Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 6 February 2019

Case Number: T 0047/18 - 3.3.05

Application Number: 10728944.9

Publication Number: 2430461

IPC: C12M1/34, C12Q1/02, C12Q1/04, G01N35/00, G01N35/04

Language of the proceedings: EN

Title of invention:
Combined detection instrument for culture specimen containers and instrument for identification and/or characterization of a microbial agent in a sample

Patent Proprietor:
bioMerieux, Inc.

Opponent:
Hoffmann Eitle

Headword:
Detection instrument/BIOMERIEUX

Relevant legal provisions:
EPC Art. 56, 84, 123(2)
RPBA Art. 13(1), 13(3)

Keyword:
New objections under Articles 84 and 123(2) EPC - discretion of the board to admit (yes) - admitted (no)
Inventive step - (yes)

Decisions cited:
G 0004/92, T 0682/11, T 1914/12, T 1307/13, T 0996/15

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 0047/18 - 3.3.05

D E C I S I O N
of Technical Board of Appeal 3.3.05
of 6 February 2019

Appellant: (Opponent)	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastrasse 30 81925 München (DE)
Representative:	Vossius & Partner Patentanwälte Rechtsanwälte mbB P.O. Box 86 07 67 81634 München (DE)
Respondent: (Patent Proprietor)	bioMerieux, Inc. 100 Rodolphe Street Durham, NC 27712 (US)
Representative:	Murgitroyd & Company Scotland House 165-169 Scotland Street Glasgow G5 8PL (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 16 October 2017 concerning maintenance of the European Patent No. 2430461 in amended form.**

Composition of the Board:

Chairman	E. Bendl
Members:	A. Haderlein
	S. Fernández de Córdoba

Summary of Facts and Submissions

I. The appeal was filed by the appellant (opponent) against the interlocutory decision of the opposition division finding that, on the basis of auxiliary request 2 underlying the impugned decision, the patent in suit met the requirements of the EPC.

II. According to the decision under appeal, auxiliary request 2 met the requirements of Articles 84 EPC and 123(2) EPC and "this had not been challenged by the Opponent" (see point 4.2.2 of the Reasons of the decision). Furthermore, according to the minutes (points 8 and 9) of the oral proceedings before the opposition division, when discussing the amendments to auxiliary request 2, the proprietor referred to specific passages of the application as filed and "[t]he opponent had no objections regarding admissibility, allowability or novelty".

In the impugned decision, the opposition division also held that the subject-matter of the independent claims of auxiliary request 2 involved an inventive step starting from

D1: Funke, G., and Funke-Kissling, P., Use of the BD PHOENIX Automated Microbiology System for Direct Identification and Susceptibility Testing of Gram-Negative Rods from Positive Blood Cultures in a Three-Phase Trial, *J. Clin. Microbiol.*, Apr. 2004, Vol. 42, No. 4, pp. 1466-1470, or

D7: Bruins, M.J., et al., Identification and Susceptibility Testing of *Enterobacteriaceae* and *Pseudomonas aeruginosa* by Direct Inoculation from Positive BACTEC Blood Culture Bottles into Vitek 2, *Clin. Microbiol.*, Jan. 2004, Vol. 42,

No. 1, pp. 7-11

as the closest prior art, possibly in combination with one of

D4: US 2008/0072664 A1
D5: US 5 578 269 or
D6: Isenberg, H.D, et al., Prototype of a Fully Automated Device for Determination of Bacterial Antibiotic Susceptibility in the Clinical Laboratory, *Appl., Microbiol.,* Vol. 22, pp. 980-986.

The following document was also referred to in the proceedings before the opposition division:

D12: Zhu, Q., et al., Raman Spectroscopic Measurement of Relative Concentrations in Mixtures of Oral Bacteria, *Appl. Spectrosc.,* Author manuscript.

III. The respondent (proprietor) replied to the grounds of appeal on 9 July 2018. It filed, *inter alia,* auxiliary requests 1 to 6.

IV. On 20 September 2018, the parties were summoned to oral proceedings to be held on 6 February 2019.

V. In a letter dated 4 December 2018, the appellant raised objections for lack of clarity under Article 84 EPC and objections under Article 123(2) EPC against the claims of the respondent's main request (corresponding to auxiliary request 2 before the opposition division).

VI. By letter dated 11 January 2019, the respondent filed auxiliary requests 7 to 15.

VII. Oral proceedings before the board took place on 6 February 2019, at the end of which the decision was announced.

VIII. The wording of the independent claims of the respondent's main request (auxiliary request 2 before the opposition division) is as follows:

"1. An automated system for rapid detection of a microbial agent in a sample and identifying and/or characterizing the microbial agent, comprising, in combination:
a detection instrument receiving a specimen container containing a sample, the detection instrument including a heated enclosure for incubating the specimen container and a detection unit interrogating the specimen container to detect whether the specimen container is positive for the presence of a microbial agent in the sample;
a supply of disposable separation devices; and
an identification/characterization instrument receiving a specimen container detected positive by the detection instrument, the characterization/identification instrument comprising:
(a) a sample removal apparatus coupled to a robotic transfer mechanism and operative to remove a portion of the sample from the specimen container and add the portion to a separation device obtained from the supply of separation devices;
(b) a separation and concentration station operative on the separation device after receiving the portion of the sample so as to separate the microbial agent from other products in the sample and concentrate the microbial agent within the separation device; and
(c) an identification and/or characterization module interrogating the concentrated microbial agent to

identify and/or characterize the microbial agent, wherein the robotic transfer mechanism moves the separation device from the separation and concentration station to the identification and/or characterization module.

11. A method for rapid identification and/or characterization of a microbial agent present in a sample, the sample loaded into a specimen container, comprising performing the following steps in an automated manner:
(a) incubating the specimen container;
(b) periodically interrogating the specimen container to determine whether it is positive for presence of a microbial agent within the specimen container;
(c) when the specimen container is determined positive, withdrawing a portion of the sample from the specimen container with a sample removal apparatus coupled to a robotic transfer mechanism;
(d) introducing the portion of the biological sample into a disposable separation device;
(e) lysing components in the portion of the biological sample, either before or after performing step (d);
(f) transferring the separation device to a separation and concentration station using the robotic transfer mechanism;
(g) separating and concentrating the microbial agent within the separation device;
(h) transferring the separation device to an identification and/or characterisation module using the robotic transfer mechanism; and
(i) analyzing the concentrated microbial agent to identify and/or characterize the microbial agent, wherein steps (a)-(i) are performed automatically with an integrated detection and identification/ characterization instrument."

Dependent claims 2 to 10 and 12 to 15 relate to preferred embodiments of the subject-matter of the independent claims.

IX. The arguments of the appellant, as far as relevant for the present decision, may be summarised as follows:

The objections raised in the letter dated 4 December 2018 should be admitted into the proceedings. They were raised for the first time after the expiry of the time limit for filing the grounds of appeal and after the issuance of the summons to oral proceedings. Had the board not have issued the summons so early, these objections would have been raised before the issuance of the summons.

D1 or D7 were the closest prior art. The subject-matter of claims 1 and 11 differed from this prior art only by the sample removal apparatus being coupled to a robotic transfer mechanism wherein the robotic transfer mechanism moved the separation device from the separation and concentration station to the identification and/or characterisation module. The problem to be solved was to increase the processing speed. The solution was obvious in view of D4, D5 or D6. If the board considered that a further distinguishing feature resided in the interrogation/ analysis being carried out on the concentrated microbial agent, this was also obvious in view of D5 and D12. Thus, the respondent's main request did not comply with the requirement of Article 56 EPC.

X. The arguments of the respondent, as far as relevant for the present decision, may be summarised as follows:

The appellant's objections under Articles 84 and

123(2) EPC were raised late and should not be admitted into the proceedings. The requirement of inventive step was met. In particular, it would not have been obvious to arrive at the subject-matter of independent claims 1 and 11 when starting from either D1 or D7.

XI. Requests

The appellant requested that the contested decision be set aside and that the patent be revoked.

The respondent requested that the appeal be dismissed. In the alternative it requested that the patent be maintained in amended form based on one of auxiliary requests 1 to 6 filed with the reply to the grounds of appeal or one of auxiliary requests 7 to 15 filed with the letter dated 11 January 2019.

Reasons for the Decision

1. *Admissibility of appellant's objections under Articles 84 and 123(2) EPC*

1.1 The statement of grounds of appeal contains neither an objection of lack of clarity of the claims nor an objection under Article 123(2) EPC. Rather, it contains only submissions with respect to inventive step. It was only after the parties had been summoned to oral proceedings that the opponent raised such objections (see V and IX above).

1.2 According to the established case law of the boards of appeal, new objections which were not raised in the statement of grounds of appeal, respectively in the reply to the grounds of appeal, are considered an amendment to a party's case. Admission of such

objections is at the discretion of the board pursuant to Article 13(1) and/or 13(3) RPBA (see for instance T 996/15, Reasons 3.1, for a new objection under Article 84 EPC; T 682/11, Reasons 3.2, for a new objection under Article 123(3) EPC; T 1307/13, Reasons 3, for a new objection regarding the validity of the priority claim).

1.3 Furthermore, the objections in question also do not constitute merely a new argument (cf. T 1914/12, Reasons 7 to 7.2) because they go beyond submissions serving to underpin the facts, evidence and grounds filed in good time (see *Keussen* in Benkard, EPÜ, 3rd ed. 2019, Art. 110, paragraph 52). Rather, they are based on new legal grounds (cf. G 4/92, Reasons 10: "des moyens nouveaux") that were not addressed before in the appeal proceedings.

1.4 The boards of appeal must exercise this discretion in view of, *inter alia,* the current state of the proceedings and the need for procedural economy (Article 13(1) RPBA).

1.5 The present main request was filed as auxiliary request 2 in the proceedings before the opposition division by letter dated 31 July 2015. In its letter dated 4 March 2016, the then opponent objected to this request only for lack of inventive step (see page 9, item IV). In its communication dated 15 September 2016 accompanying the summons, the opposition division stated that the amendments in auxiliary request 2 appeared to comply with, *inter alia,* Articles 84 and 123(2) EPC and that "this has not been challenged by the Opponent" (see item 19 of the communication). According to the minutes of the oral proceedings before the opposition division, the opponent had only

objections under Article 56 EPC against this request (see item 8 and following of the minutes). Also, the impugned decision contains the same observation as in the communication accompanying the summons (see II above).

Thus, the appellant could have raised the objections in question at several instances in the proceedings before the opposition division.

There is, therefore, no sound reason to raise these objections at such a late stage of the proceedings, i.e. only about 2 months before the oral proceedings before the board. In this context the appellant submitted at the oral proceedings that it was surprised that the summons had been issued only a little more than two months after the respondent had filed its reply to the grounds of appeal and that, had the oral proceedings taken place later, the objections would not have been filed only two months before them.

However, this argument is flawed because these objections were, in any event, raised after the appellant had filed its statement of grounds, and this is what is decisive for the discretion under Article 13(1) RPBA.

Taking these aspects into account, considering the state of the file and in particular procedural economy, the board did not admit the appellant's objections under Article 84 and 123(2) EPC into the proceedings.

2. Main request - inventive step

2.1 The invention concerns an automated system for rapid detection of a microbial agent.

2.2 It is common ground that D1 or D7 are suitable starting points for assessing inventive step, i.e. can each be considered the closest prior art.

2.2.1 According to the appellant, the subject-matter of independent claim 1 differs from both D1 and D7 only by the sample removal apparatus being coupled to a robotic transfer mechanism wherein the robotic transfer mechanism moves the separation device from the separation and concentration station to the identification and/or characterisation module.

2.2.2 It is true that neither D1 nor D7 disclose the above features. But these are not the sole distinguishing features.

In D1 (section "Materials and Methods", paragraph bridging pages 1466 and 1467) the sample is separated and concentrated in a separation device (Serum Separator Tube SST). After separation by centrifugation and removal of the supernatant, the concentrated microbial agent is resuspended, removed from the SST and eventually transferred to "panels" which are loaded into the PHX system instrument (the identification/ characterisation module). Thus, in D1 the microbial agent is resuspended or diluted after the separation or concentration step and before analysis.

Similarly, in D7 the concentrated microbial agent is resuspended before identification/characterisation (page 8, left-hand column, section "Direct method").

In contrast, claims 1 and 11 require that "interrogation" or "analysis" be carried out on the "concentrated microbial agent". The latter feature clearly refers to the "concentrated microbial agent" obtained in the separation and concentration step (b) of claim 1 or step (g) of claim 11 and thus the "interrogating" feature in claim 1 and the "analysing" feature in claim 11 clearly refer to the concentrated microbial agent obtained after separation and concentration. This interpretation is also confirmed by the description of the patent (see for instance paragraphs [0149], [0163] and following, [0205], [0237] and following, and [0325]).

It is true, as argued by the appellant, that "concentrated microbial agent" as referred to in claims 1 and 11 of the main request does not entail any particular degree of concentration, and in fact can be construed so as to only refer to the fraction containing the microbial agent after the separation step. This construction is also coherent with the passages referred to by the appellant, i.e. paragraphs [0145], [0158] and [0203] of the patent, where reference is made to "platelets". Likewise, this feature does not require that the concentrated microbial agent is "interrogated" or "analysed" while present in the separation device and also extends to "interrogation" or "analysis" of the concentrated microbial agent after its removal from the separation device as correctly pointed out by the appellant when referring to present claim 13 and paragraph [0035] of the patent. However, the feature "interrogating the concentrated microbial agent" or "analysing the concentrated microbial agent" as called for in step (c) of claim 1 and in step (i) of claim 11 requires that "interrogation" or "analysis" is carried out on the

microbial agent in its concentrated state and does not encompass "interrogation" or "analysis" on the microbial agent after dilution or resuspension thereof.

2.2.3 Thus, D1 and D7 also do not disclose that "interrogation" or "analysis" is carried out on the concentrated microbial agent.

2.3 The problem to be solved is to increase the processing speed as submitted by the appellant (see also paragraph [0015] of the patent).

2.4 The proposed solution for this problem is an automated system for rapid detection of a microbial agent comprising a sample removal apparatus, a separation and concentration station operative on a separation device, and an identification/characterisation module, characterised by the sample removal apparatus being coupled to a robotic transfer mechanism wherein the robotic transfer mechanism moves the separation device from the separation and concentration station to the identification and/or characterisation module and by interrogating or analysing the concentrated microbial agent.

2.5 As to the success of the solution, it is uncontested that the subject-matter of claims 1 and 11 leads to an increased processing speed. In particular, not only the use of a robotic transfer mechanisms contributes to the acceleration of the process but also the fact that the concentrated microbial agent contained in the separation device is transferred to the identification and/or characterisation module and that "interrogation" or "analysis" of the microbial agent is carried out on the concentrated microbial agent.

2.6 As to obviousness, the appellant referred above all to D5 and D12 but also to D4 and D6.

2.6.1 While it is uncontested that D4, D5 and D6 each teach to make manual processes automatic, e.g. by the use of a robotic transfer mechanism transferring samples between individual stations, only D5 was referred to by the appellant to show that interrogation or analysis of the concentrated microbial agent was known in the art.

2.6.2 Indeed, D5 does discloses a robotic transfer mechanism for transferring a cassette containing several wells containing samples after centrifugation from the centrifuge to an autoreader that analyses the concentrated sample using a CCD camera (column 29, lines 12 to 51). However, D5 concerns a method different from the one disclosed in D1 or D7. D1 and D7 concern identification and susceptibility testing of bacterial cells (see D1, abstract, and D7, abstract), whereas D5 concerns detecting and quantifying agglutinates in response to immunological reactions (col. 1, lines 8 to 14). There is nothing in D5 that would suggest that the data obtained from the CCD camera taking an image of the concentrated sample could be used to carry out identification and susceptibility testing as required in D1 or D7. Likewise, there is nothing in D1 or D7 that would suggest that a resuspension matching a "McFarland standard" (see D1, page 1467, left-hand column, first full sentence, and D7, page 8, left-hand column, section "Direct method") could be omitted and susceptibility testing using the "PHX system" as referred to in D1 or the "Vitek 2" as referred to in D7 could be carried out on the bacterial layer or film obtained in these methods after separation or concentration.

2.6.3 Thus, the skilled person would not have applied the teaching of D5 to the methods of D1 or D7 such that the interrogation or analysis would be carried out on the concentrated microbial agent.

Likewise, using D4 or D6 instead of D5 would not have led to a different result as neither D4 or D6 contain any incentive to modify the resuspension step of D1 or D7 to arrive at the presently claimed invention.

2.6.4 D12 discloses that a concentrated microbial agent is stored in a freezer (see the "Sample Preparation" section, penultimate sentence: "concentrated bacterial infranatant"), after which the the concentrated sample is thawed and applied to a plate which is then analysed. However, D12 does not disclose an automated system using a robotic transfer mechanism and, therefore, fails, even in combination with D1 or D7, to teach to solve the problem posed as suggested in the proposed solution.

2.6.5 It follows that it would not have been obvious to arrive at the subject-matter of claims 1 and 11 of the main request in view of the cited prior art. Thus, the requirement of Article 56 EPC is met for the independent claims. The same holds true for the dependent claims.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

C. Vodz E. Bendl

Decision electronically authenticated