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**Datasheet for the decision
of 1 July 2021**

Case Number: T 1987/18 - 3.3.01

Application Number: 11828425.6

Publication Number: 2623981

IPC: G01N33/543, G01N33/48

Language of the proceedings: EN

Title of invention:
TESTING METHOD AND DEVICE

Patent Proprietor:
FUJIFILM Corporation

Opponent:
bioMérieux Inc.

Headword:
Testing multiple diseases/FUJIFILM

Relevant legal provisions:
EPC Art. 100(a), 54
RPBA 2020 Art. 13(2)

Keyword:
Novelty - main request (no)
Amendment after summons - taken into account (no)



Beschwerdekammern

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Case Number: T 1987/18 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 1 July 2021

Appellant: FUJIFILM Corporation
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 21 June 2018
revoking European patent No. 2623981 pursuant to
Article 101(2) EPC**

Composition of the Board:

Chairman A. Lindner
Members: J. Molina de Alba
R. Romandini

Summary of Facts and Submissions

- I. This appeal by the patent proprietor (appellant) is directed against the opposition division's decision revoking European patent No. 2 623 981.

The patent had been granted with seven claims. Granted independent claim 1 reads as follows (emphasis in the original):

"1. A test method for testing with a test apparatus (1) whether a subject is positive or negative for a plurality of diseases using a specimen collected from the subject,

characterized in that

if the subject is determined to be positive for one of the plurality of diseases, a test result indicating the positive is outputted from the test apparatus (1) without waiting for completion of the testing of the other diseases; and the test result indicating the positive is sent as notice of test result from the test apparatus (1) via a first communication means to a user who requested inspection."

- II. The decision under appeal was based on the patent as granted as the sole request. In the decision the opposition division held, among other things, that the subject-matter of claim 1 was not novel in view of document D8 (WO 2007/120241).
- III. In the statement of grounds of appeal and in a subsequent letter dated 2 July 2019, the appellant contested the opposition's decision with respect to novelty.

IV. In its reply to the statement of grounds of appeal, the respondent (opponent) maintained that the claimed subject-matter was not novel and requested that the appeal be dismissed.

V. By letter dated 26 October 2020, the board summoned the parties to oral proceedings. In preparation for the oral proceedings, the board issued a communication drawing the parties' attention to salient issues that might be debated.

VI. With a letter dated 1 June 2021, the appellant filed two sets of claims as auxiliary requests 1 and 2.

Claim 1 of auxiliary request 1 differs from claim 1 as granted in that the following clause has been added at the end:

"without waiting for completion of the testing of the other diseases; and wherein the disease to be tested is an infectious disease".

Claim 1 of auxiliary request 2 differs from claim 1 as granted in that the following clause has been added at the end:

"and wherein the test method is an immunochromatographic method".

VII. With the agreement of the parties, the oral proceedings were held via videoconference on 1 July 2021. At the end of the oral proceedings, the board's decision was announced.

VIII. The appellant's arguments, where relevant to the present decision, can be summarised as follows.

Claim 1 had to be construed in line with the teaching of the patent, which conveyed the following.

- (a) Outputting and sending were two distinct, subsequent steps which did not overlap.
- (b) The feature "without waiting for completion of the testing of the other diseases" referred not only to the outputting step but also to the step of sending the notice of test result to the user who requested inspection (paragraphs [0025], [0027], [0057], [0060] and [0064], and Figure 3).
- (c) Sending implied the transmission of the test results to a location remote from the testing apparatus (paragraph [0018]). Otherwise there would have been no need to differentiate between outputting and sending.

Document D8 did not anticipate the method of claim 1. The real-time display or output of test results mentioned in D8 (page 27, lines 9-10) did not correspond to the outputting and sending steps in claim 1. First, real-time output could not be equated with outputting a positive test result without waiting for completion of the other tests, since more than one result could be outputted simultaneously if obtained at the same time. Second, the display of a graph in D8 was related to the outputting step but not to the subsequent sending step: D8 left open when the graph was displayed, and, more importantly, real-time outputting did not imply that test results were sent as they were obtained; they could be sent once all tests had been completed.

Auxiliary requests 1 and 2 should be admitted into the appeal proceedings because they constituted a response to the board's preliminary opinion. Auxiliary request 1 dealt with the board's view that the feature in claim 1 "without waiting for completion of the testing of the other diseases" referred to the outputting of the positive result but not to its sending. Auxiliary request 2 was intended to render moot any concerns regarding the novelty of the claimed method over document D8. The amendments removed the mentioned concerns at first glance; they were simple and the respondent had sufficient time to prepare before the oral proceedings.

IX. The respondent's arguments, where relevant to the present decision, can be summarised as follows.

The appellant construed claim 1 narrowly on the basis of specific embodiments in the patent. It read limitations that could not be found in the wording of claim 1. The following aspects of claim 1 required consideration.

- (a) The fact that a positive result was outputted without waiting for completion of the testing of the other diseases did not exclude that negative results were also outputted as they were obtained.
- (b) The feature "sending via a first communication means" was not restricted to physical sending. The patent mentioned in paragraph [0018] and claim 3 that the notice of test result could be sent, for instance, by telephone, i.e. verbally. Accordingly, any means of conveying information was encompassed by the feature sending via a first communication means. Moreover, sending did not necessarily imply

that the receptor (user who requested inspection) was remote to the apparatus.

- (c) Outputting simply meant transferring data from one element to another. In line with Figure 3 of the patent, it could be, for instance, a transfer of data from the control unit to the image processing unit. Sending could be the transfer of data to the display on which the user could read the data as test results.

The method of claim 1 was not novel over the content of D8. This document had the same aim as the contested patent, namely the rapid and accurate diagnosis of infectious diseases by analysing biological fluids (see D8, page 2, paragraph 2, and page 76, section 8.5). It referred specifically (page 25, paragraph 3) to the detection of a panel of infectious diseases by real-time PCR. The progress of the PCR reaction could be tracked by the user because the system detected and displayed the amount of fluorescence emission in real time (page 27, paragraph 1; page 11, paragraph 3; and page 127, paragraph 4). As fluorescence emission correlated with the amount of product, a display of the intensity of fluorescence emission was a notice of test results sent from the apparatus to the user who had requested inspection. Moreover, displaying in real time implied that positive results were both outputted and sent without waiting for the completion of the testing of other diseases. Hence, the display of fluorescence emission tracked by the user in D8 corresponded to the feature in claim 1 "sending as notice of test result from the test apparatus (1) via a first communication means to a user who requested inspection".

Auxiliary requests 1 and 2 should not be admitted, because their filing one month before the oral

proceedings before the board was not justified by any change in the proceedings. The evidence and arguments on file had not changed since the outset of the opposition proceedings, and the appellant had always relied on the patent as granted as its sole request. Furthermore, the auxiliary requests were not convergent, and their filing could justify additional searches which the respondent had not had enough time to conduct.

X. The parties' final requests were as follows.

The appellant requested:

- that the decision under appeal be set aside and that the case be remitted to the opposition division for the examination of inventive step;
- alternatively, that the patent be maintained as granted;
- further alternatively, that the case be remitted to the opposition division for the examination of inventive step on the basis of either of the claim sets filed with the letter dated 1 June 2021 as auxiliary requests 1 and 2;
- further alternatively, that the patent be maintained on the basis of the claims of either of auxiliary requests 1 and 2.

The respondent requested:

- that the appeal be dismissed and that the patent be revoked in its entirety; and
- that the comments and auxiliary requests filed by the appellant with the letter dated 1 June 2021 not be admitted into the appeal proceedings.

Reasons for the Decision

1. The appeal is admissible. It meets the requirements of Articles 106 to 108 and Rule 99(2) EPC.
2. *Construction of claim 1 as granted*

Claim 1 concerns a method for testing with a test apparatus whether a subject is positive or negative for a plurality of diseases. The method uses a specimen collected from the subject and is characterised by the fact that:

- (i) any positive result is outputted from the test apparatus without waiting for completion of the testing of other diseases; and
- (ii) the test result indicating the positive is sent as notice of test result from the apparatus via a first communication means to a user who requested inspection.

Regarding point (i), two aspects need consideration. First, as argued by the respondent, the fact that a positive result is outputted without waiting for completion of the testing of other diseases does not exclude that negative results are also outputted as they are obtained. Second, claim 1 requires that the positive test result be outputted from the apparatus but leaves open in which form and to which element the result should be outputted.

Regarding point (ii), the claim does not contain any restriction in relation to "communication means". The

board concurs with the respondent that the claim is not limited to physical means; any means that conveys information is encompassed. In addition, claim 1 does not specify where the user who requested information should be placed. The appellant's interpretation that the user should be in a remote place is not convincing. Such interpretation is based on specific embodiments disclosed in paragraph [0018] of the patent and intends to read into claim 1 limitations that are not there. The option that the user who requested inspection be next to the testing apparatus is not excluded by the wording of claim 1 and makes sense from the technical point of view. Consequently, it falls within the breadth of claim 1.

Regarding the relationship between the steps of outputting and sending, the board agrees with the appellant that test results cannot be sent without having been outputted. The board nevertheless notes that to output in computer technology is to produce information which is transferred to an external medium. Thus, outputting a positive test result is not different from sending a positive test result. The only difference between outputting and sending in the context of claim 1 lies in the receptor: while the receptor of the output is unspecified, that of the sending is a user who requested inspection. This means that, contrary to the appellant's position, the outputting and sending steps can be simultaneous or at least overlap. Claim 1 does not contain any limitation in this respect either.

3. *Novelty over document D8 - claim 1 as granted*

3.1 D8 is directed to the rapid and accurate diagnosis of infectious diseases and aims at overcoming the

limitations of PCR tests for simultaneously assaying multiple pathogens (page 2, paragraphs 2 and 3). On page 25 (penultimate paragraph), D8 explicitly refers to the detection of a panel of infectious diseases by detecting nucleic acids associated with a parasite, bacteria, fungus or virus by real-time PCR. Detection can be based on fluorescence emission (page 25, line 19 and last paragraph), and the result may be displayed as a graph or other output permitting the user to track the progress of PCR reaction in real time (page 27, paragraph 1).

- 3.2 The parties did not dispute that D8 discloses a method for testing with a test apparatus whether a subject is positive or negative for a plurality of diseases using a specimen collected from the subject.

Furthermore, as outlined in point 2 above (penultimate paragraph), claim 1 does not require the user to be in a place remote from the testing apparatus. Hence, the user in D8 who tracks the progress of the PCR reaction in real time is a user who requested inspection within the meaning of claim 1.

- 3.3 The system of D8 displays the evolution of fluorescence emission during the PCR reaction as a graph or other output permitting the user to track the progress of the reaction in real time. The parties did not dispute that the display of this information in D8 could be considered a notice of test result. The board sees no reason to take another stance, since a user observing the displayed fluorescence emission information would immediately know whether the test is positive or negative.

- 3.4 Furthermore, in line with the respondent's argument, showing a positive test result on a display can be equated with sending the positive test result from the testing apparatus to the user who tracks the progress of the PCR reaction in the display. As noted above, claim 1 does not contain any limitation in relation to the communication means. In this case, the communication means is an electric signal.
- 3.5 Test results can only be sent to the user (i.e. shown in the display) if they have been outputted (i.e. generated as an output) by the apparatus. As the notice of positive test result was sent to the user via an electric signal translated as a graph in the display, the system of D8 inevitably involved the outputting of the positive test result. As suggested by the respondent in its interpretation of claim 1, analogous to the system depicted in Figure 3 of the patent, the output step in D8 may be the sending of a signal of test result from the control unit of the apparatus to the processing unit, which subsequently generates and sends a signal in the display that can be read by the user.
- 3.6 Regarding the requirement in claim 1 that a test result indicating the positive be outputted and (arguably) sent "without waiting for completion of the testing of the other diseases", D8 explicitly states (page 27, lines 9-10) that the information displayed permits the user to track the progress of the PCR reaction in real time. This means that the apparatus outputs and sends the positive (and negative) test results to the user as they are obtained, i.e. without waiting for completion of the testing of other diseases.

In this context, the appellant's argument that tracking results in real time would not necessarily imply the output of a positive result without waiting for completion of the testing of the other diseases must fail. Tracking the progress of the PCR reaction in real time means that the fluorescence emission data registered by the apparatus are processed (outputted) and sent (displayed) as they are produced, without delay. The appellant's additional argument that the testing apparatus could gather the test results but not display them until all results are available is speculative and goes against the concept of tracking the progress of a reaction in real time.

3.7 Therefore, the board concludes that D8 discloses the combination of all features of claim 1, rendering the claimed subject-matter not novel. Consequently, the ground for opposition of Article 100(a) EPC in combination with Article 54 EPC prejudices the maintenance of the patent as granted.

4. *Admittance of auxiliary requests 1 and 2*

Article 13(2) RPBA 2020 provides that any amendment to a party's appeal case made after notification of a summons to oral proceedings is not to be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

The appellant filed auxiliary requests 1 and 2 on 1 June 2021, i.e. seven months after notification of the summons to oral proceedings and four months after the issue of the board's preliminary opinion.

According to the appellant (letter dated 1 June 2021, section 3), the auxiliary requests had been filed as a reaction to the board's preliminary opinion: i) auxiliary request 1 addressed the board's construction of claim 1 that the feature "without waiting for completion of the testing of the other diseases" referred only to the outputting and not to the sending of the positive result; and ii) auxiliary request 2 addressed the board's concerns in relation to novelty with regard to document D8.

These issues, allegedly addressed by the auxiliary requests, had already been raised in the opposition proceedings and had been dealt with in the appealed decision (see points 4.1 and 5.3.4). They had also been put forward by the respondent in its reply to the statement of grounds of appeal (see page 2, lines 12-35, and page 5, line 50 to page 7, line 3). Thus, the issues were not raised in the board's preliminary opinion for the first time; they had been on file from the outset of the appeal proceedings.

Hence, the appellant had failed to present the exceptional circumstances which justified the filing of amendments one month before the oral proceedings. For this reason the board decided to not admit auxiliary requests 1 and 2 into the appeal proceedings (Article 13(2) RPBA 2020 in combination with Articles 24(1) and 25(1) RPBA 2020).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



M. Schalow

A. Lindner

Decision electronically authenticated