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Datasheet for the decision of 10 September 2020

Case Number: T 2504/16 - 3.3.01

Application Number: 10158529.7

Publication Number: 2214015

IPC: G01N33/53, G01N33/543, G01N33/537, B01L3/00

Language of the proceedings: EN

Title of invention:
Hydrophilic diagnostic devices for use in the assaying of biological fluids

Patent Proprietor:
ADHESIVES RESEARCH, INC.

Opponent:
Zacco GmbH

Headword:
Hydrophilic diagnostic devices/ADHESIVES RESEARCH

Relevant legal provisions:
RPBA 2020 Art. 15(3)
RPBA Art. 12(4)
EPC Art. 123(2), 76(1), 84, 83, 54(2), 56

Keyword:

Late-filed request - submitted with the statement of grounds of appeal - admitted (yes)
Amendments - change of category - allowable (yes)
Divisional application - added subject-matter (no)
Claims - clarity (yes)
Sufficiency of disclosure - (yes)
Novelty - (yes)
Inventive step - (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 2504/16 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 10 September 2020

Appellant: (Patent Proprietor)	ADHESIVES RESEARCH, INC. P.O. Box 100 Glen Rock, PA 17327 (US)
Representative:	Beck Greener LLP Fulwood House 12 Fulwood Place London WC1V 6HR (GB)
Respondent: (Opponent)	Zacco GmbH Bayerstrasse 83 80335 München (DE)
Representative:	Zacco GmbH Bayerstrasse 83 80335 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 20 September 2016 revoking European patent No. 2214015 pursuant to Article 101(3)(b) EPC**

Composition of the Board:

Chairwoman	M. Pregetter
Members:	T. Sommerfeld
	P. de Heij

Summary of Facts and Submissions

I. European patent No. 2214015 is based on application No. 10158529.7, filed under Article 76 EPC as a divisional application of the earlier application No. 02728841.4 (parent application), which was itself filed as an international application and published as WO 02/085185. The patent is entitled "Hydrophilic diagnostic devices for use in the assaying of biological fluids" and was granted with 15 claims.

Granted claim 1 reads as follows:

"1. A microfluidic in-vitro diagnostic device comprised either:
(i) of a base having at least one fluid channel within which a fluid sample to be assayed passes from an inlet port to a detection zone, said at least one fluid channel being enclosed by at least one enclosure surface or
(ii) of opposing base portions separated by an adhesive spacer portion having fluid channels therein within which a fluid to be assayed passes from an inlet port to a detection zone,
wherein at least one surface of the fluid channel of (i) or at least a portion of the adhesive spacer portion of (ii) comprises a hydrophilic heat-sealable adhesive or a hydrophilic pressure-sensitive adhesive and is hydrophilic in character to increase the surface energy of the fluid flow path to enhance the flow of biological fluids in the channel."

II. Opposition was filed against the granted patent, the opponent requesting that the patent be revoked in its entirety on the grounds of lack of novelty and of

inventive step (Articles 54 and 56 EPC and Article 100(a) EPC), insufficiency of disclosure (Article 100(b) EPC) and added subject-matter (Article 100(c) EPC).

III. By its decision announced at oral proceedings, the opposition division revoked the patent under Article 101(3)(b) EPC.

The opposition division decided that all claim sets on file (main request and auxiliary requests 1 to 3) lacked novelty. The requirements of Articles 123(2) and 84 EPC were considered to be met by the main request.

IV. The patent proprietor (appellant) lodged an appeal against the decision. With the statement of grounds of appeal, dated 19 January 2017, the appellant requested that the patent be maintained on the basis of the claims of the main request or alternatively of one of auxiliary requests 1 to 20, all filed with the grounds of appeal. It moreover requested remittal to the opposition division "for a decision at first instance on inventive step" should the board find that the claims of any of the requests met the requirements of Article 54 EPC.

V. By letter of reply dated 29 May 2017, the opponent (respondent) requested that the appeal be dismissed. It moreover requested that none of the requests filed with the statement of grounds of appeal be admitted into the proceedings.

VI. A summons to oral proceedings before the board was issued, followed by a communication pursuant to Article 15(1) RPBA providing the board's preliminary opinion on the appellant's request for remittal to the opposition

division and on the admission of requests filed with the grounds of appeal.

VII. The appellant replied by a letter dated 26 May 2020, submitting therewith further auxiliary requests AR0 and AR1A to AR15A.

VIII. By a letter dated 28 July 2020, the respondent withdrew its request for oral proceedings and announced that it would not attend them.

IX. In accordance with the appellant's request in its letter dated 31 August 2020, the oral proceedings were held by videoconference. During the oral proceedings, the appellant upgraded its auxiliary request 16 to main request. At the end of the oral proceedings, the chairwoman announced the decision of the board.

X. The **main request** comprises 11 claims, of which claim 1 reads as follows:

"1. A method of manufacturing a microfluidic in-vitro diagnostic device, comprising:

providing a base having at least one fluid channel within which a fluid sample to be assayed passes from an inlet port to a detection zone; and

enclosing said at least one fluid channel with at least one enclosure surface, wherein said at least one enclosure surface of the fluid channel comprises a hydrophilic heat-sealable adhesive or a hydrophilic pressure-sensitive adhesive and is hydrophilic in character to increase the surface energy of the fluid flow path to enhance the flow of biological fluids in the channel."

Claims 2 to 11 are dependent claims and relate to specific embodiments of claim 1.

XI. The documents cited during the proceedings before the opposition division and the board of appeal include the following:

L2 US 5759364

XII. The appellant's submissions, in so far as they are relevant to the present decision, may be summarised as follows:

Admission of main request

The present claims constituted a legitimate attempt to overcome the novelty objection of the opposition division.

Article 123(2) EPC

The claims were method claims which had been drafted as a direct counterpart to the product claims of the application as filed. The change of claim category from product to method did not result in added matter. A basis was to be found in claim 2 as filed in combination with Figures 7, 16 and 17 and the corresponding passages in the description, paragraphs [0061] and [0094].

Article 54 EPC

The electrochemical sensor of L2 did not comprise an enclosure surface which also comprised the hydrophilic adhesive, since the base designated 36 in L2 was to be regarded as the enclosure surface but the hydrophilic

adhesive was attached to the lid 46, which was to be regarded as the base comprising the fluid channels of the claim under consideration.

XIII. The respondent's arguments, submitted in writing and in so far as they are relevant to the present decision, may be summarised as follows:

Admission of main request

None of the requests filed with the grounds of appeal should be admitted into the proceedings because they could have been presented at the proceedings at first instance, were in an excessive number, and did not constitute a coherent set of fallback positions.

Articles 123(2) and 76 EPC

There was no basis in the application as filed for a method claim because in the section "Objects and summary of the invention" of the application as filed the invention was exclusively defined as a device and not as a manufacturing method. The original claims of the application as filed were also directed to a device and not to a method. For the same reasons, there was also extension beyond the content of the parent application as filed.

Article 84 EPC

Claim 14 of the main request filed with the grounds of appeal did not refer to an "open fluid channel" and was therefore inconsistent with claim 1.

Article 83 EPC

The invention was not workable at all, because the location of the adhesive on the enclosure surface was not indicated. However, an adhesive arbitrarily located in or on the enclosure surface would not reproducibly and reliably result in a surface energy increase of a fluid flow path located within the microfluidic device.

Moreover, the invention was not workable over the entire range of claimed adhesives, because it was not expected that all possible adhesives falling within the groups of hydrophilic heat-sealable or pressure-sensitive adhesives would achieve the technical effects of uniform wetting and wicking and of increasing the surface energy of the fluid flow path to enhance the flow of biological fluids in the channel. In fact, the invention should be limited to the types of adhesive that were detailed in the examples of the invention.

The technical effects stated in the patent appeared to be mere allegations because there were no comparative examples showing that said effects were in fact associated with the types of adhesives used in the examples.

Finally, it appeared from figures 7, 9 and 10 of the patent that the inclusion of a surfactant in the adhesive was an essential feature in order to achieve the desired uniform wetting and wicking.

Article 54 EPC

A device having all the same technical features as the device of claim 1 of the main request filed with the grounds of appeal was disclosed in L2, in Figure 1 and

the corresponding passages of the description (column 3). Method claim 14 of the main request filed with the grounds of appeal was just product claim 1 disguised as a method claim: hence it also lacked novelty.

XIV. The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the claims of the main request (filed as auxiliary request 16 with the statement of grounds of appeal) or on the basis of one of the auxiliary requests that were filed as main request and auxiliary requests 1 to 15 and 17 to 20 with the grounds of appeal.

The respondent requested in writing that the appeal be dismissed and that none of the requests filed with the statement of grounds of appeal be admitted into the proceedings.

Reasons for the Decision

1. The appeal is admissible.

2. By letter dated 28 July 2020, the respondent withdrew its request for oral proceedings and announced that it would not attend them. In accordance with Rule 115(2) EPC, the board decided to continue the proceedings in the respondent's absence.

Moreover, pursuant to Article 15(3) RPBA, the board was not obliged to delay any step in the proceedings, including its decision, by reason only of the absence at the oral proceedings of any party duly summoned. Accordingly, the absent party was treated as relying only on its written case.

3. Main request

3.1 Admission

3.1.1 The present main request was filed as auxiliary request 16 with the statement of grounds of appeal. Pursuant to Article 12(4) RPBA 2007, which is applicable in the present appeal, everything presented by the parties with the statement of grounds of appeal and the reply thereto shall in principle be taken into account by the board, but the board has the discretionary power to hold inadmissible facts, evidence or requests which could have been presented or were not admitted in the proceedings at first instance.

3.1.2 The respondent requested in writing that all requests filed with the statement of grounds of appeal be deemed inadmissible for being in an excessive number, not convergent, and because they could and should have been filed earlier, during opposition proceedings (letter of reply, section 1 on pages 1 and 2).

3.1.3 The board notes that, in the communication accompanying the summons to oral proceedings before the opposition division, the opposition division issued a preliminary opinion acknowledging novelty and inventive step. Hence there was at that time no need for the appellant to submit further requests in order to overcome novelty objections. It was only at the oral proceedings that the opposition division changed its mind as regards novelty, and the appellant decided then not to file any further requests at oral proceedings (minutes of oral proceedings, page 2, last sentence of section "Article 54 EPC"). Hence, although the appellant could have attempted to overcome the novelty objection at the

oral-proceedings stage, it is understandable that it might have needed more time and that in fact the appeal was the first appropriate opportunity to file new requests.

3.1.4 Hence the board considers that the submission of the present main request is a legitimate reaction to the events occurring during oral proceedings before the opposition division, and ultimately to the decision under appeal. Accordingly, the board sees no reason to exclude the present main request from the proceedings.

3.2 Article 123(2) EPC

3.2.1 Claim 1 of the main request is directed to a method of manufacturing a microfluidic in-vitro diagnostic device, comprising:
- providing a base having at least one fluid channel within which a fluid sample to be assayed passes from an inlet port to a detection zone; and
- enclosing said at least one fluid channel with at least one enclosure surface, wherein said at least one enclosure surface of the fluid channel comprises a hydrophilic heat-sealable adhesive or a hydrophilic pressure-sensitive adhesive and is hydrophilic in character to increase the surface energy of the fluid flow path to enhance the flow of biological fluids in the channel.

3.2.2 According to the appellant, this claim finds a basis in claim 2 as filed in combination with *inter alia* paragraph [0094] of the application as published (EP 2214015 A1).

3.2.3 Although there is no verbatim disclosure in the application as filed for a method comprising the steps

as claimed, the board comes to the conclusion that the passages indicated by the appellant constitute an adequate basis for claim 1 of the main request.

3.2.4 Claim 2 as filed is a product claim directed to a microfluidic *in-vitro* diagnostic device which is defined as comprising the same components as the microfluidic *in-vitro* diagnostic device which is to be produced by the method of present claim 1, i.e. it discloses a microfluidic *in-vitro* diagnostic device which is comprised of a base having at least one fluid channel within which a fluid sample to be assayed passes from an inlet port to a detection zone, characterized in that said at least one fluid channel is enclosed by at least one enclosure surface, wherein at least one surface of the fluid channel comprises a hydrophilic heat-sealable adhesive or a hydrophilic pressure-sensitive adhesive and is hydrophilic in character to increase the surface energy of the fluid flow path to enhance the flow of biological fluids in the channel.

3.2.5 The method of present claim 1 is defined by steps which are in fact merely general steps to assemble the different components of the microfluidic *in-vitro* diagnostic device of claim 2 of the application as filed. Such general steps are thus considered implicit to the disclosure of the microfluidic *in-vitro* diagnostic device. The only feature of present claim 1 which is not implicit to the disclosure of claim 2 as filed is that it is the enclosure surface of the fluid channel that comprises a hydrophilic heat-sealable adhesive or a hydrophilic pressure-sensitive adhesive: claim 2 only refers to "at least one surface of the fluid channel" (not necessarily the enclosure surface) as comprising the adhesive. This feature is however

described in claim 13 as filed ("...wherein the enclosure surface comprises said hydrophilic adhesive") and in paragraph [0094] of the application as filed, which reads: "An enclosure surface or cover is placed over the top portion of the base substrate to enclose and otherwise seal the microfluidic channels. In the context of the present invention, the channels are covered with a substrate according to the present invention the surface of which is hydrophilic which covers the channels in the base substrate. The fact that the surface of the covering substrate is hydrophilic in nature enhances the flow of the liquid through the microfluidic channels. As discussed above, the hydrophilic covering substrate can comprise a variety of types of materials having hydrophilic character, such as a hydrophilic pressure-sensitive adhesive layer, a hydrophilic heat-sealable layer, or a hydrophilic surface-treated layer". This passage thus makes it clear that it is the enclosure surface that comprises the hydrophilic substrate with the functional and structural features as required by the claim.

3.2.6 The respondent essentially argued, in relation to claim 14 of the main request filed with the statement of grounds of appeal (identical to claim 1 of the present main request), that there was no basis in the application as filed for a method claim because in the section "Objects and summary of the invention" of the application as filed on pages 2 and 3 the invention was exclusively defined as a device and not as a manufacturing method, and likewise the 15 original claims of the application as filed all defined a device and not a method (letter of reply, page 5, section 1.1).

3.2.7 The board agrees that the application as filed is specifically directed to microfluidic *in-vitro* diagnostic devices and does not explicitly disclose methods for manufacturing said devices. However, it is established case law that subject-matter is not added by a change of claim category per se when there is a basis for all the features of the claim and for the new claim category. As reasoned above, there is indeed a basis for all features of the claim. In addition, the board notes that the description as filed does provide a general disclosure of steps for manufacturing the device, such as in the above-mentioned paragraph [0094].

3.2.8 There were no objections under Article 123(2) EPC by the respondent specifically directed to the dependent claims. The board moreover notes that these claims are all directly derived from the respective dependent claims 4 to 12 and 14 as filed, which further define the microfluidic device of claim 2 as filed.

3.2.9 The board thus comes to the conclusion that the claims of the main request meet the requirements of Article 123(2) EPC.

3.3 Article 76(1) EPC

3.3.1 The respondent stated that it raised the same objections under Article 76(1) EPC as had already been raised under Article 123(2) EPC (letter of reply, page 6, section 1.2). It did not raise any further objection specifically directed at claim 14 of the then main request or claim 1 of the then auxiliary request 16, these claims being identical to the present claim 1.

3.3.2 The board notes that claims 26 to 29 of the parent application as filed are directed to microfluidic *in-vitro* diagnostic devices with the same components as those disclosed in claim 2 of the application as filed. A passage corresponding to paragraph [0094] of the application as published is to be found in the parent application on page 31, line 12 to last line. Hence all features of the claim are disclosed in the parent application and, for the same reasons as given above for Article 123(2) EPC, the new claim category is also considered as having a basis in the parent application.

3.3.3 The respondent has not raised objections under Article 76(1) EPC for the dependent claims. The basis for the dependent claims 2 to 10 can be found in claims 27 to 36 of the parent application. The basis for dependent claim 11 can be found on page 32, second paragraph, of the parent application. The board thus considers that the dependent claims also comply with Article 76(1) EPC.

3.3.4 The board hence comes to the conclusion that the claims of the main request meet the requirements of Article 76(1) EPC.

3.4 Article 123(3) EPC

3.4.1 No objections were raised by the respondent under Article 123(3) EPC. The board has no such objections either.

3.5 Article 84 EPC

3.5.1 The only objection of the respondent concerning clarity in relation to claim 14 of the main request was that if the reference to "open fluid channel" in claim 1 was to

be considered clear, then "open" should also be added to the independent method claim 14 "to ensure consistency and thus clarity throughout the independent claims" (letter of reply, page 6, section 1.3).

3.5.2 Since claim 14 of the previous main request is now the only independent claim of the present main request, the respondent's clarity objection no longer applies.

3.5.3 The board thus comes to the conclusion that the claims of the main request meet the requirements of Article 84 EPC.

3.6 Article 83 EPC

3.6.1 Article 83 EPC stipulates that the application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

3.6.2 In its letter of reply to the grounds of appeal, the respondent raised objections under Article 83 EPC to the product claims of the requests then on file, but not specifically to the method claims (section III of the letter of reply, starting on page 3). However, since some of these objections are related to technical features that are also present in claim 1 of the main request, the board will examine them here.

3.6.3 The first argument by the respondent was that the invention claimed in the then main request "was not workable at all", because there was no limitation as to where the adhesive was to be located on the enclosure surface. An adhesive that was arbitrarily arranged on or within the enclosure surface/spacer portion would

however not be able to influence the surface energy of an arbitrary fluid flow path located within the device.

3.6.4 It is established case law that a patent application has to be read with a mind willing to understand, and that a skilled person would rule out interpretations that do not make technical sense. In the present case, it is evident that the adhesive has to be positioned in such a way as to allow the assembly of the device, by bonding together the base comprising the fluid channel with the enclosure surface: hence it is immediately apparent that the adhesive is to be placed on the enclosure surface on the side which faces the base with the channel. Such a configuration, which is the only one that makes technical sense, also allows the adhesive to have an effect on the flow of the channel.

3.6.5 A further argument by the respondent was that the claimed invention was at least not workable over the entire range of claimed adhesives, because there was no clear definition in the application of the conditions that had to be met by an adhesive to be hydrophilic, heat-sealable or pressure-sensitive, nor was there any generally-accepted unequivocal definition in the relevant art of what constituted a "hydrophilic", "heat-sealable" or "pressure-sensitive" adhesive. Accordingly, one could not reasonably expect that all adhesives that potentially fall under the wording of the main claims would achieve the claimed technical effect of uniform wetting and wicking (paragraph [0007] of the patent), and it would be an undue burden to test, by trial and error, all types of adhesives that might qualify as more or less hydrophilic to determine those that actually enhanced the flow of biological fluids in a microfluidic channel. The respondent concluded that the purported invention was at best

limited to the types of adhesives detailed in the examples of the patent, and that in fact the technical effects stated in the patent appeared to be mere allegations because there were no comparative examples to show that said technical effects were indeed associated with the types of adhesives detailed in the examples.

3.6.6 The board fails to see how the skilled person would have doubts in identifying which adhesives are to be considered hydrophilic heat-sealable or pressure-sensitive. Even if this were the case, this appears to be an objection of lack of clarity rather than insufficiency of disclosure, an objection which would not be admissible since these technical features were already part of the granted claims.

3.6.7 While some adhesives might be more or less hydrophilic, it is plausible that all hydrophilic adhesives will achieve the effect recited in the claim of enhancing the flow, and the respondent failed to provide any evidence to the contrary. As to the achieving of further technical effects such as wetting and wicking, the board notes that these technical effects are not part of the claim. It is established case law that an objection of insufficient disclosure cannot be based on an argument that the application does not enable a skilled person to achieve a technical effect which is not defined in the claim. The requirement of sufficiency of disclosure relates to the invention as defined in the claims, and in particular to the combination of structural and functional features of the claimed invention, and there is no legal basis for extending such a requirement also to encompass other technical effects possibly associated with the

invention but not required by the claimed subject-matter.

3.6.8 Finally, the respondent also argued that, in view of figures 7, 9 and 10 of the patent, it appeared that the inclusion of a surfactant in the adhesive was an essential feature in order to achieve the desired uniform wetting and wicking. Accordingly, to ensure enablement, the independent claims should therefore recite a surfactant. The board again notes that the technical effect of wetting and wicking is not part of the claim, and therefore whether or not it is achieved cannot form the basis of an objection of insufficiency of disclosure.

3.6.9 The claims of the main request are thus considered to comply with Article 83 EPC.

3.7 Article 54 EPC

3.7.1 The respondent made an objection of lack of novelty of the subject-matter claimed in the present claim 1 only in view of document L2, stating that: "Method claim 14 is merely claim 1 disguised as a method claim. Accordingly, the method of claim 14 is anticipated by document L2" (letter of reply, page 8, item d) of section 1.4).

3.7.2 Document L2 also discloses a microfluidic *in-vitro* diagnostic device as defined in claim 2 of the application as filed. As pointed out by the respondent, it is apparent from Figure 1 of L2 that the electrochemical biosensor of L2 has a base 46 with an open fluid channel 48 within which blood to be assayed passes from the right side in figure 1 to a detection zone embodied by the reagent layer 44. The open fluid

channel 48 is enclosed by the embossing in the base 46. This embossing is covered on its underside with a bi-functional polymeric layer, which not only acts as an adhesive to bond the base 46 to the substrate 36 but also increases the hydrophilic nature of the open fluid channel 48, as described e.g. in claim 1, item c), and column 3, lines 49 to 53, of L2. The bi-functional polymeric adhesive layer is heat-sealable, as described e.g. in claim 13, step c), and column 3, lines 14 to 16, of L2.

3.7.3 According to the present claim 1, two components have to be assembled in order to manufacture the microfluidic device disclosed in the patent. The first component is a base having at least one fluid channel within which a fluid sample to be assayed passes from an inlet port to a detection zone, and the second component is an enclosure surface which comprises a hydrophilic heat-sealable adhesive or a hydrophilic pressure-sensitive adhesive. As summarised above, the respondent considered that the base having at least one fluid channel corresponded to the base or lid 46 of the electrochemical sensor of L2, while the enclosure surface corresponded to the base 36. However, as mentioned above, the bi-functional polymeric adhesive layer disclosed in document L2 is attached to the lid 46 and not to the base 36. Hence the base 36 cannot correspond to an enclosure surface as defined in the method claim. While this difference does not distinguish the device obtained by the method of present claim 1 from the device disclosed in L2, it does however distinguish the method for manufacturing it, because claim 1 requires that an enclosure surface which comprises the adhesive material be used.

3.7.4 Claim 1 is thus considered to be novel over document L2. In the absence of any other novelty objections, the board comes to the conclusion that the claims of the main request meet the requirements of Article 54(2) EPC.

3.8 Article 56 EPC

3.8.1 The respondent has not raised any objection of lack of inventive step against the subject-matter recited in claim 1 of the present main request, and in fact has not formulated any complete objection of lack of inventive step for any of the claims on file. Under these circumstances, the board does not consider that it has to examine inventive step on its own motion.

3.8.2 Hence the board comes to the conclusion that, in the absence of objections from the respondent, the present claims have to be considered as involving an inventive step. Accordingly, the board concludes that the main request complies with Article 56 EPC.

4. Request for remittal to the opposition division

4.1 The board decided not to accede to the appellant's request for remittal of the case to the opposition division for examination of inventive step. In view of the outcome of the appeal, the board does not find it necessary to provide reasons for this point of the decision.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The case is remitted to the opposition division with the order to maintain the patent with the following claims and a description to be adapted thereto:

claims 1 to 11 of the main request, filed as auxiliary request 16 with the statement of grounds of appeal.

The Registrar: The Chairwoman:

M. Schalow M. Pregetter

Decision electronically authenticated