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Table with columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO., EXAMINER, ART UNIT, PAPER NUMBER, NOTIFICATION DATE, DELIVERY MODE. Includes application details for AmirAli Talasaz and examiner information for Kenneth R. Horlick.

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):

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***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.

**NON-PRIOR ART REJECTIONS**

2. 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 USPQ645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ644 (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(I)(I) - 706.02(I)(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).

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3. Claims 78 and 207-226 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 9,834,822. Although the claims at issue are not identical, they are not patentably distinct from each other because the patented claims and the instant

claims are related as species-genus. That is, the attaching, amplifying, sequencing, and grouping steps of the instant claims are included in the steps of the patented claims.

4. Claims 78 and 207-226 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 9,920,366. Although the claims at issue are not identical, they are not patentably distinct from each other because the patented claims and the instant claims are related as species-genus. That is, the attaching, amplifying, sequencing, and grouping steps of the instant claims are included in the steps of the patented claims.

5. Claims 78 and 207-226 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 9,902,992. Although the claims at issue are not identical, they are not patentably distinct from each other because the patented claims and the instant claims are related as species-genus. That is, the attaching, amplifying, sequencing, and grouping steps of the instant claims are included in the steps of the patented claims.

6. Claims 78 and 207-226 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 9,598,731. Although the claims at issue are not identical, they are not patentably distinct from each other because the patented claims and the instant claims are related as species-genus. That is, the attaching, amplifying, sequencing, and grouping steps of the instant claims are included in the steps of the patented claims.

7. Claims 78 and 207-226 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 21-22 of copending Application No. 15/669,779 (reference application). Although the claims at issue are not identical, they are not patentably distinct from each

other because the copending claims and the instant claims are related as species-genus. That is, the attaching, amplifying, sequencing, and grouping steps of the instant claims are included in the steps of the copending claims.

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

### **CONCLUSION**

8. Claims 78 and 207-226 are free of the prior art, but are rejected for another reason. No claims are allowable.

9. 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.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENNETH R HORLICK whose telephone number is (571)272-0784. The examiner can normally be reached on Mon. - Thurs. 8:30 - 6:30.

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>.

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11/07/19

/KENNETH R HORLICK/  
Primary Examiner, Art Unit 1637

### AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings in the above-referenced patent application. The foregoing amendments are without prejudice and do not constitute an admission regarding the patentability of the amended subject matter and should not so be construed. Applicant reserves the right to pursue the subject matter of the canceled claims in this or any other appropriate patent application.

#### Listing of Claims:

1.-77. (Cancelled).

78. (Currently amended): A method for detecting a presence or absence of a somatic genetic variant from a sample comprising cell-free deoxyribonucleic acid (cfDNA) molecules of a subject having a cancer or suspected of having a cancer, comprising:

(a) providing at least one set of tagged parent polynucleotides and for each set of tagged parent polynucleotides attaching molecular barcodes from a set of molecular barcodes to a population of the cfDNA molecules from the sample to produce tagged parent polynucleotides,

wherein a plurality of the tagged parent polynucleotides has identical molecular barcodes;

(b) amplifying a plurality of the tagged parent polynucleotides in the set to produce a corresponding set of amplified progeny polynucleotides;

(c) sequencing a plurality subset (including a proper subset) of the set of the amplified progeny polynucleotides [[,]] to produce a set of sequencing reads; [[and]]

(d) grouping a plurality of sequencing reads from the set of sequencing reads into one or more families based on sequence information from at least the molecular barcodes; collapsing the set of sequencing reads to generate a set of consensus sequences, each consensus sequence corresponding to a unique polynucleotide among the set of tagged parent polynucleotides and

(e) detecting, from among the set of sequencing reads in the one or more families, the presence or absence of the somatic genetic variant comprising a single nucleotide variant (SNV), a copy number variation (CNV), an insertion or deletion (indel), or a gene fusion.

79.-206. (Cancelled).

207. (New): The method of claim 78, wherein the sample is a bodily fluid sample.

208. (New): The method of claim 78, wherein the population of the cfDNA molecules comprises between 1 nanogram (ng) and 100 ng of the cfDNA molecules.

209. (New): The method of claim 78, wherein the set of molecular barcodes comprises between 5 and 1,000 different molecular barcodes.

210. (New): The method of claim 209, wherein the different molecular barcodes have a length of 5 to 10 base pairs.

211. (New): The method of claim 78, wherein molecules of the tagged parent polynucleotides are flanked on both ends by molecular barcodes attached thereto by sticky-end or blunt-end ligation.

212. (New): The method of claim 78, further comprising aligning a plurality of sequencing reads from the set of sequencing reads to a reference sequence.

213. (New): The method of claim 212, wherein grouping the plurality of sequencing reads is further based on a beginning base position and an end base position of aligned portions of the plurality of sequencing reads.

214. (New): The method of claim 78, wherein detecting comprises generating a consensus sequence for a family from among the one or more families.

215. (New): The method of claim 214, further comprising aligning the consensus sequence to a reference sequence.

216. (New): The method of claim 215, further comprising determining a frequency of one or more bases called at a genetic locus of the reference sequence from a plurality of consensus sequences from different families from among the one or more families.

217. (New): The method of claim 78, wherein detecting comprises determining a base call at a genetic locus of a reference sequence for a family from among the one or more families.

218. (New): The method of claim 217, further comprising determining a frequency of one or more bases called at the genetic locus from among the one or more families.

219. (New): A method for detecting a presence or absence of a somatic genetic variant from a bodily fluid sample from a subject, comprising:

- (a) attaching molecular barcodes from among a set of molecular barcodes to a population of cell-free deoxyribonucleic acid (cfDNA) molecules derived from the bodily fluid sample from the subject to produce tagged parent polynucleotides, wherein the molecular barcodes from the set of molecular barcodes are attached to both ends of a plurality of the cfDNA molecules in the population, and wherein the set of molecular barcodes comprises 2 to 1,000,000 different molecular barcodes;
- (b) amplifying at least a portion of the tagged parent polynucleotides to produce amplified progeny polynucleotides;
- (c) sequencing a plurality of the amplified progeny polynucleotides to produce a set of sequencing reads, wherein a number of different paired combinations of molecular barcodes formable by the set of molecular barcodes is sufficient to group the set of sequencing reads into one or more families, wherein members of a family from among the one or more families comprise sequencing reads corresponding to nucleic acid sequences of a cfDNA molecule from among the population of cfDNA molecules; and

(d) detecting, from among the set of sequencing reads in the one or more families, the presence or absence of the somatic genetic variant comprising a single nucleotide variant (SNV), a copy number variation (CNV), an insertion or deletion (indel), or a gene fusion.

220. (New): The method of claim 219, wherein the population of the cfDNA molecules comprises between 1 nanogram (ng) and 100 ng of the cfDNA molecules.

221. (New): The method of claim 219, wherein the set of molecular barcodes comprises 5 to 100 different molecular barcodes that have a length of 5 to 20 base pairs.

222. (New): The method of claim 219, further comprising selectively enriching the amplified progeny polynucleotides for target regions associated with cancer prior to sequencing.

223. (New): The method of claim 219, further comprising aligning the sequencing reads to a reference sequence.

224. (New): The method of claim 219, further comprising generating a consensus sequence for each family from among the one or more families.

225. (New): The method of claim 219, wherein detecting comprises determining a base call at a genetic locus of a reference sequence for a family from among the one or more families.

226. (New): The method of claim 225, further comprising determining a frequency of one or more bases called at the genetic locus from among the one or more families.

### **REMARKS**

Claims 78-83, 85-92, 94-96, 98, and 101-102 were pending prior to entry of the abovementioned amendments. Claims 79-206 are presently cancelled without prejudice or disclaimer. Claim 78 has been amended. Claims 207-226 are newly added. No new matter is added by these amendments. Accordingly, claims 78 and 207-226 are now pending.

### **Claim Amendments**

Claim 78 has been amended to clarify the claimed subject matter. Claims 207-226 are newly added. Support for these amendments and newly added claims may be found throughout the application, USSN 15/828,099, as filed, for example, at least at paragraphs [0055], [0064], [0210], [0214], [0216], [0235], [00248]-[00252], [0263], and [0267].

### **Objection**

The specification was objected to because of the following informality: the continuation information must be updated to indicate the status of the parent applications.

Applicant has amended the specification herein to update the requested information. No new matter is being introduced. Accordingly, for these reasons, withdrawal of the objection to the specification is respectfully requested.

### **Rejection Under 35 U.S.C. §112.(b) or 35 U.S.C. 112 (pre-AIA), second paragraph**

Claims 78-83, 85-92, 94-96, 98, and 101-102 were rejected under 35 U.S.C. §112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventors/Applicant regards as the invention.

Without conceding in the basis of the rejection and solely to expedite prosecution, Applicant has deleted the parenthetical “(including a proper subset)” in claim 78. Accordingly, Applicant respectfully request that the §112 rejection of claim 78 be withdrawn. Applicant submits

that the §112 rejections of claims 79-83, 85-92, 94-96, 98, and 101 are moot in view of the cancellation of these claims.

### **Nonstatutory Double Patenting Rejection**

Claims 78-83, 85-92, 94-96, 98, and 101-102 were rejected on the ground of nonstatutory double patenting as allegedly being unpatentable over claims 1-20 of U.S. Patent No. 9,834,822. Claims 78-83, 85-92, 94-96, 98, and 101-102 were rejected on the ground of nonstatutory double patenting as allegedly being unpatentable over claims 1-21 of U.S. Patent No. 9,920,366. Claims 78-83, 85-92, 94-96, 98, and 101-102 were rejected on the ground of nonstatutory double patenting as allegedly being unpatentable over claims 1-33 of U.S. Patent No. 9,902,992.

As provided above, claim 78 has been amended. Claims 79-83, 85-92, 94-96, 98, and 101-102 have been cancelled. Applicant respectfully requests the Examiner to reconsider the nonstatutory double patenting rejections in view of the aforementioned claim amendments. If only a nonstatutory double patenting rejection remains following entry of this response, Applicant respectfully requests that the Examiner telephone the undersigned attorney of record so that a Terminal Disclaimer may be timely filed.

### **Rejection Under 35 U.S.C. §102(a)(2)**

Claims 78-83, 85-92, 94-96, 98, and 101-102 were rejected under 35 U.S.C. §102(a)(2) as allegedly being anticipated by either of Schmitt et al. (US 9,752,188) (“Schmitt”) or Porreca et al. (U.S. 20120165202) (“Porreca”).

Without conceding in the basis of the rejection and solely to expedite prosecution, Applicant has amended claim 78 to clarify certain differences of the claimed subject matter over the cited references. Applicant submits that claim 78 is not anticipated by Schmitt or Porreca, at least because neither of the asserted references teaches or discloses all the elements of claim 78, including at least “[a] method for detecting a presence or absence of **a somatic genetic variant** from a sample comprising **cell-free deoxyribonucleic acid (cfDNA) molecules** of a subject having a cancer or suspected of having a cancer, comprising: (a) attaching molecular barcodes

from a set of molecular barcodes to a population of the **cfDNA molecules** from the sample to produce tagged parent polynucleotides, ... and (e) detecting, from among the set of sequencing reads in the one or more families, the presence or absence of **the somatic genetic variant** comprising a single nucleotide variant (SNV), a copy number variation (CNV), an insertion or deletion (indel), or a gene fusion.” (Emphases added.) For example, neither Schmitt nor Porreca discloses detecting a presence or absence of a somatic genetic variant from a sample comprising cfDNA molecules.

Furthermore, without acquiescing to the Examiner’s statement regarding priority, Applicant respectfully requests the Examiner to reconsider the priority claim in view of the aforementioned claim amendments.

Accordingly, Applicant respectfully requests that the §102 rejection be withdrawn. Applicant submits that the §102 rejections of claims 79-83, 85-92, 94-96, 98, and 101-102 are moot in view of the cancellation of these claims.

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It shall be understood herein that any instance in which Applicant has addressed certain comments set forth by the Office shall not be construed as a concession to other comments or arguments advanced by the Office. Any circumstance in which Applicant has amended or cancelled a claim also does not mean that Applicant concedes to the arguments or positions advanced by the Office with respect to that claim or other claims pending herein.

Attorney Ref.: 42534-704.305  
Filed October 4, 2019  
USSN: 15/828,099

**CONCLUSION**

This paper fully addresses the rejections raised in the Office Action mailed April 12, 2019. Applicant believes that the present application is now in condition for allowance and respectfully requests that the Examiner expedite the prosecution of this application to allowance. The Commissioner is authorized to charge any underpayment, or credit any overpayment to Deposit Account No. 60-2231 (Attorney Docket No. 42534-704.305).

Respectfully submitted,  
GUARDANT HEALTH, INC.

Date: October 4, 2019

By: /Timothy A. Hott/

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15/828,099	11/30/2017	AmirAli Talasaz	42534-704.305/0002US- CON6	5368
115823	7590	04/12/2019	EXAMINER	
Wilson Sonsini Goodrich & Rosati / Guardant Health 650 Page Mill Road Palo Alto, CA 94304			HORLICK, KENNETH R	
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1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

**OBJECTION**

2. The specification is objected to because of the following informality: the continuation information must be updated to indicate the status of the parent applications.

**NON-PRIOR ART REJECTIONS**

3. 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.

Claims 78-83, 85-92, 94-96, 98, and 101-102 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) These claims are confusing because it cannot be determined what is encompassed by the parenthetical '(including a proper subset)' and what is actually required in independent claim 78. Correction is required.

B) Claim 98 is further confusing because of the language 'abnormal changes in nucleic acid methylation infection' - proper punctuation may be missing. Correction is required.

C) Claims 101-102 are further confusing because 'analysis further comprises' in claim 101 lacks proper antecedent basis, and also because of the language 'such as' in claim 101, as it cannot be determined what is actually required. Correction is required.

4. 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(I)(1) - 706.02(I)(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).

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5. Claims 78-83, 85-92, 94-96, 98, and 101-102 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 9,834,822. Although the claims at issue are not identical, they are not patentably distinct from each other because the patented

claims and the instant claims are related as species-genus. That is, the providing, amplifying, sequencing, and collapsing steps of the instant claims are included in the steps of the patented claims.

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#### **PRIOR ART REJECTION**

8. 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.

9. 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.

Claims 78-83, 85-92, 94-96, 98, and 101-102 are rejected under 35 U.S.C. 102(a)(2) as being anticipated by either of Schmitt et al. (US 9,752,188; effective filing date 03/20/2012) or Porreca et al. (US 2012/0165202; effective filing date at least 04/30/2010).

It is noted that the claimed subject matter has priority to 03/15/2013, the filing date of the provisional '997 application.

These claims are drawn to a method comprising: providing a set of tagged polynucleotides; amplifying the tagged polynucleotides; sequencing a subset of the amplified polynucleotides to produce a set of sequencing reads; and collapsing the reads to generate a set of consensus sequences.

Schmitt et al. discloses such a method; see columns 5-30, especially column 20, line 39 to column 21, line 25.

Porreca et al. also discloses such a method; see paragraphs 0134-0298, especially 0298.

The claimed method cannot be distinguished from the method of either Schmitt et al. or Porreca et al.

## **CONCLUSION**

10. No claims are free of the prior art.

11. Vigneault et al. (US 2014/0357500; effective filing date 03/15/2013) is made of record as a reference of interest in that it has the same effective filing date as the instant claims and also discloses the concept of collapsing sequence reads into consensus sequences (see, for example, paragraph 0364).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENNETH R HORLICK whose telephone number is (571)272-0784. The examiner can normally be reached on Monday-Thursday 7:30 - 6:00.

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04/09/19

/KENNETH R HORLICK/  
Primary Examiner, Art Unit 1637