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14/451,876	08/05/2014	Emil Kartalov	38075-716.301	1065
21971 7590 06/06/2017 WILSON, SONSINI, GOODRICH & ROSATI 650 PAGE MILL ROAD PALO ALTO, CA 94304-1050			EXAMINER NEGIN, RUSSELL SCOTT	
			ART UNIT 1631	PAPER NUMBER
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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):

patentdocket@wsgr.com

Continuation of Disposition of Claims: Claims pending in the application are 1,2,4,5,9,13,17-19,22,27-29,34,35,37-39,42,43,45,47,49,51,53,55,56,75-88, and 90-92.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 1,2,4,5,9,13,17-19,22,27-29,34,35,37-39,42,43,45,47, and 82.

DETAILED ACTION

Comments

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

Claims 1-2, 4-5, 9, 13, 17-19, 22, 27-29, 34-35, 37-39, 42-43, 45, 47, and 82 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group or Species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3 November 2016.

Claims 1-2, 4-5, 9, 13, 17-19, 22, 27-29, 34-35, 37-39, 42-43, 45, 47, 49, 51, 53, 55-56, 75-88, and 90-92 are pending in the instant application.

Claims 49, 51, 53, 55-56, 75-81, 83-88, and 90-92 are examined in the instant Office action.

Information Disclosure Statements

The IDS filed on 5/2/2017 been considered.

Withdrawn Rejections

The rejection of claim 89 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the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention is withdrawn in view of cancellation of claim 89.

The prior art rejections are withdrawn in view of arguments on pages 8-13 of the Remarks.

Claim Rejections - 35 USC § 101

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.

The following rejection is reiterated:

Claims 49, 51, 53, 55-56, 75-81, 83-88, and 90-92 are rejected under 35 U.S.C. 101 because the claimed invention is directed to a judicial exception (i.e., a law of nature, a natural phenomenon, or an abstract idea) without significantly more. According to Step 1 of the 2014 Interim Subject Matter Eligibility Guidelines, claim(s) 49, 51, 53, 55-56, 75-81, 83-88, and 90-92 is/are directed to methods. According to Step 2A of the 2014 Interim Subject Matter Eligibility Guidelines, claim(s) 49, 51, 53, 55-56, 75-81, 83-88, and 90-92 is/are directed to the abstract idea of encoding signals in a manner that reduces or eliminates degeneracy. The signal processing is a manner of mathematical manipulation analogous to the Arrhenius equation of *Diamond v. Diehr*, 450 U.S. 175 (1981), which was also found to be abstract. The claim(s) does/do not

include additional elements that are sufficient to amount to significantly more than the judicial exception (i.e. Step 2B of the Guidelines) because providing samples, performing assays, and determine presence/absence patterns of analytes is routine and conventional in the prior art. This rejection has been made in view of the U.S. Supreme Court Decision in *Alice Corporation Pty. Ltd. V. CLS Bank International, et al.*

Response to arguments:

Applicant's arguments filed 2 May 2017 have been fully considered but they are not persuasive.

On page 15 of the Remarks, applicant highlights the portions of the claim that are not part of any judicial exception. However, while there are five limitations highlighted, these limitations are routine and conventional in the prior art. Consequently, these limitations do not constitute significantly more than the abstract idea.

On pages 16-18 of the Remarks, applicant attempts to compare the fact pattern of the instant set of claims to *BASCOM*. The claims in *BASCOM* were found to be patent eligible because the judicial exceptions could only be performed within a computer. On page 15 of the Remarks, applicant highlights limitations of the claim that require the judicial exception be performed in combination with empirical wet-lab steps.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 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 –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following rejection is necessitated by the IDS of 5/2/2017:

Claim(s) 49, 51, 53, 55-56, 75-78, 80-81, 84-88, and 90-92 is/are rejected under pre-AIA 35 U.S.C. 102(e) as being anticipated by Lin et al. [US PGPUB 2013/0261019 A1; on IDS of 5/2/2017].

Claim 49 is drawn to a method of detecting the presence or absence of each analyte of a plurality of analytes. The method comprises encoding each of the analytes as a first value of a signal, thereby generating a coding scheme, wherein each of the analytes is represented in the coding scheme by the first value, wherein the encoding is performed in a manner that reduces or eliminates degeneracy. The method comprises providing a sample comprising at least one of said analytes. The method comprises contacting the sample with analyte-specific reagents that generate the first value, as represented in the coding scheme, when each of the analytes is present. The method comprises cumulatively measuring the first values of the signal within the sample, thereby providing a cumulative measurement. The method comprises determining whether each of the analytes is present or absent based on the cumulative measurement and the coding scheme. The method non-degenerately detects the presence or absence of at least seven analytes in a single sample volume, in any

combination of presence or absence. The method does not allow immobilization of analytes, physical separation of the analytes, or mass spectrometry.

Claim 55 is drawn to similar subject matter as claim 49, the additional limitation that each of the analytes corresponds to both a first value and a second value.

Lin et al. studies nucleic acid nanostructure barcode probes [title]. Paragraph 83 of Lin et al. teaches creation of a DNA barcode. Each oligonucleotide was attached to three values/fluorophores from the group consisting of rhodamine-green, Cy3, and Cy5. Figure 5D of Lin et al. illustrates all possible of the 27 nondegenerate combinations of barcodes. Claim 1 of Lin et al. teaches providing the analyte and contacting the analyte with the barcode probe. The histogram of Figure 5D of Lin et al. illustrates the cumulative measurement of the presence/absence patterns of each of the 27 non-degenerate barcode probes. Each of the 27 non-zero bars indicates presence of the 27 barcode probes. The methods used in Lin et al. do not involve immobilization of analytes, physical separation of analytes, or mass spectrometry.

With regard to claim 49, 51, 56, and 75-78; each of the dyes of rhodamine-green, Cy3, and Cy5 of paragraph 83 of Lin et al. correspond to the wavelength ranges for blue, green, and red. The three colors of the barcode correspond to three components of the signal of the barcode.

With regard to claim 53, Figure 5B of Lin et al. illustrates that the correct measurements is greater than the sum of the incorrect measurements.

With regard to claims 80-81 and 86, the oligonucleotides to which the dyes are attached to in paragraph 83 of Lin et al. are interpreted to function as hybridization probes. Paragraph 98 of Lin et al. teaches hybridization of the barcode probes to analytes to detect target polynucleotide analytes.

With regard to claims 84-85, Figure 5D of Lin et al. illustrates a diagram comprising all the possible combinations of barcodes.

With regard to claims 87-88, paragraph 102 of Lin et al. teaches a computer network to transmit information to a user such as a health care professional.

With regard to claim 90, Figure 5D of Lin et al. illustrates non-degenerate, legitimate results. No results are eliminated because the data in Figure 5D of Lin et al. are non-degenerate.

With regard to claims 91-92, Lin et al. does not teach immobilization of the barcode labeled probes.

Response to arguments:

Applicant's arguments with respect to the instantly rejected claims have been considered but are moot because the arguments do not apply to any of the references being used in the current rejection.

Claim Rejections - 35 USC § 103

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

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter 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 under pre-AIA 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of pre-AIA 35 U.S.C. 103(c) and potential pre-AIA 35 U.S.C. 102(e), (f) or (g) prior art under pre-AIA 35 U.S.C. 103(a).

The following rejection is necessitated by the IDS of 5/2/2017:

35 U.S.C. 103 Rejection #1:

Claim 79 is/are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Lin et al. as applied to claims 49, 51, 53, 55-56, 75-78, 80-81, 84-88, and 90-92 above in further view of Nie et al. [US PGPUB 2003/0148544 A1; on IDS].

Claim 79 is further limiting wherein an electromagnetic signal is generated.

Lin et al. teaches optical encoding of analytes in microbeads as a result of intensities and wavelengths of optical signals emitted from the analytes, as discussed above.

Lin et al. does not teach electromagnetic signals.

The document of Nie et al. studies methods of preparing multicolor quantum dot tagged beads [title]. The cover figure of Nie et al. teaches that different color quantum dots within microbeads. Each type of quantum dot emits light at a different wavelength. The histograms in the cover figure of Nie et al. illustrates how the quantum dot composition within each microbead encodes a non-degenerate spectral signature in the form of intensity versus wavelength histogram. It is interpreted that the photons emitted from the quantum dots in the microbeads in the cover figure of Nie et al. to result in colored light comprises electromagnetic signaling.

It would have been obvious for someone of ordinary skill in the art at the time of the invention to modify the optical encoding of Lie et al. by use of the electromagnetic encoding of Nie et al. because it is obvious to combine known elements in the prior art to yield a predictable result. In this instance, optical encoding is an alternative to electromagnetic encoding. There would have been a reasonable expectation of success in combining Nie et al. and Craig et al. because both studies are analogously applicable to using presence/absence patterns as signatures for analyte combinations.

Response to arguments:

Applicant's arguments filed 2 May 2017 have been fully considered but they are not persuasive.

While Nie et al. is reiterated from the previous Office action, there are no arguments with regard to Nie et al. in the Remarks specific to claim 79.

The following rejection is necessitated by the IDS of 5/2/2017:

35 U.S.C. 103 Rejection #2:

Claim 83 is/are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Lin et al. as applied to claims 49, 51, 53, 55-56, 75-78, 80-81, 84-88, and 90-92 above in further view of Orpana et al. [WO 2010/128206 A1].

Claim 83 is further limiting wherein the signal is generated by PCR.

Lin et al. teaches using presence/absence patterns of biomolecules in coding schemes, as discussed above.

Lin et al. does not teach PCR.

Orpana et al. studies a method, instrument, and computer program product for quantification of PCR products [title].

It would have been obvious for someone of ordinary skill in the art at the time of the invention to modify the optical encoding of Lin et al. by use of the computerized PCR of Orpana et al. wherein the motivation would have been that computer automate the analysis and PCR facilitates understanding of the experiment by amplifying the results of the experiment [title and abstract of Orpana et al.].

Response to arguments:

Applicant's arguments filed 2 May 2017 have been fully considered but they are not persuasive.

While Orpana et al. is reiterated from the previous Office action, there are no arguments with regard to Orpana et al. in the Remarks specific to claim 83.

Double Patenting

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).

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.

The following rejection is necessitated by the IDS of 5/2/2017:

Claims 49, 51, 53, 55, and 56 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 20-24, respectively, of U.S. Patent No. 8,838,394 B2 [on IDS of 5/2/2017]. Although the claims at issue are not identical, they are not patentably distinct from each other because both sets of claims are drawn to encoding analytes in a manner that eliminated degeneracy and determining

presence/absence patterns using the barcode probes. The claims of '394 recite limitations in addition to the limitations of the instant claims and thus, anticipate the instant claims.

Response to arguments:

This rejection is newly applied.

E-mail Communications Authorization

Per updated USPTO Internet usage policies, Applicant and/or applicant's representative is encouraged to authorize the USPTO examiner to discuss any subject matter concerning the above application via Internet e-mail communications. See MPEP 502.03. To approve such communications, Applicant must provide written authorization for e-mail communication by submitting the following statement via EFS-Web (using PTO/SB/439) or Central Fax (571-273-8300):

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 by video conferencing, instant messaging, or electronic mail. I understand that a copy of these communications will be made of record in the application file.

Written authorizations submitted to the Examiner via e-mail are **NOT** proper. Written authorizations must be submitted **via EFS-Web** (using PTO/SB/439) **or Central Fax** (571-273-8300). A paper copy of e-mail correspondence will be placed in the patent application when appropriate. E-mails from the USPTO are for the sole use of the intended recipient, and may contain information subject to the confidentiality requirement set forth in 35 USC § 122. See also MPEP 502.03.

Conclusion

No claim is allowed.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 2 May 2017 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). 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 mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Russell Negin, whose telephone number is (571) 272-1083. This Examiner can normally be reached from Monday through Thursday from 10:30 am to 5 pm and variable hours on Fridays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Peter Paras, Supervisory Patent Examiner, can be reached at (571) 272-4517.

Information regarding the status of the 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.

/Russell S. Negin/
Primary Examiner, Art Unit 1631
31 May 2017