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Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.
16/672,267 01/07/2020 AmirAli TALASAZ 42534-708.304 3448

115823 7590 03/03/2020
Wilson Sonsini Goodrich & Rosati / Guardant Health
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EXAMINER

HORLICK, KENNETH R

ART UNIT PAPER NUMBER

1637

NOTIFICATION DATE DELIVERY MODE

03/03/2020

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):

Patents@guardanthealth.com
patentdocket@wsgr.com

Guardant - EXHIBIT 2005
Tempus AI, Inc. v. Guardant Health, Inc.
IPR2025-01435

Continuation of Attachment(s) 2) Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date: 12/6/19; 12/6/19; 12/6/19; 12/6/19; 12/6/19; 12/6/19; 12/6/19; 12/6/19

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)(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).

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-l.jsp.

3. Claims 31-60 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 instant claims and the patented claims are related as genus-species. That is, the steps of the instant claims are included within the steps of the patent claims.

4. Claims 31-60 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 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 instant claims and the patented claim are related as genus-species. That is, the steps of the instant claims are included within the steps of the patented claim.

5. Claims 31-60 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 31-60 of copending Application No. 16/601,168 (reference application). Although the claims at issue are not identical, they are not patentably distinct from each other because the instant claims and the copending claims are related as genus-species. That is, the steps of the instant claims are included within 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.

6. Claims 31-60 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 31-60 of copending Application No. 16/714,579 (reference application). Although the claims at issue are not identical, they are not patentably distinct from each other because the instant claims and the copending claims are related as obvious species-genus. That is, the 'more than a 30X molar excess' of the instant claims is a clearly suggested species within the genus 'at least a 10X molar excess' of the copending claims.

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

PRIOR ART REJECTION

7. 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.

8. 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.

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.

Claims 31-60 are rejected under 35 U.S.C. 103 as being unpatentable over Schmitt et al. (US 9,752,188; effective filing date 3/20/12) in view of Deciu et al. (US 2013/0288244; effective filing date 3/14/13), and further in view of Sacko et al. (US 2010/0264331).

These claims are drawn to methods comprising: ligating barcodes to cell-free nucleic acid molecules, using more than a 30X molar excess of barcodes relative to cell-free nucleic acid molecules, wherein at least 20% of said molecules are attached to barcodes; amplifying tagged molecules; and selectively enriching tagged molecules for genomic regions of interest.

Schmitt et al. discloses a method comprising: tagging DNA molecules with a set of tags comprising barcodes; and selectively enriching (amplifying) for tagged strands that map to a region of interest. See columns 5-30, especially column 20, line 39 to column 21, line 25.

Schmitt et al. does not disclose wherein more than a 30X molar excess of adapters/barcodes is used such that at least 20% of molecules are tagged, nor wherein the DNA is cell-free DNA.

Deciu et al. discloses the desirability to optimize ligation of adaptors to both ends of a polynucleotide (see paragraph [1152]).

Sacko et al. discloses detecting cell-free DNA from blood of cancer patients because it comprises DNA having microsatellite mutations and instabilities, which are useful in diagnostics (see paragraph 0005).

One of ordinary skill in the art would have been motivated to modify the method of Schmitt et al. by using more than a 30X molar excess of adapters/barcodes such that at least 20% of nucleic acid molecules are tagged because this would have merely involved routine optimization of known-important reaction parameters, which as well established in U.S. patent practice does not support unobviousness (see M.P.E.P. 2144.05). This is supported by Deciu et al., which discloses the desirability to optimize ligation of adaptors to both ends of a polynucleotide in paragraph [1152]. Ligation reactions were textbook-level subject matter for which the important parameters, such as enzyme and polynucleotide component concentrations, were unarguably known. It is submitted that the further limitations of the dependent claims also fall within the category of routine optimization of known-important reaction parameters. The skilled artisan would have been motivated to modify the method of Schmitt et al. by using cell-free DNA because Sacko et al. disclosed that cell-free DNA may contain somatic genetic variants associated with cancers, and is thus useful in diagnostics. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the application was filed to carry out the claimed methods.

CONCLUSION

9. No claims are free of the prior art.

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>.

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.

02/27/20

/KENNETH R HORLICK/
Primary Examiner, Art Unit 1637