ROBERTSON_2007_p651_NPL.pdf	452260 9ef8a0788c3642b3049c00fa2b4355ff89696802	no	8
Warnings:					
Information:					
52	Non Patent Literature	ROMAN_1999_p236_NPL.pdf	2626739 86a8672c46a877ba0edfa431d5418e9b89492a87	no	3
Warnings:					
Information:					
53	Non Patent Literature	RUANO_1990_p6296_NPL.pdf	1396279 0f10f23b1812c974284c2d887e3add9de54c038a	no	5
Warnings:					
Information:					
54	Non Patent Literature	SAMURA_2001_p1622_NPL.pdf	313880 b311a9cac1c823a0b940d8bdbb8c83ad2f3b116a	no	5
Warnings:					
Information:					
55	Non Patent Literature	SEPPO_2008_p815_NPL.pdf	4080483 69d5aed92a7f12c5dd6b947631cb9d72d65e0d8d	no	7
Warnings:					
Information:					

56	Non Patent Literature	SPENCER_2001_p270_NPL.pdf	911311 15d953867e2518969608973daf44566ea74ddfe0	no	4
Warnings:					
Information:					
57	Non Patent Literature	SPENCER_2001_p441_NPL.pdf	59193 dc6e34e4a79c4f925be45cfd8c25004ee39474f5	no	4
Warnings:					
Information:					
58	Non Patent Literature	SWINKELS_2003_p525_NPL.pdf	102753 1f784d5a3f0e3ad2f08efb5c5031311127efbc46	no	2
Warnings:					
Information:					
59	Non Patent Literature	SYVANEN_2005_p55_NPL.pdf	1063631 4e307462d22a8ecddc2db44dfb6c4423339d72b6	no	6
Warnings:					
Information:					
60	Non Patent Literature	TSANGARIS_2006_p9236_NPL.pdf	9263094 12f0b29ec6f6933f5c59958875f52969cbd69053	no	10
Warnings:					
Information:					
61	Fee Worksheet (SB06)	fee-info.pdf	30749 fa052287c4e7d60b8b5c99c104058837057270fe	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	186416360		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/288,351
	Filing Date	Feb 28, 2019
	First Named Inventor	Joshua BABIARZ
	Art Unit	1637
	Examiner Name	Teresa E. Strzelecka
	Attorney Docket Number	N.012.US.10

U.S. PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code [1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

U.S. PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code [1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		20110015096	A1	2011-01-20	CHIU, K. P.	

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code [4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns, Lines where Relevant Passages or Relevant Figures Appear	T [5]
		2007/073171	WO	A2	2007-06-28	VANEIJK, M. J.		
		2010/127186	WO	A1	2010-11-04	CHEE, M. S.		
		2011/051283	WO	A1	2011- 05-05	BENZ, M. et al.		

NON-PATENT LITERATURE DOCUMENTS

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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	First Named Inventor	Joshua BABIARZ
	Art Unit	1637
	Examiner Name	Teresa E. Strzelecka
	Attorney Docket Number	N.012.US.10

Examiner Initials*	Cite No	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[5]
		BINLADEN, J. et al., "The Use of Coded PCR Primers Enables High-Throughput Sequencing of Multiple Homolog Amplification Products by 454 Parallel Sequencing", PLOS One, Issue 2, FEB 2007, 9 pages	
		GNIRKE, A. et al., "Solution hybrid selection with ultra-long oligonucleotides for massively parallel targeted sequencing", Nature Biotechnology, Vol. 27, No. 2, FEB 2009, 182-189	
		TEWHEY, R. et al., "Microdroplet-based PCR enrichment for large-scale targeted sequencing", Nature Biotechnology, Vol. 27, No. 11, NOV 2009, 1025-1031	
		ZHOU, W. et al., "Counting alleles to predict recurrence of early-stage colorectal cancers", The Lancet, Vol. 359, 19 JAN 2002, 219-225	

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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(Not for submission under 37 CFR 1.99)

Application Number	16/288,351
Filing Date	Feb 28, 2019
First Named Inventor	Joshua BABIARZ
Art Unit	1637
Examiner Name	Teresa E. Strzelecka
Attorney Docket Number	N.012.US.10

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.
[4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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	Application Number	16/288,351
	Filing Date	Feb 28, 2019
	First Named Inventor	Joshua BABIARZ
	Art Unit	1637
	Examiner Name	Teresa E. Strzelecka
	Attorney Docket Number	N.012.US.10

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ None

The submission of this Information Disclosure Statement does not constitute an admission that a search was made, does not constitute an admission that any information cited is prior art, and does not constitute an admission that no other or better art exists.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Tianran Yan/	Date (YYYY-MM-DD)	2021-02-04
Name/Print	Tianran Yan	Registration Number	67,162

This collection of information is required by 37 CFR 1.97 and 1.98. 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 1.14. This collection is estimated to take 1 hour 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. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Electronic Patent Application Fee Transmittal

Application Number:	16288351
Filing Date:	28-Feb-2019
Title of Invention:	DETECTING MUTATIONS AND PLOIDY IN CHROMOSOMAL SEGMENTS
First Named Inventor/Applicant Name:	Joshua BABIARZ
Filer:	Anton John Bokal/Angela McGowan
Attorney Docket Number:	N.012.US.10

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	1806	1	260	260
		Total in USD ($)		**260**

Electronic Acknowledgement Receipt

EFS ID:	41837436
Application Number:	16288351
International Application Number:	
Confirmation Number:	1764
Title of Invention:	DETECTING MUTATIONS AND PLOIDY IN CHROMOSOMAL SEGMENTS
First Named Inventor/Applicant Name:	Joshua BABIARZ
Customer Number:	110711
Filer:	Anton John Bokal/Angela McGowan
Filer Authorized By:	Anton John Bokal
Attorney Docket Number:	N.012.US.10
Receipt Date:	04-FEB-2021
Filing Date:	28-FEB-2019
Time Stamp:	14:07:27
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$260
RAM confirmation Number	E202124E07584048
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Non Patent Literature	VOGELSTEIN_1999_p9236_NPL.pdf	610258 2e6eb2884393f8020917649c119034692a11cdd4	no	6
Warnings:					
Information:					
2	Non Patent Literature	YARON_2016_P391_NPL.pdf	900436 2f41f2231fe1f7c140b327f5f86aac2430f6661e	no	6
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	N012US10_SB08_SIGNED_02.pdf	80186 e5e391900c2c12784adb10f7b0341afd0b515e1f	no	4
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
4	Foreign Reference	WO2007073171A2.pdf	1096739 49a095580df21c1d2cd8c5e41d0dc6fa3358a20a	no	61
Warnings:					
Information:					
5	Foreign Reference	WO2010127186A1.pdf	1077269 f013230545d13ee9caca6979edebec9ec2fdf68d	no	65
Warnings:					
Information:					
6	Foreign Reference	WO2011051283A1.PDF	1750555 70a440764689ac90bff3f7e534a32aa590e6422f	no	46
Warnings:					

Information:					
7	Non Patent Literature	BINLADEN_2007_9pgs_NPL.PDF	832428 ee1a1528689c5fa002c641c48d97acdaf624c529	no	9
Warnings:					
Information:					
8	Non Patent Literature	GNIRKE_2009_p182_NPL.PDF	776585 2ed780445427bde28a494c41940819d2b259b3b8	no	8
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Information:					
9	Non Patent Literature	TEWHEY_2009_p1025_NPL.PDF	1106220 d333ac3326d76d76532bcba1091bbec56adcecd4	no	11
Warnings:					
Information:					
10	Non Patent Literature	ZHOU_2002_p219_NPL.PDF	821351 5a954530bcd2e70297a40bb79a971ed7065d4b90	no	7
Warnings:					
Information:					
11	Fee Worksheet (SB06)	fee-info.pdf	30749 5cade09babb2faa5a16d018a60014f8f13d5d439	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	9082776	

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New Applications Under 35 U.S.C. 111

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New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/288,351	02/28/2019	Joshua BABIARZ	N.012.US.10	1764

110711 7590 12/30/2020

Natera, Inc.
201 Industrial Road
Suite 410
San Carlos, CA 94070

EXAMINER	
STRZELECKA, TERESA E	

ART UNIT	PAPER NUMBER
1637	

NOTIFICATION DATE	DELIVERY MODE
12/30/2020	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):

IP@natera.com

Office Action Summary	Application No. 16/288,351	Applicant(s) BABIARZ et al.	
	Examiner TERESA E STRZELECKA	Art Unit 1637	AIA (FITF) Status Yes

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 16 November 2020.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☑ This action is **FINAL.** 2b) ☐ This action is non-final.

3)☐ 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.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-4,6-7 and 9-26 is/are pending in the application.

5a) Of the above claim(s) 4,6,9-10,13,17-19 and 21-22 is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-3,7,11-12,14-16,20 and 23-26 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, 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.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ 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)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date 11/16/20.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

2. This office action is in response to an amendment filed November 16, 2020. Claims 1-24 were previously pending, with claims 4, 6, 9, 10, 13, 17-19, 21 and 22 withdrawn from consideration. Applicant cancelled claims 5 and 8, amended claims 1, 3, 4, 6, 7, 9, 11, 13-18 and 24 and added new claims 25 and 26. Claims 1-3, 7, 11, 12, 14-16, 20 and 23-26 are under consideration.

3. Applicant's cancellation of claims 5 and 8 obviated the previously presented rejections for these claims. Applicant's amendments overcame the previously presented statutory claim rejections. The previously presented obviousness-type double patenting rejections are maintained since no terminal disclaimers were provided.

4. This office action contains new grounds for rejection necessitated by amendment.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on November 16, 2020 was filed after the mailing date of the Non-final office action on June 18, 2020. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

> (a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 25 and 26 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for applications subject to pre-AIA 35 U.S.C. 112, the inventor(s), at the time the application was filed, had possession of the claimed invention.

A) Claim 25 is drawn to the method of claim 1, further comprising transmitting sequence data from the sequencing step via a cloud computing architecture.

Applicant did not point out to the support for this claim. Search of the specification for "transmit" and "cloud" revealed the following paragraphs:

"[0564] In some embodiments obtaining genetic data includes (i) acquiring DNA sequence information by laboratory techniques, e.g., by the use of an automated high throughput DNA sequencer, or (ii) acquiring information that had been previously obtained by laboratory techniques, wherein the information is electronically transmitted, e.g., by a computer over the internet or by electronic transfer from the sequencing device."

"[0757] It should be noted that the simulation, synthesis and/or manufacture of various embodiments may be accomplished, in part, through the use of computer readable code, including general programming languages (such as C or C++), hardware description languages

(HDL) such as, for example, Verilog HDL, VHDL, Altera HDL (AHDL), or other available programming tools. This computer readable code can be disposed in any known computer-usable medium including a semiconductor, magnetic disk, optical disk (such as CD-ROM, DVD-ROM). As such, the code can be transmitted over communication networks including the Internet."

"[0742] In an example embodiment, system architecture X00 operates as a service-oriented architecture and uses a client-server model that would be understood by one of skill in the relevant art(s) to enable various forms of interaction and communication between LIS X04 and analysis platform X08. System architecture X00 may be distributed over various types of networks X02 and/or may operate as cloud computing architecture. Cloud computing architecture may include any type of distributed network architecture. By way of example and not of limitation, cloud computing architecture is useful for providing software as a service (SaaS), infrastructure as a service (IaaS), platform as a service (PaaS), network as a service (NaaS), data as a service (DaaS), database as a service (DBaaS), backend as a service (BaaS), test environment as a service (TEaaS), API as a service (APIaaS), integration platform as a service (IPaaS) etc."

As can be seen from these paragraphs, they do not support sequencing data transmission via cloud architecture, therefore this claim introduces new matter into the disclosure.

B) Claim 26 is drawn to the method of claim 1, wherein step (c) further comprises: before amplifying and sequencing the DNA, tagging the isolated cell-free DNA such that the tagged cell-free DNA comprises a molecular barcode.

There is no support in the specification or in the originally filed claims for this limitation. Search for the term "molecular barcode" within the specification returned the following paragraph:

"[0140] Primer, also "PCR probe" refers to a single nucleic acid molecule (such as a DNA molecule or a DNA oligomer) or a collection of nucleic acid molecules (such as DNA molecules or DNA oligomers) where the molecules are identical, or nearly so, and wherein the primer contains a region that is designed to hybridize to a targeted locus (e.g., a targeted polymorphic locus or a non-polymorphic locus) or to a universal priming sequence, and may contain a priming sequence designed to allow PCR amplification. A primer may also contain a molecular barcode. A primer may contain a random region that differs for each individual molecule."

"[0557] In some embodiments, two or more (such as 3 or 4) target amplicons (such as amplicons from the miniPCR method disclosed herein) are ligated together and then the ligated products are sequenced. Combining multiple amplicons into a single ligation product increases the efficiency of the subsequent sequencing step. In some embodiments, the target amplicons are less than 150, 100, 90, 75, or 50 base pairs in length before they are ligated. The selective enrichment and/or amplification may involve tagging each individual molecule with different tags, molecular barcodes, tags for amplification, and/or tags for sequencing…."

Therefore Applicant did not describe any method in which cell-free DNA is tagged with molecular barcodes before being amplified with primers specific to target loci of the subject, therefore this claim introduces new matter into the disclosure. Further, such tagging would result in inoperable barcodes, since barcodes are usually attached to 3' and/or 5' ends of target molecules. If barcoded molecules would then be amplified with target-specific primers, the barcodes would not be amplified, therefore the final amplification product would not contain barcodes.

In conclusion, Applicant was not in possession of the invention as claimed.

Claim Rejections - 35 USC § 112

8. The following is a quotation of 35 U.S.C. 112(b):

> (b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 26 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

Claim 26 is drawn to the method of claim 1, wherein step (c) further comprises:

before amplifying and sequencing the DNA, tagging the isolated cell-free DNA such that the tagged cell-free DNA comprises a molecular barcode.

It is not clear what role the barcode plays. Barcodes are usually attached to 3' and/or 5' ends of target molecules. If barcoded molecules would then be amplified with target-specific primers, the barcodes would not be amplified, therefore the final amplification product would not contain barcodes. In conclusion, the claim does not have clear metes and bounds.

Claim Rejections - 35 USC § 102

10. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a)(2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

12. Claims 1-3, 7, 11, 20 and 23-25 are rejected under 35 U.S.C. 102(a)(2) as being anticipated by Diehn et al. (US 2016/0032396 A1; with a filing date of March 12, 2014; newly cited).

Regarding claims 1 and 2, Diehn et al. teach a method for preparing biological samples useful for monitoring the progression of cancer in a subject comprising:

(a) performing sequencing on a tumor biopsy sample of the subject to identify a plurality of tumor-specific mutations (Fig. 4I; Fig. 6; [0015]; [0261]; [0270]-[0271]; [0427]; [0436]-[0440]; [0509]; [0598]; [0915]; claim 84);

(b) evaluating results of the sequencing on the tumor biopsy sample to determine a plurality of target loci specific to the subject, wherein each target locus spans a tumor-specific mutation of the identified plurality of tumor specific mutations (Fig. 6; [0015]; [0261]; [0270]-[0271]; [0281]-[0283]; [0427]; [0436]-[0440]; [0598]; [0704]; [0915]); and

(c) assaying cell-free DNA isolated from a plurality of biological samples obtained from the subject at different time points (Fig. 4A-D; Fig. 6; [0015]; [0020]; [0029]; [0328]; [0915]), wherein assaying comprises:

amplifying the isolated cell-free DNA using primers specific to the plurality of target loci for the individual subject (claim 43; [0015]; [0398]; [0485]; [0492]-[0493]; [0523]; [0915]); and

sequencing the amplified DNA comprising the plurality of target loci (Fig. 4A-D; Fig. 4I; [0015]; [0053]; [0915]).

Regarding claims 3, 7 and 11, Diehn et al. teach single nucleotide variant (SNVs) in EGFR gene, and clonal and subclonal mutations ([0024]; Fig. 4A-D; [0446]; [0804]).

Regarding claim 20, Diehn et al. teach lung cancer ([0027]; [0063]; [0088]; [0785]).

Regarding claim 23, Diehn et al. teach plasma samples ([0046]; [0443]; [0702]).

Regarding claim 24, Diehn et al. teach whole exome sequencing ([0271]; [0559]; [0785]).

Regarding claim 25, Diehn et al. teach transmitting sequencing data via cloud architecture ([0494]).

Claim Rejections - 35 USC § 103

13. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

14. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

16. Claim 12 is rejected under 35 U.S.C. 103 as being unpatentable over Diehn et al. (US 2016/0032396 A1; filed March 12, 2014; newly cited) and Murtaza et al. (Nature, vol. 497, pp. 108-112, 2013; cited in the IDS; previously cited).

A) Diehn et al. teach detection of cancer-specific mutations in plasma of patients with lung cancer, and detection of clonal and subclonal mutations, but do not specifically teach determining clonal heterogeneity of the cancer sample.

B) Murtaza et al. teach detection of clonal heterogeneity of cancer samples by exome sequencing of serial plasma samples from patients with different cancer types, including lung cancer (Abstract; page 108-111; Fig. 1, 2; Table 1).

It would have been *prima facie* obvious to one of ordinary skill in the art before the effective filing date of the claimed invention to have used the data of Diehn et al. to determine clonal tumor heterogeneity as suggested by Murtaza et al. The motivation to do so is provided by Murtaza et al. (page 111, second paragraph):

"In this proof of principle study, we demonstrate that exome analysis of plasma ctDNA represents a novel paradigm for non-invasive characterization of tumour evolution. Our data, together with recent reports[5,7], show that CNAs and somatic mutations identified in ctDNA are widely representative of the tumour genome and provide an alternative method of tumour sampling that can overcome limitations of repeated biopsies. Cell-free DNA fragments from multiple lesions in the same individual all mix together in the peripheral blood5, therefore ctDNA is likely to contain a wider representation of the genomes from multiple metastatic sites, whereas mutations present in a single biopsy or minor sub-clone may be missed. This strengthens the case for the use of ctDNA as a biomarker for monitoring tumour burden or for

the analysis of hotspot mutation regions[1,6,16,17], but also indicates that tracking different mutations for assessment of tumour heterogeneity and clonal evolution is now possible."

17. Claims 14-16 are rejected under 35 U.S.C. 103 as being unpatentable over Diehn et al. (US 2016/0032396 A1; with a filing date of March 12, 2014; newly cited), Mertes et al. (Brief. Funct. Genomics, vol. 10, pp. 374-386, 2011; cited in the IDS; previously cited), Nguyen-Dumont et al. (Biotechniques, vol. 55, pp. 69-74, 2013; cited in the IDS; previously cited) and Wang et al. (Science, vol. 280, pp. 1077-1082, 1998; previously cited).

A) Regarding claims 14 and 15, Diehn et al. teach detection of mutations in 10 to 300 genomic regions ([0047]). They teach selection of the regions to be sequenced using amplification, but they do not teach multiplex PCR.

Regarding claim 16, Diehn et al. teach high-throughput sequencing (claim 12; [0053]; [0137]).

B) Mertes et al. teach that selection and enrichment of sequences to be used in next generation sequencing (NGS) can be performed using one of three methods: hybrid capture, selective circularization and PCR (page 375, fourth paragraph; Fig. 1; page 379, last two paragraphs; page 380, paragraphs 1-3).

It would have been *prima facie* obvious to one of ordinary skill in the art before the effective filing date of the claimed invention to have used multiplex amplification as suggested by Mertes et al. in the method of whole exome sequencing of Diehn et al. The motivation to do so is provided by Mertes et al. (page 379, fifth paragraph):

"Enrichment by PCR (Figures 1.3a–c) is in terms of methodology, a more straightforward method compared with the other genome partioning techniques. It takes advantage of the great power of PCR to enrich genome regions from small amounts of target material. Just as for circularization methods, if the PCR product sizes fall within the sequencing length of the applied

NGS platform (maximum read length for SOLiD: 110 bp, Illumina: 240 bp and 454: 1000 bp) PCR-based enrichment can allow one to bypass the need for shot-gun library preparation by using suitably 50-tailed primers in the final amplification steps."

The reasonable expectation of success is provided by the references of Nguyen-Dumont et al. and Wang et al. Nguyen-Dumont et al. teach successful amplification of 60 different target in a single PCR reaction (Abstract; page 70, third paragraph; page 72, paragraphs 4 and 5).

Wang et al. teach multiplex amplification of target genomic fragments for detection of SNPs on microarrays. They teach successful amplification and mapping of 23, 46 and 92 loci (page 1080, paragraphs 1-4).

Double Patenting

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting

provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP §§ 706.02(l)(1) - 706.02(l)(3) for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

19. Claims 1-3, 7, 11, 12, 14-16, 20, 23 and 24 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-4, 8, 12-14, 16, 19, 22 and 23 of copending Application No. 16/288,416 (reference application). Although the claims at issue are not identical, they are not patentably distinct from each other because the instant claims are obvious over claims of the ‘416 application.

Specifically, claim 1 of the instant application is drawn to a method for preparing biological samples useful for monitoring the progression of cancer in a subject comprising:

(a) performing sequencing on a tumor biopsy sample of the subject to identify a plurality of tumor-specific mutations;

(b) evaluating results of the sequencing on the tumor biopsy sample to determine a plurality of target loci specific to the subject, wherein each target locus spans a tumor-specific mutation of the identified plurality of tumor specific mutations; and

(c) assaying cell-free DNA isolated from a plurality of biological samples obtained from the subject at different time points, wherein assaying comprises:

amplifying the isolated cell-free DNA using primers specific to the plurality of target loci for the individual subject; and

sequencing the amplified DNA comprising the plurality of target loci.

Claim 1 of the '416 application is drawn to a method for preparing cell-free DNA for use in monitoring the progression of cancer comprising:

(a) evaluating results of sequencing on a tumor biopsy sample of a subject to determine a plurality of target loci specific to the subject, wherein each target locus spans a tumor-specific mutation of a plurality of tumor specific mutations identified in the tumor biopsy sample;

(b) performing a multiplex amplification reaction to amplify the plurality of target loci from cell-free DNA isolated from a first biological sample of the subject; and

(c) determining the sequences of the amplified target loci.

Claim 25 of the '416 application is drawn to the method of claim 1, further comprising:
(d) determining the presence or absence of tumor specific mutations based on the sequencing results of step (c).

Claim 2 of the '416 application is drawn to the method of claim 25, further comprising:

(e) repeating steps (a)-(d) on cell-free DNA isolated from a second biological sample obtained from the subject at a subsequent time point.

Therefore claim 2 of the '416 application anticipates claims 1 and 14 of the instant application. Instant claims 2, 3, 7, 11, 12, 14-16, 20, 23 and 24 are obvious over claims 3, 4, 8, 12, 14, 16, 23, 19, 22 and 13, respectively.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

20. Claims 1-3, 7, 11, 12, 14-16, 20, 23 and 24 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-4, 8, 12-14, 16, 19, 22 and 23 of copending Application No. 16/288,462 (reference application). Although the claims at issue are not identical, they are not patentably distinct from each other because the instant claims are obvious over claims of the '462 application.

Specifically, claim 1 of the instant application is drawn to a method for preparing biological samples useful for monitoring the progression of cancer in a subject comprising:

(a) performing sequencing on a tumor biopsy sample of the subject to identify a plurality of tumor-specific mutations;

(b) evaluating results of the sequencing on the tumor biopsy sample to determine a plurality of target loci specific to the subject, wherein each target locus spans a tumor-specific mutation of the identified plurality of tumor specific mutations; and

(c) assaying cell-free DNA isolated from a plurality of biological samples obtained from the subject at different time points, wherein assaying comprises:

amplifying the isolated cell-free DNA using primers specific to the plurality of target loci for the individual subject; and

sequencing the amplified DNA comprising the plurality of target loci.

Claim 1 of the '462 application is drawn to a method for preparing cell-free DNA for use in monitoring the progression of cancer comprising:

(a) evaluating results of sequencing on a tumor biopsy sample of a subject to determine a plurality of target loci specific to the subject, wherein each target locus spans a tumor-specific mutation of a plurality of tumor specific mutations identified in the tumor biopsy sample;

(b) determining the sequences of the amplified target loci, wherein the amplified target loci are amplified from the plurality of target loci determined in step (a) performing in cell-free DNA isolated from a first biological sample of the subject.

Claim 25 of the '462 application is drawn to the method of claim 1, further comprising:

(c) determining the presence or absence of tumor specific mutations based on the sequencing results.

Claim 2 of the '462 application is drawn to the method of claim 25, further comprising:

(d) repeating steps (a)-(c) on a plurality of amplified target loci amplified from cell-free DNA isolated from a second biological sample obtained from the subject at a subsequent time point..

Therefore claim 2 of the '462 application anticipates claims 1 and 14 of the instant application. Instant claims 2, 3, 7, 11, 12, 14-16, 20, 23 and 24 are obvious over claims 3, 4, 8, 12, 14, 16, 23, 19, 22 and 13, respectively.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

21. Claims 1-3, 7, 11, 12, 14-16, 20, 23 and 24 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 2, 5-7, 11, 15, 19, 21 and 22 of copending Application No. 16/399,941 (reference application). Although the claims at issue are

not identical, they are not patentably distinct from each other because the instant claims are obvious over claims of the '941 application.

Specifically, claim 1 of the instant application is drawn to a method for preparing biological samples useful for monitoring the progression of cancer in a subject comprising:

(a) performing sequencing on a tumor biopsy sample of the subject to identify a plurality of tumor-specific mutations;

(b) evaluating results of the sequencing on the tumor biopsy sample to determine a plurality of target loci specific to the subject, wherein each target locus spans a tumor-specific mutation of the identified plurality of tumor specific mutations; and

(c) assaying cell-free DNA isolated from a plurality of biological samples obtained from the subject at different time points, wherein assaying comprises:

amplifying the isolated cell-free DNA using primers specific to the plurality of target loci for the individual subject; and

sequencing the amplified DNA comprising the plurality of target loci.

Claim 2 of the '941 application is drawn to method for monitoring the progression of cancer comprising:

(a) performing whole exome sequencing of a tumor biopsy sample of a subject to identify tumor-specific mutations and determining clonal heterogeneity thereof;

(b) performing a multiplex amplification reaction to amplify at least 10 different target loci from cell-free DNA isolated from a first biological sample of the subject in a single reaction volume, wherein the target loci each spans a mutation identified in the tumor biopsy sample of the subject in step (a), and wherein the multiplex amplification comprises

nested PCR which comprises a first PCR reaction with a first universal primer and a first set of target-specific primers and a second PCR reaction with a second universal primer and a second set of target-specific primers;

(c) performing high throughput sequencing to sequence the amplified target loci obtained in the multiplex amplification reaction; and

(d) determining the presence of the mutations based on the sequencing results, thereby monitoring the progression of cancer.

Claim 5 of the '941 application is drawn to the method of claim 2, further comprising:

(d) repeating steps (a)-(c) on cell-free DNA isolated from a second biological sample obtained from the subject at a subsequent time point.

Therefore claim 5 of the '941 application anticipates instant claims 1, 12, 14-16 and 24. Instant claims 2, 3, 7, 11, 16, 20 and 23 are obvious over claims 6, 7, 9, 11, 12, 15, 21 and 23 of the '941 application.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

22. No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TERESA E STRZELECKA whose telephone number is (571)272-0789. The examiner can normally be reached on M-F 9-7.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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 https://ppair-my.uspto.gov/pair/PrivatePair. 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.

/TERESA E STRZELECKA/
Primary Examiner, Art Unit 1637
December 23, 2020

Notice of References Cited	Application/Control No. 16/288,351	Applicant(s)/Patent Under Reexamination BABIARZ et al.	
	Examiner TERESA E STRZELECKA	Art Unit 1637	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20160032396-A1	02-2016	Diehn; Maximilian	G16B30/00	506/2
	B					
	C					
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/288,351	BABIARZ et al.
	Examiner	**Art Unit**
	TERESA E STRZELECKA	1637

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	06/10/2020	12/23/2020							
	1	✓	✓							
	2	✓	✓							
	3	✓	✓							
	4	N	N							
	5	✓	-							
	6	N	N							
	7	✓	✓							
	8	✓	-							
	9	N	N							
	10	N	N							
	11	✓	✓							
	12	✓	✓							
	13	N	N							
	14	✓	✓							
	15	✓	✓							
	16	✓	✓							
	17	N	N							
	18	N	N							
	19	N	N							
	20	✓	✓							
	21	N	N							
	22	N	N							
	23	✓	✓							
	24	✓	✓							
	25		✓							
	26		✓							

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/288,351	BABIARZ et al.
	Examiner	Art Unit
	TERESA E STRZELECKA	1637

CPC - Searched*		
Symbol	Date	Examiner
C12Q1/6869 |C12Q2600/156 | G16B20/20 plus text search	12/22/2020	/TS/

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
Inventor name search	06/08/2020	/TS/
WEST	06/10/2020	/TS/
IDS (10/24/19; 3/10/20; 4/20/20; 5/4/20)	06/10/2020	/TS/
Pubmed	06/10/2020	/TS/
IDS (11/16/20)	12/18/2020	/TS/
Google	12/22/2020	/TS/
WEST	12/22/2020	/TS/

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/288,351	BABIARZ et al.
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Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

NeoGenomics
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PTO/SB/08a (01-10)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/288,351
	Filing Date	Feb 28, 2019
	First Named Inventor	Joshua BABIARZ
	Art Unit	1637
	Examiner Name	Teresa E. Strzelecka
	Attorney Docket Number	N.012.US.10

U.S. PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/288,351
	Filing Date	Feb 28, 2019
	First Named Inventor	Joshua BABIARZ
	Art Unit	1637
	Examiner Name	Teresa E. Strzelecka
	Attorney Docket Number	N.012.US.10

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EXAMINER SIGNATURE

Examiner Signature	/TERESA E STRZELECKA/	Date Considered	12/18/2020

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

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Web Search History

date, time	web site	search string
12/22/2020 1:56:01 PM	Google	cell-free DNA mutations sequencing barcode
12/22/2020 2:30:17 PM	Google	plos one
12/22/2020 2:34:18 PM	Google	sequencing data transfer cloud

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WEST Search History for Application 16288351

Creation Date: 2020122215:37

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(US-5635366-$ | US-5716776-$ | US-5753467-$ | US-5824467-$ | US-5860917-$ | US-5972602-$ | US-5994148-$ | US-6001611-$ | US-6025128-$ | US-6066454-$ | US-6100029-$ | US-6108635-$ | US-6124120-$ | US-6143496-$ | US-6156504-$ | US-6180349-$ | US-6214558-$ | US-6258540-$ | US-6300077-$ | US-6440706-$ | US-6479235-$ | US-6489135-$ | US-6720140-$ | US-6794140-$ | US-6807491-$ | US-6852487-$ | US-6958211-$ | US-6964847-$ | US-7035739-$ | US-7058517-$ | US-7058616-$ | US-7218764-$ | US-7297485-$ | US-7332277-$ | US-7414118-$ | US-7442506-$ | US-7459273-$ | US-7645576-$ | US-7700325-$ | US-7718367-$ | US-7718370-$ | US-7727720-$ | US-7805282-$ | US-7838647-$ | US-7888017-$ | US-8008018-$ | US-8024128-$ | US-8133719-$ | US-8137912-$ | US-8168389-$ | US-8173370-$ | US-8195415-$ | US-8296076-$ | US-8304187-$ | US-8318430-$ | US-8450063-$ | US-8467976-$ | US-8515679-$ | US-8532930-$ | US-8682592-$ | US-8825412-$ | US-9085798-$ | US-9323888-$ | US-9476095-$ | US-9487829-$ | US-9598731-$ | US-9677118-$).DID.						
((US-5635366-$ | US-5716776-$ | US-5753467-$ | US-5824467-$ | US-5860917-$ | US-5972602-$ | US-5994148-$ | US-6001611-$ | US-6025128-$ | US-6066454-$ | US-6100029-$ | US-6108635-$ | US-6124120-$ | US-6143496-$ | US-6156504-$ | US-6180349-$ | US-6214558-$ | US-6258540-$ | US-6300077-$ | US-6440706-$ | US-6479235-$ | US-6489135-$ | US-6720140-$ | US-6794140-$ | US-6807491-$ | US-6852487-$ | US-6958211-$ | US-6964847-$ | US-7035739-$ | US-7058517-$ | US-7058616-$ | US-7218764-$ | US-7297485-$ | US-7332277-$ | US-7414118-$ | US-7442506-$ | US-7459273-$ | US-7645576-$ | US-7700325-$ | US-7718367-$ | US-7718370-$ | US-7727720-$ | US-7805282-$ | US-7838647-$ | US-7888017-$ | US-8008018-$ | US-8024128-$ | US-8133719-$ | US-8137912-$ | US-8168389-$ | US-8173370-$ | US-8195415-$ | US-8296076-$ | US-8304187-$ | US-8318430-$ | US-8450063-$ | US-8467976-$ |	USPT	27	ADJ	YES	ASSIGNEE	06-10-2020

US-8515679-$ | US-8532930-$ | US-8682592-$ | US-8825412-$ | US-9085798-$ | US-9323888-$ | US-9476095-$ | US-9487829-$ | US-9598731-$ | US-9677118-$).DID.) and (cell-free or cell free or circulat$5) near3 (DNA or RNA or nucleic)						
((US-5635366-$ | US-5716776-$ | US-5753467-$ | US-5824467-$ | US-5860917-$ | US-5972602-$ | US-5994148-$ | US-6001611-$ | US-6025128-$ | US-6066454-$ | US-6100029-$ | US-6108635-$ | US-6124120-$ | US-6143496-$ | US-6156504-$ | US-6180349-$ | US-6214558-$ | US-6258540-$ | US-6300077-$ | US-6440706-$ | US-6479235-$ | US-6489135-$ | US-6720140-$ | US-6794140-$ | US-6807491-$ | US-6852487-$ | US-6958211-$ | US-6964847-$ | US-7035739-$ | US-7058517-$ | US-7058616-$ | US-7218764-$ | US-7297485-$ | US-7332277-$ | US-7414118-$ | US-7442506-$ | US-7459273-$ | US-7645576-$ | US-7700325-$ | US-7718367-$ | US-7718370-$ | US-7727720-$ | US-7805282-$ | US-7838647-$ | US-7888017-$ | US-8008018-$ | US-8024128-$ | US-8133719-$ | US-8137912-$ | US-8168389-$ | US-8173370-$ | US-8195415-$ | US-8296076-$ | US-8304187-$ | US-8318430-$ | US-8450063-$ | US-8467976-$ | US-8515679-$ | US-8532930-$ | US-8682592-$ | US-8825412-$ | US-9085798-$ | US-9323888-$ | US-9476095-$ | US-9487829-$ | US-9598731-$ | US-9677118-$).DID. and (cell-free or cell free or circulat$5) near3 (DNA or RNA or nucleic)) and (tumor or cancer)	USPT	25	ADJ	YES	ASSIGNEE	06-10-2020
((US-5635366-$ | US-5716776-$ | US-5753467-$ | US-5824467-$ | US-5860917-$ | US-5972602-$ | US-5994148-$ | US-6001611-$ | US-6025128-$ | US-6066454-$ | US-6100029-$ | US-6108635-$ | US-6124120-$ | US-6143496-$ | US-6156504-$ | US-6180349-$ | US-6214558-$ | US-6258540-$ | US-6300077-$ | US-6440706-$ | US-6479235-$ | US-6489135-$ | US-6720140-$ | US-6794140-$ | US-6807491-$ | US-6852487-$ | US-6958211-$ | US-6964847-$ | US-7035739-$ | US-7058517-$ | US-7058616-$ | US-7218764-$ |	USPT	n/a	ADJ	YES	ASSIGNEE	06-10-2020

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US-7297485-$ | US-7332277-$ | US-7414118-$ | US-7442506-$ | US-7459273-$ | US-7645576-$ | US-7700325-$ | US-7718367-$ | US-7718370-$ | US-7727720-$ | US-7805282-$ | US-7838647-$ | US-7888017-$ | US-8008018-$ | US-8024128-$ | US-8133719-$ | US-8137912-$ | US-8168389-$ | US-8173370-$ | US-8195415-$ | US-8296076-$ | US-8304187-$ | US-8318430-$ | US-8450063-$ | US-8467976-$ | US-8515679-$ | US-8532930-$ | US-8682592-$ | US-8825412-$ | US-9085798-$ | US-9323888-$ | US-9476095-$ | US-9487829-$ | US-9598731-$ | US-9677118-$).DID. and (cell-free or cell free or circulat$5) near3 (DNA or RNA or nucleic) and (tumor or cancer)) and lung (near3 tumor or cancer)						
((US-5635366-$ | US-5716776-$ | US-5753467-$ | US-5824467-$ | US-5860917-$ | US-5972602-$ | US-5994148-$ | US-6001611-$ | US-6025128-$ | US-6066454-$ | US-6100029-$ | US-6108635-$ | US-6124120-$ | US-6143496-$ | US-6156504-$ | US-6180349-$ | US-6214558-$ | US-6258540-$ | US-6300077-$ | US-6440706-$ | US-6479235-$ | US-6489135-$ | US-6720140-$ | US-6794140-$ | US-6807491-$ | US-6852487-$ | US-6958211-$ | US-6964847-$ | US-7035739-$ | US-7058517-$ | US-7058616-$ | US-7218764-$ | US-7297485-$ | US-7332277-$ | US-7414118-$ | US-7442506-$ | US-7459273-$ | US-7645576-$ | US-7700325-$ | US-7718367-$ | US-7718370-$ | US-7727720-$ | US-7805282-$ | US-7838647-$ | US-7888017-$ | US-8008018-$ | US-8024128-$ | US-8133719-$ | US-8137912-$ | US-8168389-$ | US-8173370-$ | US-8195415-$ | US-8296076-$ | US-8304187-$ | US-8318430-$ | US-8450063-$ | US-8467976-$ | US-8515679-$ | US-8532930-$ | US-8682592-$ | US-8825412-$ | US-9085798-$ | US-9323888-$ | US-9476095-$ | US-9487829-$ | US-9598731-$ | US-9677118-$).DID. and (cell-free or cell free or circulat$5) near3 (DNA or RNA or nucleic) and (tumor or cancer)) and lung near3 (tumor or cancer)	USPT	13	ADJ	YES	ASSIGNEE	06-10-2020
(US-20060210997-$ | US-20060216738-$ | US-20060281105-$ | US-20070020640-$ |	PGPB	154	ADJ	YES	ASSIGNEE	06-10-2020

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US-20070042384-$ | US-20070128624-$ |						
US-20070027636-$ | US-20070059707-$ |						
US-20070122805-$ | US-20070178478-$ |						
US-20070178501-$ | US-20070184467-$ |						
US-20070202525-$ | US-20070202536-$ |						
US-20070207466-$ | US-20070212689-$ |						
US-20070243549-$ | US-20070259351-$ |						
US-20080090239-$ | US-20080138809-$ |						
US-20080220422-$ | US-20080020390-$ |						
US-20080026390-$ | US-20080038733-$ |						
US-20080070792-$ | US-20080071076-$ |						
US-20080085836-$ | US-20080096766-$ |						
US-20080102455-$ | US-20080182244-$ |						
US-20080193927-$ | US-20080234142-$ |						
US-20080243398-$ | US-20080305473-$ |						
US-20090143570-$ | US-20090023190-$ |						
US-20090029377-$ | US-20090087847-$ |						
US-20090098534-$ | US-20090099041-$ |						
US-20090176662-$ | US-20090221620-$ |						
US-20090317817-$ | US-20100129874-$ |						
US-20100273678-$ | US-20100035232-$ |						
US-20100112575-$ | US-20100112590-$ |						
US-20100120038-$ | US-20100124751-$ |						
US-20100138165-$ | US-20100171954-$ |						
US-20100184069-$ | US-20100184152-$ |						
US-20100196892-$ | US-20100203538-$ |						
US-20100216153-$ | US-20100248231-$ |						
US-20100255492-$ | US-20100256013-$ |						
US-20100285537-$ | US-20100291572-$ |						
US-20100291635-$ | US-20100323352-$ |						
US-20110071031-$ | US-20110159499-$ |						
US-20110160078-$ | US-20110033862-$ |						
US-20110039724-$ | US-20110086769-$ |						
US-20110092763-$ | US-20110105353-$ |						
US-20110151442-$ | US-20110178719-$ |						
US-20110201507-$ | US-20110224087-$ |						
US-20110246083-$ | US-20110251149-$ |						
US-20110288780-$ | US-20110300608-$ |						
US-20110318734-$ | US-20120010085-$ |						
US-20120295819-$ | US-20120003635-$ |						
US-20120034603-$ | US-20120122701-$ |						
US-20120165203-$ | US-20120185176-$ |						
US-20120190020-$ | US-20120190021-$ |						
US-20120191358-$ | US-20120196754-$ |						
US-20120214678-$ | US-20120264121-$ |						
US-20120270212-$ | US-20130116130-$ |						
US-20130130923-$ | US-20130017549-$ |						
US-20130024127-$ | US-20130034546-$ |						
US-20130060483-$ | US-20130069869-$ |						
US-20130090250-$ | US-20130123120-$ |						
US-20130178373-$ | US-20130190653-$ |						

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US-20130196862-$ | US-20130210644-$ | US-20130225422-$ | US-20130252824-$ | US-20130253369-$ | US-20130261004-$ | US-20130274116-$ | US-20130303461-$ | US-20130323731-$ | US-20130325360-$ | US-20140038830-$ | US-20140227705-$ | US-20140256558-$ | US-20140272956-$ | US-20140287934-$ | US-20140032128-$ | US-20140051585-$ | US-20140065621-$ | US-20140087385-$ | US-20140094373-$ | US-20140100126-$ | US-20140100134-$ | US-20140141981-$ | US-20140154682-$ | US-20140155274-$ | US-20140162269-$ | US-20140193816-$ | US-20140206552-$ | US-20140256569-$ | US-20140329245-$ | US-20140336060-$ | US-20150197786-$ | US-20150265995-$ | US-20150051087-$ | US-20150064695-$ | US-20150147815-$ | US-20150232938-$ | US-20160201124-$ | US-20160257993-$ | US-20160289740-$ | US-20160289753-$ | US-20160312276-$ | US-20160319345-$ | US-20160145682-$ | US-20160369333-$ | US-20170121716-$ | US-20170342477-$ | US-20180148777-$).DID.						
((US-20060210997-$ | US-20060216738-$ | US-20060281105-$ | US-20070020640-$ | US-20070042384-$ | US-20070128624-$ | US-20070027636-$ | US-20070059707-$ | US-20070122805-$ | US-20070178478-$ | US-20070178501-$ | US-20070184467-$ | US-20070202525-$ | US-20070202536-$ | US-20070207466-$ | US-20070212689-$ | US-20070243549-$ | US-20070259351-$ | US-20080090239-$ | US-20080138809-$ | US-20080220422-$ | US-20080020390-$ | US-20080026390-$ | US-20080038733-$ | US-20080070792-$ | US-20080071076-$ | US-20080085836-$ | US-20080096766-$ | US-20080102455-$ | US-20080182244-$ | US-20080193927-$ | US-20080234142-$ | US-20080243398-$ | US-20080305473-$ | US-20090143570-$ | US-20090023190-$ | US-20090029377-$ | US-20090087847-$ | US-20090098534-$ | US-20090099041-$ | US-20090176662-$ | US-20090221620-$ | US-20090317817-$ | US-20100129874-$ | US-20100273678-$ | US-20100035232-$ | US-20100112575-$ | US-20100112590-$ | US-20100120038-$ | US-20100124751-$ | US-20100138165-$ | US-20100171954-$ |	PGPB	14	ADJ	YES	ASSIGNEE	06-10-2020

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US-20100184069-$ | US-20100184152-$ |						
US-20100196892-$ | US-20100203538-$ |						
US-20100216153-$ | US-20100248231-$ |						
US-20100255492-$ | US-20100256013-$ |						
US-20100285537-$ | US-20100291572-$ |						
US-20100291635-$ | US-20100323352-$ |						
US-20110071031-$ | US-20110159499-$ |						
US-20110160078-$ | US-20110033862-$ |						
US-20110039724-$ | US-20110086769-$ |						
US-20110092763-$ | US-20110105353-$ |						
US-20110151442-$ | US-20110178719-$ |						
US-20110201507-$ | US-20110224087-$ |						
US-20110246083-$ | US-20110251149-$ |						
US-20110288780-$ | US-20110300608-$ |						
US-20110318734-$ | US-20120010085-$ |						
US-20120295819-$ | US-20120003635-$ |						
US-20120034603-$ | US-20120122701-$ |						
US-20120165203-$ | US-20120185176-$ |						
US-20120190020-$ | US-20120190021-$ |						
US-20120191358-$ | US-20120196754-$ |						
US-20120214678-$ | US-20120264121-$ |						
US-20120270212-$ | US-20130116130-$ |						
US-20130130923-$ | US-20130017549-$ |						
US-20130024127-$ | US-20130034546-$ |						
US-20130060483-$ | US-20130069869-$ |						
US-20130090250-$ | US-20130123120-$ |						
US-20130178373-$ | US-20130190653-$ |						
US-20130196862-$ | US-20130210644-$ |						
US-20130225422-$ | US-20130252824-$ |						
US-20130253369-$ | US-20130261004-$ |						
US-20130274116-$ | US-20130303461-$ |						
US-20130323731-$ | US-20130325360-$ |						
US-20140038830-$ | US-20140227705-$ |						
US-20140256558-$ | US-20140272956-$ |						
US-20140287934-$ | US-20140032128-$ |						
US-20140051585-$ | US-20140065621-$ |						
US-20140087385-$ | US-20140094373-$ |						
US-20140100126-$ | US-20140100134-$ |						
US-20140141981-$ | US-20140154682-$ |						
US-20140155274-$ | US-20140162269-$ |						
US-20140193816-$ | US-20140206552-$ |						
US-20140256569-$ | US-20140329245-$ |						
US-20140336060-$ | US-20150197786-$ |						
US-20150265995-$ | US-20150051087-$ |						
US-20150064695-$ | US-20150147815-$ |						
US-20150232938-$ | US-20160201124-$ |						
US-20160257993-$ | US-20160289740-$ |						
US-20160289753-$ | US-20160312276-$ |						
US-20160319345-$ | US-20160145682-$ |						
US-20160369333-$ | US-20170121716-$ |						
US-20170342477-$ | US-20180148777-$).DID.						

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) and (cell-free or cell free or circulat$5) near3 (DNA or RNA or nucleic) and lung near3 (cancer or tumor)						
(US-20180155775-$ | US-20180155776-$ | US-20180155779-$ | US-20180155785-$ | US-20180155786-$ | US-20180155792-$ | US-20180171409-$ | US-20180171420-$ | US-20180173845-$ | US-20180173846-$ | US-20180201995-$ | US-20180237841-$ | US-20180298439-$ | US-20180300448-$ | US-20190010543-$ | US-20190106737-$ | US-20190106751-$ | US-20190185913-$ | US-20190185936-$ | US-20190194743-$ | US-20190194759-$ | US-20190203290-$ | US-20190203294-$).DID.	PGPB	23	ADJ	YES	ASSIGNEE	06-10-2020
((US-20180155775-$ | US-20180155776-$ | US-20180155779-$ | US-20180155785-$ | US-20180155786-$ | US-20180155792-$ | US-20180171409-$ | US-20180171420-$ | US-20180173845-$ | US-20180173846-$ | US-20180201995-$ | US-20180237841-$ | US-20180298439-$ | US-20180300448-$ | US-20190010543-$ | US-20190106737-$ | US-20190106751-$ | US-20190185913-$ | US-20190185936-$ | US-20190194743-$ | US-20190194759-$ | US-20190203290-$ | US-20190203294-$).DID.) and (cell-free or cell free or circulat$5) near3 (DNA or RNA or nucleic) and lung near3 (cancer or tumor)	PGPB	7	ADJ	YES	ASSIGNEE	06-10-2020
(US-20180155775-$ | US-20180155776-$ | US-20180155779-$ | US-20180155785-$ | US-20180155786-$ | US-20180155792-$ | US-20180171409-$ | US-20180171420-$ | US-20180173845-$ | US-20180173846-$ | US-20180201995-$ | US-20180237841-$ | US-20180298439-$ | US-20180300448-$ | US-20190010543-$ | US-20190106737-$ | US-20190106751-$ | US-20190185913-$ | US-20190185936-$ | US-20190194743-$ | US-20190194759-$ | US-20190203290-$ | US-20190203294-$ | US-20190211391-$ | US-20190211392-$ | US-20190211393-$ | US-20190211399-$ | US-20190211402-$ | US-20190211406-$ | US-20190249241-$ | US-20190256906-$ | US-20190256907-$ | US-20190256909-$ | US-20190256916-$ | US-20190256917-$ | US-20190264277-$ | US-20190264280-$ | US-20190264288-$ | US-20190271043-$ | US-20190276888-$ |	PGPB	46	ADJ	YES	ASSIGNEE	06-10-2020

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US-20190284623-$ | US-20190300950-$ | US-20190309358-$ | US-20190309359-$ | US-20190309365-$ | US-20190316184-$).DID.						
((US-20180155775-$ | US-20180155776-$ | US-20180155779-$ | US-20180155785-$ | US-20180155786-$ | US-20180155792-$ | US-20180171409-$ | US-20180171420-$ | US-20180173845-$ | US-20180173846-$ | US-20180201995-$ | US-20180237841-$ | US-20180298439-$ | US-20180300448-$ | US-20190010543-$ | US-20190106737-$ | US-20190106751-$ | US-20190185913-$ | US-20190185936-$ | US-20190194743-$ | US-20190194759-$ | US-20190203290-$ | US-20190203294-$ | US-20190211391-$ | US-20190211392-$ | US-20190211393-$ | US-20190211399-$ | US-20190211402-$ | US-20190211406-$ | US-20190249241-$ | US-20190256906-$ | US-20190256907-$ | US-20190256909-$ | US-20190256916-$ | US-20190256917-$ | US-20190264277-$ | US-20190264280-$ | US-20190264288-$ | US-20190271043-$ | US-20190276888-$ | US-20190284623-$ | US-20190300950-$ | US-20190309358-$ | US-20190309359-$ | US-20190309365-$ | US-20190316184-$).DID.) and (cell-free or cell free or circulat$5) near3 (DNA or RNA or nucleic) and lung near3 (cancer or tumor)	PGPB	10	ADJ	YES	ASSIGNEE	06-10-2020
("10081839" | "10083273" | "10308981" | "10316362").pn.	PGPB	0	ADJ	YES	ASSIGNEE	06-10-2020
("10081839" | "10083273" | "10308981" | "10316362").pn.	USPT	4	ADJ	YES	ASSIGNEE	06-10-2020
("20010051341" | "20010053519" | "20020006622" | "20020107640" | "20030009295" | "20030065535" | "20030077586" | "20030101000" | "20030119004" | "20030228613" | "20040033596" | "20040137470" | "20040146866" | "20040157243" | "20040197797" | "20040209299" | "20040229231" | "20040236518" | "20040259100" | "20050009069" | "20050049793" | "20050053950" | "20050079535" | "20050123914" | "20050130173" | "20050142577" | "20050144664" | "20050164241" | "20050216207" | "20050221341" |	PGPB	49	ADJ	YES	ASSIGNEE	06-10-2020

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"20050227263" | "20050250111" | "20050255508" | "20050272073" | "20060019278" | "20060040300" | "20060052945" | "20060057618" | "20060068394" | "20060088574" | "20060099614" | "20060121452" | "20060134662" | "20060141499" | "20060210997" | "20060216738" | "20060229823" | "20060248031" | "20060281105").PN.						
(("20010051341" | "20010053519" | "20020006622" | "20020107640" | "20030009295" | "20030065535" | "20030077586" | "20030101000" | "20030119004" | "20030228613" | "20040033596" | "20040137470" | "20040146866" | "20040157243" | "20040197797" | "20040209299" | "20040229231" | "20040236518" | "20040259100" | "20050009069" | "20050049793" | "20050053950" | "20050079535" | "20050123914" | "20050130173" | "20050142577" | "20050144664" | "20050164241" | "20050216207" | "20050221341" | "20050227263" | "20050250111" | "20050255508" | "20050272073" | "20060019278" | "20060040300" | "20060052945" | "20060057618" | "20060068394" | "20060088574" | "20060099614" | "20060121452" | "20060134662" | "20060141499" | "20060210997" | "20060216738" | "20060229823" | "20060248031" | "20060281105").PN.) and (cell-free or cell free or circulat$5) near3 (DNA or RNA or nucleic) and lung near3 (cancer or tumor)	PGPB	3	ADJ	YES	ASSIGNEE	06-10-2020
Natera.asn. and (cell-free or cell free or circulat$5) near3 (DNA or RNA or nucleic) and (cancer or tumor) and sequencing and progress$8	PGPB	27	ADJ	YES	ASSIGNEE	06-10-2020
Natera.asn. and (cell-free or cell free or circulat$5) near3 (DNA or RNA or nucleic) and (cancer or tumor) and sequencing and progress$8	USPT	12	ADJ	YES	ASSIGNEE	06-10-2020
(cell-free or cell free or circulat$5) near3 (DNA or RNA or nucleic) and (cancer or tumor) and sequencing and (mutation or	PGPB	141	ADJ	YES	ASSIGNEE	06-10-2020

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variant or alteration or polymorphism or SNP) near3 (clonal or subclonal or sub-clonal)						
((cell-free or cell free or circulat$5) near3 (DNA or RNA or nucleic) and (cancer or tumor) and sequencing and (mutation or variant or alteration or polymorphism or SNP) near3 (clonal or subclonal or sub-clonal)) and tumor near3 heterogen$8	PGPB	72	ADJ	YES	ASSIGNEE	06-10-2020
((cell-free or cell free or circulat$5) near3 (DNA or RNA or nucleic) and (cancer or tumor) and sequencing and (mutation or variant or alteration or polymorphism or SNP) near3 (clonal or subclonal or sub-clonal)) and tumor near3 heterogen$8	PGPB	72	ADJ	YES	ASSIGNEE	06-10-2020
(cell-free or cell free or circulat$5) near3 (DNA or RNA or nucleic) and (cancer or tumor) and sequencing and (mutation or variant or alteration or polymorphism or SNP) near3 (clonal or subclonal or sub-clonal)	USPT	70	ADJ	YES	ASSIGNEE	06-10-2020
((cell-free or cell free or circulat$5) near3 (DNA or RNA or nucleic) and (cancer or tumor) and sequencing and (mutation or variant or alteration or polymorphism or SNP) near3 (clonal or subclonal or sub-clonal)) and tumor near3 heterogen$8	USPT	22	ADJ	YES	ASSIGNEE	06-10-2020
(cell-free or cell free or circulat$5) near3 (DNA or RNA or nucleic) and (cancer or tumor) and sequencing and (mutation or variant or alteration or polymorphism or SNP) near3 (clonal or subclonal or sub-clonal)	PGPB	141	ADJ	YES	ASSIGNEE	06-10-2020
(cell-free or cell free or circulat$5) near3 (DNA or RNA or nucleic) and (cancer or tumor) and sequencing and (mutation or variant or alteration or polymorphism or SNP) near3 (clonal or subclonal or sub-clonal)	DWPI	6	ADJ	YES	ASSIGNEE	06-10-2020
US-20150087535-A1.did.	PGPB	1	ADJ	YES	ASSIGNEE	06-10-2020
("10179937" | "10597708" | "10711309" | "10731220" | "10774380" | "10793912" | "20040009518" | "20110130558" | "20120270739" | "20150315657" | "20160244838" | "20170107576" |	PGPB, USPT	28	ADJ	YES	ASSIGNEE	12-22-2020

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"20200181697" | "20200190570" | "20200190573" | "20200190591" | "20200208196" | "20200208221" | "20200224273" | "20200232036" | "20200232037" | "20200248264" | "20200248266" | "20200318191" | "20200347454" | "20200350034" | "6927028" | "7410764").PN.						
Guardant Health.asn. and (cell-free or cell free or circulat$8) near3 (DNA or nucleic) and (cell-free or cell free or circulat$8) near3 barcod$8 and sequencing and (mutation or polymorphism or SNV) near3 detect$8	PGPB	3	ADJ	YES	ASSIGNEE	12-22-2020
14/425589.app.	PGPB	1	ADJ	YES	ASSIGNEE	12-22-2020
14/425189.app.	PGPB	1	ADJ	YES	ASSIGNEE	12-22-2020
16/288351.app.	PGPB	1	ADJ	YES	ASSIGNEE	12-22-2020
(cell-free or cell free or circulat$8) near3 (DNA or nucleic) and (cell-free or cell free or circulat$8) near3 barcod$8 and sequencing and (mutation or polymorphism or SNV) near3 detect$8 and ((C12Q1/6869 | C12Q2600/156 | G16B20/20).CPC.)	PGPB	48	ADJ	YES	ASSIGNEE	12-22-2020
(cell-free or cell free or circulat$8) near3 (DNA or nucleic) and (cell-free or cell free or circulat$8) near3 barcod$8 and sequencing and (mutation or polymorphism or SNV) near3 detect$8 and ((C12Q1/6869 | C12Q2600/156 | G16B20/20).CPC.)	PGPB	48	ADJ	YES	ASSIGNEE	12-22-2020
(cell-free or cell free or circulat$8) near3 (DNA or nucleic) and (cell-free or cell free or circulat$8) near3 barcod$8 and sequencing and (mutation or polymorphism or SNV) near3 detect$8 and ((C12Q1/6869 | C12Q2600/156 | G16B20/20).CPC.)	USPT	23	ADJ	YES	ASSIGNEE	12-22-2020
(cell-free or cell free or circulat$8) near3 (DNA or nucleic) and (cell-free or cell free or circulat$8) near3 barcod$8 and sequencing and (mutation or polymorphism or SNV) near3 detect$8 and ((C12Q1/6869 | C12Q2600/156 | G16B20/20).CPC.)	DWPI	1	ADJ	YES	ASSIGNEE	12-22-2020

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/288,351	02/28/2019	Joshua BABIARZ	N.012.US.10

CONFIRMATION NO. 1764

110711
Natera, Inc.
201 Industrial Road
Suite 410
San Carlos, CA 94070

POA ACCEPTANCE LETTER

OC000000121404298

Date Mailed: 11/19/2020

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 11/16/2020.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/dtdinh/

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/288,351	02/28/2019	Joshua BABIARZ	N.012.US.10

CONFIRMATION NO. 1764

106224
White & Case LLP
701 13th Street NW
Washington, DC 20005

POWER OF ATTORNEY NOTICE

OC000000121404232

Date Mailed: 11/19/2020

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 11/16/2020.

- The Power of Attorney to you in this application has been revoked by the applicant. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/dtdinh/

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82A (07-13)
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NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	16/288,351
Filing Date	Feb. 28, 2019
First Named Inventor	Joshua BABIARZ
Title	DETECTING MUTATIONS AND PLOIDY IN CHROMOSOMAL SEGMENTS
Art Unit	1637
Examiner Name	Strzelecka, Teresa E.
Attorney Docket Number	N.012.US.10

SIGNATURE of Applicant or Patent Practitioner

Signature	/Anton Bokal/	Date (Optional)	
Name	Anton Bokal	Registration Number	51,243
Title (if Applicant is a juristic entity)	Chief IP Counsel		
Applicant Name (if Applicant is a juristic entity)	Natera, Inc.		

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.

☑ *Total of 2 forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. 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 3 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. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82B (07-13)
Approved for use through 01/31/2018. OMB 0651-0035
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POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☑ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 110711

OR

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

☑ The address associated with the above-mentioned Customer Number

OR

☐ The address associated with Customer Number:

OR

☐ Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

Natera, Inc.

☐ Inventor or Joint Inventor (title not required below)

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☑ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature	/Anton Bokal/	Date (Optional)	
Name	Anton Bokal		
Title	Chief IP Counsel		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☑ Total of 2 forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. 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 3 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. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
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.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

REMARKS

SUMMARY OF APPLICANT'S RESPONSE

Claims 1-3, 7, 11, 12, 14-16, 20, and 23-26 are currently pending in the application. Claims 4, 6, 9, 10, 13, 17-19, 21 and 22 have been withdrawn (*See* p. 3 of the Action). Claims 1, 3, 4, 6, 7, 9, 11, 13-18, and 24 have been presently amended. Claims 5 and 8 have been cancelled. Applicant has added new claims 25 and 26.

Applicant submits that the amendments and new claims are fully supported by the application as originally filed, and no new matter is added. Applicant reserves the right to pursue the subject matter of any cancelled claims in continuing applications. Applicant respectfully requests consideration and favorable action on the claims at issue in view of the amendments and remarks presented herein.

SUMMARY OF EXAMINER INTERVIEW

Applicant thanks the Office for the courtesy of the telephonic interview that took place on October 16, 2020. The rejections under 35 U.S.C. § 112, 35 U.S.C. § 101, and 35 U.S.C. § 102 were discussed, and Applicant presented draft claim amendments. No agreement was reached with respect to the rejections or amendments, but possible routes for expediting prosecution were explored.

REJECTIONS UNDER 35 U.S.C. § 112

Claims 1-3, 5, 7, 8, 11, 12, 14-16, 20 and 23-24 stand rejected as being indefinite. Claims 5 and 8 stand rejected on the basis they contains improper Markush grouping of alternatives. Applicant respectfully traverses these rejections.

The Office alleges that claim 1 "is indefinite over the recitation of '…assaying cell-free DNA … for the presence or absence of the cancer-specific mutations…", because it is allegedly "not clear how one can assay for an absence of mutations." Action, p. 5.

As provided in the MPEP, "[a] decision on whether a claim is indefinite under 35 U.S.C. 112(b) or pre-AIA 35 U.S.C. 112, second paragraph requires a determination of whether those skilled

in the art would understand what is claimed when the claim is read *in light of the specification*." MPEP 2173.02. (Emphasis added). Applicant submits that in light of the specification, one of skill in the art would readily understand how to measure the "absence" of a mutation. Examples are described at least in paragraphs [0292], [0515], and [0516]. The example in [0516] is illustrative: "*the magnitude of the difference between the calculated and expected allele ratios for a potential [copy number variation] (CNV) is less than (such as significantly less) than* [sic] *the corresponding magnitude for the reference for the CNV, thereby confirming the absence of a CNV.*" (Emphasis added). As that quoted passage explains, a CNV can be considered "absent" if its calculated allele ratio is less than that of the reference, irrespective of the absolute level of the CNV. The example does not require establishing an absolute lack of any amount of the CNV. Similarly, as claimed, a biological sample of cell-free DNA from a patient may contain regular cell-free DNA and tumor-derived cell-free DNA, so one may compare measured amounts of genetic material from the tumor biopsy to reference amounts and thereby determine whether the measured amounts exceed the reference amounts or not and, therefore, whether a mutation, particularly one that affects copy number such as deletion or duplication, is present or absent. Accordingly, it is clear in view of the claims and specification as to how one can assay for a presence or an absence of mutations, and the claims have clear metes and bounds.

The Office also alleges that the Markush groupings of claims 5 and 8 are improper "because the alternatives defined by the Markush grouping do not share both a single structural similarity and a common use for the following reasons: each of the genes encodes a protein with a different function and structure." Action, pp. 6-7. Applicant disagrees with the Examiner's position and notes that the groups do in fact share sufficient structural similarity and use to satisfy the Markush requirements, at least because the listed members of the groups are all genes that are susceptible to mutation by cancer. But without conceding patentability or scope of the previous claims and solely to expedite prosecution, Applicant has cancelled claims 5 and 8. Accordingly, the rejection is rendered moot.

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. § 112.

REJECTIONS UNDER 35 U.S.C. § 101

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Claims 1-3, 5, 7, 8, 11, 12, 14-16, 20 and 23-24 stand rejected under 35 U.S.C. § 101 because the claimed invention is allegedly "directed to a judicial exception without significantly more." Action at p. 7. Applicant respectfully disagrees and traverses this rejection.

The claims presented previously did not recite a judicial exception as alleged by the Office. See Action at pp. 7-8. Moreover, even if the claims are mischaracterized as having recited a judicial exception, any alleged judicial exception would be integrated into a practical application.

Without conceding patentability and solely to expedite prosecution, Applicant has amended claim 1 to recite a "method for preparing biological samples useful for monitoring the progression of cancer in a subject," with additional method steps also included as set forth above.

Claim 1 does not recite any judicial exceptions and is patent-eligible under 35 U.S.C. § 101. All other claims are dependent from claim 1 and patent-eligible for at least the same reason. Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 101.

REJECTIONS UNDER 35 U.S.C. § 102 and § 103

Claims 1-3, 7, 11, 20 and 23-24 stand rejected under 35 U.S.C. § 102 as allegedly being anticipated by U.S. Patent Publication No. 2014/0296081 ("Diehn"). Claim 12 stands rejected under 35 U.S.C. § 103 as being unpatentable over Diehn and Nature, vol. 497, pp. 108-112, 2013 ("Murtaza"). Claims 14-16 stand rejected under 35 U.S.C. § 103 as being unpatentable over Diehn, Brief. Funct. Genomics, vol. 10, pp. 374-386, 2011 ("Mertes"), Biotechniques, vol. 55, pp. 69-74, 2013 ("Nguyen-Dumont") and Science, vol. 280, pp. 1077-1082, 1998 ("Wang"). Applicant respectfully traverses this rejection.

Claim 1 as amended recites, *inter alia*, "performing sequencing on a tumor biopsy sample of the subject to identify a plurality of tumor-specific mutations; evaluating results of the sequencing on the tumor biopsy sample to determine a plurality of target loci specific to the subject, wherein each target locus spans a tumor-specific mutation of the identified plurality of tumor-specific mutations; and assaying cell-free DNA isolated from a plurality of biological samples obtained from the subject at different time points to determine the presence or absence of the tumor-specific mutations, wherein assaying comprises: amplifying the isolated cell-free DNA using primers specific to the plurality of

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target loci for the individual subject; and sequencing the amplified DNA comprising the plurality of target loci."

Diehn describes "an ultrasensitive and specific strategy for analysis of cancer-derived cfDNA to detect single nucleotide variants, insertions/deletions, and rearrangements, *without the need for patient-specific optimization*." *Diehn* at [0122]. (Emphasis added). Diehn seeks to accomplish this "by covering mutations in the majority of patients." *Id.*, [0138]. Diehn discloses methods involving looking for mutations at a "plurality of target regions [] selected from a plurality of genomic regions that are recurrently mutated in the specific cancer." *Id.*, [0119]. Accordingly, Diehn's method is cancer-specific, such that it uses pre-formed panels with a preformed set of DNA target regions taken from a population of other patients having the given type of cancer. To target those pre-determined regions, Diehn uses "selector libraries [] designed to identify mutations in tumors from a large percentage of all patients," such that "it is not necessary to optimize the library for each patient." *Id.*, [0104]. In fact, Diehn teaches that methods which use "optimization of molecular assays for each patient" suffer from "limiting their widespread clinical application." *Id.*, [0002].

Diehn does not teach, *at least,* the use of a personalized set of target loci or the step of "evaluating results of the sequencing on the tumor biopsy sample to determine a plurality of target loci specific to the subject," as recited by claim 1, and therefore does not teach any of the steps of "amplifying the isolated cell-free DNA using primers specific to the plurality of target loci for the individual subject; and sequencing the amplified DNA comprising the plurality of target loci," as recited by claim 1. Diehn teaches an entirely different method compared to the claim and does not anticipate claim 1.

Murtaza, Mertes, Nguyen-Dumont, and Wang, cited with respect to various dependent claims, fail to remedy the deficiencies of Diehn as discussed above. Claim 1 is thus patentable over the art of record. All remaining claims depend, directly or indirectly, from claim 1 and are thus patentable over the art of record for at least the reasons discussed above by virtue of their dependency. In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. § 102 and § 103.

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DOUBLE PATENTING

Claims 1-3, 7, 11, 12, 14-16, 20, 23 and 24 stand rejected on the ground of nonstatutory double patenting as allegedly being unpatentable over claims 1-4, 6, 8, 9, 12-14, 16, 19, 22 and 23 of co-pending Application Nos. 16/288,416 ("416"), 16/288,462 ("462") and claims 2, 5-7, 9, 11, 15, 19 and 21-23 of co-pending Application No. 16/399,941 ("941").

Applicant respectfully requests that the double patenting rejection be held in abeyance until all other rejections are withdrawn.

NEW CLAIMS

New claims 25 and 26 has been added. Claims 25 and 26 are supported by the application as filed and no new matter is added. Claims 25 and 26 are dependent from claim 1 and therefore patentable for at least the reasons discussed above by virtue of dependency.

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CONCLUSION

In view of the above amendment, Applicant believes the pending application is in condition for allowance. Reconsideration and prompt allowance of this application are accordingly respectfully requested.

Applicant believes no fee is due with this response other than those indicated on the Fee Transmittal. However, if an additional fee is due, please charge our Deposit Account No. 50-6075, under Order No. N.012.US.10 from which the undersigned is authorized to draw.

Dated: Nov. 16, 2020

Respectfully submitted,

/Luke Burton/

Luke Burton
Registration No. 73614
Customer No. 110711
312-576-3366
IP@natera.com
Attorney for Applicant

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in this application:

Listing of claims:

1. (Currently Amended) A method for preparing biological samples useful for monitoring the progression of cancer in a subject, the method comprising:

(a) performing sequencing on a ~~cancer~~ tumor biopsy sample of the subject to identify a plurality of ~~cancer-specific~~ tumor-specific mutations; [[and]]

(b) evaluating results of the sequencing on the tumor biopsy sample to determine a plurality of target loci specific to the subject, wherein each target locus spans a tumor-specific mutation of the identified plurality of tumor-specific mutations; and

(c) assaying cell-free DNA isolated from a plurality of biological samples obtained from the subject at different time points ~~for the presence or absence of the cancer-specific mutations, thereby monitoring the progression of cancer~~, wherein assaying comprises:

amplifying the isolated cell-free DNA using primers specific to the plurality of target loci for the individual subject; and

sequencing the amplified DNA comprising the plurality of target loci.

2. (Original) The method of claim 1, wherein the cell-free DNA comprises circulating tumor DNA.

3. (Currently Amended) The method of claim 1, wherein the ~~cancer-specific~~ tumor-specific mutations comprise one or more single nucleotide variant (SNV) mutations.

4. (Withdrawn – Currently Amended) The method of claim 1, wherein the ~~cancer-specific~~ tumor-specific mutations comprise one or more copy number variation (CNV) mutations.

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5. (Cancelled)

6. (Withdrawn – Currently Amended) The method of claim 1, wherein the ~~cancer-specific~~ tumor-specific mutations comprise one or more SNV mutations in a gene selected from the group consisting of CYFIP1, FAT1, MLLT4, RASA1, HERC4, JAK2, MSH2, MTOR, PLCG2, GABRG1, and TRIM67.

7. (Currently Amended) The method of claim 1, wherein the ~~cancer-specific~~ tumor-specific mutations comprise one or more clonal SNV mutations.

8. (Cancelled)

9. (Withdrawn – Currently Amended) The method of claim 1, wherein the ~~cancer-specific~~ tumor-specific mutations comprise one or more subclonal SNV mutations.

10. (Withdrawn) The method of claim 9, wherein at least one subclonal SNV mutation is in a gene selected from the group consisting of CIC, KDM6A, NF1, and TRIM67.

11. (Currently Amended) The method of claim 1, wherein the ~~cancer-specific~~ tumor-specific mutations comprise one or more clonal SNV mutations and one or more subclonal SNV mutations.

12. (Previously Presented) The method of claim 1, wherein the method further comprises determining clonal heterogeneity of the cancer sample.

13. (Withdrawn – Currently Amended) The method of claim 1, wherein the method further comprises designing targeted PCR assays for the ~~cancer-specific~~ tumor-specific mutations identified in the cancer sample.

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14. (Currently Amended) The method of claim 1, wherein ~~step (b)~~ amplifying comprises targeted multiplex PCR amplification of [[a]] the plurality of target loci comprising the ~~cancer-specific~~ tumor-specific mutations from the cell-free DNA.

15. (Currently Amended) The method of claim 14, wherein ~~step (b)~~ amplifying comprises targeted multiplex PCR amplification of 10 to 50 of the target loci.

16. (Currently Amended) The method of claim 14, wherein ~~step (b)~~ sequencing comprises ~~determining the sequences of the amplified target loci by~~ high-throughput sequencing.

17. (Withdrawn – Currently Amended) The method of claim 14, wherein step [[(b)]] (c) comprises determining the sequences of the amplified target loci by microarray.

18. (Withdrawn – Currently Amended) The method of claim 1, wherein the method further comprises detecting recurrence and/or metastases of the cancer from the ~~cancer-specific~~ tumor-specific mutations detected in the cell-free DNA.

19. (Withdrawn) The method of claim 1, wherein the cancer is colorectal cancer.

20. (Original) The method of claim 1, wherein the cancer is lung cancer.

21. (Withdrawn) The method of claim 1, wherein the cancer is bladder cancer.

22. (Withdrawn) The method of claim 1, wherein the cancer is breast cancer.

23. (Original) The method of claim 1, wherein the biological sample is a blood, serum, plasma, or urine sample.

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Exhibit 1003 Page 624

24. (Currently Amended) The method of claim 1, wherein step (a) comprises performing whole exome sequencing on a tumor biopsy sample of the subject to identify [[a]] the plurality of tumor-specific mutations.

25. (New) The method of claim 1, further comprising:

transmitting sequence data from the sequencing step via a cloud computing architecture.

26. (New) The method of claim 1, wherein step (c) further comprises:

before amplifying and sequencing the DNA, tagging the isolated cell-free DNA such that the tagged cell-free DNA comprises a molecular barcode.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/288,351
	Filing Date	Feb 28, 2019
	First Named Inventor	Joshua BABIARZ
	Art Unit	1637
	Examiner Name	Teresa E. Strzelecka
	Attorney Docket Number	N.012.US.10

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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	Attorney Docket Number	N.012.US.10

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CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Tianran Yan/	Date (YYYY-MM-DD)	2020-11-16
Name/Print	Tianran Yan	Registration Number	67,162

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Electronic Patent Application Fee Transmittal

Application Number:	16288351
Filing Date:	28-Feb-2019
Title of Invention:	DETECTING MUTATIONS AND PLOIDY IN CHROMOSOMAL SEGMENTS
First Named Inventor/Applicant Name:	Joshua BABIARZ
Filer:	Anton John Bokal/Angela McGowan
Attorney Docket Number:	N.012.US.10

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension - 2 months with $0 paid	1252	1	640	640
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	1806	1	260	260
		Total in USD ($)		**900**

Electronic Acknowledgement Receipt	
EFS ID:	41137231
Application Number:	16288351
International Application Number:	
Confirmation Number:	1764
Title of Invention:	DETECTING MUTATIONS AND PLOIDY IN CHROMOSOMAL SEGMENTS
First Named Inventor/Applicant Name:	Joshua BABIARZ
Customer Number:	106224
Filer:	Anton John Bokal/Angela McGowan
Filer Authorized By:	Anton John Bokal
Attorney Docket Number:	N.012.US.10
Receipt Date:	16-NOV-2020
Filing Date:	28-FEB-2019
Time Stamp:	18:23:37
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$900
RAM confirmation Number	E2020AFI24050434
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	01_N012US10_POA.pdf	204394 ad0012b4cba8ca523c2d8167b4bad286a31f2105	no	3
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Information:					
2		02_N012US10_Response_to_Non_Final_Office_Action_dated_18JUN2020_SIGNED.pdf	66704 481fec65c789e2b215fba42bf68f3d6fa797a0f6	yes	11

Multipart Description/PDF files in .zip description

Document Description	Start	End
Applicant Arguments/Remarks Made in an Amendment	6	11
Claims	2	5
Amendment/Req. Reconsideration-After Non-Final Reject	1	1

Warnings:					
Information:					
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14	Foreign Reference	EP3134541B1.pdf	19027627 4fd2799ad010c87dee67b9f5a4413650b48ea637	no	190
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Warnings:					
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23	Non Patent Literature	HE_2018_p133_NPL.pdf	2035499 1d2d86ac53e13de42aec76d2fadaaa70a0381606	no	8
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Warnings:					
Information:					
29	Non Patent Literature	PIRKER_2004_p26_NPL.pdf	1112000 4670128f86e38b22ecf145691bd62ecdba050ab9	no	9
Warnings:					
Information:					
30	Non Patent Literature	SANCHEZ_2018_12pgs_NPL.pdf	1373257 331aa3269739cc5fc8e704f401cd58ba9fb195b9	no	12
Warnings:					
Information:					
31	Non Patent Literature	SCARPA_2013_6pgs_NPL.pdf	861299 a3eb1cddd623042ab50048ea6fffe38a125a3017	no	6
Warnings:					
Information:					
32	Non Patent Literature	SHORT_2020_p1670_NPL.pdf	831082 7684eef428eb8e8db15cd11565bd0b1b1c30473b	no	8
Warnings:					
Information:					

33	Non Patent Literature	SIEBERT_1995_p1087_NPL.pdf	468473 bc3719cb197f3ae15925a808f9c3802b461f181d	no	2
Warnings:					
Information:					
34	Non Patent Literature	Vallone.pdf	1184161 534050ae0c190443fe8df18c35f2eba6a5cb7274	no	6
Warnings:					
Information:					
35	Non Patent Literature	VAN_DEN_OEVER_2012_p669_NPL.pdf	1160955 7d2279946a520533a8cf2c4313f840144c218eb5	no	8
Warnings:					
Information:					
36	Non Patent Literature	WITTWER_2001_p430_NPL.pdf	1107619 20dc9cb4a3006276fc576aae3c31f522428792b4	no	13
Warnings:					
Information:					
37	Non Patent Literature	YAMADA_2006_pW665_NPL.pdf	905480 5af4094a4c9c269df0adbd713318edb327e02696	no	5
Warnings:					
Information:					
38	Non Patent Literature	ZHANG_1999_p1741_NPL.pdf	686658 91ee1c170f85482ac93f00e60a7349994e2628df	no	6
Warnings:					
Information:					
39	Fee Worksheet (SB06)	fee-info.pdf	32788 5baa785d3b6c1ff18cef2d13f7c90f94fc347246	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	76274843		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Docket No.: N.012.US.10
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Joshua BABIARZ, et al.

Application No.: 16/288,351 | Confirmation No.: 1764

Filed: February 28, 2019 | Art Unit: 1637

For: DETECTING MUTATIONS AND PLOIDY IN CHROMOSOMAL SEGMENTS | Examiner: Teresa E. Strzelecka

RESPONSE TO NON-FINAL OFFICE ACTION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INTRODUCTORY COMMENTS

In response to the Non-Final Office Action dated June 18, 2020 (hereinafter, "Action"), please amend the above-identified U.S. patent application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper; and

Remarks/Arguments begin on page 6 of this paper.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/288,351	Filing Date 02/28/2019	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $460 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	11/16/2020	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 24	Minus	** 24	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/LINDA HUMES/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. 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 1.14. 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. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/288,351	02/28/2019	Joshua BABIARZ	N.012.US.10	1764

106224 7590 10/26/2020

White & Case LLP
701 13th Street NW
Washington, DC 20005

EXAMINER	
STRZELECKA, TERESA E	

ART UNIT	PAPER NUMBER
1637	

NOTIFICATION DATE	DELIVERY MODE
10/26/2020	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):

wcpatents@whitecase.com

Applicant-Initiated Interview Summary	**Application No.** 16/288,351	**Applicant(s)** BABIARZ et al.	
	Examiner TERESA E STRZELECKA	**Art Unit** 1637	**AIA (FITF) Status** Yes

All participants (applicant, applicants representative, PTO personnel):

(1) Teresa Strzelecka.

(3) Charles Larson.

(2) Walter Piszker.

(4) Sean Boyle.

Date of Interview: 16 October 2020.

Type: ☑ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☑ No.
If Yes, brief description: _____.

Issues Discussed ☑101 ☐112 ☑102 ☐103 ☐Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: 1.

Identification of prior art discussed: Diehn et al..

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

The interview centered on case 16/288,351, but two other cases with similar claims (16/288,416 and 16/288,462) were also discussed. Prior to the interview Applicant's representative submitted proposed claim amendments for the three cases (copies attached). Examiner asked for explanation of the invention. Applicant's representatives explained that the invention lies in the determination of mutations in a tumor obtained from a subject and following up the mutations in cell-free DNA obtained from the subject. Applicant's representatives argued that the invention differs from Diehn et al. because Diehn et al. tests for mutations in a pre-selected set of genes, whereas the instant claim 1 does not require any specific genes. However, claim 5 of the application lists a large number of pre-selected genes, therefore this argument is not persuasive. With regard to the rejection of claim 5 under 35 U.S.C. 112(b) as drawn to an improper Markush group, examiner explained that there was no common structure or functionality between the claimed genes. Finally, regarding the rejection under 35 U.S.C. 101 Applicant's representatives argued that the rejection is improper. No agreement was reached with respect to any of the claims..

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/TERESA E STRZELECKA/ Primary Examiner, Art Unit 1637	

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiners responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicants correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,-
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicants record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiners version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, Interview Record OK on the paper recording the substance of the interview along with the date and the examiners initials.

CLAIMS FOR EXAMINER INTERVIEW – DO NOT ENTER

Listing of Claims:

1. (Currently Amended) A method for preparing cell-free DNA for use in monitoring the progression of cancer comprising:

(a) determining the sequences of a plurality of amplified target loci, wherein [[the]] each amplified target locus is determined, by assaying a tumor biopsy from the subject, to span a tumor-specific mutation ~~loci each spans a cancer-specific mutation~~ identified in ~~a cancer~~ the tumor biopsy sample ~~of a subject~~, and wherein the amplified target loci are amplified from cell-free DNA isolated from a first biological sample of the subject~~; and~~

~~(b) determining the presence or absence of the cancer-specific tumor-specific mutations based on the sequencing results, thereby monitoring the progression of cancer~~.

2. (Currently Amended) The method of claim 25 [[1]], further comprising:

(c) repeating steps (a)-(b) on a plurality of amplified target loci amplified from cell-free DNA isolated from a second biological sample obtained from the subject at a subsequent time point, thereby monitoring the progression of cancer.

3. (Original) The method of claim 1, wherein the cell-free DNA comprises circulating tumor DNA.

4. (Currently Amended) The method of claim 1, wherein the ~~cancer-specific~~ tumor-specific mutations comprise one or more single nucleotide variant (SNV) mutations.

5. (Withdrawn – Currently Amended) The method of claim 1, wherein the ~~cancer-specific~~ tumor-specific mutations comprise one or more copy number variation (CNV) mutations.

6. (Currently Amended) The method of claim 1, wherein the ~~cancer-specific~~ tumor-specific mutations comprise one or more SNV mutations in a gene selected from the group consisting of TP53, PTEN, PIK3CA, APC, EGFR, NRAS, NF2, FBXW7, ERBBs, ATAD5, KRAS, BRAF, VEGF, EGFR, HER2, ALK, p53, BRCA, BRCA1, BRCA2, SETD2, LRP1B, PBRM, SPTA1,

DNMT3A, ARID1A, GRIN2A, TRRAP, STAG2, EPHA3/5/7, POLE, SYNE1, C20orf80, CSMD1, CTNNB1, ERBB2. FBXW7, KIT, MUC4, ATM, CDH1, DDX11, DDX12, DSPP, EPPK1, FAM186A, GNAS, HRNR, KRTAP4-11, MAP2K4, MLL3, NRAS, RB1, SMAD4, TTN, ABCC9, ACVR1B, ADAM29, ADAMTS19, AGAP10, AKT1, AMBN, AMPD2, ANKRD30A, ANKRD40, APOBR, AR, BIRC6, BMP2, BRAT1, BTNL8, C12orf4, C1QTNF7, C20orf186, CAPRIN2, CBWD1, CCDC30, CCDC93, CD5L, CDC27, CDC42BPA, CDH9, CDKN2A, CHD8, CHEK2, CHRNA9, CIZ1, CLSPN, CNTN6, COL14A1, CREBBP, CROCC, CTSF, CYP1A2, DCLK1, DHDDS, DHX32, DKK2, DLEC1, DNAH14, DNAH5, DNAH9, DNASE1L3, DUSP16, DYNC2H1, ECT2, EFHB, RRN3P2, TRIM49B, TUBB8P5, EPHA7, ERBB3, ERCC6, FAM21A, FAM21C, FCGBP, FGFR2, FLG2, FLT1, FOLR2, FRYL, FSCB, GAB1, GABRA4, GABRP, GH2, GOLGA6L1, GPHB5, GPR32, GPX5, GTF3C3, HECW1, HIST1H3B, HLA-A, HRAS, HS3ST1, HS6ST1, HSPD1, IDH1, JAK2, KDM5B, KIAA0528, KRT15, KRT38, KRTAP21-1, KRTAP4-5, KRTAP4-7, KRTAP5-4, KRTAP5-5, LAMA4, LATS1, LMF1, LPAR4, LPPR4, LRRFIP1, LUM, LYST, MAP2K1, MARCH1, MARCO, MB21D2, MEGF10, MMP16, MORC1, MRE11A, MTMR3, MUC12, MUC17, MUC2, MUC20, NBPF10, NBPF20, NEK1, NFE2L2, NLRP4, NOTCH2, NRK, NUP93, OBSCN, OR11H1, OR2B11, OR2M4, OR4Q3, OR5D13, OR8I2, OXSM, PIK3R1, PPP2R5C, PRAME, PRF1, PRG4, PRPF19, PTH2, PTPRC, PTPRJ, RAC1, RAD50, RBM12, RGPD3, RGS22, ROR1, RP11-671M22.1, RP13-996F3.4, RP1L1, RSBN1L, RYR3, SAMD3, SCN3A, SEC31A, SF1, SF3B1, SLC25A2, SLC44A1, SLC4A1, SMAD2, SPTA1, ST6GAL2, STK11, SZT2, TAF1L, TAX1BP1, TBP, TGFBI, TIF1, TMEM14B, TMEM74, TPTE, TRAPPC8, TRPS1, TXNDC6, USP32, UTP20, VASN, VPS72, WASH3P, WWTR1, XPO1, ZFHX4, ZMIZ1, ZNF167, ZNF436, ZNF492, ZNF598, ZRSR2, ABL1, AKT2, AKT3, ARAF, ARFRP1, ARID2, ASXL1, ATR, ATRX, AURKA, AURKB, AXL, BAP1, BARD1, BCL2, BCL2L2, BCL6, BCOR, BCORL1, BLM, BRIP1, BTK, CARD11, CBFB, CBL, CCND1, CCND2, CCND3, CCNE1, CD79A, CD79B, CDC73, CDK12, CDK4, CDK6, CDK8, CDKN1B, CDKN2B, CDKN2C, CEBPA, CHEK1, CIC, CRKL, CRLF2, CSF1R, CTCF, CTNNA1, DAXX, DDR2, DOT1L, EMSY (C11orf30), EP300, EPHA3, EPHA5, EPHB1, ERBB4, ERG, ESR1, EZH2, FAM123B (WTX), FAM46C, FANCA, FANCC, FANCD2, FANCE, FANCF, FANCG,

FANCL, FGF10, FGF14, FGF19, FGF23, FGF3, FGF4, FGF6, FGFR1, FGFR2, FGFR3, FGFR4, FLT3, FLT4, FOXL2, GATA1, GATA2, GATA3, GID4 (C17orf39), GNA11, GNA13, GNAQ, GNAS, GPR124, GSK3B, HGF, IDH1, IDH2, IGF1R, IKBKE, IKZF1, IL7R, INHBA, IRF4, IRS2, JAK1, JAK3, JUN, KAT6A (MYST3), KDM5A, KDM5C, KDM6A, KDR, KEAP1, KLHL6, MAP2K2, MAP2K4, MAP3K1, MCL1, MDM2, MDM4, MED12, MEF2B, MEN1, MET, MITF, MLH1, MLL, MLL2, MPL, MSH2, MSH6, MTOR, MUTYH, MYC, MYCL1, MYCN, MYD88, NF1, NFKBIA, NKX2-1, NOTCH1, NPM1, NRAS, NTRK1, NTRK2, NTRK3, PAK3, PALB2, PAX5, PBRM1, PDGFRA, PDGFRB, PDK1, PIK3CG, PIK3R2, PPP2R1A, PRDM1, PRKAR1A, PRKDC, PTCH1, PTPN11, RAD51, RAF1, RARA, RET, RICTOR, RNF43, RPTOR, RUNX1, SMARCA4, SMARCB1, SMO, SOCS1, SOX10, SOX2, SPEN, SPOP, SRC, STAT4, SUFU, TET2, TGFBR2, TNFAIP3, TNFRSF14, TOP1, TP53, TSC1, TSC2, TSHR, VHL, WISP3, WT1, ZNF217, and ZNF703.

7. (Currently Amended) The method of claim 1, wherein the ~~cancer-specific~~ tumor-specific mutations comprise one or more SNV mutations in a gene selected from the group consisting of CYFIP1, FAT1, MLLT4, RASA1, HERC4, JAK2, MSH2, MTOR, PLCG2, GABRG1, and TRIM67.

8. (Currently Amended) The method of claim 1, wherein the ~~cancer-specific~~ tumor-specific mutations comprise one or more clonal SNV mutations.

9. (Currently Amended) The method of claim 8, wherein at least one clonal SNV mutation is in a gene selected from the group consisting of BRIP1, CARS, FAT1, MLLT4, NFE2L2, ~~TP53, TP53, EGFR,~~ EGFR, TP53, KDM6A, and ROS1.

10. (Withdrawn – Currently Amended) The method of claim 1, wherein the ~~cancer-specific~~ tumor-specific mutations comprise one or more subclonal SNV mutations.

11. (Withdrawn) The method of claim 10, wherein at least one subclonal SNV mutation is in a gene selected from the group consisting of CIC, KDM6A, NF1, and TRIM67.

12. (Currently Amended) The method of claim 1, wherein the ~~cancer-specific~~ tumor-specific mutations comprise one or more clonal SNV mutations and one or more subclonal SNV mutations.

13. (Currently Amended) The method of claim 1, wherein the ~~method further comprises~~ tumor-specific mutations are identified by whole exome sequencing of [[a]] the tumor biopsy sample ~~to identify tumor-specific mutations~~.

14. (Original) The method of claim 13, wherein the method further comprises determining clonal heterogeneity of the tumor biopsy sample.

15. (Original) The method of claim 13, wherein the method further comprises designing targeted PCR assays for the tumor-specific mutations.

16. (Original) The method of claim 1, wherein the method further comprises targeted multiplex PCR amplification of 10 to 50 target loci from the cell-free DNA.

17. (Currently Amended) The method of claim 1, wherein the method further comprises detecting recurrence and/or metastases of the cancer from the ~~cancer-specific~~ tumor-specific mutations detected in the cell-free DNA.

18. (Withdrawn) The method of claim 1, wherein the cancer is colorectal cancer.

19. (Original) The method of claim 1, wherein the cancer is lung cancer.

20. (Withdrawn) The method of claim 1, wherein the cancer is bladder cancer.

21. (Withdrawn) The method of claim 1, wherein the cancer is breast cancer.

22. (Original) The method of claim 1, wherein the biological sample is a blood, serum, plasma, or urine sample.

23. (Original) The method of claim 1, wherein the sequences of the amplified target loci are determined by high-throughput sequencing.

24. (Withdrawn) The method of claim 1, wherein the sequences of the amplified target loci are determined by microarray.

25. (New) The method of claim 1, further comprising:

(b) determining the presence or absence of the tumor-specific mutations based on the sequencing results.

NeoGenomics
Exhibit 1003 Page 653

CLAIMS FOR EXAMINER INTERVIEW – DO NOT ENTER

Listing of Claims:

1. (Currently Amended) A method for preparing cell-free DNA for use in monitoring the progression of cancer comprising:

(a) performing a multiplex amplification reaction to amplify a plurality of target loci from cell-free DNA isolated from a first biological sample of a subject, wherein [[the]] each target locus is determined, by assaying a tumor biopsy sample from the subject, to span a tumor-specific mutation ~~loci each spans a cancer-specific mutation~~ identified in ~~a cancer~~ the tumor biopsy sample ~~of the subject~~; and

(b) determining the sequences of the amplified target loci~~; and~~

~~(c) determining the presence or absence of the cancer-specific tumor-specific mutations based on the sequencing results, thereby monitoring the progression of cancer~~.

2. (Currently Amended) The method of claim 25 [[1]], further comprising:

(d) repeating steps (a)-(c) on cell-free DNA isolated from a second biological sample obtained from the subject at a subsequent time point, thereby monitoring the progression of cancer.

3. (Original) The method of claim 1, wherein the cell-free DNA comprises circulating tumor DNA.

4. (Currently Amended) The method of claim 1, wherein the ~~cancer-specific~~ tumor-specific mutations comprise one or more single nucleotide variant (SNV) mutations.

5. (Withdrawn – Currently Amended) The method of claim 1, wherein the ~~cancer-specific~~ tumor-specific mutations comprise one or more copy number variation (CNV) mutations.

6. (Currently Amended) The method of claim 1, wherein the ~~cancer-specific~~ tumor-specific mutations comprise one or more SNV mutations in a gene selected from the group consisting of TP53, PTEN, PIK3CA, APC, EGFR, NRAS, NF2, FBXW7, ERBBs, ATAD5, KRAS, BRAF,

VEGF, EGFR, HER2, ALK, p53, BRCA, BRCA1, BRCA2, SETD2, LRP1B, PBRM, SPTA1, DNMT3A, ARID1A, GRIN2A, TRRAP, STAG2, EPHA3/5/7, POLE, SYNE1, C20orf80, CSMD1, CTNNB1, ERBB2. FBXW7, KIT, MUC4, ATM, CDH1, DDX11, DDX12, DSPP, EPPK1, FAM186A, GNAS, HRNR, KRTAP4-11, MAP2K4, MLL3, NRAS, RB1, SMAD4, TTN, ABCC9, ACVR1B, ADAM29, ADAMTS19, AGAP10, AKT1, AMBN, AMPD2, ANKRD30A, ANKRD40, APOBR, AR, BIRC6, BMP2, BRAT1, BTNL8, C12orf4, C1QTNF7, C20orf186, CAPRIN2, CBWD1, CCDC30, CCDC93, CD5L, CDC27, CDC42BPA, CDH9, CDKN2A, CHD8, CHEK2, CHRNA9, CIZ1, CLSPN, CNTN6, COL14A1, CREBBP, CROCC, CTSF, CYP1A2, DCLK1, DHDDS, DHX32, DKK2, DLEC1, DNAH14, DNAH5, DNAH9, DNASE1L3, DUSP16, DYNC2H1, ECT2, EFHB, RRN3P2, TRIM49B, TUBB8P5, EPHA7, ERBB3, ERCC6, FAM21A, FAM21C, FCGBP, FGFR2, FLG2, FLT1, FOLR2, FRYL, FSCB, GAB1, GABRA4, GABRP, GH2, GOLGA6L1, GPHB5, GPR32, GPX5, GTF3C3, HECW1, HIST1H3B, HLA-A, HRAS, HS3ST1, HS6ST1, HSPD1, IDH1, JAK2, KDM5B, KIAA0528, KRT15, KRT38, KRTAP21-1, KRTAP4-5, KRTAP4-7, KRTAP5-4, KRTAP5-5, LAMA4, LATS1, LMF1, LPAR4, LPPR4, LRRFIP1, LUM, LYST, MAP2K1, MARCH1, MARCO, MB21D2, MEGF10, MMP16, MORC1, MRE11A, MTMR3, MUC12, MUC17, MUC2, MUC20, NBPF10, NBPF20, NEK1, NFE2L2, NLRP4, NOTCH2, NRK, NUP93, OBSCN, OR11H1, OR2B11, OR2M4, OR4Q3, OR5D13, OR8I2, OXSM, PIK3R1, PPP2R5C, PRAME, PRF1, PRG4, PRPF19, PTH2, PTPRC, PTPRJ, RAC1, RAD50, RBM12, RGPD3, RGS22, ROR1, RP11-671M22.1, RP13-996F3.4, RP1L1, RSBN1L, RYR3, SAMD3, SCN3A, SEC31A, SF1, SF3B1, SLC25A2, SLC44A1, SLC4A1, SMAD2, SPTA1, ST6GAL2, STK11, SZT2, TAF1L, TAX1BP1, TBP, TGFBI, TIF1, TMEM14B, TMEM74, TPTE, TRAPPC8, TRPS1, TXNDC6, USP32, UTP20, VASN, VPS72, WASH3P, WWTR1, XPO1, ZFHX4, ZMIZ1, ZNF167, ZNF436, ZNF492, ZNF598, ZRSR2, ABL1, AKT2, AKT3, ARAF, ARFRP1, ARID2, ASXL1, ATR, ATRX, AURKA, AURKB, AXL, BAP1, BARD1, BCL2, BCL2L2, BCL6, BCOR, BCORL1, BLM, BRIP1, BTK, CARD11, CBFB, CBL, CCND1, CCND2, CCND3, CCNE1, CD79A, CD79B, CDC73, CDK12, CDK4, CDK6, CDK8, CDKN1B, CDKN2B, CDKN2C, CEBPA, CHEK1, CIC, CRKL, CRLF2, CSF1R, CTCF, CTNNA1, DAXX, DDR2, DOT1L, EMSY (C11orf30), EP300, EPHA3, EPHA5, EPHB1, ERBB4, ERG, ESR1, EZH2,

FAM123B (WTX), FAM46C, FANCA, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCL, FGF10, FGF14, FGF19, FGF23, FGF3, FGF4, FGF6, FGFR1, FGFR2, FGFR3, FGFR4, FLT3, FLT4, FOXL2, GATA1, GATA2, GATA3, GID4 (C17orf39), GNA11, GNA13, GNAQ, GNAS, GPR124, GSK3B, HGF, IDH1, IDH2, IGF1R, IKBKE, IKZF1, IL7R, INHBA, IRF4, IRS2, JAK1, JAK3, JUN, KAT6A (MYST3), KDM5A, KDM5C, KDM6A, KDR, KEAP1, KLHL6, MAP2K2, MAP2K4, MAP3K1, MCL1, MDM2, MDM4, MED12, MEF2B, MEN1, MET, MITF, MLH1, MLL, MLL2, MPL, MSH2, MSH6, MTOR, MUTYH, MYC, MYCL1, MYCN, MYD88, NF1, NFKBIA, NKX2-1, NOTCH1, NPM1, NRAS, NTRK1, NTRK2, NTRK3, PAK3, PALB2, PAX5, PBRM1, PDGFRA, PDGFRB, PDK1, PIK3CG, PIK3R2, PPP2R1A, PRDM1, PRKAR1A, PRKDC, PTCH1, PTPN11, RAD51, RAF1, RARA, RET, RICTOR, RNF43, RPTOR, RUNX1, SMARCA4, SMARCB1, SMO, SOCS1, SOX10, SOX2, SPEN, SPOP, SRC, STAT4, SUFU, TET2, TGFBR2, TNFAIP3, TNFRSF14, TOP1, TP53, TSC1, TSC2, TSHR, VHL, WISP3, WT1, ZNF217, and ZNF703.

7. (Currently Amended) The method of claim 1, wherein the ~~cancer-specific~~ tumor-specific mutations comprise one or more SNV mutations in a gene selected from the group consisting of CYFIP1, FAT1, MLLT4, RASA1, HERC4, JAK2, MSH2, MTOR, PLCG2, GABRG1, and TRIM67.

8. (Currently Amended) The method of claim 1, wherein the ~~cancer-specific~~ tumor-specific mutations comprise one or more clonal SNV mutations.

9. (Currently Amended) The method of claim 8, wherein at least one clonal SNV mutation is in a gene selected from the group consisting of BRIP1, CARS, FAT1, MLLT4, NFE2L2, ~~TP53, TP53, EGFR,~~ EGFR, TP53, KDM6A, and ROS1.

10. (Withdrawn – Currently Amended) The method of claim 1, wherein the ~~cancer-specific~~ tumor-specific mutations comprise one or more subclonal SNV mutations.

11. (Withdrawn) The method of claim 10, wherein at least one subclonal SNV mutation is in a gene selected from the group consisting of CIC, KDM6A, NF1, and TRIM67.

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12. (Currently Amended) The method of claim 1, wherein the ~~cancer-specific~~ tumor-specific mutations comprise one or more clonal SNV mutations and one or more subclonal SNV mutations.

13. (Currently Amended) The method of claim 1, wherein the ~~method further comprises~~ tumor-specific mutations are identified by whole exome sequencing of [[a]] the tumor biopsy sample ~~to identify tumor-specific mutations~~.

14. (Original) The method of claim 13, wherein the method further comprises determining clonal heterogeneity of the tumor biopsy sample.

15. (Original) The method of claim 13, wherein the method further comprises designing targeted PCR assays for the tumor-specific mutations.

16. (Original) The method of claim 1, wherein step (a) comprises targeted multiplex PCR amplification of 10 to 50 target loci from the cell-free DNA.

17. (Currently Amended) The method of claim 1, wherein the method further comprises detecting recurrence and/or metastases of the cancer from the ~~cancer-specific~~ tumor-specific mutations detected in the cell-free DNA.

18. (Withdrawn) The method of claim 1, wherein the cancer is colorectal cancer.

19. (Original) The method of claim 1, wherein the cancer is lung cancer.

20. (Withdrawn) The method of claim 1, wherein the cancer is bladder cancer.

21. (Withdrawn) The method of claim 1, wherein the cancer is breast cancer.

22. (Original) The method of claim 1, wherein the biological sample is a blood, serum, plasma, or urine sample.

23. (Original) The method of claim 1, wherein the sequences of the amplified target loci are determined by high-throughput sequencing.

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24. (Withdrawn) The method of claim 1, wherein the sequences of the amplified target loci are determined by microarray.

25. (New) The method of claim 1, further comprising:

(c) determining the presence or absence of the tumor-specific mutations based on the sequencing results of step (b).

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CLAIMS FOR EXAMINER INTERVIEW – DO NOT ENTER

Listing of Claims:

1. (Currently Amended) A method for monitoring the progression of cancer in a subject comprising:

(a) performing sequencing on a cancer sample of the subject to identify a plurality of ~~cancer-specific~~ tumor-specific mutations; and

(b) assaying cell-free DNA isolated from a plurality of biological samples obtained from the subject at different time points [[for]] to determine the presence or absence of the ~~cancer-specific~~ tumor-specific mutations, thereby monitoring the progression of cancer, wherein assaying comprises:

tagging the isolated cell-free DNA such that the tagged cell-free DNA comprises a molecular barcode;

amplifying the tagged cell-free DNA using primers specific to a plurality of target loci of the cell-free DNA, wherein the target loci are determined based on the identified plurality of tumor-specific mutations for the subject; and

sequencing the amplified DNA comprising the plurality of target loci.

2. (Original) The method of claim 1, wherein the cell-free DNA comprises circulating tumor DNA.

3. (Currently Amended) The method of claim 1, wherein the ~~cancer-specific~~ tumor-specific mutations comprise one or more single nucleotide variant (SNV) mutations.

4. (Withdrawn – Currently Amended) The method of claim 1, wherein the ~~cancer-specific~~ tumor-specific mutations comprise one or more copy number variation (CNV) mutations.

5. (Currently Amended) The method of claim 1, wherein the ~~cancer-specific~~ tumor-specific mutations comprise one or more SNV mutations in a gene selected from the group consisting of

TP53, PTEN, PIK3CA, APC, EGFR, NRAS, NF2, FBXW7, ERBBs, ATAD5, KRAS, BRAF, VEGF, EGFR, HER2, ALK, p53, BRCA, BRCA1, BRCA2, SETD2, LRP1B, PBRM, SPTA1, DNMT3A, ARID1A, GRIN2A, TRRAP, STAG2, EPHA3/5/7, POLE, SYNE1, C20orf80, CSMD1, CTNNB1, ERBB2. FBXW7, KIT, MUC4, ATM, CDH1, DDX11, DDX12, DSPP, EPPK1, FAM186A, GNAS, HRNR, KRTAP4-11, MAP2K4, MLL3, NRAS, RB1, SMAD4, TTN, ABCC9, ACVR1B, ADAM29, ADAMTS19, AGAP10, AKT1, AMBN, AMPD2, ANKRD30A, ANKRD40, APOBR, AR, BIRC6, BMP2, BRAT1, BTNL8, C12orf4, C1QTNF7, C20orf186, CAPRIN2, CBWD1, CCDC30, CCDC93, CD5L, CDC27, CDC42BPA, CDH9, CDKN2A, CHD8, CHEK2, CHRNA9, CIZ1, CLSPN, CNTN6, COL14A1, CREBBP, CROCC, CTSF, CYP1A2, DCLK1, DHDDS, DHX32, DKK2, DLEC1, DNAH14, DNAH5, DNAH9, DNASE1L3, DUSP16, DYNC2H1, ECT2, EFHB, RRN3P2, TRIM49B, TUBB8P5, EPHA7, ERBB3, ERCC6, FAM21A, FAM21C, FCGBP, FGFR2, FLG2, FLT1, FOLR2, FRYL, FSCB, GAB1, GABRA4, GABRP, GH2, GOLGA6L1, GPHB5, GPR32, GPX5, GTF3C3, HECW1, HIST1H3B, HLA-A, HRAS, HS3ST1, HS6ST1, HSPD1, IDH1, JAK2, KDM5B, KIAA0528, KRT15, KRT38, KRTAP21-1, KRTAP4-5, KRTAP4-7, KRTAP5-4, KRTAP5-5, LAMA4, LATS1, LMF1, LPAR4, LPPR4, LRRFIP1, LUM, LYST, MAP2K1, MARCH1, MARCO, MB21D2, MEGF10, MMP16, MORC1, MRE11A, MTMR3, MUC12, MUC17, MUC2, MUC20, NBPF10, NBPF20, NEK1, NFE2L2, NLRP4, NOTCH2, NRK, NUP93, OBSCN, OR11H1, OR2B11, OR2M4, OR4Q3, OR5D13, OR8I2, OXSM, PIK3R1, PPP2R5C, PRAME, PRF1, PRG4, PRPF19, PTH2, PTPRC, PTPRJ, RAC1, RAD50, RBM12, RGPD3, RGS22, ROR1, RP11-671M22.1, RP13-996F3.4, RP1L1, RSBN1L, RYR3, SAMD3, SCN3A, SEC31A, SF1, SF3B1, SLC25A2, SLC44A1, SLC4A1, SMAD2, SPTA1, ST6GAL2, STK11, SZT2, TAF1L, TAX1BP1, TBP, TGFBI, TIF1, TMEM14B, TMEM74, TPTE, TRAPPC8, TRPS1, TXNDC6, USP32, UTP20, VASN, VPS72, WASH3P, WWTR1, XPO1, ZFHX4, ZMIZ1, ZNF167, ZNF436, ZNF492, ZNF598, ZRSR2, ABL1, AKT2, AKT3, ARAF, ARFRP1, ARID2, ASXL1, ATR, ATRX, AURKA, AURKB, AXL, BAP1, BARD1, BCL2, BCL2L2, BCL6, BCOR, BCORL1, BLM, BRIP1, BTK, CARD11, CBFB, CBL, CCND1, CCND2, CCND3, CCNE1, CD79A, CD79B, CDC73, CDK12, CDK4, CDK6, CDK8, CDKN1B, CDKN2B, CDKN2C, CEBPA, CHEK1, CIC, CRKL, CRLF2, CSF1R, CTCF, CTNNA1, DAXX, DDR2,

DOT1L, EMSY (C11orf30), EP300, EPHA3, EPHA5, EPHB1, ERBB4, ERG, ESR1, EZH2, FAM123B (WTX), FAM46C, FANCA, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCL, FGF10, FGF14, FGF19, FGF23, FGF3, FGF4, FGF6, FGFR1, FGFR2, FGFR3, FGFR4, FLT3, FLT4, FOXL2, GATA1, GATA2, GATA3, GID4 (C17orf39), GNA11, GNA13, GNAQ, GNAS, GPR124, GSK3B, HGF, IDH1, IDH2, IGF1R, IKBKE, IKZF1, IL7R, INHBA, IRF4, IRS2, JAK1, JAK3, JUN, KAT6A (MYST3), KDM5A, KDM5C, KDM6A, KDR, KEAP1, KLHL6, MAP2K2, MAP2K4, MAP3K1, MCL1, MDM2, MDM4, MED12, MEF2B, MEN1, MET, MITF, MLH1, MLL, MLL2, MPL, MSH2, MSH6, MTOR, MUTYH, MYC, MYCL1, MYCN, MYD88, NF1, NFKBIA, NKX2-1, NOTCH1, NPM1, NRAS, NTRK1, NTRK2, NTRK3, PAK3, PALB2, PAX5, PBRM1, PDGFRA, PDGFRB, PDK1, PIK3CG, PIK3R2, PPP2R1A, PRDM1, PRKAR1A, PRKDC, PTCH1, PTPN11, RAD51, RAF1, RARA, RET, RICTOR, RNF43, RPTOR, RUNX1, SMARCA4, SMARCB1, SMO, SOCS1, SOX10, SOX2, SPEN, SPOP, SRC, STAT4, SUFU, TET2, TGFBR2, TNFAIP3, TNFRSF14, TOP1, TP53, TSC1, TSC2, TSHR, VHL, WISP3, WT1, ZNF217, and ZNF703.

6. (Currently Amended) The method of claim 1, wherein the ~~cancer-specific~~ tumor-specific mutations comprise one or more SNV mutations in a gene selected from the group consisting of CYFIP1, FAT1, MLLT4, RASA1, HERC4, JAK2, MSH2, MTOR, PLCG2, GABRG1, and TRIM67.

7. (Currently Amended) The method of claim 1, wherein the ~~cancer-specific~~ tumor-specific mutations comprise one or more clonal SNV mutations.

8. (Currently Amended) The method of claim 7, wherein at least one clonal SNV mutation is in a gene selected from the group consisting of BRIP1, CARS, FAT1, MLLT4, NFE2L2, ~~TP53, TP53, EGFR,~~ EGFR, TP53, KDM6A, and ROS1.

9. (Withdrawn – Currently Amended) The method of claim 1, wherein the ~~cancer-specific~~ tumor-specific mutations comprise one or more subclonal SNV mutations.

10. (Withdrawn) The method of claim 9, wherein at least one subclonal SNV mutation is in a gene selected from the group consisting of CIC, KDM6A, NF1, and TRIM67.

11. (Currently Amended) The method of claim 1, wherein the ~~cancer-specific~~ tumor-specific mutations comprise one or more clonal SNV mutations and one or more subclonal SNV mutations.

12. (Previously Presented) The method of claim 1, wherein the method further comprises determining clonal heterogeneity of the cancer sample.

13. (Currently Amended) The method of claim 1, wherein the method further comprises designing targeted PCR assays for the ~~cancer-specific~~ tumor-specific mutations identified in the cancer sample.

14. (Currently Amended) The method of claim 1, wherein ~~step (b)~~ amplifying comprises targeted multiplex PCR amplification of [[a]] the plurality of target loci comprising the ~~cancer-specific~~ tumor-specific mutations from the cell-free DNA.

15. (Currently Amended) The method of claim 14, wherein ~~step (b)~~ amplifying comprises targeted multiplex PCR amplification of 10 to 50 of the target loci.

16. (Currently Amended) The method of claim 14, wherein ~~step (b)~~ sequencing comprises ~~determining the sequences of the amplified target loci by~~ high-throughput sequencing.

17. (Withdrawn) The method of claim 14, wherein step (b) comprises determining the sequences of the amplified target loci by microarray.

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18. (Currently Amended) The method of claim 1, wherein the method further comprises detecting recurrence and/or metastases of the cancer from the ~~cancer-specific~~ tumor-specific mutations detected in the cell-free DNA.

19. (Withdrawn) The method of claim 1, wherein the cancer is colorectal cancer.

20. (Original) The method of claim 1, wherein the cancer is lung cancer.

21. (Withdrawn) The method of claim 1, wherein the cancer is bladder cancer.

22. (Withdrawn) The method of claim 1, wherein the cancer is breast cancer.

23. (Original) The method of claim 1, wherein the biological sample is a blood, serum, plasma, or urine sample.

24. (Currently Amended) The method of claim 1, wherein step (a) comprises performing whole exome sequencing on a tumor biopsy sample of the subject to identify [[a]] the plurality of tumor-specific mutations.

26. (New) The method of claim 1, further comprising:
transmitting sequence data from the sequencing step via a cloud computing architecture.

NeoGenomics
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/288,351	02/28/2019	Joshua BABIARZ	N.012.US.10

CONFIRMATION NO. 1764

106224
White & Case LLP
701 13th Street NW
Washington, DC 20005

POA ACCEPTANCE LETTER

OC000000120706552

Date Mailed: 10/20/2020

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 10/15/2020.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/nbekele/

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/288,351	02/28/2019	Joshua BABIARZ	N.012.US.10

CONFIRMATION NO. 1764

110711
Natera, Inc.
201 Industrial Road
Suite 410
San Carlos, CA 94070

POWER OF ATTORNEY NOTICE

OC000000120706541

Date Mailed: 10/20/2020

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 10/15/2020.

- The Power of Attorney to you in this application has been revoked by the applicant. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/nbekele/

Doc Code: ECOMM.AUTH/ECOMM.WTDW
Doc Description: Internet Communications Authorized/Internet Communications Authorization Withdrawn

PTO/SB/439 (11-15)

AUTHORIZATION FOR INTERNET COMMUNICATIONS IN A PATENT APPLICATION OR REQUEST TO WITHDRAW AUTHORIZATION FOR INTERNET COMMUNICATIONS

Application No.	16/288,351
Filing Date	February 28, 2019
First Named Inventor	Joshua BABIARZ
Art Unit	1637
Examiner Name	Teressa E. Strzelecka
Practitioner Docket No.	N.012.US.10

To: Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I. To authorize permission for Internet Communications.

☑ Recognizing that Internet communications are not secure, I hereby authorize the USPTO to communicate with the undersigned and practitioners in accordance with 37 CFR 1.33 and 37 CFR 1.34 concerning any subject matter of this application via video conferencing, instant messaging, or electronic mail. I understand that a copy of these communications will be made of record in the application file. (MPEP 502.03)

II. To withdraw authorization for Internet Communications.

☐ The authorization given on _____, to the USPTO to communicate with the undersigned and any practitioner in accordance with 37 CFR 1.33 and 37 CFR 1.34 concerning any subject matter of this application via Internet communications such as video conferencing, instant messaging, or electronic mail is hereby withdrawn. I understand that the withdrawal is effective when approved rather than when received.

I am the

☐ applicant.

☑ attorney or agent of record. Registration number 78,682.

☐ attorney or agent acting under 37 CFR 1.34. Registration number _____.

/Walter J. Piszker/ — Signature

October 15, 2020 — Date

Walter J. Piszker — Typed or printed name

617-979-9364 — Telephone Number

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Juristic entities must be represented by a patent practitioner (see 37 CFR 1.31, which is applicable to any paper filed on or after September 16, 2012, that is presented on behalf of a juristic entity, regardless of application filing date). Submit multiple forms if more than one signature is required, see below*.

☐ * Total of _____ forms are submitted.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
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 inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	40860413
Application Number:	16288351
International Application Number:	
Confirmation Number:	1764
Title of Invention:	DETECTING MUTATIONS AND PLOIDY IN CHROMOSOMAL SEGMENTS
First Named Inventor/Applicant Name:	Joshua BABIARZ
Customer Number:	110711
Filer:	Walter Joseph Piszker/Bridget McAuliffe
Filer Authorized By:	Walter Joseph Piszker
Attorney Docket Number:	N.012.US.10
Receipt Date:	15-OCT-2020
Filing Date:	28-FEB-2019
Time Stamp:	23:36:49
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Internet Communications Authorized	1887174-0002-012-110_Authorization.pdf	74964 e312f354bc08b776c655e13a57d2c1748afb f352	no	2

Warnings:

Information:	
Total Files Size (in bytes):	74964

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82B (07-13)
Approved for use through 11/30/2014. OMB 0651-0051
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date
16/288,351	February 28, 2019

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

[X] I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 106224

OR

[ ] I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

[ ] The address associated with the above-mentioned Customer Number

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Firm or Individual Name					
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City		State		Zip	
Country					
Telephone		Email			

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

NATERA, INC.

[ ] Inventor or Joint Inventor (title not required below)

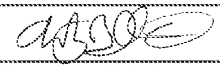
[ ] Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

[X] Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

[ ] Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature		Date (Optional)	10 / 15 / 2020
Name	Dr. Anton Bokal		
Title	Vice President, Chief IP Counsel		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

[ ] Total of 2 forms are submitted.

AMERICAS 104449654

Doc ID: 3382948cc6dec7ac0369cd58503f09e1f8605d7d

NeoGenomics
Exhibit 1003 Page 670

Electronic Acknowledgement Receipt

EFS ID:	40860362
Application Number:	16288351
International Application Number:	
Confirmation Number:	1764
Title of Invention:	DETECTING MUTATIONS AND PLOIDY IN CHROMOSOMAL SEGMENTS
First Named Inventor/Applicant Name:	Joshua BABIARZ
Customer Number:	110711
Filer:	Walter Joseph Piszker/Bridget McAuliffe
Filer Authorized By:	Walter Joseph Piszker
Attorney Docket Number:	N.012.US.10
Receipt Date:	15-OCT-2020
Filing Date:	28-FEB-2019
Time Stamp:	23:27:54
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	1887174-0002-012-110_POA.pdf	102600 1ea1483002774729526e1ab2e3902c902755ac0b	no	1

Warnings:

Information:	
Total Files Size (in bytes):	102600

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New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/288,351	02/28/2019	Joshua BABIARZ	N.012.US.10	1764

110711 7590 06/18/2020

Natera, Inc.
201 Industrial Road
Suite 410
San Carlos, CA 94070

EXAMINER	
STRZELECKA, TERESA E	

ART UNIT	PAPER NUMBER
1637	

NOTIFICATION DATE	DELIVERY MODE
06/18/2020	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):

IP@natera.com

Office Action Summary	Application No. 16/288,351	Applicant(s) BABIARZ et al.	
	Examiner TERESA E STRZELECKA	Art Unit 1637	AIA (FITF) Status Yes

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 5/4/20.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ 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.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-24 is/are pending in the application.

5a) Of the above claim(s) 4,6,9-10,13,17-19 and 21-22 is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-3,5,7-8,11-12,14-16,20 and 23-24 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, 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.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 2/28/19 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ 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)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date 10/24/19;3/10/20;4/20/20;5/4/20;6/10/20.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Election/Restrictions

2. Applicant's election with traverse of species C, F, K, N, S and EGFR gene in the reply filed on May 4, 2020 is acknowledged. The traversal is on the ground(s) that:

"…Applicant respectfully traverses the species election requirements on the grounds that there is no serious burden upon the Office to examine all of the species together. Applicant further submits that certain species election requirements are inconsistent with MPEP 806.04. As set forth in MPEP 806.04(f):

> *"Where two or more species are claimed, **a requirement for restriction to a single species may be proper if the species are mutually exclusive.** Claims to different species are mutually exclusive if one claim recites limitations disclosed for a first species but not a second, while a second claim recites limitations disclosed only for the second species and not the first. This may also be expressed by saying that **to require restriction between claims limited to species, the claims must not overlay in scope.**"*

Here, with respect to "Species of cancer-specific mutations", the subject matter of claim 3 (SNV mutation), claim 7 (clonal SNV mutation) and claim 11 (one or more clonal SNV mutations and one or more subclonal SNV mutations) overlap in scope and are not mutually exclusive. For example, while Applicant has provisionally elected clonal SNV mutation, the elected species also falls squarely within the scope of claims 3 and 11.

In addition, with respect to "Species of further method steps", the subject matter of claim 12 (determining clonal heterogeneity of the cancer sample), claim 13 (designing targeted

PCR assays for the cancer-specific mutations identified in the cancer sample), and claim 18 (detecting recurrence and/or metastases of the cancer from the cancer-specific mutations detected in the cell-free DNA) overlap in scope and are not mutually exclusive. Indeed, they recite sequential steps of a single process.

Therefore, as the aforementioned species election requirements are inconsistent with MPEP 806.04, Applicant respectfully requests reconsideration and withdrawal thereof."

Response

While the argument regarding SNV mutations is persuasive, Applicant's argument regarding further method steps is not found persuasive because there is absolutely no overlap between a method of determining clonal heterogeneity of a tumor, a method of designing PCR assays or a method of detecting recurrence and/or metastases of cancer. Applicant did not provide any reasoning in support of the assertion that these methodologies are overlapping in scope.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4, 6, 9, 10, 13, 17-19, 21 and 22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 4, 2020.

3. Claims 1-3, 5, 7, 8, 11, 12, 14-16, 20, 23 and 24 are under consideration, with respect to the elected species.

Priority

4. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or

provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of 35 U.S.C. 112(a) or the first paragraph of pre-AIA 35 U.S.C. 112, except for the best mode requirement. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994)

The disclosure of the prior-filed applications, Application No. 61/982,245 (filed 4/21/2014); Application No. 61/987,407 (filed 5/01/2014); Application No. 61/994,791 (filed 5/16/2014; Application No. 62/066,514 (filed October 21, 2014), fail to provide adequate support or enablement in the manner provided by 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112, first paragraph for one or more claims of this application.

Specifically, claims 7-12, drawn to clonal and subclonal SNV mutations and clonal tumor heterogeneity, do not have support in the disclosures of these applications. Consequently, the priority date of claims 7, 8, 11 and 12 (and withdrawn claims 9 and 10) is April 10, 2015, filing date of the provisional application No. 62/146,188.

Information Disclosure Statement

5. The information disclosure statements (IDSs) submitted on October 24, 2019, March 10, 2020 and April 20, 2020 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

6. The information disclosure statements (IDSs) submitted on May 4, 2020 and June 10, 2020 were filed after the mailing date of the Restriction/Election Requirement on April 22, 2020. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements ae being considered by the examiner.

Claim Rejections - 35 USC § 112

7. The following is a quotation of 35 U.S.C. 112(b):

> (b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.
>
> The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-3, 5, 7, 8, 11, 12, 14-16, 20, 23 and 24 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

A) Claims 1-3, 5, 7, 8, 11, 12, 14-16, 20, 23 and 24 are indefinite in claim 1. Claim 1 is indefinite over the recitation of "...assaying cell-free DNA....for the presence or absence of the cancer-specific mutations..." It is not clear how one can assay for an absence of mutations, therefore the claims do not have clear metes and bounds.

B) Claim 5 is rejected on the basis that it contains an improper Markush grouping of alternatives. See *In re Harnisch*, 631 F.2d 716, 721-22 (CCPA 1980) and *Ex parte Hozumi*, 3 USPQ2d 1059, 1060 (Bd. Pat. App. & Int. 1984). A Markush grouping is proper if the alternatives defined by the Markush group (i.e., alternatives from which a selection is to be made in the context of a combination or process, or alternative chemical compounds as a whole) share a "single structural similarity" and a common use. A Markush grouping meets these requirements in two situations. First, a Markush grouping is proper if the alternatives are all members of the same recognized physical or chemical class or the same art-recognized class, and are disclosed in the specification or known in the art to be functionally equivalent and have a common use. Second, where a Markush grouping describes alternative chemical compounds, whether by words or chemical formulas, and the alternatives do not belong to a recognized class

as set forth above, the members of the Markush grouping may be considered to share a "single structural similarity" and common use where the alternatives share both a substantial structural feature and a common use that flows from the substantial structural feature. See MPEP § 706.03(y).

The Markush grouping of claim 5 is improper because the alternatives defined by the Markush grouping do not share both a single structural similarity and a common use for the following reasons: each of the genes encodes a protein with a different function and structure.

To overcome this rejection, Applicant may set forth each alternative (or grouping of patentably indistinct alternatives) within an improper Markush grouping in a series of independent or dependent claims and/or present convincing arguments that the group members recited in the alternative within a single claim in fact share a single structural similarity as well as a common use.

C) Claim 8 is rejected on the basis that it contains an improper Markush grouping of alternatives. See *In re Harnisch*, 631 F.2d 716, 721-22 (CCPA 1980) and *Ex parte Hozumi*, 3 USPQ2d 1059, 1060 (Bd. Pat. App. & Int. 1984). A Markush grouping is proper if the alternatives defined by the Markush group (i.e., alternatives from which a selection is to be made in the context of a combination or process, or alternative chemical compounds as a whole) share a "single structural similarity" and a common use. A Markush grouping meets these requirements in two situations. First, a Markush grouping is proper if the alternatives are all members of the same recognized physical or chemical class or the same art-recognized class, and are disclosed in the specification or known in the art to be functionally equivalent and have a common use. Second, where a Markush grouping describes alternative chemical compounds, whether by words or chemical formulas, and the alternatives do not belong to a recognized class

as set forth above, the members of the Markush grouping may be considered to share a "single structural similarity" and common use where the alternatives share both a substantial structural feature and a common use that flows from the substantial structural feature. See MPEP § 706.03(y).

The Markush grouping of claim 8 is improper because the alternatives defined by the Markush grouping do not share both a single structural similarity and a common use for the following reasons: each of the genes encodes a protein with a different function and structure.

To overcome this rejection, Applicant may set forth each alternative (or grouping of patentably indistinct alternatives) within an improper Markush grouping in a series of independent or dependent claims and/or present convincing arguments that the group members recited in the alternative within a single claim in fact share a single structural similarity as well as a common use.

D) Claims 8 is indefinite because TP53 is listed three times and EGFR is listed twice. It is not clear whether the multiple listings designate multiple forms of these genes.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 1-3, 5, 7, 8, 11, 12, 14-16, 20, 23 and 24 are rejected under 35 U.S.C. 101 because the claimed invention is directed to a judicial exception without significantly more. The claim(s) recite a method of monitoring a progression of cancer by identifying cancer-specific mutations in a subject and assaying cell-free DNA from the subject for the presence or absence of such mutations, therefore the claims are directed to a naturally-occurring phenomenon of a correlation

between the presence or absence of mutations and cancer progression. This judicial exception is not integrated into a practical application because the claims do not include additional elements which are sufficient to amount to "significantly more" than the judicial exception. Claims 1-3, 5, 7, 8, 11, 12, 20 and 23 do not require any specific method of sequencing or assaying cell-free DNA for mutations. Further, determination of mutations in cell-free DNA of cancer patients was well-known, routine and conventional in the art at the time of the invention, as evidenced by PubMed search results for "cell-free DNA" AND mutation AND cancer AND sequencing, which returned 1043 results up to 2014. Finally, multiplex amplification of target loci for sequencing and mutation detection was well-known and conventional in the art, as evidenced by Mertes et al. (Briefings in Functional Genomics, vol. 10, pp. 374-386, 2011; cited in the IDS).

Therefore the claims as recited do not amount to significantly more than the judicial exception, thus they are not patent-eligible under 35 U.S.C. 101.

Claim Rejections - 35 USC § 102

11. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale or otherwise available to the public before the effective filing date of the claimed invention.

13. Claims 1-3, 5, 7, 8, 11, 20, 23 and 24 are rejected under 35 U.S.C. 102(a)(2) as being anticipated by Diehn et al. (US 2014/0296081 A1; filed March 13, 2014 with a priority date of March 15, 2013).

Regarding claims 1 and 2, Diehn et al. teach a method for monitoring the progression of cancer in a subject comprising:

(a) performing sequencing on a cancer sample of the subject to identify a plurality of cancer-specific mutations (Fig. 1a and Fig. 2; [0025]-[0031]; [0104]-[0108]; [0111]); and

(b) assaying cell-free DNA isolated from a plurality of biological samples obtained from the subject at different time points for the presence or absence of the cancer-specific mutations, thereby monitoring the progression of cancer (Fig. 1a and Fig. 2; Fig. 11; Fig. 14; Fig. 17; [0041]-[0044]; [0075]; [0078]; [0081]; [0135]; since the method of Diehn et al. performs the required method steps, Diehn et al. inherently teach determination of the progression of cancer).

Regarding claims 3, 5, 7, 8 and 11, Diehn et al. teach single nucleotide variant (SNVs) in EGFR gene, and clonal and subclonal mutations (Fig. 1; Fig. 11; Fig. 14).

Regarding claim 20, Diehn et al. teach lung cancer ([0082]; [0124]).

Regarding claim 23, Diehn et al. teach plasma samples ([0135]).

Regarding claim 24, Diehn et al. teach whole exome sequencing ([0124]).

Claim Rejections - 35 USC § 103

14. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

15. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

17. Claim 12 is rejected under 35 U.S.C. 103 as being unpatentable over Diehn et al. (US 2014/0296081 A1; filed March 13, 2014 with a priority date of March 15, 2013) and Murtaza et al. (Nature, vol. 497, pp. 108-112, 2013; cited in the IDS).

A) Diehn et al. teach detection of cancer-specific mutations in plasma of patients with lung cancer, and detection of clonal and subclonal mutations, but do not specifically teach determining clonal heterogeneity of the cancer sample.

B) Murtaza et al. teach detection of clonal heterogeneity of cancer samples by exome sequencing of serial plasma samples from patients with different cancer types, including lung cancer (Abstract; page 108-111; Fig. 1, 2; Table 1).

It would have been *prima facie* obvious to one of ordinary skill in the art before the effective filing date of the claimed invention to have used the data of Diehn et al. to determine

clonal tumor heterogeneity as suggested by Murtaza et al. The motivation to do so is provided by Murtaza et al. (page 111, second paragraph):

"In this proof of principle study, we demonstrate that exome analysis of plasma ctDNA represents a novel paradigm for non-invasive characterization of tumour evolution. Our data, together with recent reports[5,7], show that CNAs and somatic mutations identified in ctDNA are widely representative of the tumour genome and provide an alternative method of tumour sampling that can overcome limitations of repeated biopsies. Cell-free DNA fragments from multiple lesions in the same individual all mix together in the peripheral blood5, therefore ctDNA is likely to contain a wider representation of the genomes from multiple metastatic sites, whereas mutations present in a single biopsy or minor sub-clone may be missed. This strengthens the case for the use of ctDNA as a biomarker for monitoring tumour burden or for the analysis of hotspot mutation regions[1,6,16,17], but also indicates that tracking different mutations for assessment of tumour heterogeneity and clonal evolution is now possible."

18. Claims 14-16 are rejected under 35 U.S.C. 103 as being unpatentable over Diehn et al. (US 2014/0296081 A1; filed March 13, 2014 with a priority date of March 15, 2013), Mertes et al. (Brief. Funct. Genomics, vol. 10, pp. 374-386, 2011; cited in the IDS), Nguyen-Dumont et al. (Biotechniques, vol. 55, pp. 69-74, 2013; cited in the IDS) and Wang et al. (Science, vol. 280, pp. 1077-1082, 1998).

A) Regarding claims 14-16, Diehn et al. teach detection of mutations in 10 to 5000 genomic regions ([0016]; [0032]; [0094]-[0095]). They teach selection of the regions to be sequenced using hybridization capture to probe arrays ([0145]-[0146]), but do not teach selecting regions for sequencing by multiplex amplification. Regarding claim 16, Diehn et al. teach high-troughput sequencing ([0142]-[0144]; [0147]).

B) Mertes et al. teach that selection and enrichment of sequences to be used in next generation sequencing (NGS) can be performed using one of three methods: hybrid capture, selective circularization and PCR (page 375, fourth paragraph; Fig. 1; page 379, last two paragraphs; page 380, paragraphs 1-3).

It would have been *prima facie* obvious to one of ordinary skill in the art before the effective filing date of the claimed invention to have used multiplex amplification as suggested by Mertes et al. in the method of whole exome sequencing of Diehn et al. The motivation to do so is provided by Mertes et al. (page 379, fifth paragraph):

"Enrichment by PCR (Figures 1.3a–c) is in terms of methodology, a more straightforward method compared with the other genome partioning techniques. It takes advantage of the great power of PCR to enrich genome regions from small amounts of target material. Just as for circularization methods, if the PCR product sizes fall within the sequencing length of the applied NGS platform (maximum read length for SOLiD: 110 bp, Illumina: 240 bp and 454: 1000 bp) PCR-based enrichment can allow one to bypass the need for shot-gun library preparation by using suitably 50-tailed primers in the final amplification steps."

The reasonable expectation of success is provided by the references of Nguyen-Dumont et al. and Wang et al. Nguyen-Dumont et al. teach successful amplification of 60 different target in a single PCR reaction (Abstract; page 70, third paragraph; page 72, paragraphs 4 and 5).

Wang et al. teach multiplex amplification of target genomic fragments for detection of SNPs on microarrays. They teach successful amplification and mapping of 23, 46 and 92 loci (page 1080, paragraphs 1-4).

Double Patenting

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP §§ 706.02(l)(1) - 706.02(l)(3) for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-

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20. Claims 1-3, 5, 7, 8, 11, 12, 14-16, 20, 23 and 24 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-4, 6, 8, 9, 12-14, 16, 19, 22 and 23 of copending Application No. 16/288,416 (reference application). Although the claims at issue are not identical, they are not patentably distinct from each other because the instant claims are obvious over claims of the '416 application.

Specifically, claim 1 of the instant application is drawn to a method for monitoring the progression of cancer in a subject comprising:

(a) performing sequencing on a cancer sample of the subject to identify a plurality of cancer-specific mutations; and

(b) assaying cell-free DNA isolated from a plurality of biological samples obtained from the subject at different time points for the presence or absence of the cancer-specific mutations, thereby monitoring the progression of cancer.

Claim 1 of the '416 application is drawn to a method for monitoring the progression of cancer comprising:

(a) performing a multiplex amplification reaction to amplify a plurality of target loci from cell-free DNA isolated from a first biological sample of a subject, wherein the target loci each spans a cancer-specific mutation identified in a cancer sample of the subject;

(b) determining the sequences of the amplified target loci; and

(c) determining the presence or absence of the cancer-specific mutations based on the sequencing results, thereby monitoring the progression of cancer.

Claim 2 of the '416 application is drawn to the method of claim 1, further comprising:

(d) repeating steps (a)-(c) on cell-free DNA isolated from a second biological sample obtained from the subject at a subsequent time point.

Therefore claim 2 of the '416 application anticipates claims 1 and 14 of the instant application. Instant claims 2, 3, 5, 7, 8, 11, 12, 14-16, 20, 23 and 24 are obvious over claims 3, 4, 6, 8, 9, 12, 14, 16, 23, 19, 22 and 13, respectively.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

21. Claims 1-3, 5, 7, 8, 11, 12, 14-16, 20, 23 and 24 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-4, 6, 8, 9, 12-14, 16, 19, 22 and 23 of copending Application No. 16/288,462 (reference application). Although the claims at issue are not identical, they are not patentably distinct from each other because the instant claims are obvious over claims of the '462 application.

Specifically, claim 1 of the instant application is drawn to a method for monitoring the progression of cancer in a subject comprising:

(a) performing sequencing on a cancer sample of the subject to identify a plurality of cancer-specific mutations; and

(b) assaying cell-free DNA isolated from a plurality of biological samples obtained from the subject at different time points for the presence or absence of the cancer-specific mutations, thereby monitoring the progression of cancer.

Claim 1 of the '462 application is drawn to a method for monitoring the progression of cancer comprising:

(a) determining the sequences of a plurality of amplified target loci, wherein the amplified target loci each spans a cancer-specific mutation identified in a cancer sample of a

subject, and wherein the amplified target loci are amplified from cell-free DNA isolated from a first biological sample of the subject; and

(b) determining the presence or absence of the cancer-specific mutations based on the sequencing results, thereby monitoring the progression of cancer.

Claim 2 of the '462 application is drawn to the method of claim 1, further comprising:

(c) repeating steps (a)-(b) on a plurality of amplified target loci amplified from cell-free DNA isolated from a second biological sample obtained from the subject at a subsequent time point.

Therefore claim 2 of the '462 application anticipates claims 1 and 14 of the instant application. Instant claims 2, 3, 5, 7, 8, 11, 12, 14-16, 20, 23 and 24 are obvious over claims 3, 4, 6, 8, 9, 12, 14, 16, 23, 19, 22 and 13, respectively.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

22. Claims 1-3, 5, 7, 8, 11, 12, 14-16, 20, 23 and 24 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 2, 5-7, 9, 11, 15, 19, and 21-23 of copending Application No. 16/399,941 (reference application). Although the claims at issue are not identical, they are not patentably distinct from each other because the instant claims are obvious over claims of the '941 application.

Specifically, claim 1 of the instant application is drawn to a method for monitoring the progression of cancer in a subject comprising:

(a) performing sequencing on a cancer sample of the subject to identify a plurality of cancer-specific mutations; and

(b) assaying cell-free DNA isolated from a plurality of biological samples obtained from the subject at different time points for the presence or absence of the cancer-specific mutations, thereby monitoring the progression of cancer.

Claim 2 of the '941 application is drawn to method for monitoring the progression of cancer comprising:

(a) performing whole exome sequencing of a tumor biopsy sample of a subject to identify tumor-specific mutations and determining clonal heterogeneity thereof;

(b) performing a multiplex amplification reaction to amplify at least 10 different target loci from cell-free DNA isolated from a first biological sample of the subject in a single reaction volume, wherein the target loci each spans a mutation identified in the tumor biopsy sample of the subject in step (a), and wherein the multiplex amplification comprises nested PCR which comprises a first PCR reaction with a first universal primer and a first set of target-specific primers and a second PCR reaction with a second universal primer and a second set of target-specific primers;

(c) determining the sequences of the amplified target loci; and

(d) determining the presence or absence of the mutations based on the sequencing results, thereby monitoring the progression of cancer.

Claim 5 of the '941 application is drawn to the method of claim 2, further comprising:

(d) repeating steps (a)-(c) on cell-free DNA isolated from a second biological sample obtained from the subject at a subsequent time point.

Therefore claim 5 of the '941 application anticipates instant claims 1, 12, 14, 15 and 24. Instant claims 2, 3, 5, 7, 8, 11, 16, 20 and 23 are obvious over claims 6, 7, 9, 11, 12, 15 and 21-23.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

23. No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TERESA E STRZELECKA whose telephone number is (571)272-0789. The examiner can normally be reached on M-F 9-7.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

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/TERESA E STRZELECKA/
Primary Examiner, Art Unit 1637
June 11, 2020

Notice of References Cited	Application/Control No. 16/288,351	Applicant(s)/Patent Under Reexamination BABIARZ et al.	
	Examiner TERESA E STRZELECKA	Art Unit 1637	Page 1 of 1

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	C					
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	M					

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/288,351	BABIARZ et al.
	Examiner	Art Unit
	TERESA E STRZELECKA	1637

CPC - Searched*		
Symbol	Date	Examiner

CPC Combination Sets - Searched*		
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US Classification - Searched*			
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Search Notes		
Search Notes	Date	Examiner
Inventor name search	06/08/2020	/TS/
WEST	06/10/2020	/TS/
IDS (10/24/19; 3/10/20; 4/20/20; 5/4/20)	06/10/2020	/TS/
Pubmed	06/10/2020	/TS/

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/288,351	BABIARZ et al.
	Examiner	**Art Unit**
	TERESA E STRZELECKA	1637

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	06/10/2020								
	1	✓								
	2	✓								
	3	✓								
	4	N								
	5	✓								
	6	N								
	7	✓								
	8	✓								
	9	N								
	10	N								
	11	✓								
	12	✓								
	13	N								
	14	✓								
	15	✓								
	16	✓								
	17	N								
	18	N								
	19	N								
	20	✓								
	21	N								
	22	N								
	23	✓								
	24	✓								

COVID-19 is an emerging, rapidly evolving situation.
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/288,351
	Filing Date	Feb 28, 2019
	First Named Inventor	Joshua BABIARZ
	Art Unit	1637
	Examiner Name	Teresa E. Strzelecka
	Attorney Docket Number	N.012.US.10

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	Attorney Docket Number	N.012.US.10

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	Art Unit	1637
	Examiner Name	Teresa E. Strzelecka
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	First Named Inventor	Joshua BABIARZ
	Art Unit	1637
	Examiner Name	Teresa E. Strzelecka
	Attorney Docket Number	N.012.US.10

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Bibliographic Data

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Title: DETECTING MUTATIONS AND PLOIDY IN CHROMOSOMAL SEGMENTS

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CONTINUING DATA

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14692703 has PRO of 62148173 04/15/2015

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14692703 has PRO of 61982245 04/21/2014

FOREIGN APPLICATIONS

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CERTIFICATION STATEMENT

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /T.E.S/

WEST Search History for Application 16288351

Creation Date: 2020061013:37

Prior Art Searches

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	USPT	67	ADJ	YES	ASSIGNEE	06-10-2020

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((US-5635366-$ | US-5716776-$ | US-5753467-$ | US-5824467-$ | US-5860917-$ | US-5972602-$ | US-5994148-$ | US-6001611-$ | US-6025128-$ | US-6066454-$ | US-6100029-$ | US-6108635-$ | US-6124120-$ | US-6143496-$ | US-6156504-$ | US-6180349-$ | US-6214558-$ | US-6258540-$ | US-6300077-$ | US-6440706-$ | US-6479235-$ | US-6489135-$ | US-6720140-$ | US-6794140-$ | US-6807491-$ | US-6852487-$ | US-6958211-$ | US-6964847-$ | US-7035739-$ | US-7058517-$ | US-7058616-$ | US-7218764-$ | US-7297485-$ | US-7332277-$ | US-7414118-$ | US-7442506-$ | US-7459273-$ | US-7645576-$ | US-7700325-$ | US-7718367-$ | US-7718370-$ | US-7727720-$ | US-7805282-$ | US-7838647-$ | US-7888017-$ | US-8008018-$ | US-8024128-$ | US-8133719-$ | US-8137912-$ | US-8168389-$ | US-8173370-$ | US-8195415-$ | US-8296076-$ | US-8304187-$ | US-8318430-$ | US-8450063-$ | US-8467976-$ | US-8515679-$ | US-8532930-$ | US-8682592-$ | US-8825412-$ | US-9085798-$ | US-9323888-$ | US-9476095-$ | US-9487829-$ | US-9598731-$ | US-9677118-$).DID. and (cell-free or cell free or circulat$5) near3 (DNA or RNA or nucleic)) and (tumor or cancer)	USPT	25	ADJ	YES	ASSIGNEE	06-10-2020
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) and (cell-free or cell free or circulat$5) near3 (DNA or RNA or nucleic) and lung near3 (cancer or tumor)						
(US-20180155775-$ | US-20180155776-$ | US-20180155779-$ | US-20180155785-$ | US-20180155786-$ | US-20180155792-$ | US-20180171409-$ | US-20180171420-$ | US-20180173845-$ | US-20180173846-$ | US-20180201995-$ | US-20180237841-$ | US-20180298439-$ | US-20180300448-$ | US-20190010543-$ | US-20190106737-$ | US-20190106751-$ | US-20190185913-$ | US-20190185936-$ | US-20190194743-$ | US-20190194759-$ | US-20190203290-$ | US-20190203294-$).DID.	PGPB	23	ADJ	YES	ASSIGNEE	06-10-2020
((US-20180155775-$ | US-20180155776-$ | US-20180155779-$ | US-20180155785-$ | US-20180155786-$ | US-20180155792-$ | US-20180171409-$ | US-20180171420-$ | US-20180173845-$ | US-20180173846-$ | US-20180201995-$ | US-20180237841-$ | US-20180298439-$ | US-20180300448-$ | US-20190010543-$ | US-20190106737-$ | US-20190106751-$ | US-20190185913-$ | US-20190185936-$ | US-20190194743-$ | US-20190194759-$ | US-20190203290-$ | US-20190203294-$).DID.) and (cell-free or cell free or circulat$5) near3 (DNA or RNA or nucleic) and lung near3 (cancer or tumor)	PGPB	7	ADJ	YES	ASSIGNEE	06-10-2020
(US-20180155775-$ | US-20180155776-$ | US-20180155779-$ | US-20180155785-$ | US-20180155786-$ | US-20180155792-$ | US-20180171409-$ | US-20180171420-$ | US-20180173845-$ | US-20180173846-$ | US-20180201995-$ | US-20180237841-$ | US-20180298439-$ | US-20180300448-$ | US-20190010543-$ | US-20190106737-$ | US-20190106751-$ | US-20190185913-$ | US-20190185936-$ | US-20190194743-$ | US-20190194759-$ | US-20190203290-$ | US-20190203294-$ | US-20190211391-$ | US-20190211392-$ | US-20190211393-$ | US-20190211399-$ | US-20190211402-$ | US-20190211406-$ | US-20190249241-$ | US-20190256906-$ | US-20190256907-$ | US-20190256909-$ | US-20190256916-$ | US-20190256917-$ | US-20190264277-$ | US-20190264280-$ | US-20190264288-$ | US-20190271043-$ | US-20190276888-$ |	PGPB	46	ADJ	YES	ASSIGNEE	06-10-2020

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("10081839" | "10083273" | "10308981" | "10316362").pn.	USPT	4	ADJ	YES	ASSIGNEE	06-10-2020
("20010051341" | "20010053519" | "20020006622" | "20020107640" | "20030009295" | "20030065535" | "20030077586" | "20030101000" | "20030119004" | "20030228613" | "20040033596" | "20040137470" | "20040146866" | "20040157243" | "20040197797" | "20040209299" | "20040229231" | "20040236518" | "20040259100" | "20050009069" | "20050049793" | "20050053950" | "20050079535" | "20050123914" | "20050130173" | "20050142577" | "20050144664" | "20050164241" | "20050216207" | "20050221341" |	PGPB	49	ADJ	YES	ASSIGNEE	06-10-2020

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(("20010051341" | "20010053519" | "20020006622" | "20020107640" | "20030009295" | "20030065535" | "20030077586" | "20030101000" | "20030119004" | "20030228613" | "20040033596" | "20040137470" | "20040146866" | "20040157243" | "20040197797" | "20040209299" | "20040229231" | "20040236518" | "20040259100" | "20050009069" | "20050049793" | "20050053950" | "20050079535" | "20050123914" | "20050130173" | "20050142577" | "20050144664" | "20050164241" | "20050216207" | "20050221341" | "20050227263" | "20050250111" | "20050255508" | "20050272073" | "20060019278" | "20060040300" | "20060052945" | "20060057618" | "20060068394" | "20060088574" | "20060099614" | "20060121452" | "20060134662" | "20060141499" | "20060210997" | "20060216738" | "20060229823" | "20060248031" | "20060281105").PN.) and (cell-free or cell free or circulat$5) near3 (DNA or RNA or nucleic) and lung near3 (cancer or tumor)	PGPB	3	ADJ	YES	ASSIGNEE	06-10-2020
Natera.asn. and (cell-free or cell free or circulat$5) near3 (DNA or RNA or nucleic) and (cancer or tumor) and sequencing and progress$8	PGPB	27	ADJ	YES	ASSIGNEE	06-10-2020
Natera.asn. and (cell-free or cell free or circulat$5) near3 (DNA or RNA or nucleic) and (cancer or tumor) and sequencing and progress$8	USPT	12	ADJ	YES	ASSIGNEE	06-10-2020
(cell-free or cell free or circulat$5) near3 (DNA or RNA or nucleic) and (cancer or tumor) and sequencing and (mutation or	PGPB	141	ADJ	YES	ASSIGNEE	06-10-2020

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variant or alteration or polymorphism or SNP) near3 (clonal or subclonal or sub-clonal)						
((cell-free or cell free or circulat$5) near3 (DNA or RNA or nucleic) and (cancer or tumor) and sequencing and (mutation or variant or alteration or polymorphism or SNP) near3 (clonal or subclonal or sub-clonal)) and tumor near3 heterogen$8	PGPB	72	ADJ	YES	ASSIGNEE	06-10-2020
((cell-free or cell free or circulat$5) near3 (DNA or RNA or nucleic) and (cancer or tumor) and sequencing and (mutation or variant or alteration or polymorphism or SNP) near3 (clonal or subclonal or sub-clonal)) and tumor near3 heterogen$8	PGPB	72	ADJ	YES	ASSIGNEE	06-10-2020
(cell-free or cell free or circulat$5) near3 (DNA or RNA or nucleic) and (cancer or tumor) and sequencing and (mutation or variant or alteration or polymorphism or SNP) near3 (clonal or subclonal or sub-clonal)	USPT	70	ADJ	YES	ASSIGNEE	06-10-2020
((cell-free or cell free or circulat$5) near3 (DNA or RNA or nucleic) and (cancer or tumor) and sequencing and (mutation or variant or alteration or polymorphism or SNP) near3 (clonal or subclonal or sub-clonal)) and tumor near3 heterogen$8	USPT	22	ADJ	YES	ASSIGNEE	06-10-2020
(cell-free or cell free or circulat$5) near3 (DNA or RNA or nucleic) and (cancer or tumor) and sequencing and (mutation or variant or alteration or polymorphism or SNP) near3 (clonal or subclonal or sub-clonal)	PGPB	141	ADJ	YES	ASSIGNEE	06-10-2020
(cell-free or cell free or circulat$5) near3 (DNA or RNA or nucleic) and (cancer or tumor) and sequencing and (mutation or variant or alteration or polymorphism or SNP) near3 (clonal or subclonal or sub-clonal)	DWPI	6	ADJ	YES	ASSIGNEE	06-10-2020
US-20150087535-A1.did.	PGPB	1	ADJ	YES	ASSIGNEE	06-10-2020

PALM INTRANET

Day : Monday
Date: 6/8/2020
Time: 10:34:32

Inventor Name Search

Enter the **first few letters** of the Inventor's Last Name.
Additionally, enter the **first few letters** of the Inventor's First name.

Last Name	First Name	
Babiarz	Joshua	Search

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Inventor Name Search

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Last Name	**First Name**	
Constantin	Tudor	Search

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Last Name	First Name	
Eubank	Lane	Search

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Inventor Name Search

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Additionally, enter the **first few letters** of the Inventor's First name.

Last Name	First Name	
Gemelos	George	Search

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Inventor Name Search

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Last Name	First Name	
Hill	Matthew	Search

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Inventor Name Search

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Last Name	First Name	
Kirkizlar	Huseyin	Search

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Inventor Name Search

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Additionally, enter the **first few letters** of the Inventor's First name.

Last Name	First Name	
Rabinowitz	Matthew	Search

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Inventor Name Search

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Additionally, enter the **first few letters** of the Inventor's First name.

Last Name	First Name	
Sakarya	Onur	Search

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Inventor Name Search

Enter the **first few letters** of the Inventor's Last Name.
Additionally, enter the **first few letters** of the Inventor's First name.

Last Name	First Name	
Sigurjonsson	Styrmir	Search

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Inventor Name Search

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Additionally, enter the **first few letters** of the Inventor's First name.

Last Name	First Name	
Zimmermann	Bernhard	Search

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/288,351
	Filing Date	Feb 28, 2019
	First Named Inventor	Joshua BABIARZ
	Art Unit	1637
	Examiner Name	Teresa E. Strzelecka
	Attorney Docket Number	N.012.US.10

U.S. PATENTS						
Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
U.S. PATENT APPLICATION PUBLICATIONS						
Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		20030211489	A1	2003-11-13	SHEN, M.-J. R., et al.	
		20050079521	A1	2005-04-14	BEAULIEU, M. et al.	
		20120034685	A1	2012-02-09	SPARKS, A. et al.	
		20120108460	A1	2012- 05-03	QUAKE, S. R., et al.	
		20120295810	A1	2012-11-22	QUAKE, S. R., et al.	
		20190256894	A1	2019-08-22	ZIMMERMANN, B. et al.	
		20190256908	A1	2019-08-22	RABINOWITZ, M. et al.	
		20190256912	A1	2019-08-22	RABINOWITZ, M. et al.	
		20190256919	A1	2019-08-22	BABIARZ, J. et al.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/288,351
	Filing Date	Feb 28, 2019
	First Named Inventor	Joshua BABIARZ
	Art Unit	1637
	Examiner Name	Teresa E. Strzelecka
	Attorney Docket Number	N.012.US.10

		20190256931	A1	2019-08-22	BABIARZ, J. et al.		
		20190323076	A1	2019-10-24	RABINOWITZ, M. et al.		
		20190360036	A1	2019-11-28	RABINOWITZ, M. et al.		
		20200024653	A1	2020-01-23	BETHKE, A.		

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns ,Lines where Relevant Passages or Relevant Figures Appear	T[5]
		2019/241349	WO	A1	2019-12-19	ZIMMERMANN, B. et al.		
		2020/010255	WO	A1	2020-01-09	MOSHKEVICH, S. et al.		
		2020/018522	WO	A1	2020-01-23	EGILSSON, A. et al.		

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	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[5]

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	First Named Inventor	Joshua BABIARZ
	Art Unit	1637
	Examiner Name	Teresa E. Strzelecka
	Attorney Docket Number	N.012.US.10

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	Art Unit	1637
	Examiner Name	Teresa E. Strzelecka
	Attorney Docket Number	N.012.US.10

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	First Named Inventor	Joshua BABIARZ
	Art Unit	1637
	Examiner Name	Teresa E. Strzelecka
	Attorney Docket Number	N.012.US.10

		SHI, H. et al., "Melanoma whole-exome sequencing identifies V600E B-RAF amplification-mediated acquired B-RAF inhibitor resistance", Nature Communications, Vol. 3, No. 724, 6 MAR 2012, 8 pages	
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		WAPNER, R. J. et al., "Expanding the scope of noninvasive prenatal testing: detection of fetal microdeletion syndromes", American Journal of Obstetrics & Gynecology, Vol. 212, 17 DEC 2014, 1.e1-1.e9	
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		ZACHARIAH, R. et al., "Circulating cell-free DNA as a potential biomarker for minimal and mild endometriosis", Reproductive BioMedicine Online, Vol. 18, No. 3, 27 JAN 2009, 4007-411	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /T.E.S/

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/288,351
	Filing Date	Feb 28, 2019
	First Named Inventor	Joshua BABIARZ
	Art Unit	1637
	Examiner Name	Teresa E. Strzelecka
	Attorney Docket Number	N.012.US.10

EXAMINER SIGNATURE

Examiner Signature	/TERESA E STRZELECKA/	Date Considered	06/10/2020

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.
[4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

CERTIFICATION STATEMENT

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☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

SIGNATURE

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U.S. PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		10655180	B2	2020- 05-19	BABIARZ, J. et al.	

U.S. PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		20180127744	A1	2018- 05-10	HU, J. et al.	
		20200140950	A1	2020- 05-07	BABIARZ, J. et al.	
		20200149111	A1	2020- 05-14	BABIARZ, J. et al.	
		20200157629	A1	2020- 05-21	BABIARZ, J. et al.	
		20200172977	A1	2020-06-04	RABINOWITZ, M. et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns, Lines where Relevant Passages or Relevant Figures Appear	T[5]

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	Art Unit	1637
	Examiner Name	Teresa E. Strzelecka
	Attorney Docket Number	N.012.US.10

		2013/169339	WO	A1	2013-11-14	IAFRATE, A. J., et al.		
		2017205540	WO	A1	2017-11-30	MURTAZA, M. et al.		

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	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[5]
		WANG, W.-P. et al., "Multiplex single nucleotide polymorphism genotyping by adapter ligation-mediated allele-specific amplification", Analytical Biochemistry, Vol. 355, 5 MAY 2006, 240-248	

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	Attorney Docket Number	N.012.US.10

CERTIFICATION STATEMENT

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OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Tianran Yan/	Date (YYYY-MM-DD)	2020-06-10
Name/Print	Tianran Yan	Registration Number	67,162

This collection of information is required by 37 CFR 1.97 and 1.98. 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 1.14. This collection is estimated to take 1 hour 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. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Electronic Acknowledgement Receipt

EFS ID:	39685542
Application Number:	16288351
International Application Number:	
Confirmation Number:	1764
Title of Invention:	DETECTING MUTATIONS AND PLOIDY IN CHROMOSOMAL SEGMENTS
First Named Inventor/Applicant Name:	Joshua BABIARZ
Customer Number:	110711
Filer:	Anton John Bokal/Angela McGowan
Filer Authorized By:	Anton John Bokal
Attorney Docket Number:	N.012.US.10
Receipt Date:	10-JUN-2020
Filing Date:	28-FEB-2019
Time Stamp:	18:47:04
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	N012US10_SB08_SIGNED.pdf	76312 1edcafd632cd63f7bbe19a5833131a8b7d0cb40d	no	3

Warnings:

Information:					
This is not an USPTO supplied IDS fillable form					
2	Foreign Reference	WO2013169339A1.pdf	3867543 3085e9635eb2b301fb47b4527fa117eb4b8d0049	no	69
Warnings:					
Information:					
3	Foreign Reference	WO2017205540A1.pdf	1483546 f3cfbd6697475ab0eaa062cb6ae10a1bf6e916c9	no	33
Warnings:					
Information:					
4	Non Patent Literature	WANG_2006_p240_NPL.pdf	458166 a1aeaba3239019213c33653a348165705e8d938e	no	9
Warnings:					
Information:					
			Total Files Size (in bytes):	5885567	

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

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	Filing Date	Feb 28, 2019
	First Named Inventor	Joshua BABIARZ
	Art Unit	1637
	Examiner Name	Teresa E. Strzelecka
	Attorney Docket Number	N.012.US.10

U.S. PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		10260096	B2	2019-04-16	RABINOWITZ, M. et al.	
		10266893	B2	2019-04-23	RABINOWITZ, M. et al.	
		10597709	B2	2020-03-24	ZIMMERMANN, B. et al.	

U.S. PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		20200123612	A1	2020-04-23	BABIARZ, J. et al.	
		20200126634	A1	2020-04-23	SIGURJONSSON, S. et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns, Lines where Relevant Passages or Relevant Figures Appear	T[5]
		02/090505	WO	A2	2002-11-14	CHEN, X.		

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	Art Unit	1637
	Examiner Name	Teresa E. Strzelecka
	Attorney Docket Number	N.012.US.10

		2013/177220	WO	A1	2013-11-28	HEAD, S. R., et al.		
		2015/148494	WO	A1	2015-10-01	CHENG, S.-M.		

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	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[5]

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

SIGNATURE

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Signature	/Tianran Yan/	Date (YYYY-MM-DD)	2020-05-04
Name/Print	Tianran Yan	Registration Number	67,162

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Electronic Acknowledgement Receipt

EFS ID:	39341448
Application Number:	16288351
International Application Number:	
Confirmation Number:	1764
Title of Invention:	DETECTING MUTATIONS AND PLOIDY IN CHROMOSOMAL SEGMENTS
First Named Inventor/Applicant Name:	Joshua BABIARZ
Customer Number:	110711
Filer:	Anton John Bokal/Angela McGowan
Filer Authorized By:	Anton John Bokal
Attorney Docket Number:	N.012.US.10
Receipt Date:	04-MAY-2020
Filing Date:	28-FEB-2019
Time Stamp:	14:37:11
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Applicant Response to Pre-Exam Formalities Notice	01_N012US10_Response_to_Restriction_Requirement_dated_22APR2020_SIGNED.pdf	35924 0c62c447b780b21cb2807d75521f788e3fd7b81d	no	3

Warnings:

Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	02_N012US10_SB08_SIGNED.pdf	76328 ed16495b273a8fa4093149fc6f18a3ce48eb05c0	no	3
Warnings:					
Information:					
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3	Foreign Reference	WO02090505A2.pdf	2298315 615ded5f5bedc53314267d896fc9fa3da64725d6	no	46
Warnings:					
Information:					
4	Foreign Reference	WO2013177220A1.pdf	859732 a74d50646f4b2eae0563526b04a1f76621aeb3da	no	107
Warnings:					
Information:					
5	Foreign Reference	WO2015148494A1.pdf	2903009 ab7715582adb93c4a5ff35f501d455f6f882946c	no	51
Warnings:					
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			Total Files Size (in bytes):	6173308	

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor Name:	Joshua BABIARZ
Title:	DETECTING MUTATIONS AND PLOIDY IN CHROMOSOMAL SEGMENTS
Application No.:	16/288,351
Filing Date:	2/28/2019
Examiner:	STRZELECKA, TERESA E
Art Unit:	1637
Conf. No.:	1764

RESPONSE TO RESTRICTION REQUIREMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

In response to the species election requirement set forth in the Office Action mailed April 22, 2020, Applicant hereby provisionally elects the following species for examination with traverse:

- Species of cancer-specific mutations – clonal SNV mutation;
- Species of further method steps – determining clonal heterogeneity of the cancer sample;
- Species of sequence determination method – high-throughput sequencing;
- Species of cancer – lung cancer;
- Species of biological sample – plasma;
- Species of genes – EGFR.

Claims 1-3, 5-8, 11-16, 18, 20 and 23-24 encompass the elected species. Applicant respectfully traverses the species election requirements on the grounds that there is no serious burden upon the Office to examine all of the species together. Applicant further submits that certain species election requirements are inconsistent with MPEP 806.04. As set forth in MPEP 806.04(f):

> "*Where two or more species are claimed,* ***a requirement for restriction to a single species may be proper if the species are mutually exclusive****. Claims to different species are mutually exclusive if one claim recites limitations disclosed for a first species but not a second, while a second claim recites limitations disclosed only for the second species and not the first. This may also be expressed by saying that* ***to require restriction between claims limited to species, the claims must not overlap in scope****.*"

Here, with respect to "Species of cancer-specific mutations", the subject matter of claim 3 (SNV mutation), claim 7 (clonal SNV mutation) and claim 11 (one or more clonal SNV mutations and one or more subclonal SNV mutations) overlap in scope and are not mutually exclusive. For example, while Applicant has provisionally elected clonal SNV mutation, the elected species also falls squarely within the scope of claims 3 and 11.

In addition, with respect to "Species of further method steps", the subject matter of claim 12 (determining clonal heterogeneity of the cancer sample), claim 13 (designing targeted PCR assays for the cancer-specific mutations identified in the cancer sample), and claim 18 (detecting recurrence and/or metastases of the cancer from the cancer-specific mutations detected in the cell-free DNA) overlap in scope and are not mutually exclusive. Indeed, they recite sequential steps of a single process.

Therefore, as the aforementioned species election requirements are inconsistent with MPEP 806.04, Applicant respectfully requests reconsideration and withdrawal thereof.

Applicant believes that the application is in condition for allowance. Favorable consideration is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance prosecution.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-6075. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extension fees to Deposit Account No. 50-6075.

Respectfully submitted,

Date 5-4-2020

By /Tianran Yan/

Tianran Yan
Registration No. 67162
Customer No. 110711
202-295-4781
IP@natera.com
Attorney for Applicant

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/288,351	02/28/2019	Joshua BABIARZ	N.012.US.10	1764

110711 7590 04/22/2020

Natera, Inc.
201 Industrial Road
Suite 410
San Carlos, CA 94070

EXAMINER	
STRZELECKA, TERESA E	

ART UNIT	PAPER NUMBER
1637	

NOTIFICATION DATE	DELIVERY MODE
04/22/2020	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):

IP@natera.com

Office Action Summary	Application No. 16/288,351	Applicant(s) BABIARZ et al.	
	Examiner TERESA E STRZELECKA	Art Unit 1637	AIA (FITF) Status Yes

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ 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.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-24 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☐ Claim(s) _____ is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☑ Claim(s) 1-24 are subject to restriction and/or election requirement

* If any claims have been determined allowable, 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.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ 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)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

DETAILED ACTION

Election/Restriction

2. This application contains claims directed to the following patentably distinct species:

Species of cancer-specific mutations

A) single nucleotide variant mutations (claims 3, 5 and 6),

B) copy number variation mutations (claim 4),

C) clonal SNV mutations (claims 7 and 8),

D) subclonal SNV mutations (claims 9 and 10),

E) one or more clonal SNV mutations and one or more subclonal SNV mutations (claim 11).

Species of further method steps

F) determining clonal heterogeneity of the cancer sample (claim 12),

G) designing targeted PCR assays for the tumor-specific mutations identified in the tumor sample (claim 14),

H) detecting recurrence of the cancer from the tumor-specific mutations detected in the cell-free DNA (claim 18),

I) detecting recurrence metastases of the cancer from the tumor-specific mutations detected in the cell-free DNA (claim 18),

J) detecting recurrence and metastases of the cancer from the tumor-specific mutations detected in the cell-free DNA (claim 18).

Species of sequence determination method

K) high-throughput sequencing (claim 16),

L) microarray (claim 17).

Species of cancer

M) colorectal (claim 19),

N) lung (claim 20),

O) bladder (claim 21),

P) breast (claim 22).

Species of biological sample

Q) blood (claim 23),

R) serum (claim 23),

S) plasma (claim 23),

T) urine (claim 23).

Species of genes

U) Please select a gene from claims 5 or 6 (if specie A is elected), or from claim 8 (if species C is elected), or from claim 10 (if specie D is elected).

3. The species are independent or distinct because the claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each of the sets of species detailed above, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply:

The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of

the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 or pre-AIA 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TERESA E STRZELECKA whose telephone number is (571)272-0789. The examiner can normally be reached on M-F 9-7.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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.

/TERESA E STRZELECKA/
Primary Examiner, Art Unit 1637
April 17, 2020

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/288,351
	Filing Date	Feb 28, 2019
	First Named Inventor	Joshua BABIARZ
	Art Unit	1637
	Examiner Name	Teresa E. Strzelecka
	Attorney Docket Number	N.012.US.10

U.S. PATENTS						
Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		5854033		1998-12-29	Lizardi, P. M.	
		6235472	B1	2001-02-22	Landegren, U. et al.	
		6221603	B1	2001-04-24	Mahtani, M. M.	
		10351906	B2	2019-07-16	ZIMMERMANN, B. et al.	
		10526658	B2	2020-01-07	BABIARZ, J. et al.	
		10538814	B2	2020-01-21	BABIARZ, J. et al.	
		10557172	B2	2020-02-11	BABIARZ, J. et al.	
		10597723	B2	2020-03-24	BABIARZ, J. et al.	

U.S. PATENT APPLICATION PUBLICATIONS						
Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

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		20070031857	A1	2007-02-08	Makarov, V. L., et al.	
		20150087535	A1	2015-03-26	Patel, A. A.	
		20160186253	A1	2016-06-30	Talasaz, A.A. H., et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns, Lines where Relevant Passages or Relevant Figures Appear	T[5]
		2016/077313	WO	A1	2016- 05-19	TANG, Y. T.		

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	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[5]
		ANDRAS, S. C. et al., "Strategies for Signal Amplification in Nucleic Acid Detection", Molecular Biotechnology, Vol. 19, 2001, 29-44	

PTO/SB/08a (01-10)
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		BAI, H. et al., "Detection and Clinical Significance of Intratumoral EGFR Mutational Heterogeneity in Chinese Patients with Advanced Non-Small Cell Lung Cancer", PLOS One, Vol. 8, No. 2, FEB 2013, 7 pages	
		DIEHL, F. et al., "Detection and quantification of mutations in the plasma of patients with colorectal tumors", PNAS, Vol. 102, No. 45, 8 NOV 2005, 16368-16373	
		FOUQUET, C. et al., "Rapid and Sensitive p53 Alteration Analysis in Biopsies from Lung Cancer Patients Using a Functional Assay and A Universal Oligonudeotide Array: A Prospective Study", Clinical Cancer Research, Vol. 10, 15 MAY 2004, 3479-3489	
		SPERTINI, D. et al., "Screening of Transgenic Plants by Amplification of Unknown Genomic DNA Flanking T-DNA", BioTechniques, Vol. 27, AUG 1999, 308-314	

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.
[4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

CERTIFICATION STATEMENT

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Attorney Docket Number	N.012.US.10

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Tianran Yan/	Date (YYYY-MM-DD)	2020-04-20
Name/Print	Tianran Yan	Registration Number	67,162

This collection of information is required by 37 CFR 1.97 and 1.98. 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 1.14. This collection is estimated to take 1 hour 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. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Electronic Acknowledgement Receipt

EFS ID:	39206089
Application Number:	16288351
International Application Number:	
Confirmation Number:	1764
Title of Invention:	DETECTING MUTATIONS AND PLOIDY IN CHROMOSOMAL SEGMENTS
First Named Inventor/Applicant Name:	Joshua BABIARZ
Customer Number:	110711
Filer:	Anton John Bokal/Angela McGowan
Filer Authorized By:	Anton John Bokal
Attorney Docket Number:	N.012.US.10
Receipt Date:	20-APR-2020
Filing Date:	28-FEB-2019
Time Stamp:	14:54:23
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	N012US10_SB08_SIGNED.pdf	82435 4f320f7cae24b68ccef9ea7511f5bb33b3a48e90	no	4

Warnings:

Information:					
This is not an USPTO supplied IDS fillable form					
2	Foreign Reference	WO2016077313A1.pdf	1485463 a14e651f7841106b4033830e0b5616b6956fafa1	no	34
Warnings:					
Information:					
3	Non Patent Literature	ANDRAS_2001_p29_NPL.pdf	2293462 0b71f977ffc1d4d79a51b6a28d106d074ba926c8	no	16
Warnings:					
Information:					
4	Non Patent Literature	BAI_2013_7pgs_NPL.pdf	845177 013846a54c355a8e2ff7d54b7ad3d150163a10f2	no	7
Warnings:					
Information:					
5	Non Patent Literature	DIEHL_2005_p16368_NPL.pdf	1645276 567d419d278cf90860b743ed2bb1b257fe5f297f	no	12
Warnings:					
Information:					
6	Non Patent Literature	FOUQUET_2004_p3479_NPL.pdf	1630434 27acbcfc463048a8d945994f95483de3f67b9071	no	13
Warnings:					
Information:					
7	Non Patent Literature	SPERTINI_1999_p308_NPL.pdf	314979 9749e427bbcd91286f02e51dbd76bd15f8292166	no	6
Warnings:					
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		Total Files Size (in bytes):	8297226		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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	Attorney Docket Number	N.012.US.10

U.S. PATENTS						
Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
U.S. PATENT APPLICATION PUBLICATIONS						
Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		20030211489	A1	2003-11-13	SHEN, M.-J. R., et al.	
		20050079521	A1	2005-04-14	BEAULIEU, M. et al.	
		20120034685	A1	2012-02-09	SPARKS, A. et al.	
		20120108460	A1	2012- 05-03	QUAKE, S. R., et al.	
		20120295810	A1	2012-11-22	QUAKE, S. R., et al.	
		20190256894	A1	2019-08-22	ZIMMERMANN, B. et al.	
		20190256908	A1	2019-08-22	RABINOWITZ, M. et al.	
		20190256912	A1	2019-08-22	RABINOWITZ, M. et al.	
		20190256919	A1	2019-08-22	BABIARZ, J. et al.	

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		20190256931	A1	2019-08-22	BABIARZ, J. et al.	
		20190323076	A1	2019-10-24	RABINOWITZ, M. et al.	
		20190360036	A1	2019-11-28	RABINOWITZ, M. et al.	
		20200024653	A1	2020-01-23	BETHKE, A.	

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns ,Lines where Relevant Passages or Relevant Figures Appear	T[5]
		2019/241349	WO	A1	2019-12-19	ZIMMERMANN, B. et al.		
		2020/010255	WO	A1	2020-01-09	MOSHKEVICH, S. et al.		
		2020/018522	WO	A1	2020-01-23	EGILSSON, A. et al.		

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	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[5]

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		ALLAN, J. et al., "Micrococcal Nuclease Does Not Substantially Bias Nucleosome Mapping", Journal of Molecular Biology, Vol. 417, 30 JAN 2012, 152-164	
		BECK, J. et al., "Digital Droplet PCR for Rapid Quantification of Donor DNA in the Circulation of Transplant Recipients as a Potential Universal Biomarker of Graft Injury", Clinical Chemistry, Vol. 59, No. 12, 2013, 1732–1741	
		CHEUNG, V. G. et al., "Whole genome amplification using a degenerate oligonucleotide primer allows hundreds of genotypes to be performed on less than one nanogram of genomic DNA", Proceedings of the National Academy of Sciences, USA, Vol. 93, DEC 1996, 14676-14679	
		DAWSON, S.J. et al., "Analysis of Circulating Tumor DNA to Monitor Metastatic Breast Cancer", The New England Journal of Medicine, Vol. 368, No. 13, 28 MAR 20136, 1199-1209	
		DIEHL, F. et al., "Circulating mutant DNA to assess tumor dynamics", NATURE MEDICINE, Vol. 14, No. 9, 31 JUL 2008, 985-990	
		GIELIS, E. M. et al., "Plasma donor-derived cell-free DNA kinetics after kidney transplantation using a single tube multiplex PCR assay", PLOS One, Vol. 13, No. 12, e0208207, 6 DEC 2018, 16 pgs.	
		GRSKOVIC, M. et al., "Validation of a Clinical-Grade Assay to Measure Donor-Derived Cell-Free DNA in Solid Organ Transplant Recipients", The Journal of Molecular Diagnostics, Vol. 18, No. 6 + Supplemental Appendix S1, NOV 2016, 890-902	
		IMIELINSKI, M. et al., "Mapping the Hallmarks of Lung Adenocarcinoma with Massively Parallel Sequencing", Cell, Vol. 150, 14 SEPT 2012, 1107-1120	

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	Attorney Docket Number	N.012.US.10

		LINDBERG, J. et al., "Exome Sequencing of Prostate Cancer Supports the Hypothesis of Independent Tumour Origins", European Urology, Vol. 63, 2013, 347-353	
		NCBI, , "dbSNP record for rs1294331", Retrieved from the Internet: <URL: www.ncbi.nlm.nih.gov/snp/?term=rs 1294331 >, 2019, 2 pgs.	
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		SCHWARZENBACH, H. et al., "Cell~free nucleic acids as biomarkers in cancer patients", Nature Reviews: Cancer, Vol. 11, June 2011, 426-437	

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	Filing Date	Feb 28, 2019
	First Named Inventor	Joshua BABIARZ
	Art Unit	1637
	Examiner Name	Teresa E. Strzelecka
	Attorney Docket Number	N.012.US.10

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Approved for use through 07/31/2012. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/288,351
	Filing Date	Feb 28, 2019
	First Named Inventor	Joshua BABIARZ
	Art Unit	1637
	Examiner Name	Teresa E. Strzelecka
	Attorney Docket Number	N.012.US.10

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

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☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

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	Attorney Docket Number	N.012.US.10

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Tianran Yan/	Date (YYYY-MM-DD)	2020-03-06
Name/Print	Tianran Yan	Registration Number	67,162

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EFS ID:	38822292
Application Number:	16288351
International Application Number:	
Confirmation Number:	1764
Title of Invention:	DETECTING MUTATIONS AND PLOIDY IN CHROMOSOMAL SEGMENTS
First Named Inventor/Applicant Name:	Joshua BABIARZ
Customer Number:	110711
Filer:	Anton John Bokal/Angela McGowan
Filer Authorized By:	Anton John Bokal
Attorney Docket Number:	N.012.US.10
Receipt Date:	10-MAR-2020
Filing Date:	28-FEB-2019
Time Stamp:	15:07:01
Application Type:	Utility under 35 USC 111(a)

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Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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New Applications Under 35 U.S.C. 111

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National Stage of an International Application under 35 U.S.C. 371

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New International Application Filed with the USPTO as a Receiving Office

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Electronic Acknowledgement Receipt

EFS ID:	37485756
Application Number:	16288351
International Application Number:	
Confirmation Number:	1764
Title of Invention:	DETECTING MUTATIONS AND PLOIDY IN CHROMOSOMAL SEGMENTS
First Named Inventor/Applicant Name:	Joshua BABIARZ
Customer Number:	110711
Filer:	Anton John Bokal/Angela McGowan
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Attorney Docket Number:	N.012.US.10
Receipt Date:	24-OCT-2019
Filing Date:	28-FEB-2019
Time Stamp:	13:02:08
Application Type:	Utility under 35 USC 111(a)

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Electronic Acknowledgement Receipt

EFS ID:	37482706
Application Number:	16288351
International Application Number:	
Confirmation Number:	1764
Title of Invention:	DETECTING MUTATIONS AND PLOIDY IN CHROMOSOMAL SEGMENTS
First Named Inventor/Applicant Name:	Joshua BABIARZ
Customer Number:	110711
Filer:	Anton John Bokal/Angela McGowan
Filer Authorized By:	Anton John Bokal
Attorney Docket Number:	N.012.US.10
Receipt Date:	24-OCT-2019
Filing Date:	28-FEB-2019
Time Stamp:	13:09:08
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

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1	Foreign Reference	CN1650032A_WO03074723A2_1of2.pdf	17005481 0c849da6e851b677ac2a1ff1cb6067d16266e524	no	329

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Electronic Acknowledgement Receipt

EFS ID:	37483070
Application Number:	16288351
International Application Number:	
Confirmation Number:	1764
Title of Invention:	DETECTING MUTATIONS AND PLOIDY IN CHROMOSOMAL SEGMENTS
First Named Inventor/Applicant Name:	Joshua BABIARZ
Customer Number:	110711
Filer:	Anton John Bokal/Angela McGowan
Filer Authorized By:	Anton John Bokal
Attorney Docket Number:	N.012.US.10
Receipt Date:	24-OCT-2019
Filing Date:	28-FEB-2019
Time Stamp:	13:08:23
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Foreign Reference	WO2008059578A1.pdf	3796138 ee6142e3ede643780a0441c938848c61597f492e	no	109

Warnings:

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2	Foreign Reference	WO2008081451.pdf	2186477 645c594d3762310fd36583db882cceb5dbd67901	no	53
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Information:					

58	Non Patent Literature	Caliendo.pdf	122838 0e44e0bab84b8cfe55d7ac3fb63d2ee27b5cf251	no	5
Warnings:					
Information:					
59	Non Patent Literature	CANSAR_2018_50pgs_NPL.pdf	5122878 72af3a908854216a2c42e6f8696e7bd2decd6d6e	no	50
Warnings:					
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60	Non Patent Literature	CARNEVALE_1998.pdf	1347513 579dd3606124dc46e3e26909408b5ed31fee1ad7	no	6
Warnings:					
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		Total Files Size (in bytes):	189794275		

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