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Datasheet for the decision of 21 May 2026

Case Number: T 0733/24 - 3.3.08

Application Number: 19172152.1

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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/BRUKER DALTONICS

Relevant legal provisions:
EPC Art. 83

Keyword:
Sufficiency of disclosure - (no)

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Case Number: T 0733/24 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 21 May 2026

Appellant: (Patent Proprietor)	Bruker Daltonics GmbH & Co. KG Fahrenheitstraße 4 28359 Bremen (DE)
Representative:	Kuttenkeuler, David SKM-IP PartGmbB Oberanger 45 80331 München (DE)
Respondent: (Opponent 1)	Definition IP Limited The Core Bath Lane Newcastle Helix Newcastle upon Tyne, Tyne and Wear NE4 5TF (GB)
Representative:	Definition IP Limited The Core Newcastle Helix Bath Lane Newcastle Upon Tyne NE4 5TF (GB)
Respondent: (Opponent 2)	Thermo Fisher Scientific Oy. Ratastic 2 01620 Vantaa (FI)
Representative:	J A Kemp LLP 80 Turnmill Street London EC1M 5QU (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted/electronically transmitted on 1 March 2024 revoking European patent No. 3543700 pursuant to Article 101(3)(b) EPC**

Composition of the Board:

Chairwoman	T. Sommerfeld
Members:	A. Schmitt
	L. Bühler

Summary of Facts and Submissions

I. The patent proprietor's (appellant's) appeal is against the opposition division's decision to revoke European patent No. 3 543 700 (the patent).

II. The patent, entitled "*Identification of pathogens in body fluids*", was granted on the basis of European patent application No. 19 172 152.1 (the application), which was a divisional application from European patent application No. 14 185 334.0 (the earlier application), which in turn was a divisional application from European patent application No. 08 852 388.1 filed as an international patent application published as WO 2009/065580 A1 (the earliest application).

III. Two oppositions were filed against the patent. The opposition proceedings were based on the grounds for opposition under Article 100(a) EPC in relation to novelty (Article 54 EPC) and inventive step (Article 56 EPC), as well as those under Article 100(b) and (c) EPC.

IV. In the decision under appeal, the opposition division considered sets of claims of a main request and of 32 auxiliary requests. It found, *inter alia*, that the invention as defined in claim 1 of the main request and of each of auxiliary requests 1 to 32 was insufficiently disclosed (Article 83 EPC).

V. With the statement of grounds of appeal, the appellant re-submitted the requests considered by the opposition division (main request and auxiliary requests 1 to 32).

Claim 1 of the main request reads as follows:

"1. A method for the identification of microbial and non-microbial infectious pathogens in a body fluid in which infection is suspected, consisting basically of separating the pathogens from a body fluid sample by centrifuging the pathogens into pellets, and subjecting the pathogens to mass spectrometric analysis of their proteins for an identification, further including culturing the pathogens in the body fluid by incubating in order to generate the body fluid sample before the pathogens are centrifuged into pellets and subjected to mass spectrometric identification, wherein the body fluid contains a large number of body fluid particles and is whole blood which requires the method for the identification to include additional steps in order to destroy and remove the body fluid particles."

Claim 1 of auxiliary request 1 is identical to claim 1 of the main request.

Claims 1 of auxiliary requests 2 to 32 are amended compared with claim 1 of the main request in that they comprise one or more of the following additional feature(s) [1] to [5] (numbering of the features introduced by the board; requests containing the respective feature indicated in brackets):

[1] "wherein the method does not involve culturing colonies of the microbes in nutrient media in petri dishes" (auxiliary requests 2, 6, 10, 13, 18, 22, 26, 29)

[2] "wherein the method is without culturing the pathogens in external nutrient media" (auxiliary

requests 3, 7 to 9, 11, 14 to 17, 19, 23 to 25, 27, 30 to 32)

[3] "consisting of" instead of "consisting basically of" (auxiliary requests 4, 6, 8, 9, 12, 13, 15, 16, 20, 22, 24, 25, 28, 29, 31, 32)

[4] "wherein the pathogens are subjected to mass spectrometric analysis of their proteins for an identification by applying matrix-assisted laser desorption to the pathogens smeared onto sample support plates" (auxiliary requests 5, 10 to 17, 21, 26 to 32)

[5] (microbial and non-microbial infectious pathogens) "of acute infections" (auxiliary requests 7, 9, 14, 16, 17, 23, 25, 30, 32)

VI. Opponent 1 (respondent I) - but not opponent 2 (respondent II) - replied to the appeal.

VII. The board summoned the parties to oral proceedings as per their requests and, in a communication under Article 15(1) RPBA, expressed its preliminary opinion that, *inter alia*, none of the requests on file met the requirements of Article 83 EPC.

VIII. The appellant and respondent I were represented at the oral proceedings. Respondent II did not attend the oral proceedings, as announced in writing on 9 March 2026.

IX. The following documents are referred to in this decision:

D3 WO 02/021108
D9 WO 2011/006911

D15 C. H. Zierdt, J. Clin. Microbiol., 23(3), 1986, 452-5

D25 Experimental report submitted by the appellant

X. The parties' arguments relevant to the board's decision are referred to, where appropriate, in the Reasons for the Decision.

XI. The parties' requests relevant to the decision were as follows.

The appellant requested that the decision under appeal be set aside and the patent be maintained in amended form on the basis of the set of claims of the main request or, in the alternative, on the basis of the set of claims of one of auxiliary requests 1 to 32.

Respondent I requested that the appeal be dismissed.

Respondent II did not formulate any requests.

Reasons for the Decision

Main request
Claim interpretation - claim 1

1. The claim concerns a method for the identification of microbial and non-microbial infectious pathogens *in a body fluid* that is defined as "*consisting basically of*" a step of separating the pathogens from a body fluid sample by centrifuging them into pellets, and a step of subjecting the pathogens to mass spectrometric analysis of their proteins, this method "*further including*" a step of culturing the pathogens in the body fluid "*by incubating in order to generate the body fluid sample*

before the pathogens are centrifuged into pellets and subjected to mass spectrometric identification".

2. The use of the expressions "consisting basically of" and "further including" in the claim implies that the expression "consisting basically of" has the same meaning as "comprising". This is confirmed by the patent's description, where the expression "consisting of" is used in various paragraphs to describe open lists of method steps (e.g. paragraphs [0031] and [0039]) with further optional method steps expressed either in the same (e.g. paragraph [0031]) or in subsequent paragraphs (e.g. paragraphs [0040] to [0043]. Hence "consisting basically of" used in the claim means "comprising", and the claim allows for the presence of further method steps. This was not contested by either party.

3. The claim further specifies that the body fluid contains a large number of body fluid particles and is whole blood "*which requires the method for the identification to include additional steps in order to destroy and remove the body fluid particles*" (see section V. above for the full wording of the claim).

4. It is clear from the wording of this feature that the claim does not specify when these "*additional steps*" required "*in order to destroy and remove the body fluid particles*" take place. Instead, it allows for these steps to take place at any stage of the claimed method in which body fluid particles are present, i.e. in the body fluid after it has been taken from the subject, in the body fluid "sample" after culturing the pathogens in the body fluid, and in the pellets after the centrifugation step.

5. The appellant did not contest this claim interpretation during the oral proceedings before the board.

Sufficiency of disclosure (Article 83 EPC) - claim 1

6. In the discussion of sufficiency of disclosure, the parties referred to the patent, the application or the earliest application. As sufficiency of disclosure should be satisfied at the filing of the earliest application and the claims of the main request are amended compared with the claims of the patent as granted, the board finds it appropriate to cite the respective passages in the earliest application. Apart from the numbering, the cited paragraphs are identical in all three documents.

7. The claim is directed to a method for the identification of microbial and non-microbial infectious pathogens in whole blood by mass spectrometry. The pathogens are cultured in the whole blood by incubation and afterwards are centrifuged into pellets and subjected to mass spectrometric identification. In order to remove the particles contained in the body fluid, i.e. in the whole blood, the method further includes "*additional steps in order to destroy and remove the body fluid particles*". These steps are not further defined in the claim.

8. In order to carry out the claimed method, the skilled person must hence know, *inter alia*, with which additional steps the recited destruction and removal of the blood particles can be achieved such that an identification of any microbial and non-microbial infectious pathogen possibly present in the whole blood by mass spectrometry can be achieved.

9. The (earliest) application does not contain any working example of the claimed method. Instead, it contains a single hypothetical example in which the sample is whole blood infected by microbes (paragraph [63] of the earliest application). There, it is proposed to destroy and remove the blood particles by firstly separating the pathogens together with the blood particles by centrifugation and then dissolving the pellet in distilled water to destroy the blood particles by osmosis while leaving the microbes intact. Subsequent washing and further centrifugation steps supposedly result in a "*pellet containing well enriched microbes*" that can be identified by mass spectroscopy.

10. The skilled person is hence taught that in the case of a microbial blood infection the claimed method can be carried out by destroying and removing the microbes in that manner.

11. However, this method does not work, as evident from document D9, which discusses, in paragraphs [19] to [22], the teaching in the earliest application. It first describes, in paragraphs [19] to [21], the embodiment concerning the direct separation of the pathogens from body fluids for subsequent identification by mass spectroscopy, which method can be applied to all clear body fluids and for which a cultivation stage is not required (e.g. last sentence of paragraph [19] and first sentence of paragraph [21] of D9).

12. Subsequently, from the second sentence of paragraph [21] onwards, D9 discusses the embodiment claimed in the opposed patent, i.e. the detection of pathogens in body fluids containing endogenous particles, such as whole blood. In this embodiment, the method requires

intermediate steps of culturing the microbes in the blood and destroying the blood particles (second sentence of paragraph [21] of D9).

13. The third and fourth sentences of paragraph [21] of D9 recapitulate that the earliest application adds distilled water for the destruction of the particles to destroy the cell membranes by osmotic pressure, and that "[b]*y repeated addition of distilled water and centrifugation a sufficiently clean pellet should be obtained which should no longer contain any residues of the human particles*" (last sentence of paragraph [21] of D9).

14. However, as continued in paragraph [22] of D9, "*experiments carried out in the applicant's laboratory with this method of adding distilled water did not succeed in providing sufficiently clean centrifuge deposits, even when the washing and centrifuging processes were repeated a few times. Even if the deposits did not retain a slightly reddish color, superimpositions with human protein signals always interfered with the microbial protein signals from these deposits to such an extent that an identification becomes uncertain*" (paragraph [22] of D9).

15. Therefore document D9 is evidence that the single hypothetical example described for the claimed method in paragraph [63] of the earliest application is unsuitable to identify microbes in infected whole blood, let alone any microbial and non-microbial pathogens in a whole blood sample. In view of this and in the absence of any evidence that the skilled person could have remedied this deficiency by common general knowledge, it must be concluded that the skilled person

could not carry out the claimed method without undue burden at the effective filing date of the application.

16. In a first line of argument, the appellant submitted that each of the separate method steps recited in the claim - the culturing of microbes in blood, the precipitation of pathogens by centrifugation, the destruction of pathogens by osmosis, the preparation for and identification of pathogens by mass spectroscopy using validated commercial libraries of reference spectra - were well-known to the skilled person and/or described in the patent. The skilled person could hence carry out the claimed method without undue burden based on the teaching in the patent and their common general knowledge. The opposition division's reasoning was merely based on an allegation that the claims were too broad or too vague, which was not an issue to be dealt with under Article 83 EPC.

17. This reasoning cannot be accepted, however, because, in addition to the individual method steps discussed by the appellant, the claim recites the purpose "for the identification of microbial and non-microbial infectious pathogens" in whole blood. It is therefore not sufficient that, as asserted by the appellant, each of the individual method steps of the claim was known and could, one way or the other, be carried out by the skilled person. Instead, the skilled person must know which (combination of) possible alternatives for each method step results in achieving the recited purpose.

18. Under these circumstances, a very abstract - and therefore broad and general - definition of a method can become relevant under Article 83 EPC, namely if the skilled person does not know or cannot find out without undue burden how each of the abstract and general

method steps should concretely be implemented and possibly modified such that the recited purpose is indeed achieved. In the case at hand, document D9 is evidence that the only combination of method steps proposed in the application is not suitable to achieve this purpose (see points 11. to 15. above). As the application does not contain any indication that or how the proposed method works, there are serious doubts that the skilled person could carry out the claimed method without undue experimentation.

19. In this context, the appellant asserted that document D9 was not suitable evidence to demonstrate failure of the claimed method because it taught, in the first sentence of paragraph [20], that the method described in the earliest application was actually successful.

20. This is not true, however, because paragraph [20] of document D9 refers to another method disclosed in the application, namely the identification of pathogens in clear body fluids for which neither a cultivation step nor the destruction of blood particles are necessary and according to which the pathogens are directly separated from the clear body fluids by centrifugation or filtration (see also point 11. above). This method is described in paragraph [19] of document D9, and the first sentence of paragraph [20] of that document refers to this other method, as evident from the wording of this sentence: "*This method of direct centrifugation or filtration is successful because* ...".

21. The claimed method for the identification of pathogens in blood is discussed in document D9 only after this disclosure in paragraphs [21] and [22], and it is in

this subsequent section where it is unambiguously disclosed that and why the method described in the patent for the claimed embodiment does not work (see also points 12. to 15. above).

22. The appellant also pointed out that document D9 described the analysis of difficult hospital samples (paragraph [48]), which might be the reason for the method failing. There were only few possibilities of how and when to destroy blood particles, and in document D9 a solution to the problem described for the earliest application was easily found. This demonstrated that there might have been room for improvement of the patent's method, but not that there was insufficient disclosure. In fact, document D3, which was cited in the patent, described the lysis of blood cells with tensides, i.e. the solution proposed in document D9. This method was also known from e.g. document D15.

23. This line of argument cannot be accepted, however. Document D9 discloses that the centrifugation pellets obtained by the patent's method are insufficiently clean, and teaches that this problem could be overcome by using specific tensides instead of distilled water to dissolve the blood cells. Document D9 therefore points out the problem with the method of the patent and suggests a solution, which is in fact the invention claimed in document D9 (see e.g. claim 1 of D9). That document is however post-published and therefore cannot demonstrate that the skilled person would have identified, without undue experimentation, that and how the protocol disclosed in the patent must be altered in the lysis step in order to succeed in carrying out the claimed method.

24. Document D3 cited in paragraph [24] of the earliest application cannot remedy this deficiency either. It is true that paragraph [0025] of the patent mentions that D3 describes the lysis of human particles in the pellet by tensides. However, paragraph [0025] of the patent was not present in the earliest application, which did not contain any reference to this lysis method. Instead, document D3 was cited in the earliest application merely as describing a method to extract, separate and purify microbes including viruses by two-dimensional ultra-centrifuging directly from body fluids or homogenised tissue, whereby particles having a higher sedimentation speed than the microbes are removed in a first centrifugation step (paragraph [24] of the earliest application). No reference is made to the lysis of blood particles in this method.

25. Since in the earliest application only the particular ultra-centrifugation technique used in document D3 is discussed and contrasted with the method described in the patent (paragraphs [28] and [37] of the earliest application), the earliest application did not contain any indication that any of the techniques used in document D3, let alone the lysis method that was not even mentioned, could be relevant to the claimed method.

26. Document D15 is merely evidence that the destruction of blood particles with detergents was known in the prior art. However, there is no indication that, despite the clear instructions on how to destroy the blood particles in paragraph [63] of the earliest application, this different technique should be used and would lead to success in the context of the claimed method.

27. The appellant also asserted that the comment in document D9 that the claimed method did not work was incorrect, as evident from experimental report D25, which was filed by the appellant as "*representative of the general knowledge of the skilled person*" (last full paragraph on page 11 of the statement of grounds of appeal). D25 demonstrated that the claimed method could in fact be carried out.

28. However, firstly, a post-published experimental report cannot demonstrate the skilled person's common general knowledge at the effective filing date of the patent. Secondly, as pointed out by the opposition division and the respondent, the method carried out in D25 differs from that described in the patent's hypothetical example at least in that the blood corpuscles are destroyed by osmotic shock with deionised water before (and not after) the centrifugation of the blood sample (see steps a) to c) on page 1 of D25).

29. Hence the protocol used in D25 does not correspond to the (only) protocol disclosed for the claimed method in the opposed patent. Since D25 therefore does not attempt to repeat the method steps as proposed in the patent, it cannot support the notion that the skilled person could carry out the claimed method at the effective filing date of the patent based on the teaching in the patent and their common general knowledge without undue burden.

30. In fact, it is not apparent from the evidence on file that the skilled person would have recognised that the only protocol proposed in the patent was unsuitable to achieve the purpose recited in the claim, or that the skilled person would have understood from their common general knowledge in which step(s) problems with this

protocol might arise and how this/these step(s) should be carried out instead in order to remedy the deficiencies of the proposed protocol. Consequently, D25 cannot demonstrate that the skilled person could have carried out the claimed method at the effective filing date of the patent without undue burden.

31. In view of these considerations, the invention defined in claim 1 of the main request is not disclosed in the patent application in a manner sufficiently clear and complete for it to be carried out by the skilled person without undue burden (Article 83 EPC).

Auxiliary requests 1 to 32
Sufficiency of disclosure (Article 83 EPC)

32. Claim 1 of auxiliary request 1 is identical to claim 1 of the main request and therefore does not meet the requirements of Article 83 EPC for the same reasons as claim 1 of the main request.

33. Claim 1 of auxiliary requests 2 to 32 is amended compared with claim 1 of the main request in that it comprises one or more of the additional feature(s) [1] to [5] as summarised in section V. above.

34. None of these features [1] to [5] is concerned with the precipitation of the pathogens or the destruction of the blood particles of the blood sample, and hence none of these features, alone or in combination, is suitable to remedy the deficiencies identified above under Article 83 EPC for claim 1 of the main request. No arguments to the contrary were presented by the appellant.

35. Consequently, the same considerations on sufficiency of disclosure presented above for the invention defined in claim 1 of the main request apply, *mutatis mutandis*, to the invention as defined in claim 1 of each of auxiliary requests 1 to 32. Therefore auxiliary requests 1 to 32 do not meet the requirements of Article 83 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairwoman:

C. Rodríguez Rodríguez T. Sommerfeld

Decision electronically authenticated