**Internal distribution code:**

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

# Datasheet for the decision of 1 February 2022

**Case Number:** T 1568/18 - 3.3.01

**Application Number:** 08852388.1

**Publication Number:** 2227692

**IPC:** G01N33/569, G01N33/68

**Language of the proceedings:** EN

**Title of invention:**
IDENTIFICATION OF PATHOGENS IN BODY FLUIDS

**Patent Proprietor:**
Bruker Daltonics GmbH & Co. KG

**Opponents:**
Definition IP Limited
Thermo Fisher Scientific Oy.

**Headword:**
Identification of pathogens in body fluids/BRUKER

**Relevant legal provisions:**
EPC Art. 123(2), 123(3), 56
EPC R. 103(1)(a), 106

**Keyword:**

Amendments - main request, auxiliary requests 1 to 15 - added subject-matter (yes) - extension beyond the content of the application as filed (yes) - auxiliary request 16 - extension beyond the content of the patent (yes)
Inventive step - auxiliary request 17 - (no)
Obligation to raise objections - objection dismissed
Reimbursement of appeal fee - (no)

**Decisions cited:**

R 0008/15, R 0018/09, R 0015/10

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 1568/18 - 3.3.01**

# D E C I S I O N
# of Technical Board of Appeal 3.3.01
# of 1 February 2022

| | |
|---|---|
| **Appellant 1:**<br>(Patent Proprietor) | Bruker Daltonics GmbH & Co. KG<br>Fahrenheitstraße 4<br>28359 Bremen (DE) |
| **Representative:** | Kuttenkeuler, David<br>Boehmert & Boehmert<br>Anwaltspartnerschaft mbB<br>Pettenkoferstrasse 22<br>80336 München (DE) |
| **Appellant 2:**<br>(Opponent 1) | Definition IP Limited<br>The Core<br>Science Central<br>Bath Lane<br>Newcastle Upon Tyne, NE4 5TF (GB) |
| **Representative:** | Rutherford, Claire<br>Definition IP Limited<br>The Core<br>Science Central<br>Bath Lane<br>Newcastle upon Tyne NE4 5TF (GB) |
| **Appellant 3:**<br>(Opponent 2) | Thermo Fisher Scientific Oy.<br>Ratastic 2<br>01620 Vantaa (FI) |
| **Representative:** | J A Kemp LLP<br>80 Turnmill Street<br>London EC1M 5QU (GB) |
| **Decision under appeal:** | **Interlocutory decision of the Opposition Division of the European Patent Office posted on 9 April 2018 concerning maintenance of the European Patent No. 2227692 in amended form.** |

**Composition of the Board:**

| | |
|---|---|
| **Chairwoman** | T. Sommerfeld |
| **Members:** | M. Pregetter |
| | R. Romandini |

## Summary of Facts and Submissions

I. European patent No. 2227692 is based on European patent application No. 08852388.1, filed as an international application published as WO 2009/065580.

It was granted with three independent claims, which read as follows.

"1. A method for the mass spectrometric identification of pathogens in a whole blood sample, comprising the following steps:
(a) destruction of the blood particles in the whole blood sample,
(b) precipitating by centrifuging the pathogens without further multiplication from the whole blood sample directly into a pellet,
(c) subjecting the pathogens to a mass spectrometric analysis of their proteins, and
(d) identifying the pathogens by comparison of the protein mass spectra with reference protein mass spectra."

"9. A method for the mass spectrometric identification of pathogens in a whole blood sample, comprising the following steps:
(a) multiplication of the pathogens within the whole blood sample by incubation,
(b) destruction of the blood particles in the whole blood sample,
(c) precipitating by centrifuging the pathogens without further multiplication from the whole blood sample directly into a pellet,
(d) subjecting the pathogens to a mass spectrometric

analysis of their proteins, and
(e) identifying the pathogens by comparison of the protein mass spectra with reference protein mass spectra."

"12. A method for the mass spectrometric identification of pathogens in a whole blood sample, comprising the following steps:
(a) separating by centrifuging the pathogens together with the blood particles into a pellet,
(b) dissolving the pellet in distilled water and destruction of the blood particles in the pellet by osmosis,
(c) depositing a pellet containing enriched pathogens by washing and centrifuging,
(d) subjecting the pathogens to a mass spectrometric analysis of their proteins, and
(e) identifying the pathogens by comparison of the protein mass spectra with reference protein mass spectra."

II. The following documents, cited during the opposition and appeal proceedings, are referred to below:

(1) US 2005/0061967

(4) US 7020559

(24) Stevens M. & Parish G.T., J. Med. Microbiol., 1986, 21, 215-218

(47) WO 2011/006911

III. The patent was opposed under Article 100(a), (b) and (c) EPC on the grounds that the claimed subject-matter lacked novelty and inventive step, was not disclosed in

a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, and extended beyond the content of the application as filed. The validity of the priority was also questioned.

In the course of the opposition proceedings, the patent proprietor requested that the patent be maintained based on a main request or auxiliary requests 1 to 7, all filed on 22 December 2017, or on auxiliary requests 8 to 10, filed on 26 February 2018 during oral proceedings before the opposition division.

IV. The opposition division found that the subject-matter of auxiliary request 9 met the requirements of the EPC. The subject-matter of the main request and auxiliary requests 1 to 7 was not allowable in view of Article 123(2) EPC. The subject-matter of auxiliary request 8 did not meet the requirements of Article 123(3) EPC.

V. All the parties appealed this decision. In the following the appellant parties will be identified by their roles in the opposition proceedings.

Together with the statement of grounds of appeal the patent proprietor re-submitted the main request, first filed on 22 December 2017, and submitted auxiliary requests 1 to 16. Auxiliary requests 2, 4, 6, 8, 10, 12, 14 and 16 are identical to auxiliary requests 1, 2, 3, 4, 5, 6, 7 and 8, respectively, underlying the decision under appeal. In the reply to the opponents' grounds of appeal, the patent proprietor indicated that auxiliary requests 9 and 10 of the opposition proceedings constituted auxiliary requests 17 and 18, respectively. Furthermore, they submitted auxiliary request 19.

Claim 1 of the main request reads as follows.

"1. A method for the mass spectrometric identification of pathogens in a whole blood sample, comprising the following steps:
(a) multiplication of the pathogens within the whole blood sample by incubation,
(b) destruction of the blood particles in the whole blood sample,
(c) precipitating by centrifuging the pathogens without further multiplication from the whole blood sample directly into a pellet,
(d) subjecting the pathogens to a mass spectrometric analysis of their proteins, and
(e) identifying the pathogens by comparison of the protein mass spectra with reference protein mass spectra."

Claim 1 of auxiliary request 1 differs in that feature (b) reads "(b) destroying and removing of the blood particles in the whole blood sample".

Claim 1 of auxiliary request 2 and claim 1 of auxiliary request 3 are identical to claim 1 of the main request and claim 1 of auxiliary request 1, respectively.

Claim 1 of auxiliary requests 4 and 6 differs from claim 1 of the main request on account of amendments to feature (d). Claim 1 of auxiliary request 5 and claim 1 of auxiliary request 7 have also had feature (b) replaced in the same way as in claim 1 of auxiliary request 1.

Claim 1 of auxiliary requests 8 and 10 differs from claim 1 of the main request on account of further

amendments to feature (d). Claim 1 of auxiliary request 9 and claim 1 of auxiliary request 11 have also had feature (b) replaced in the same way as in claim 1 of auxiliary request 1.

Claim 1 of auxiliary requests 12 and 14 differs from claim 1 of the main request on account of the addition of the term "wherein the pathogens of the pellet are washed and further centrifuged" to feature (c). Claim 1 of auxiliary request 13 and claim 1 of auxiliary request 15 have also had feature (b) replaced in the same way as in claim 1 of auxiliary request 1.

Claim 1 of auxiliary request 16 reads as follows.

"1. A method for the mass spectrometric identification of pathogens involved in an acute infection in a whole blood sample, comprising the following steps:
(a) multiplication of the pathogens within the whole blood sample by incubation,
(b) precipitating by centrifuging the pathogens without further multiplication from the whole blood sample directly into a pellet, followed by a washing stage and further centrifuging, wherein the corpuscles contained in the whole blood sample are destroyed in an intermediate stage,
(c) subjecting the pathogens to a mass spectrometric analysis of their proteins, and
(d) identifying the pathogens by comparison of the protein mass spectra with reference protein mass spectra."

Claim 1 of auxiliary request 17 reads as follows.

"1. A method for the mass spectrometric identification of pathogens in a whole blood sample, comprising the

following steps:
(a) culturing the pathogens in the whole blood sample inside a blood bag;
(b) separating by centrifuging the pathogens together with the blood particles into a pellet,
(c) dissolving the pellet in distilled water and destruction of the blood particles in the pellet by osmosis,
(d) depositing a pellet containing enriched pathogens by washing and centrifuging,
(e) subjecting the pathogens to a mass spectrometric analysis of their proteins, and
(f) identifying the pathogens by comparison of the protein mass spectra with reference protein mass spectra."

VI. By letter dated 20 December 2019, opponent 2 submitted document (47).

VII. In a communication pursuant to Rule 100(2) EPC, the board invited the parties to provide comments on the compliance of the decision under appeal with Rule 111(2) EPC.

VIII. In a communication pursuant to Article 15(1) RPBA 2020, the board indicated, *inter alia*, which technical features could be crucial for the discussion of the amendments in light of the decision under appeal and the parties' submissions.

IX. Oral proceedings before the board were held on 1 February 2022.

During the oral proceedings, appellant 1 (patent proprietor) raised an objection under Rule 106 EPC in relation to an alleged violation of their right to be

heard. The board dismissed this objection.

In addition, the patent proprietor withdrew auxiliary requests 18 and 19.

X. The patent proprietor's arguments, insofar as they are relevant to the present decision, may be summarised as follows.

*Amendments*

Claim 1 of the main request was based on claim 1 as filed combined with paragraph [0029] as filed. Claim 1 of the main request did not define a temporal sequence of its steps, apart from the logical sequence derivable by the person skilled in the art. Paragraph [0029] disclosed that the sample could be whole blood and that for a whole blood sample an intermediate stage for destruction of the corpuscles could be included. In a method comprising certain method steps the term "intermediate" was not restrictive in any way. In addition, paragraph [0062] also described that in body fluids containing a large number of particles, such as whole blood, additional steps for destroying and removing particles were required. Claim 11 as filed defined that the pathogens could be multiplied within the body fluid by incubation. The very specific disclosure of the implementation of the method in paragraph [0063] was no reason to disregard the disclosure of paragraph [0029] discussed above.

No additional arguments were put forward for auxiliary requests 1 to 15.

Claim 1 of auxiliary request 16 defined subject-matter which had been restricted compared with the claims as

granted. The terms "corpuscles" and "particles" were used interchangeably in the patent and the application as filed. This could be seen in paragraphs [0029] and [0062] as filed, which used nearly identical wording. There was no indication that these two terms differed in meaning. These terms were thus synonyms referring to any corporal component which was contained in a body fluid and needed to be separated from the pathogens to be identified by the method of the invention. Furthermore, the person skilled in the art working with whole blood samples would have understood that blood corpuscles and blood particles were mostly cellular components.

*Admission of document (47)*

Document (47) was not to be admitted since it was filed late and *prima facie* not relevant.

*Inventive step*

The present invention was distinguished from the disclosure of document (1) by a multitude of features. Document (1) failed to disclose the identification of pathogens in a whole blood sample. Furthermore, the steps of culturing pathogens in a whole blood sample inside a blood bag, the centrifuging of the pathogens together with blood particles into a pellet and the dissolving of the pellet in distilled water, the destruction of the blood particles in the pellet by osmosis and the depositing of a pellet containing enriched pathogens by washing and centrifuging were not described. In addition, document (1) did not directly and unambiguously disclose the identification of the pathogens by comparison of protein mass spectra with reference protein mass spectra, and instead different

biomarkers such as DNA, RNA and lipids were equally disclosed. When blood was mentioned, it was described as a source of analytical information in the form of blood proteins, such as haemoglobin. Document (24) failed to disclose a blood culture treatment which encompassed joint pelleting of blood particles and pathogens and destroying blood particles in a pellet by osmotic effect of distilled water. Furthermore, it did not mention mass spectrometry or the identification of pathogens based on their protein content. Instead, document (24) relied on a dual wavelength analyser measuring differential light absorbance and a metabolic, growth-based analytical profile index.

*Reimbursement of the appeal fee*

The opposition division's decision was not in line with Rule 111(2) EPC since arguments central to the patent proprietor's case and relating to the order of the method steps had not been taken into account. These arguments were not discussed at all in the decision under appeal. This lack of proper reasoning constituted a substantial procedural violation that justified reimbursement of the appeal fee pursuant to Rule 103(1)(a) EPC.

*Objection pursuant to Rule 106 EPC*

The following objection pursuant to Rule 106 EPC was raised:

"Our right to be heard according to Article 113 EPC with respect to the argument of Article 123(2) is violated, because without any claim construction we are left without the possibility to discuss further. Any reasons [provided in the decision to be written] not

discussed, will show this. The procedure as conducted here puts the proprietor in a position that the proprietor cannot present all its arguments. The board rejects the main request and all auxiliary requests without giving any further indication as to its reasoning so the proprietor cannot react". The patent proprietor stated that they intended to raise an objection and this objection was "that the procedure as conducted here puts them in a position in which they cannot present their arguments".

XI. The opponents' arguments, insofar as they are relevant to the present decision, may be summarised as follows.

*Amendments*

Paragraph [0029] could not serve as a basis for the subject-matter of claim 1 of the main request as it was not directed to a method having the specific features of claim 1. In addition, paragraph [0029] could not be read on its own but, as could be seen from its introductory terms, as following on from the method described in paragraphs [0026] to [0028]. It was thus clear that paragraph [0029] did not relate to a method including culturing of the pathogens in a whole blood sample. Furthermore, the term "intermediate" made it clear that the step of destruction could only take place between steps (a) and (b) of claim 1 as filed, which was confirmed by claim 9 as filed and was in line with the preceding paragraphs. Paragraph [0063] provided the first disclosure in the application as filed that gave any details of whole blood as a sample. The whole blood sample was first centrifuged, then distilled water was added for destruction of the blood particles. This was in line with claim 11 as filed. Therefore, method step (c), as defined in claim 1 of

the main request, was disclosed as necessarily taking place before method step (b). In addition, paragraph [0063] provided the only information concerning the actual destruction (or the "destroying and removing") of blood particles, as mentioned in paragraph [0062]. Combining the additional steps of destroying and removing particles mentioned in paragraph [0062] without including the other features disclosed in paragraph [0063] was not allowable. Therefore, the description as filed merely provided a basis for a temporal sequence of steps (a), (c) and (b) in claim 1 of the main request. No support could be found for any other temporal sequence, be it any undefined sequence or the sequence step (a), step (b) and then step (c).

The subject-matter of claim 1 of auxiliary request 16 extended the protection conferred by the claims as granted, *inter alia*, because the term "corpuscles" was narrower than the term "blood particles" and consequently less particulate matter was mandatorily removed. The claims as granted additionally required the destruction of non-cellular blood particles.

*Admission of document (47)*

Document (47) was relevant and had been filed at the earliest possible point in time. The content of this document could not have been a surprise to the patent proprietor.

*Inventive step*

Either document (4) or document (1) represented the closest prior art.

Document (1), as could be seen from its title and

paragraphs [0006], [0011] and [0012], related to mass spectrometric identification of protein profiles of various biological agents, especially pathogens including identification of species and strains (paragraph [0022]). The analyte could be a body fluid, such as blood or serum (paragraph [0041]). The distinction between blood and serum made it clear that the term "blood" was to be read as meaning "whole blood". This was further supported by the term "total blood" used in paragraph [0043], which related to the assay mixture, i.e. the mixture including the analyte and other components (such as contaminants). Paragraph [0072] explicitly described that the method in document (1) was used to identify and characterise a microorganism of interest, such as an infectious agent, in a sample by its mass spectrum, whereby the pattern of peaks was representative of the microorganism. Details leading to this identification and characterisation were given in paragraph [0082], which linked the spectral data to specific useful proteins. Some information on sample preparation was provided in paragraphs [0085], [0086], [0088], [0090] and [0095]. Document (1) was thus clearly directed to providing a method of identification of pathogens by mass spectrometry. It did not explicitly disclose the steps of culturing the pathogens in the whole blood sample inside a blood bag, centrifugation in the presence of blood particles and a step of osmosis for the removal of blood particles; however, these steps were found in the general disclosure of document (1) and, in addition, in the common general knowledge. The details of the sample preparation were routine for the person skilled in the art. The necessary steps could, for example, be found in document (24).

*Reimbursement of the appeal fee*

The opposition division provided reasoning sufficient to allow the board of appeal to reach a conclusion in respect of these appeal proceedings. The patent proprietor did not argue that they had not had a proper opportunity to be heard. Instead, they stressed that they had repeatedly put forward their various (counter) arguments in the context of added subject-matter.

XII. The parties' final requests were as follows.

Appellant 1 requested:
- that the appeal fee be reimbursed,
- that the decision under appeal be set aside and that a patent be maintained based on:
  - the main request, first filed on 22 December 2017 and re-submitted with the grounds of appeal,
  - or alternatively, any of auxiliary requests 1 to 16, also filed with the grounds of appeal,
- or alternatively, that the opponents' appeals be dismissed (auxiliary request 17).

Appellants 2 and 3 requested that the decision under appeal be set aside and that the patent be revoked.

## Reasons for the Decision

1. The appeals are admissible.

2. *Amendments (Article 123(2) and (3) EPC)*

2.1 *Main request and auxiliary requests 1 to 15*

2.1.1 *Main request*

Claim 1 of the main request defines a method comprising steps (a) to (e). It is common ground that steps (a) to (c) are to be carried out before steps (d) and (e). A contentious issue is the temporal order of steps (a) to (c) and its basis in the application as filed. A close look at steps (a), (b) and (c) is thus necessary.

The claims as filed do not lead to the claimed subject-matter. Claim 1 as filed defines what is now step (c) as its first step, since it is the only step to be carried out before the steps that correspond to the present steps (d) and (e). Claim 1 of the main request further differs from claim 1 as filed in that a specific sample, whole blood, has been identified. Of the remaining claims as filed, only claims 9 and 11 have been discussed. Claim 9 as filed defines a step that is more specific than the present step (b) and is thus irrelevant in the present context. Claim 11 defines that the multiplication of the pathogens takes place before the pathogens are precipitated into pellets; however, it does not define whole blood as a sample.

The patent proprietor has based their line of argument mainly on paragraphs [0029] and [0062].

Paragraph [0029] relates to an intermediate stage for destruction of corpuscles in samples containing these and lists whole blood as an example of such a sample. Bearing in mind that paragraph [0029] talks about an "intermediate stage", the context of the disclosure of paragraph [0029] is crucial. The term "intermediate" clearly discloses a stage that takes place after the initial stages and before the final stages of a method.

Paragraph [0029] itself does not identify any further method steps or stages; however, by starting with the term "this method", it points to a method disclosed in a/the preceding paragraph(s). In paragraphs [0027] and [0028] and indeed in the entire disclosure preceding paragraph [0029], the first method step is exclusively described as directly precipitating the pathogens and the only method for doing so is disclosed as being centrifugation. Any steps/stages of incubating (or multiplying) the pathogens are disclosed only in later parts of the description as filed. Reading paragraph [0029] in context thus leads to an understanding that the intermediate stage for destruction is disclosed as taking place after a step of centrifugation.

Paragraph [0062] refers to body fluids containing a large number of particles, such as whole blood and some others, and points to the general necessity to destroy and remove the particles in additional steps.

Due to their disclosure being very general, these passages cannot be directly read in combination with a method comprising more specific steps, such as the present step (a), which defines culturing the pathogens in the whole blood sample.

Paragraph [0032] deals with the possibility of culturing the pathogens directly in the whole blood; however, no destruction of blood particles, as required by the present step (c), is disclosed.

In fact, the only passages in the description as filed that deal with the present method steps (a), (b) and (c) in combination and in the context of whole blood as a sample are found in paragraphs [0063] and [0064].

Paragraph [0063] clearly discloses that the destruction of the particles takes place after the pathogens have been precipitated by centrifugation, i.e. that step (c) takes place before step (b). Paragraph [0064] adds that, if the quantity of pathogens in the blood is not sufficient for direct separation together with the blood particles by centrifuging, the pathogens can be cultured in the whole blood inside the blood bag, and thus that step (a) takes place before step (c), in line with claim 11 and paragraph [0039] as filed.

Consequently, the description as filed, when using whole blood as the sample and when including steps of (i) culturing or multiplying the pathogens by incubation and (ii) destroying blood particles, discloses only one single temporal sequence of the method steps (a), (b) and (c) and this single disclosed sequence is step (a) before step (c) before step (b), irrespective of whether step (b) relies on the terms "particles" or "corpuscles" or the terms "destruction" or "destroy and remove" as used in the various passages discussed above.

Having come to the conclusion that the application as filed solely discloses a method with the temporal sequence of steps (a), (c) and then (b), in the context of the allowability of amendments, it is irrelevant whether the wording of claim 1 merely allows for an interpretation of a temporal sequence of (a), (b), (c) or any temporal sequence, since neither option is disclosed in the application as filed and this thus extends the claimed subject-matter beyond the content of the application as filed.

The subject-matter of claim 1 of the main request

contravenes the requirements of Article 123(2) EPC.

2.1.2 *Auxiliary request 1*

Claim 1 of auxiliary request 1 differs from claim 1 of the main request on account of the wording of step (b). Step (b) of claim 1 of auxiliary request 1 reads "(b) destroying and removing of the blood particles in the whole blood sample".

The wording of this feature can be found in paragraph [0062] as filed; however, the wording of this paragraph pertains to a very general disclosure that does not directly and unambiguously lead to the more specific method defined in claim 1. For a detailed discussion see point 2.1.1 above.

The subject-matter of claim 1 of auxiliary request 1 contravenes the requirements of Article 123(2) EPC.

2.1.3 *Auxiliary requests 2 to 11*

Each claim 1 of auxiliary requests 2, 4, 6, 8 and 10 contains the same steps (a), (b) and (c) as claim 1 of the main request. The same reasons as given under point 2.1.1 apply.

Each claim 1 of auxiliary requests 3, 5, 7, 9 and 11 contains the same steps (a), (b) and (c) as claim 1 of auxiliary request 1. The same reasons as given under points 2.1.1 and 2.1.2 apply.

The subject-matter of claim 1 of auxiliary requests 2 to 11 contravenes the requirements of Article 123(2) EPC.

2.1.4 *Auxiliary requests 12 to 15*

Auxiliary requests 12 to 15 contain an additional feature in step (c), namely that "the pathogens of the pellet are washed and further centrifuged"; however, since the reasons provided under points 2.1.1 and 2.1.2 above hinge on the point in time at which certain steps, including centrifugation leading to the creation of a pellet, first take place, the same arguments as provided in these paragraphs also apply, *mutatis mutandis*, to the subject-matter of claim 1 of auxiliary requests 12 to 15, which consequently also contravenes the requirements of Article 123(2) EPC.

2.2 *Auxiliary request 16*

Claim 1 of auxiliary request 16 comprises a stage defining that "corpuscles contained in the whole blood sample are destroyed". No further step relating to the destruction of "blood particles" is included.

However, all the claims as granted include a step of "destruction of the blood particles" (see step (a) of claim 1 as granted and step (b) of claims 9 and 12 as granted).

It is thus necessary to take a closer look at the terms "corpuscles" and "blood particles". The patent proprietor has pointed to the fact that the term "corpuscles", in the context of blood, defines blood cells. This may indeed be the usual understanding of the person skilled in the art; however the term "blood particles" is not limited to blood cells, but also includes any other non-cellular particulate matter. The mere fact that such other particulate matter is not identified does not limit the term "blood particles" to

blood cells. Therefore, the term "blood particles" is broader than the term "corpuscles".

The patent proprietor argued that these terms were used synonymously in the description of the patent in suit; however, although both terms are used in the description, there is no passage that indicates that the two terms would have exactly the same meaning, i.e. would be synonyms. Paragraph [0029] as filed (or paragraph [0030] of the patent as granted) is the only passage that uses the term "corpuscles". All the other passages use the term "particles" or "blood particles". As pointed out by the patent proprietor, the context in paragraph [0029] is very similar to the context in paragraph [0062] as filed (paragraph [0063] of the patent as granted). The board, however, fails to see how a single mention of a more specific term renders it synonymous with a more generic term, even though this more specific term may have been mentioned in a similar context. The application as filed (or the description of the patent in suit) merely provides information as to which ingredients of a sample may have to be considered during sample preparation. It does not discuss the meaning of the terms under consideration and thus does not identify them as being synonyms.

Since the term "corpuscles" is more specific than the term "blood particles", a step of destroying corpuscles destroys less of the particulate material potentially interfering with the analytical steps (c) and (d) in claim 1 of auxiliary request 16 than a step of destroying blood particles. Therefore, the method according to claim 1 has less stringent requirements for sample preparation and is thus broader than the methods defined in the claims as granted.

Consequently, the subject-matter of claim 1 of auxiliary request 16 contravenes the requirements of Article 123(3) EPC.

Having come to this conclusion, possible changes to the order of steps need not be discussed.

3. *Admission of document (47)*

Document (47) was submitted after the reply to the grounds of appeal had been received and after the time limit set for submitting the reply had expired.

The mere fact that a document has only come to a party's attention at a very late point in time does not justify its admission at this late stage.

Document (47) is a post-published document and has been cited in the context of inventive step, opening up a new line of argument.

In view of the state of the appeal proceedings, the discussion of the content of document (47) and the line of argument provided by opponent 2 would clearly run counter to procedural economy. Consequently, the board, exercising its discretion under Article 13(1) RPBA 2020, which applies in the present case, decided not to admit document (47).

4. *Auxiliary request 17 - inventive step*

4.1 The patent in suit relates to a method for the identification of infectious pathogens without first culturing them in external nutrient media, by mass spectrometric measurement of their protein profiles obtained from the pathogens directly precipitated from

a body fluid in form of whole blood into pellets by centrifuging. This method allows for identification of the pathogens in a very short time (paragraphs [0002], [0030] and [0064]).

4.2 In line with the decision under appeal, the board considers document (1) to represent the closest prior art. None of the parties has contested the suitability of document (1) as the closest prior art.

Document (1) defines a method of detecting the presence of an analyte in a sample by mass spectrometry comprising comparing the data from a set of peaks of a mass spectrum of this sample to data from a library of reference set of mass spectral data representative of analytes of known identity (claim 1). Mass spectrometry is discussed in the context of complex samples, for generating specific protein profiles for various biological agents, thereby providing a means for distinguishing between bacteria of different genera, species and strains (paragraphs [0002], [0006] and [0022]). The focus of document (1) is the identification of a microorganism in an analyte mixture (paragraphs [0011] and [0082]). The identification of pathogens / infectious agents, in particular, is explicitly disclosed (paragraphs [0054] and [0072]). While it is true that document (1) also envisages carrying out this identification via DNA-related, RNA-related and/or lipid-related characteristics, protein-related characteristics are nevertheless highlighted by the disclosure of paragraph [0006] and the fact that Example 1, which demonstrates the different adducts formed in a MALDI spectrum from one molecular fragment in a sample, uses bovine insulin, i.e. a protein. The assay mixture contains the analyte and other components. Examples of these are urine, sera, blood

plasma, total blood, saliva, tear fluid, cerebrospinal fluid, secretory fluids from nipples and the like (paragraph [0043]). Listed next to sera and blood plasma, the term "total blood" can only be understood as meaning "whole blood". Sample preparation is broadly discussed in paragraphs [0085] to [0097]. Sample clean up, concentration and culture of microorganisms in the sample are disclosed as exemplary procedures in the introductory paragraph, paragraph [0086]. In the context of sample clean up, the microorganism being freed from particulate debris, for example host cells or lysed fragments, by centrifugation or ultrafiltration is explicitly mentioned (paragraph [0090]). The microorganisms may be cultured solely to increase the number of microorganisms in the sample or, as a further option, to provide a sample that has been grown on a known or standardised medium (paragraph [0095]). From the exemplified assay mixture and the steps listed in the context of sample preparation the board understands that document (1) intends the use of any of the exemplified assay mixtures as a sample for analysis by mass spectrometry. Protein profiles generated by mass spectrometry are highlighted. Furthermore, it is clear that whole blood is envisaged as a sample and is thus one of the embodiments that may serve as a starting point when carrying out the problem-solution approach. In summary, document (1) describes, among other possibilities, that pathogens present in a sample that may be whole blood can be identified using mass spectrometry relying on proteins.

4.3 The difference between the subject-matter of claim 1 of auxiliary request 17 and the disclosure of document (1) are the precise method steps to be undertaken in the preparation of the sample.

No surprising technical effects have been invoked for any of steps (a) to (d).

The technical problem is thus to provide a protocol for the preparation of a sample for the identification of pathogens in whole blood by mass spectrometry.

It is assumed that the problem has been solved.

4.4 It remains to be examined whether the solution to the problem as defined in claim 1 of auxiliary request 17 in steps (a) to (d) is obvious.

The person skilled in the art can only find sketchy information on sample preparation in the disclosure of document (1). They would thus seek further guidance for carrying out the steps of sample clean up, including concentration and culture of microorganisms in the sample as disclosed in paragraph [0086] of document (1). Such guidance for sample preparation in the context of identification of microorganisms in blood can be found in document (24). In this document, detailed information for culturing and concentrating microorganisms from a whole blood sample is provided. Culturing is carried out by adding the blood to a culture bottle containing nutrients. Subsequently, the cultures are mixed with distilled water and centrifuged at low speed. Next comes a step of depositing cells by centrifugation (1650 g for 5 minutes), followed by washing of the pellet with distilled water (page 215, right-hand column, first paragraph to page 216, left-hand column, first paragraph). A cleaned sample is thus obtained. When discussing these steps of sample preparation, document (24) confirms that the use of distilled water leads to lysing of the erythrocytes, which are blood particles (page 217, paragraph bridging

the columns).

Therefore, the method of sample preparation in document (24) describes all the technical features of steps (a) to (d) in claim 1 of auxiliary request 17, with the exception of the blood bag. The container in which the culturing of the pathogens in the whole blood sample takes place has not been discussed by the parties as having any relevance for the assessment of inventive step. In the present context blood bottles and blood bags are to be seen as equivalent alternative receptacles at the disposal of the person skilled in the art.

In summary, the person skilled in the art trying to put the method of document (1) into practice would have turned to document (24) for a protocol for the sample preparation and would thus have arrived at the claimed subject-matter without exercising inventive skill.

The subject-matter of claim 1 of auxiliary request 17 does not involve an inventive step (Article 56 EPC).

Having come to this conclusion, it is not necessary to discuss document (4).

5. *Reimbursement of the appeal fee (Rule 103(1)(a) EPC)*

A precondition for reimbursement of the appeal fee pursuant to Rule 103(1)(a) EPC is the allowability of the appeal. In the present case the patent proprietor's appeal is not allowable. As this precondition is not met, it is not necessary to establish whether a reimbursement would have been equitable by reason of the alleged substantial procedural violation.

The appeal fee is not reimbursed.

6. *Objection pursuant to Rule 106 EPC*

6.1 At the oral proceedings, after the board announced that it considered that the main request did not comply with Article 123(2) EPC, the patent proprietor raised an objection under Rule 106 EPC. The patent proprietor contended that, without knowing the reasons why the main request was not allowable under Article 123(2) EPC, they were deprived of the right to be heard, since they were not in a position to provide arguments as to why the objection under Article 123(2) EPC did not apply to the requests concerned or to file new requests. The board has dismissed this objection for the following reasons.

6.2 A party's right to be heard comprises the right to present their view on the factual and legal aspects which form the basis for the decision-making process; however, the right to be heard does not include the right to know the final position which the board intends to adopt; in particular, it does not mean the right to know which of the reasons or arguments made by a/the other party convinced the board. Instead, as observed by the Enlarged Board of Appeal, it is the duty of the party concerned to anticipate a possible adverse decision, and it is up to the party to make any respective submissions of its own motion (see R 8/15, point 2.1.2.2 of the Reasons, with further references to the case law; see also R 18/09, points 14 to 15 and 18 of the Reasons; and R 15/10, points 7 to 9 of the Reasons). The board of appeal, in turn, makes its final decision after the parties have been heard, and not before. It is the function of the written reasoning of

the decision to explain why a specific request was found not to be allowable.

6.3 The appellant's opinion that such reasoning must also be anticipated to allow the party to respond with new arguments or new requests not only does not find a basis in the case law of the Enlarged Board of Appeal, but it is also not consistent with the applicable procedural framework. Under the Rules of Procedure a party has to present its complete appeal case in the statement of grounds and in the reply (Article 12(3) RPBA 2020, which is applicable in the present case). Only in exceptional circumstances could the board eventually admit new requests filed after notification of a summons to the oral proceedings (Article 13(2) RPBA). Therefore, the ordinary function of an oral hearing in appeal proceedings, whether *ex parte* or *inter partes*, cannot be to discuss with the board why a request is not allowable and, on the basis of this discussion, present new arguments, evidence or requests.

The board considers the patent proprietor's right to be heard to have been respected during oral proceedings.

6.4 The objection under Rule 106 EPC is therefore dismissed.

**Order**

**For these reasons it is decided that:**

- the appealed decision is set aside,
- the patent is revoked, and
- the request for reimbursement of the appeal fee is rejected.

The Registrar: The Chairwoman:

M. Schalow T. Sommerfeld

Decision electronically authenticated