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Datasheet for the decision of 26 June 2024

Case Number: T 0344/23 - 3.2.02

Application Number: 06748733.0

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Language of the proceedings: EN

Title of invention:
POINT-OF-CARE FLUIDIC SYSTEMS AND USES THEREOF

Patent Proprietor:
Labrador Diagnostics LLC

Opponents:
James Poole Limited
bioMérieux Deutschland GmbH
bioMérieux

Headword:

Relevant legal provisions:
EPC Art. 54
RPBA 2020 Art. 13(1), 13(2)

Keyword:

Novelty - main request (no) - first auxiliary request (no)
Amendment to appeal case - amendment overcomes issues raised - new first auxiliary request (no) - amendment detrimental to procedural economy - second and third auxiliary requests (yes) - taken into account (no)

Decisions cited:

Catchword:

Europäisches Patentamt
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Beschwerdekammern

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Case Number: T 0344/23 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 26 June 2024

Appellant: (Patent Proprietor)	Labrador Diagnostics LLC 701 S. Carson Street Suite 200 Carson City, NV 89701 (US)
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Representative:	August Debouzy 7, rue de Téhéran 75008 Paris (FR)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on**

9 December 2022 concerning the maintenance of European Patent No. 1883341 in amended form

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	D. Ceccarelli
	C. Schmidt

Summary of Facts and Submissions

I. The patent proprietor and opponent 1 appealed against the Opposition Division's decision that, account having been taken of the amendments in accordance with auxiliary request 4, the patent and the invention to which it relates met the requirements of the EPC.

II. Opponents 2 and 3 intervened in the opposition proceedings under Article 105(1)(a) EPC after proceedings for infringement of the patent were instituted against them.

III. Oral proceedings took place on 26 June 2024.

The appellant / patent proprietor ("proprietor") requested that the decision under appeal be set aside and that the patent be maintained as granted (main request), or alternatively on the basis of the "New First Auxiliary Request", filed during the oral proceedings before the Board, or on the basis of one of the first to third auxiliary requests, filed on 4 March 2024.

The appellant / opponent 1 ("opponent 1") and opponents 2 and 3 requested that the decision under appeal be set aside and the patent revoked.

IV. The following document is mentioned in this decision:

D1: US 2004/0228766 A1

V. **Claim 1 of the main request** reads as follows:

"A system for detecting an analyte in a bodily fluid collected from a subject, comprising:

a) an external device;

b) a fluidic device (2), said fluidic device comprising:

an identifier to provide an identity of the fluidic device adapted to trigger transmission of a protocol from the external device,

a sample collection unit (4), and

an assay assembly for a sample of bodily fluid from the sample collection unit to react with reactants contained within said assay assembly to yield a signal indicative of the presence of said analyte;

c) a reader assembly comprising:

a detection assembly for detecting said signal,

actuating elements to direct flow of fluid through the fluidic device, and

a controller to control the actuating elements on the basis of instructions to control the actuating elements to direct flow of fluid through the fluidic device; and

d) a communication assembly for:

receiving the protocol from the external device, the protocol dependent on the identity of the fluidic device and comprising the instructions to control the actuating elements to direct flow of fluid through the fluidic device, and

transmitting said signal to said external device."

Claim 1 of the "New First Auxiliary Request" reads as follows:

"A method for detecting an analyte in a bodily fluid collected from a subject, comprising:

a) providing a system for detecting an analyte in a bodily fluid collected from a subject, the system comprising:

i) an external device;

ii) a fluidic device (2), said fluidic device comprising:

an identifier to provide an identity of the fluidic device adapted to trigger transmission of a protocol from the external device,

a sample collection unit (4), and

an assay assembly for a sample of bodily fluid from the sample collection unit to react with reactants contained within said assay assembly to yield a signal indicative of the presence of said analyte;

iii) a reader assembly comprising:

a detection assembly for detecting said signal,

actuating elements to direct flow of fluid through the fluidic device, and

a controller to control the actuating elements on the basis of instructions to control the actuating elements to direct flow of fluid through the fluidic device; and

iv) a communication assembly for:

receiving the protocol from the external device, the protocol dependent on the identity of the fluidic device

and comprising the instructions to control the actuating elements to direct flow of fluid through the fluidic device, and

transmitting said signal to said external device,

b) receiving, by the communication assembly, the protocol from the external device;

c) controlling, by the controller, on the basis of the instructions, the actuating elements to direct flow of fluid through the fluidic device;

d) the sample of bodily fluid from the sample collection unit reacting with the reactants contained within said assay assembly to yield the signal indicative of the presence of said analyte; and

e) detecting, by the detection assembly, said signal."

Claim 1 of the first auxiliary request reads as follows:

"A system for detecting an analyte in a bodily fluid collected from a subject, comprising:

a) an external device;

b) a fluidic device (2), said fluidic device comprising:

an identifier to provide an identity of the fluidic device adapted to trigger transmission of a protocol from the external device, the protocol dependent on the identity of the fluidic device and comprising instructions to a controller to perform the protocol on the fluidic device,

a sample collection unit (4), and

an assay assembly for a sample of bodily fluid from the sample collection unit to react with reactants contained within said assay assembly to yield a signal indicative of the presence of said analyte;

c) a reader assembly comprising:

a detection assembly for detecting said signal,

actuating elements to direct flow of fluid through the fluidic device, and

the controller, to control the actuating elements on the basis of the instructions to the controller to perform the protocol on the fluidic device, by controlling the actuating elements to direct flow of fluid through the fluidic device; and

d) a communication assembly for:

receiving the protocol from the external device, and

transmitting said signal to said external device."

Claim 1 of the second auxiliary request reads as follows:

"A system for detecting an analyte in a bodily fluid collected from a subject, comprising:

a) an external device;

b) a fluidic device (2), said fluidic device comprising:

an identifier to provide an identity of the fluidic device adapted to trigger transmission of a protocol from the external device,

a sample collection unit (4), and

an assay assembly for a sample of bodily fluid from the sample collection unit to react

with reactants contained within said assay assembly to yield a signal indicative of the presence of said analyte;

c) a reader assembly comprising:

a detection assembly for detecting said signal,

actuating elements to direct flow of fluid through the fluidic device, and

a controller to control the actuating elements on the basis of instructions to control the actuating elements to direct flow of fluid through the fluidic device; and

d) a communication assembly for:

receiving the protocol from the external device, the protocol dependent on the identity of the fluidic device and comprising the instructions to control the actuating elements to direct flow of fluid through the fluidic device, and

transmitting said signal to said external device,

wherein:

the fluidic device has more than one reaction site to allow for detection of multiple analytes of interest from the same sample of bodily fluid, and

the fluidic device has reagent chambers, wherein a reagent chamber is in fluid communication with at least one reaction site, and when the fluidic device is actuated by the actuating elements, reagents contained in said reagent chambers are released into fluidic channels within the fluidic device."

Claim 1 of the third auxiliary request reads as follows:

"A system for detecting an analyte in a bodily fluid collected from a subject, comprising:

a) an external device;

b) a fluidic device (2), said fluidic device comprising:

an identifier to provide an identity of the fluidic device adapted to trigger transmission of a protocol from the external device, the protocol dependent on the identity of the fluidic device and comprising instructions to a controller to perform the protocol on the fluidic device,

a sample collection unit (4), and

an assay assembly for a sample of bodily fluid from the sample collection unit to react with reactants contained within said assay assembly to yield a signal indicative of the presence of said analyte;

c) a reader assembly comprising:

a detection assembly for detecting said signal,

actuating elements to direct flow of fluid through the fluidic device, and

the controller, to control the actuating elements on the basis of the instructions to the controller to perform the protocol on the fluidic device, by controlling the actuating elements to direct flow of fluid through the fluidic device; and

d) a communication assembly for:

receiving the protocol from the external device, and

transmitting said signal to said external device,

wherein:

the fluidic device has more than one reaction site to allow for detection of multiple analytes of interest from the same sample of bodily fluid, and

the fluidic device has reagent chambers, wherein a reagent chamber is in fluid communication with at least one reaction site, and when the fluidic device is actuated by the actuating elements, reagents contained in said reagent chambers are released into fluidic channels within the fluidic device."

VI. The proprietor's arguments relevant to this decision can be summarised as follows.

Main request - novelty

The subject-matter of claim 1 of the main request was novel over D1 because this document did not directly and unambiguously disclose the following features:

- an identifier to provide an identity of the fluidic device adapted to trigger transmission of a protocol from the external device,

- a controller to control the actuating elements on the basis of instructions to control the actuating elements to direct flow of fluid through the fluidic device, and

- a communication assembly for receiving the protocol from the external device, the protocol dependent on the identity of the fluidic device and comprising the instructions to control the actuating elements to direct flow of fluid through the fluidic device.

D1 was not a well-written patent specification. It was ambiguous in many respects. What it disclosed was different modules with slots for detecting analytes in a bodily fluid, with each type of slot having "unique technologies that correspond to one or more selected chemistries" (paragraph [0043]) and so being for use with a dedicated cartridge type. Each module/slot in D1 was pre-configured to run a particular test on a particular cartridge type. There was no instructing of a module by a host computer on how to run a particular test (e.g. how to control fluid flow in a cartridge dependent on an identity of the cartridge). This would not make technical sense because a given cartridge had a dedicated module or slot (Figures 1(b) and 4 to 6 showed different modules and slots). The control instructions would be the same regardless of the identity of the cartridge.

D1 focused on quality control ("QC"), and the host computer was used for QC purposes to monitor operation of the modules using shared QC protocols. The "test type" information in Table 2, point 6 of "Model POCT Platform Operating Procedure" of D1 simply referred to the host computer needing to know the test type of the cartridge to monitor a test run for QC purposes. In fact, Table 2 contained a list of possible QC protocols.

The expression "determines a test protocol for a cartridge" in paragraph [0056] of D1 was ambiguous and could mean that the host computer simply noted or checked the test type for a patient's QC test record to be logged in specific databases as mentioned in paragraphs [0045] and [0047] of D1. The same applied to the "serialized identification" mentioned in paragraph [0058] of D1.

The third to fifth boxes in Figure 9 of D1 did not demonstrate any dependence of a protocol transmitted from the host computer on the identity of the cartridge. They only disclosed generic instructions to a module, regardless of the identity of the cartridge. The fact that the fourth and fifth boxes were listed after the third box could mean that the host computer directed the module processor to perform fluid control operations after reading the bar code, but there was nothing to suggest that the directions sent by the host computer were dependent on the identity of the cartridge. The same applied to the disclosure of the reading of a bar code of a cartridge initiating the sequential operation of the fluid movement and detection in paragraph [0059] of D1.

It also had to be borne in mind that for an implicit disclosure to be present the condition was that no realistic alternative would be considered by the person skilled in the art.

"New First Auxiliary Request" - admittance

The "New First Auxiliary Request" was derived from the main request, from which claims 1 to 6 had been deleted and claim 7 had been drafted to recite the features of claim 1 explicitly. Hence claim 1 of the "New First Auxiliary Request" corresponded to claim 7 of the main request.

According to case law, new requests in which claims were merely deleted were to be admitted even if they had been filed at a late stage in the proceedings.

In the "New First Auxiliary Request", some important

aspects, such as the step of receiving, by the communication assembly, the protocol from the external device, had been made explicit. Moreover, procedural economy was not affected by filing this request, as no alternative considerations were required with respect to the main request.

Hence the "New First Auxiliary Request" should be admitted into the appeal proceedings.

First auxiliary request - admittance and novelty

The first auxiliary request corresponded to the request found allowable by the Opposition Division in the impugned decision. It should be admitted into the appeal proceedings.

In claim 1 of the first auxiliary request it had been specified that the controller controlled the actuating elements on the basis of instructions to the controller to perform the protocol on the fluidic device. This was not known from D1.

Second and third auxiliary requests - admittance

The proprietor acknowledged that if the main and first auxiliary requests were found to be invalid for lack of novelty over D1, which objection had been raised by opponent 1, the admission of the second and third auxiliary requests, filed after the reply of opponent 1 to the proprietor's statement of grounds of appeal, was subject to the discretion of the Board under Article 13(1) RPBA.

These requests should be admitted because the reason for submitting them only became apparent after studying

the publications identified in the interventions. Moreover, after the finding of lack of novelty over D1 the proprietor would have filed them anyway, even if there had been no interventions.

VII. The opponents' arguments relevant to this decision can be summarised as follows.

Main request - novelty

The subject-matter of claim 1 of the main request was not novel over D1.

D1 disclosed a system for detecting an analyte in a bodily fluid collected from a subject, in the form of a point of care diagnostic platform with a user interface, host computer, multiple single-cartridge test processing modules and an external communication system (paragraph [0028]). The host computer, coupled to the modules (paragraph [0045]), was the external device as claimed.

The test cartridges, which were fluidic devices in accordance with the claim, could "*include electronic identifiers, including but not limited to bar-coded identifiers, with information for test protocols*" (paragraph [0058]). They could also include serialised identification. D1 also discloses that a module processor read a cartridge bar code and sent a cartridge test protocol code to a host computer (Figure 9). The host computer, in combination with a processor, then determined a test protocol for the cartridge accordingly (paragraph [0056]). It followed that D1 disclosed an identifier to provide an identity of the fluidic device adapted to trigger transmission of a protocol from the external device within the

meaning of the claim.

D1 disclosed that each module had a module processor which actuated fluid control mechanisms, directed by the host computer (paragraphs [0056] and [0061], and Figure 9). The module processor was the controller within the meaning of claim 1 of the main request. It followed that D1 also disclosed a controller to control the actuating elements on the basis of instructions to control the actuating elements to direct flow of fluid through the fluidic device.

D1 disclosed that the modules were coupled to an external communication link/a wireless communication system (paragraph [0044] and claim 3) and to the host computer. Hence D1 disclosed a communication assembly for receiving the protocol from the external device. According to Figure 9, third box, the module processor read the cartridge bar code and sent the cartridge test protocol code to the host computer. Then the host computer determined a test protocol for the cartridge (paragraph [0056] and Figure 9, fourth box). The determination of the test protocol and quality control were two different aspects of D1. According to paragraph [0059], the bar-coded identifiers, once read by the module processor, triggered the provision of a protocol. The expression "this initiates" in this paragraph indicated a causal link. Hence the protocol was dependent on the information content of the bar-coded identifiers. If that had not been the case, i.e. if the result of the test protocol had been the same for each identifier, the step of reading and sending the test protocol code would have been entirely unnecessary or redundant, which was not a logical or sensible reading of D1. Moreover, it would make no sense to have the same test protocol with cartridges

with different reagents, as disclosed in paragraph [0055]. Finally, paragraphs [0018] and [0024] as well as claim 11 of D1 explicitly disclosed cartridges "bar-coded with information for test protocols". Thus the protocol received was dependent on the identity of the fluidic device and comprised the instructions to control the actuating elements to direct flow of fluid through the fluidic device, within the meaning of claim 1 of the main request.

"New First Auxiliary Request" - admittance

The "New First Auxiliary Request" should not be admitted into the appeal proceedings. It constituted a change of case and, *prima facie,* did not overcome the objections over D1.

First auxiliary request - admittance and novelty

The first auxiliary request should not be admitted into the appeal proceedings. In any case, the subject-matter of claim 1 of this request did not introduce any feature which was not already present in claim 1 of the main request, as even conceded by the proprietor on page 5 of its statement of grounds of appeal. As a consequence, the subject-matter of claim 1 of the first auxiliary request could not be novel over D1.

Second and third auxiliary requests - admittance

The second and third auxiliary requests had been filed after the reply of opponent 1 to the proprietor's statement of grounds. They should not be admitted into the appeal proceedings. The higher-ranking requests were not allowable for lack of novelty over D1. This objection had been raised at the beginning of the

opposition proceedings and there was no reason to file further requests addressing that objection at a late stage of the appeal proceedings. The fact that interventions had been filed did not justify the filing, because the second and third auxiliary requests could not be considered a legitimate response to the interventions. Opponent 1 could not be put at a disadvantage because interventions had been filed. Moreover, the second and third auxiliary requests constituted a considerable shift with respect to the higher-ranking requests and their admission would run against procedural economy.

Reasons for the Decision

1. Subject-matter of the patent

The invention as defined in claim 1 of the patent as granted relates to a system for detecting an analyte in a bodily fluid collected from a subject. The analyte may be one of the many known disease biomarkers and can be used to monitor possible adverse drug reactions in patients (paragraphs [0002] to [0004] of the patent).

The claimed system comprises an external device, a fluidic device, a reader assembly and a communication assembly.

The external device may be a computer system (paragraph [0081] of the patent).

The fluidic device comprises an identifier (such as a bar code) to provide an identity of the fluidic device adapted to trigger transmission of a protocol from the external device, a sample collection unit and an assay

assembly for a sample of bodily fluid from the sample collection unit to react with reactants contained within the assay assembly to yield a signal indicative of the presence of the analyte.

The reader assembly comprises a detection assembly for detecting the signal, actuating elements to direct flow of fluid through the fluidic device, and a controller to control the actuating elements on the basis of instructions to control the actuating elements to direct flow of fluid through the fluidic device.

The communication assembly is for receiving the protocol from the external device, the protocol being dependent on the identity of the fluidic device and comprising the instructions to control the actuating elements to direct flow of fluid through the fluidic device, and transmitting the signal to the external device.

By providing different reactants and different protocols for detecting different analytes, a flexible and convenient detection system is provided.

2. Main request - novelty

The opponents argued that the subject-matter of claim 1 of the main request lacked novelty over D1.

2.1 D1 discloses a system for detecting an analyte in a bodily fluid collected from a subject (Figure 1(a) and paragraph [0028]) comprising an external device (host computer 14 described in paragraph [0045]), a fluidic device (cartridge 20), a reader assembly (module 12) and a communication assembly (implicit for communication between module 12 and host computer 14,

see also paragraphs [0044] and [0046]).

The fluidic device comprises an identifier (paragraph [0058]) to provide an identity of the fluidic device adapted to trigger transmission of a protocol from the external device (paragraph [0056] and third and fourth box in Figure 9), a sample collection unit (according to paragraph [0052], cartridge 20 can accept a blood sample tube 40 from a standard sample draw, Figure 4) and an assay assembly for a sample of bodily fluid from the sample collection unit to react with reactants contained within the assay assembly (comprising flow channel 60 and flow cell 38, Figure 4 - see also paragraphs [0050] and [0054]) to yield a signal indicative of the presence of the analyte (flow cell 38 is described as a detection chamber in paragraph [0050] and the cartridge performs an assay protocol according to point 7 in Table 2).

The reader assembly comprises a detection assembly for detecting the signal (paragraph [0046], first sentence and paragraph [0053], last sentence), actuating elements to direct flow of fluid through the fluidic device (the external pump and the external activator in module 12 mentioned in paragraph [0062]), and a controller to control the actuating elements on the basis of instructions to control the actuating elements to direct flow of fluid through the fluidic device (processor 56, Figure 1(b) and Figure 9, fifth box).

The communication assembly is for receiving the protocol from the external device, the protocol dependent on the identity of the fluidic device and comprising the instructions to control the actuating elements to direct flow of fluid through the fluidic device (according to paragraph [0056] the host

computer, in combination with the processor, determines a test protocol and then a fluid control mechanism in the cartridge is actuated), and transmitting the signal to the external device (the signal is sent to the host computer for storage in memory and display on the user interface, see also paragraph [0045] and Figure 8, penultimate box).

Hence D1 discloses all the features of claim 1 of the main request.

2.2 The proprietor argued that D1 did not disclose an identifier to provide an identity of the fluidic device adapted to trigger transmission of a protocol from the external device.

This argument is not convincing, since paragraph [0058] of D1 expressly recites that "*cartridges 20 can include electronic identifiers, including but not limited to bar-coded identifiers, with information for test protocols and lot expiration dates*" and can also include "*serialized identification*", and paragraph [0059] discloses that "*the bar code of cartridge 20, with its unique sample, are read. This initiates the sequential operation of the fluid movement and detection*". It follows that the bar codes provide an identity of the cartridges ("*unique sample*", "*serialized identification*") and are adapted to trigger transmission of a protocol ("*information for test protocol*" and initiation of "*sequential operation*"). The protocol is transmitted from the host computer, as disclosed in Figure 9, fourth to sixth box ("*Host Computer Directs Module Processor to Actuate Fluid Control Mechanism*").

2.3 The proprietor argued that D1 did not disclose a controller to control the actuating elements on the basis of instructions to control the actuating elements to direct flow of fluid through the fluidic device.

This argument is not convincing either. Figure 9, fifth box, expressly discloses that the "*Host Computer Directs Module Processor to Actuate Fluid Control Mechanism for Flow and Timing of Self-Contained Test Chemistry(s) from Reagent Chambers to Cartridge Test Site*". This means that the module processor, i.e. the controller in accordance with the claim, controls the fluid control mechanism, which includes the actuating elements in accordance with the claim, to direct flow through the cartridge, i.e. the fluidic device in accordance with the claim, on the basis of instructions from the host computer.

2.4 Finally, the proprietor argued that D1 did not disclose a communication assembly for receiving the protocol from the external device, the protocol being dependent on the identity of the fluidic device and comprising the instructions to control the actuating elements to direct flow of fluid through the fluidic device.

However, D1 expressly discloses that "*the bar code of cartridge 20, with its unique sample, are read. This initiates the sequential operation of the fluid movement and detection*" (paragraph [0059]). Moreover, the bar code includes "*information for test protocols*" (paragraph [0058]) or "*test type*" (Table 2, point 6 of "*Model POCT Platform Operating Procedure*"), which is sent to the host computer (Figure 9, third box). Subsequently, the host computer directs the module processor to actuate the actuating elements in the cartridge (Figure 9, fourth to sixth box) by

determining, in combination with the module processor, "*a test protocol for a cartridge*" (paragraph [0056]) or "*a designated assay protocol*" (Table 2, point 7 of "*Model POCT Platform Operating Procedure*").

Whether D1 focuses on quality control, as the proprietor argued, is not crucial. D1 also discloses modules and cartridges with different testing capabilities (paragraph [0049]).

The argument that each cartridge type had a dedicated module or slot and that therefore there would be no need to send a test protocol to the modules is not convincing either. D1 expressly teaches modules that can be utilised with more than one cartridge (paragraph [0048]). Contrary to the proprietor's assertion, D1 does not state that such modules should have dedicated slots for different cartridge types. The disclosure that a "*test protocol*" or an "*assay protocol*" is determined for a cartridge, and after that an identifier including information for test protocols on the cartridge is read, implies without ambiguity that the protocol determined must depend on the identification of the cartridge, i.e. an identity of the cartridge. The fact that the "*test protocol*" is sent to the host computer and that, thereafter, the host computer directs the module processor to actuate the fluid control mechanism (Figure 9, fourth to sixth box) implies without ambiguity that the test protocol forms the basis for instructions from the host computer to the module processor. If the simple insertion of a cartridge in a slot triggered control instructions independent of the identity of the cartridge provided on the cartridge identifier, the provision of "*test type*" information in the identifier and the determination of a "*test protocol*" or "*assay protocol*"

would not make any technical sense, not even for logging purposes, as the proprietor argued. The system would know from the outset, without any need for reading further information on a bar code, but simply by the insertion of a cartridge into its particular dedicated slot, which test and which cartridge were in use. Hence the person skilled in the art, when reading D1, would exclude an interpretation according to which the host computer would not transmit a test protocol dependent on the identity of the cartridge to the module processor.

2.5 In conclusion, the patent cannot be maintained on the basis of the main request for lack of novelty (Articles 52(1) and 54(1) and (2) EPC) of the subject-matter of claim 1 in view of D1.

3. "New First Auxiliary Request" - admittance

The "New First Auxiliary Request" was filed during the oral proceedings before the Board. It is derived from the main request, from which claims 1 to 6 have been deleted and claim 7 has been drafted to recite the features of claim 1 explicitly.

It is common ground that the "New First Auxiliary Request" constitutes an amendment to the proprietor's appeal case and its admittance is at the Board's discretion under Article 13(2) RPBA.

As the proprietor noted, there is a considerable amount of case law in which new requests based on the mere deletion of claims of previous requests were admitted even if they had been filed at a late stage in the proceedings.

However, an important criterion to be considered by the Board, in exercising its discretion for deciding on the admittance of a request under Article 13(2) RPBA, is whether the proprietor has demonstrated that the request, *prima facie*, overcomes the issues raised by the opponents (the criteria listed under Article 13(1) RPBA also apply when assessing the admittance of a request under the stricter provision of Article 13(2) RPBA). This criterion is in addition to considerations of procedural economy, commented on by the proprietor.

Claim 1 of the "New First Auxiliary Request" is directed to a method for detecting an analyte in a bodily fluid with a system according to claim 1 of the main request. It has been shown that the system as such is anticipated by D1. As pointed out by the opponents, the claimed method steps for the detection are related to the performance of the functional features of the elements of the system, which functional features are also anticipated by D1, as explained in points 2.1 to 2.4 above. Hence the subject-matter of claim 1 of the "New First Auxiliary Request" cannot, on a *prima facie* basis, establish novelty over D1.

For this reason, the "New First Auxiliary Request" is not admitted into the appeal proceedings, under Article 13(2) RPBA.

4. First auxiliary request - admittance and novelty

The first auxiliary request corresponds to the request found allowable by the Opposition Division in the impugned decision. The Board sees no reason to disregard this request.

However, the first auxiliary request was filed to

overcome an objection of added subject-matter and claim 1 of this request does not differ in substance from claim 1 of the main request. The wording in claim 1 of the first auxiliary request that the protocol comprises "instructions to a controller to perform the protocol on the fluidic device" is not more limiting than the feature in claim 1 of the main request of the protocol comprising the instructions to control the actuating elements, because the actuating elements are responsible for the performance of the protocol on the fluidic device by directing flow of fluid through the fluidic device in accordance with claim 1 of the main request.

It follows that the subject-matter of claim 1 of the first auxiliary request is not novel over D1 either.

Hence the patent cannot be maintained on the basis of the first auxiliary request for lack of novelty (Articles 52(1) and 54(1) and (2) EPC) of the subject-matter of claim 1 in view of D1.

5. Second and third auxiliary requests - admittance

The second and third auxiliary requests were filed by the proprietor after the reply to the proprietor's statement of grounds of appeal filed by opponent 1, together with the response to the interventions filed by opponents 2 and 3.

It is common ground that, since the patent cannot be maintained on the basis of higher-ranking requests because of evidence and objections filed by opponent 1 in its statement of grounds of appeal and in its reply to the proprietor's statement of grounds of appeal, and not because of new objections raised in the

interventions, the admission of the second and third auxiliary requests is at the Board's discretion, subject to Article 13(1) RPBA.

5.1 According to Article 13(1) RPBA, the proprietor would have had to provide reasons for submitting the second and third auxiliary requests at this stage of the appeal proceedings. The proprietor argued that the reason for submitting the new requests was that the desirability of filing them only became apparent after studying the publications identified in the interventions. However, this is not a convincing reason for allowing amendments for overcoming an objection based on D1, which was already on file since the beginning of the proceedings at first instance and did not relate to any further publications identified in the interventions.

5.2 According to Article 13(1) RPBA, the Board must exercise its discretion on the admittance of the second and third auxiliary requests, considering whether these requests are detrimental to procedural economy.

The second and third auxiliary requests develop in a direction different from that of the admitted requests and of the auxiliary requests on file prior to the oral proceedings at first instance, as the latter requests related to features of the control of the actuating members, whereas the second and third auxiliary requests introduce features of the fluidic device. The admittance of the second and third auxiliary requests into the appeal proceedings at a late stage would require opponent 1 to reassess its case and consider a reaction to these requests. Instead, opponent 1 should be entitled to rely on its original objections and the timely development of the case in response to and as a

consequence of these objections. The reaction of opponent 1, in turn, would have to be considered by all parties and the Board. This is detrimental to procedural economy.

Whether the proprietor would have filed the second and third auxiliary requests even in the absence of the interventions, after a finding of lack of novelty over D1 by the Board, does not change the picture. The admittance of these requests would still have been at the Board's discretion, taking into consideration the same criterion of procedural economy.

5.3 For these reasons, the second and third auxiliary requests are not admitted into the appeal proceedings, under Article 13(1) RPBA.

6. As a consequence, the patent must be revoked since there is no request which may form a basis for its maintenance.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated