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(54) Title: DEVICES AND METHODS FOR TRANSPORTING SAMPLES IN DIAGNOSTIC LABORATORY SYSTEMS

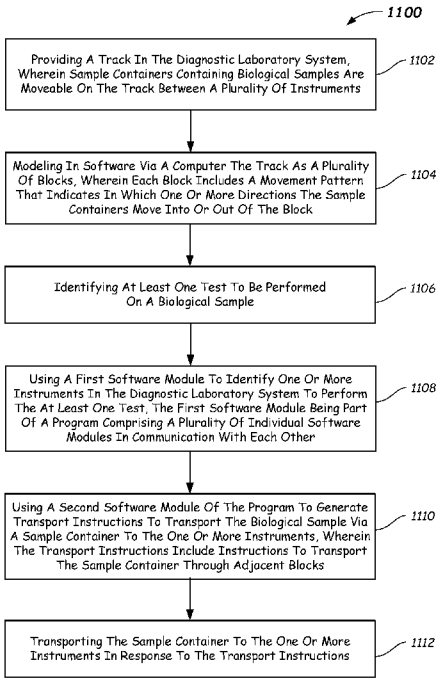

FIG. 11

(57) Abstract: A method of operating a diagnostic laboratory system for analyzing a biological sample includes modeling in software a track in the diagnostic laboratory system as a plurality of blocks. At least one test to be performed on a biological sample is identified. A first software module is used to identify one or more instruments in the diagnostic laboratory system to perform the test, wherein the first software module is part of a program comprising a plurality of individual software modules in communication with each other. A second software module of the program is used to generate transport instructions to transport the biological sample via a sample container to the one or more instruments, wherein the transport instructions include instructions to transport the sample container through adjacent blocks. The sample container is transported to the one or more instruments in response to the transport instructions. Other methods and apparatus are disclosed.

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[Continued on next page]

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 23/80004

A. CLASSIFICATION OF SUBJECT MATTER

IPC - INV. G01N 35/00 (2024.01)
ADD. G01N 33/50, B01L 3/00 (2024.01)

CPC - INV. G01N 35/0099
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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2022/213047 A1 (SIEMENS HEALTHCARE DIAGNOSTICS INC.) 6 October 2022 (06.10.2022) Abstract; para [0008]; [0009]; [0012]; [0016]; [0021]; [0029]; [0030]; [0031]; [0032]; [0037]; [0049]; [0050]; [0057]; [0058]; [0060]; [0062]; [0063]; [0064]; [0067]	1-12
A	US 2013/0337432 A1 (WELLSTAT DIAGNOSTICS LLC) 19 December 2013 (19.12.2013) Abstract	1-12

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 February 2024	APR 23 2024
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Kari Rodriquez Telephone No. PCT Helpdesk: 571-272-4300

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 23/80004

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
----Please see continuation in first extra sheet ----------

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-12

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 23/80004

Continuation of Box No. III. Observations where unity of invention is lacking.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I, claims 1-12, directed to a method of operating a diagnostic laboratory system for analyzing a biological sample, wherein the track is modeled in software via a computer as a plurality of blocks.

Group II, claims 13-16, directed to a method of operating a diagnostic laboratory system for analyzing biological samples, wherein the track is modeled as a graph via a computer, the graph comprising a plurality of nodes and edges.

Group III, claims 17-20, directed to a diagnostic laboratory system for analyzing a biological sample.

The inventions listed as Groups I-III do not relate to a single special technical feature under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Special Technical Features:

Group I has the special technical feature of a method of operating a diagnostic laboratory system for analyzing a biological sample, wherein the track is modeled in software via a computer as a plurality of blocks, that is not required by Groups II-III.

Group II has the special technical feature of a method of operating a diagnostic laboratory system for analyzing biological samples, wherein the track is modeled as a graph via a computer, the graph comprising a plurality of nodes and edges, that is not required by Groups I and III.

Group III has the special technical feature of a diagnostic laboratory system for analyzing a biological sample, that is not required by Groups I-II.

Common Technical Features:

Groups I-III share the common technical feature of:
a diagnostic laboratory system for analyzing a biological sample, comprising:
a track configured to transport a sample container to and from the at least one instrument, wherein the sample container is configured to contain therein the biological sample to be analyzed; and
a computer configured to:
model in software the track;
identify at least one test to be performed on a biological sample by at least one instrument; and
execute a program to control operation of the diagnostic laboratory system, the program having an architecture comprising a plurality of individual software modules in communication with each other, the plurality of individual software modules including:
a first software module to identify one or more instruments in the diagnostic laboratory system to perform the at least one test, and
a second software module to generate transport instructions to transport the biological sample to the one or more instruments, wherein the transport instructions include instructions to transport the biological sample from one block to an adjacent block.

However, this shared technical feature does not represent a contribution over prior art, because this shared technical feature is made obvious by WO 2022/213047 A1 to Siemens Healthcare Diagnostics Inc. (hereinafter 'Siemens').

Continuation of Box No. III. Observations where unity of invention is lacking.

Siemens teaches a diagnostic laboratory system for analyzing a biological sample, comprising:
a track configured to transport a sample container to and from the at least one instrument, wherein the sample container is configured to contain therein the biological sample to be analyzed (Abstract - 'Diagnostic instruments and methods of operating diagnostic instruments are provided. Methods of operating a diagnostic instrument includes providing the diagnostic instrument having one or more modules, wherein the one or more modules are configured to analyze specimens; providing a specimen sorter coupled to the diagnostic instrument; and sorting specimens into at least first group and a second group, wherein specimens in the first group are to be analyzed by at least one of the one or more modules, and specimens in the second group are not to be analyzed by any of the one or more modules. Other sorting methods and diagnostic instruments are provided.'; para [0021] - 'The diagnostic laboratory systems may include a transport system such as a track or the like that transports specimen containers between the different modules and/or the instruments. Thus, a diagnostic laboratory system may include a plurality of modules and/or diagnostic instruments with the track extending between the modules and the diagnostic instruments.'), and a computer (para [0030] - 'The diagnostic laboratory system 100 may include a computer 118 or be configured to communicate with an external computer. The computer 118 may be a microprocessor-based central processing unit CPU with suitable memory, software, and conditioning electronics and drivers for operating the various components, modules 108, and instruments 110 of the system 100') configured to: identify at least one test to be performed on a biological sample by at least one instrument; and
execute a program to control operation of the diagnostic laboratory system, the program having an architecture comprising a plurality of individual software modules in communication with each other, the plurality of individual software modules including:
a first software module to identify one or more instruments in the diagnostic laboratory system to perform the at least one test, and
a second software module to generate transport instructions to transport the biological sample to the one or more instruments, wherein the transport instructions include instructions to transport the biological sample from one block to an adjacent block (para [0031] - 'The computer 118, by way of the programs 118C, may control movement of the carriers 114 to and from the loading area 106, about the system track 112, to and from the modules 108 and the instruments 110, and to and from other modules and components of the system 100. The operation of each of the modules 108, the instruments 110, and other components and modules may be performed by the computer 118.'; para [0060] - 'Both the reader 358 and the robot 352 may be in communication with the computer 118 and/or the LIS 124. Thus, data generated by the reader 358 may be transmitted to the computer 118 and/or the LIS 124. Instructions for moving the robot 352 may be generated by one or more of the programs 118C and may be transmitted to the robot 352 to move the specimen containers 102 to specific locations, such as specific ones of the holders 350 and/or the transport system 312'; Claim 1 - 'A method of operating a diagnostic instrument, comprising : providing a diagnostic instrument having one or more modules, wherein the one or more modules are configured to analyze specimens; providing a specimen sorter coupled to the diagnostic instrument; and sorting specimens into at least a first group and a second group using the specimen sorter, wherein specimens in the first group are to be analyzed in at least one of the one or more modules, and specimens in the second group are not to be analyzed in any of the one or more modules.'; Claim 1 - 'The method of claim 1, comprising moving specimens in the first group to at least a first rack.'; Claim 13 - 'The method of claim 1, comprising: providing a transport system interconnecting the specimen sorter and at least one of the one or more modules; and moving specimens in the first group by way of the transport system.'; para [0025] - 'The diagnostic instrument may then request information regarding a specimen state, which may include testing (e.g., analyses) and/or processes that are to be performed on the specimens. In some embodiments, the diagnostic instrument may request the state of testing of the specimen from a LIS or the like.'; para [0027] - 'In some embodiments, the specimen containers may be sorted such that specimen containers containing specimens that are to have additional testing performed by other diagnostic instruments may be grouped together. Specimen containers containing specimens that are finished with testing may be grouped together. Specimen containers containing specimens that do not have any testing status may be grouped together.'; para [0049] - ' The programs 118C may transmit instructions to the robot 144 that instruct the robot 144 to place specific ones of the specimen containers 102 in specific ones of the racks 104 or specific locations within the racks 104'; para [0060] - 'Instructions for moving the robot 352 may be generated by one or more of the programs 118C and may be transmitted to the robot 352 to move the specimen containers 102 to specific locations, such as specific ones of the holders 350 and/or the transport system 312'). Siemens does not expressly teach model in software the track. However, since Siemens teaches use of software, and model generation using software was well known in the art, it would have been obvious to one of ordinary skill in the art that the software could be used to generate a model for the track, for ease of manipulation by the user.

As the technical features were known in the art, they cannot be considered special technical features that would otherwise unify the groups.

Therefore, Group I-III inventions lack unity under PCT Rule 13 because they do not share the same or corresponding special technical feature.