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Datasheet for the decision of 9 May 2023

Case Number: T 0280/18 - 3.5.01

Application Number: 10736446.5

Publication Number: 2391979

IPC: G06Q10/00

Language of the proceedings: EN

Title of invention:
TISSUE TRACKING

Applicant:
Omnicell, Inc.

Headword:
Tissue tracking/OMNICELL

Relevant legal provisions:
EPC Art. 56
RPBA 2020 Art. 13(1), 13(2)

Keyword:

Inventive step - indicating and giving reasons for the sequestering of tissue samples (no - not technical) - operating a locking device for sequestered samples (no - obvious)
Amendment after summons - exceptional circumstances (no)
Amendment to appeal case - suitability of amendment to resolve issues raised (no)

Decisions cited:

T 0641/00

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Case Number: T 0280/18 - 3.5.01

D E C I S I O N
of Technical Board of Appeal 3.5.01
of 9 May 2023

Appellant: (Applicant)	Omnicell, Inc. 1201 Charleston Road Mountain View, CA 94043 (US)
Representative:	Evens, Paul Jonathan Maguire Boss 24 East Street St. Ives, Cambridgeshire PE27 5PD (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 4 July 2017 refusing European patent application No. 10736446.5 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	W. Chandler
Members:	N. Glaser
	C. Schmidt

Summary of Facts and Submissions

I. The application was refused according to the state of the file for lack of inventive step (Article 56 EPC), because claim 1 of the main request was an obvious adaptation of the tissue tracking system of D3 (US2003/034390) based on a non-technical specification.

Claim 1 of the first auxiliary request was found not to involve an inventive step, because the additional features of claim 1 were known from D3.

Claim 1 of the second auxiliary request was found not to involve an inventive step, because the additional features of claim 1 were known from D3 and D4 (US2008/215363).

II. In the statement setting out the grounds of appeal the appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the refused main or auxiliary requests 1 or 2, refiled therewith. Oral proceedings were requested if the main request was not allowable.

III. The Board notified the appellant in a first communication about its provisional opinion that the subject-matter of claim 1 of the main and auxiliary requests 1 and 2 was not inventive. The Board referred in addition to D2 (US5842179).

IV. In response, the appellant presented arguments in favour of inventive step and submitted additional requests labelled main request A, auxiliary request 1A, auxiliary request 2A, main request B, auxiliary request

1B and auxiliary request 2B. The previous requests were maintained.

V. In the communication accompanying the summons to oral proceedings, the Board maintained its provisional opinion.

VI. In response, the appellant presented arguments in favour of inventive step and submitted additional requests labelled main request C, auxiliary request 1C, auxiliary request 2C, main request D, auxiliary request 1D, auxiliary request 2D and auxiliary request 3. The previous requests were maintained.

VII. The oral proceedings took place on 9 May 2023 as a videoconference. At the end of the oral proceedings, the Chairman announced the decision.

VIII. The appellant confirmed its requests as follows, that the decision under appeal be set aside and a patent be granted on the basis of the main request, or on the basis of one of the auxiliary requests designated as main requests A, B, C and D and auxiliary requests 1, 1A, 1B, 1C, 1D, 2, 2A, 2B, 2C, 2D or 3, filed on 3 November 2017 (main request and auxiliary requests 1 and 2), on 13 December 2021 (main requests A and B and auxiliary requests 1A, 1B, 2A and 2B) and on 6 April 2023 (main requests C and D, auxiliary requests 1C, 1D, 2C, 2D and auxiliary request 3).

IX. Claim 1 of the main request reads as follows :

"1. A tissue tracking system comprising:

a database for storing information associated with a sample of tissue;

a computer system coupled with the database, the computer system being configured to associate a serial number with the tissue and to generate and store a record of issuance in the database indicating that the sample of tissue has been issued to a user, the record of issuance including the associated serial number and user identification information;

a user interface in communication with the computer system and configured to receive a request from a user to issue the tissue; and

a storage location configured to store the tissue, wherein the storage location includes a locking device;

characterised in that:

the computer system is configured to receive an indication that the tissue has been sequestered based on notification of an adverse event related to the tissue, wherein the adverse event is selected from the group consisting of tissue born infection, tissue disease, bacterial infection, and the temperature of the tissue falling outside of an acceptable range, and wherein the computer system includes instructions to record an indication in the database that the tissue has been sequestered; and

the locking device remains locked in response to the request from the user to issue the tissue when the tissue is flagged in the database as being sequestered, and wherein the locking device is unlocked when the record associated with the tissue sample indicates that the tissue has not been flagged as sequestered."

Claim 1 of auxiliary request 1 is based on claim 1 of the main request with the additional feature: "*the storage location includes a thermometer configured to measure a temperature within the storage location and wherein the temperature is communicated to the database at predetermined intervals*" in line 12 and replacing the feature "*the computer system ... that the tissue has been sequestered*" with the feature "*the computer system includes instructions to record an indication in the database that the tissue has been sequestered when the measured temperature lies outside of an acceptable range*".

Claim 1 of auxiliary request 2 is based on claim 1 of auxiliary request 1 by adding the feature "with the *frequency of the predetermined intervals being set based on the type of tissue*" in line 14 and the feature "*the storage location (130) includes at least one climate control device (136) comprising one or more of a refrigeration unit, a heater and a humidifier, wherein the at least one climate control device (136) is used in conjunction with the thermometer (132) to maintain a climate within the storage location (130)*".

Claim 1 of main request A and auxiliary request 1A and 2A, essentially specifies in claim 1 of the main and auxiliary request 1 and 2, respectively, that the "*storage location*" is a "*tissue storage cabinet*" which *"includes a plurality of patient specific tissue bins (133)".*

Claim 1 of main request B and auxiliary request 1B and 2B essentially specifies in claim 1 of main request A and auxiliary request 1A and 2A, respectively, that the locking device remains locked "*for each received request to issue a tissue sample*".

Claim 1 of main request C and auxiliary request 1C and 2C replaces in claim 1 of main request B and auxiliary request 1B and 2B, respectively, the feature "*a plurality of patient specific tissue bins (133)*" with "*dispensing units that provide lockable units*".

Claim 1 of main request D and auxiliary requests 1D and 2D adds to the end of claim 1 of main request B and auxiliary request 1B and 2B, respectively, the feature "*wherein the user interface is configured to display a warning message when a tissue sample is flagged as being sequestered and the user is required to acknowledge the warning message before they are allowed to proceed".*

Claim 1 of the third auxiliary request adds in line 18 of claim 1 of main request B the feature "*wherein for adverse events that include tissue born infection, tissue disease, bacterial infection the tissue is sequestered based on a request from a tissue source facility*".

Reasons for the Decision

1. The invention

1.1 The invention relates to tissue tracking according to regulatory requirements, see [0002], which may be those of the U.S. Food and Drug Administration, see [0029]. The term "tissue" covers, see [0022], any type of tissue specimens including bone, cornea, skin, heart tissue, valves/conduits, tendons, cord blood, etc.

1.2 A large number of patient populations and multifarious tissues handled within hospitals makes it difficult to comply with regulatory requirements, see [0002].

1.3 The invention aims to solve this problem by proposing a system which documents tissues from their reception at a facility to their issuance to a patient, see [0021] and [0023]. Tissue data is recorded in a database and may be serial numbers, environmental data, time data, files, images, records, documents, and other data related to a tissue, see [0024]. The tissue records satisfy regulatory requirements and can be used to track tissue and to ensure compliance with regulations.

1.4 The recorded data includes an indication whether the tissue has been "*sequestered*", apparently meaning isolated, see [0046], which may have a variety of causes. For instance, the temperature within the storage cabinet was out of range, or it may be discovered by internal investigation, or by an adverse event, such as tissue born infection, tissue disease, or bacterial infection.

1.5 Tissues are stored in a storage cabinet that provides secure storage for temperature-sensitive tissues, see [0043]. The storage cabinet includes a locking device, see [0037], which remains locked if a tissue has been flagged as sequestered, see [0091]. The user is informed by a message if a tissue is regarded as sequestered, see Figures 11A and 11B.

2. Main request - Article 56 EPC

2.1 The examining division considered claim 1 to lack an inventive step over D3 (US2003/034390), from which it was distinguished by the feature "*wherein the adverse event is selected from the group consisting of tissue born infection, tissue disease, bacterial infection, and the temperature of the tissue falling outside of an acceptable range*". The examining division regarded the

distinguishing feature as being non-technical and its implementation on the D3 system to be straightforward for the person skilled in the art of data processing.

2.2 D3 discloses a micro-warehouse ("MW") which may take the form of a refrigerated cabinet, a freezer, or other storage container, see [0022] and which may store life science research products, such as component cells, see [0021]. The micro-warehouse MW is suitable for the claimed purpose and for use at a medical facility. The micro-warehouse MW includes a door, an electric actuated lock, a proximity sensor and an output device. It may further comprise a transmitter and reader which communicate with a RFID tag of a user. The micro-warehouse may comprise an internal temperature sensor, see [0023], and an inventory RFDC module which scans the products which are placed into it and which are taken from it, see [0031]. The electronic lock has two functions: granting access only to authorised users and maintaining the temperature in the cabinet within an appropriate range, see [0030].

2.3 A product is recalled, because of its lifetime having passed or because of its temperature history, which might have exceeded the maximum temperature. This corresponds to an indication of a product as being "sequestered", see point 4.2 of the impugned decision. The inventory system of D3 provides an indication whether a product is to be removed, which in the Board's view anticipates the temperature condition of the adverse event of claim 1. In such a situation the electronic lock of the cabinet of D3 is actuated to prevent the stored product being issued. If a single product is stored in the cabinet, then a single product is prevented from being issued which anticipates the

feature of an adverse event of a temperature of the tissue falling outside of an acceptable range.

2.4 The Board judges that claim 1 is distinguished from D3 in that the micro-warehouse MW does not comprise "*a user interface in communication with the computer system and configured to receive a request from a user to issue the tissue*". D3, [0032], explains that an authenticated user opens the door of the micro-warehouse MW and removes the products he or she requests. An internal inventory system of the client controller of the micro-warehouse scans the remaining products after the door has been closed. The technical effect of the distinguishing feature is an individualised access to tissue samples which leads to a better control of which tissues can be taken. The Board accepts the argument of the appellant that there is no motivation for the person skilled in the art to modify D3 by providing an additional user interface for receiving a request for a tissue. D3 provides a complete solution by its automatic inventory system which teaches away from the present invention.

2.5 Claim 1 of the main request is therefore novel (Article 54 EPC) and inventive (Article 56 EPC) over D3.

2.6 The Board accepts that D2 (US5842179) represents a better closest prior art, because it operates as an item-based mechanism where a user enters via a user interface the identifier of the specimen which he or she intends to remove, see column 9, lines 24 to 40, prior to removing it.

2.7 D2 discloses a freezer with various compartments for the storage of specimens, such as tissues, which must be kept at very low temperatures, see column 1, lines

12 to 19, and column 2, lines 46 to 64, together with an inventory method which helps to keep track of the status of a specimen and to record whether it is in storage or has been removed, see column 3, lines 33 to 40. Each compartment of the freezer comprises a plurality of individually movable racks for holding the specimen. Each rack supports a plurality of boxes and each box is divided in a plurality of volumetric locations, see column 4, line 46, to column 5, line 6. The freezer has a main door and each compartment has a compartment door. Each location for a specimen is identified by a row and a unique location within the row. In column 6, the section entitled "The Method", explains that an inventory of the specimens stored in the freezer is maintained. The inventory holds the sample id, a description, its location, e.g. door, rack, box and position, as well as status information. According to Figure 9, it would seem that an allowed temperature range for the storage of specimen can be defined.

2.8 A security mechanism, see column 8, lines 55 to 65, is provided which requires entering a personal identification number. D2 does not detail the security mechanism, but column 9, lines 47 to 53, explains that its purpose is to prevent a specimen being placed in a compartment (storage location) or one specimen being removed. It is further explained that automatic freezer locks can be incorporated to prevent first-level entry into a freezer. The Board interprets this disclosure as an automated locking device which acts in response to an (access) request from a user to issue a specimen.

2.9 It is common ground that the distinguishing features of claim 1 are those in the characterising portion, namely

the indication of and the reasons for sequestering and the operation of the locking device.

2.10 The appellant explained the invention with reference to Figure 7, steps 760 and 765, and [0091] of the application, illustrating that the user is first alerted about a "sequestered" tissue, see Figure 11A and 11B, and then the tissue is barred from being issued, because locks on the storage cabinet "may not open". Thus, the lock is a safety feature which does not prevent access to an item, but which prevents its accidental removal. In this respect it is a sort of "haptic feedback" device. The appellant explained that a request for two tissue samples would permit access to a "sequestered" tissue sample if the first tissue sample was not sequestered and the locking device therefore unlocked.

2.11 Regarding the first distinguishing feature, the Board considers the labelling of a tissue as being "sequestered" based on "notification of an adverse event related to the tissue, wherein the adverse event is selected from the group consisting *of tissue born infection, tissue disease, bacterial infection, and the temperature of the tissue falling outside of an acceptable range*" to define an administrative policy which sets out the conditions under which specimens should not be issued. This feature does not have a technical effect, but is rather part of regulatory requirements, see point 1.1 of this decision. The Board thus agrees on this point with the examining division, see points 4.3 and 4.4 of the impugned decision.

2.12 The Board judges that the second distinguishing feature, the locking device, has to be interpreted broadly in view of the application.

Paragraph [0037] describes the lock to be a physical lock, opened by a key, or an electronic lock; it [singular] grants access to the storage cabinet only for authenticated personnel. Paragraph [0047] explains that the cabinet remains locked so that the "sequestered" tissue cannot be issued to a user. Original method claim 21 defines that the "storage device may be unlocked", which covers a manual operation of a user who uses a key or who presents an id card to unlock the storage device.

Basis for an automatic "locking" control of locks might be found in [0091], penultimate sentence, which mentions that locks [plural] "may not open" when a tissue is flagged as sequestered. However, in the Board's view, this does not provide a basis for a lock being "unlocked" automatically.

The Board concludes that the claimed feature is to be interpreted broadly and to define that some locks may not open when a sequestered flag of a tissue is set.

2.13 According to the COMVIK approach (see T 641/00), non-technical features may form part of the objective technical problem which the Board defines as how to securely avoid the issue of an individual tissue sample from the storage location which has been indicated as "sequestered", in other words, to use a "sequestered" flag of a tissue as triggering information for avoiding its issuing.

2.14 The inclusion of a "sequestered" flag for each specimen in the inventory of D2 does not achieve a technical effect and a fine-tuning of the locking device of D2 based on this information is obvious for the person skilled in the art based on common general knowledge.

This is all the more so as the triggered operation of a locking device based on the status of a tissue is known from D3, [0033], which discloses operating a lock based on the "recall" status of products.

2.15 The subject-matter of claim 1 does not involve an inventive step over a combination of D2 with common general knowledge or with D3.

2.16 The Board is not convinced by the argument of the appellant that the provision of a warning message on the freezer of D2 solves the mentioned objective technical problem, see point 2.13. This does not restrict the issuance of a "sequestered" tissue. The skilled person would rather adapt the automatic freezer locks, which can be provided to the freezer in addition to the id-based lock, such that these locks remain locked to restrict access to the sequestered tissue.

3. Auxiliary requests 1 and 2

3.1 The subject-matter of claim 1 of these auxiliary requests does not involve an inventive step for the reasons set out below.

3.2 Claim 1 of auxiliary request 1 adds the feature of a thermometer configured to measure a temperature within the storage location; the temperature is communicated to the database in predetermined intervals.

3.3 The Board judges this feature to be known from D2 which illustrates in Figure 9 a display of the current internal temperature of a freezer together with two alarm settings. Column 1, lines 12 to 35, explains that the specimen must be kept at a specific temperature range

and column 2, lines 46 to 54, details the inventory function for these specimens.

3.4 Claim 1 of auxiliary request 2 adds the feature that the frequency of the predetermined intervals is set based on the type of tissue, and that the storage location is defined to comprise a climate control device which is used together with the thermometer to maintain a climate within the storage location.

3.5 The Board judges this feature to relate to the administrative policy which defines the conditions per type of tissue under which they must be stored. For instance, D4, see [0109] to [0111], explains specific storage conditions for tissues, such as that each type of tissue product specifies the specific temperature range at which it must be kept. The adaptation of the climate control device of the freezer of D2 together with the thermometer to maintain an appropriate climate within the storage location follows directly from this administrative policy.

3.6 The skilled person may also refer to D3 which teaches taking periodic temperature measurements, see [0022] to [0023], [0030], to record the temperature history of individual products, see [0033], as well as the time which a product remained in the micro-warehouse.

4. Auxiliary requests A and B

4.1 Auxiliary requests A, A1, A2, B, B1 and B2 were filed after the statement setting out the grounds of appeal which is expected to contain a party's complete case.

4.2 According to 13(1) RPBA 2020, the Board has a discretion to disregard requests, facts and evidence filed

after the statement setting out the grounds of appeal has been filed. The discretion shall be exercised in view of inter alia the complexity of the amended subject-matter, the current state of the proceedings and the need for procedural economy (Article 13(1) RPBA).

4.3 The Board decides to admit these requests into the proceedings because they include only a small number of amendments to clarify the subject-matter claimed.

4.4 The subject-matter of claim 1 of these auxiliary requests does not involve an inventive step for the reasons set out below.

4.5 Claim 1 of auxiliary requests A adds the feature "*tissue storage cabinet*" which *"includes a plurality of patient specific tissue bins"*. This feature is known from D2, column 4, line 46, to column 5, line 13, which illustrates a plurality of individual positions for holding a single specimen.

4.6 Claim 1 of auxiliary requests B adds the feature "*for each received request to issue a tissue sample*". The Board judges that this feature was already present in the preceding claim 1 which defined that the locking device was operating on an item request basis.

5. Auxiliary requests C and D and 3

5.1 Auxiliary requests C, C1, C2, D, D1, D2 and 3 were filed after the summons to oral proceedings. According to Article 13(2) RPBA 2020, such changes are disregarded unless there are exceptional circumstances.

5.2 The appellant explained that these requests were filed strictly in response to the observations of the Board and include only a small number of simple amendments to further clarify the claims already under consideration.

5.3 The Board does not consider the reasons given to represent exceptional circumstances in the meaning of Article 13(2) RPBA. Claim 1 of these requests comprises additional features which do not converge with the preceding requests and which lead to subject-matter to which the first instance could not take a position.

5.4 The Board therefore does not admit these requests into the proceedings.

6. Accordingly, as none of the appellant's requests are allowable, the appeal has to be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

T. Buschek W. Chandler

Decision electronically authenticated