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**Datasheet for the decision
of 21 October 2016**

Case Number: T 0668/12 - 3.2.02

Application Number: 06075525.3

Publication Number: 1674037

IPC: A61B5/15, A61M5/32

Language of the proceedings: EN

Title of invention:

Integrated lance and strip for analyte measurement

Patent Proprietor:

LifeScan, Inc.

Opponent:

Roche Diagnostics GmbH

Headword:

Relevant legal provisions:

EPC Art. 54, 56, 76(1), 84, 123(2), 123(3)
RPBA Art. 12(2)

Keyword:

Claims - clarity - main, first and second auxiliary request (no)

Amendments - broadening of claim - main, first and second auxiliary request (yes), third auxiliary request (no)

Added subject-matter - third auxiliary request (no)

Novelty - third auxiliary request (yes)

Inventive step - third auxiliary request (yes)

Decisions cited:

Catchword:



Beschwerdekammern
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Case Number: T 0668/12 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 21 October 2016

Appellant: Roche Diagnostics GmbH
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Decision under appeal: **Interlocutory decision of the Opposition**
Division of the European Patent Office posted on
25 January 2012 concerning maintenance of the
European patent No. 1674037 in amended form.

Composition of the Board:

Chairman E. Dufrasne
Members: D. Ceccarelli
P. L. P. Weber

Summary of Facts and Submissions

- I. The opponent has appealed the Opposition Division's decision, dispatched on 25 January 2012, that European patent No. 1 674 037 as amended according to the then pending main request could be maintained.
- II. The patent, which is derived from a divisional application of parent application No. 04 251 803.5, was opposed on the grounds of insufficiency of disclosure, added subject-matter, lack of novelty and lack of inventive step.
- III. The notice of appeal was received on 19 March 2012. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 24 May 2012.
- IV. The respondent replied to the statement of grounds by letter dated 22 October 2012.
- V. The Board summoned the parties to oral proceedings and set out its provisional opinion in communications dated 18 July 2016 and 5 August 2016.
- VI. By letter dated 22 August 2016 the appellant announced that it would not be attending the oral proceedings.
- VII. The respondent filed further written submissions on 21 September 2016.
- VIII. Oral proceedings took place on 21 October 2016 in the appellant's absence.

The appellant had requested in writing that the decision under appeal be set aside and that the patent

be revoked.

The respondent requested that the appeal be dismissed or, in the alternative, that the decision under appeal be set aside and that the patent be maintained on the basis of one of the first to ninth auxiliary requests filed on 21 September 2016.

IX. The following documents are mentioned in the present decision:

E3: WO-A-01/72220;
E4: WO-A-03/009759;
E6: WO-A-02/056751;
E8: EP-A-1 284 121;
E15: US-A-4,753,641;
E16: US-A-2002/0168290.

X. Claim 1 of the request found allowable by the Opposition Division (the main request) reads as follows:

"A lance (15) comprising:
a lancing element (22) having a first sharpened end point (38);
a separation element (24) having a second end point (40) wherein said second end point (40) is positioned proximal to said first sharpened end point (38),
a connector connecting a proximal portion of said lancing element (22) to a proximal portion of said separation element (24), said connector forming an open channel (42),
wherein:
said separation element (24) is for holding an incision open when the lancing element (22) is in the

incision and preventing the edges of the incision from closing on the lancing element (22) and partially or fully blocking the open channel (42);

said lancing element (22), said separation element (24) and said channel (42) are formed from a single sheet of metal; and

at least a portion of said open channel (42) is treated with a hydrophilic surface coating."

Claim 7 of the main request reads as follows:

"A lance (15) according to Claim 1, wherein said lancing element (22) and said separation element (24) form a gap therebetween, the separation between the lancing element (22) and the separation element (24) increasing from the distal end to the proximal end of the gap."

Compared with claim 1 of the main request, in claim 1 of the first auxiliary request the following has been added at the end of the claim:

"wherein a space between said lancing element (22) and said separation element (24) forms a gap, said gap increasing in size proximal to said second end point (40)".

Compared with claim 1 of the main request, in claim 1 of the second auxiliary request the following has been added at the end of the claim:

"wherein said separation element (24) is positioned at an angle to said lancing element (22)".

Compared with the main request, the only amendment in the third auxiliary request is the deletion of

"partially or fully" in claim 1.

The third auxiliary request comprises seven claims. Claims 2 to 7 are dependent claims.

XI. The appellant's arguments, as far as relevant for the present decision, may be summarised as follows:

Its detailed submissions in the statement setting out the grounds of appeal had to be considered simply as supporting and completing the arguments it had presented in the first-instance proceedings. It referred in particular to all objections and arguments already presented before the Opposition Division as well as to the documents of the prior art considered by the Examining Division in the proceedings which had led to the grant of the patent in suit.

Added subject-matter - Articles 76(1) and 123(2) EPC

Claim 1 of the main request defined an "open channel" formed by the connector. In contrast, claim 1 of the application as originally filed and of the patent as granted required that the connector simply formed a channel. In the impugned decision the Opposition Division referred to page 2, lines 14 to 16 of the application as originally filed as providing a basis for this amendment. However, this text passage belonged to the section "Problem to be Solved". It followed that it was not a disclosure relating to the claimed invention. Moreover, the lance described on page 2, lines 12 to 16 of the original application comprised a lancing element which was flat or partially curved and included an open channel and a separation element. Hence, the open channel and the separation element were part of the lancing element. This was in contradiction

with claim 1 of the main request, according to which the lance comprised three elements in the form of a lancing element, a separation element and a connector, the latter forming the open channel. Furthermore, extracting only the word "open" from the combination of features described on page 2, lines 12 to 16 of the original application constituted a non-allowable intermediate generalisation, since that word had to be understood in the light of the characterisation of the "lancing element" as a "flat or partially curved piece". It was the specific combination of such a construction of the lancing element and the separation element which made it possible to obtain an open channel. As a result, the introduction of the word "open" into claim 1 of the main request did not comply with Article 123(2) EPC.

For the same reasons, the introduction of the features that the "separation element (24) is for holding an incision open when the lancing element (22) is in the incision and preventing the edges of the incision from closing on the lancing element (22) and partially or fully blocking the open channel", allegedly based on the same passage on page 2, lines 14 to 16 of the application as originally filed, was likewise a non-allowable intermediate generalisation in contravention of Article 123(2) EPC.

Also claim 7 of the main request contravened Article 123(2) EPC. The passage on page 7, lines 20 to 22, which, according to the respondent, provided a basis for the subject-matter claimed, concerned a specific embodiment of a lance produced by bending a metal sheet. Claiming only the geometry of the "gap" formed by the lancing element and the separation element, while omitting the necessary manufacturing

technique, was not allowable.

Extension of protection - Article 123(3) EPC

Claim 1 of the patent as granted defined a separation element which prevented the edges of the incision from "blocking said channel". According to claim 1 of the main request, however, the separation element was for preventing the edges of the incision from "partially or fully blocking the open channel". As a result, possibly any partial blocking of the channel, obtained by the mere presence of the channel walls, was now included in the scope of the claim, which had been significantly extended in contravention of Article 123(3) EPC.

Moreover, while according to claim 1 of the patent as granted the separation element was used to "hold open an incision made by the lance", claim 1 of the main request simply required that the separation element was "for holding an incision open". Doing away with the requirement that the incision be made by the lance itself contemplated the situation that the incision be made, for example, by a different, separate lance. This constituted a non-allowable extension of the scope of protection, contrary to the requirements of Article 123(3) EPC.

Clarity - Article 84 EPC

The feature in claim 1 of the main request that the separation element was for preventing the edges of the incision from "partially or fully blocking the open channel", which was not structural but only functional, was unclear. It possibly covered any separation element which only minimally hindered the closure of the channel. More particularly, the expression "partially

or fully" possibly covered any situation in which only 0.001% of the section of the channel was blocked, up to a situation in which almost all the channel section was blocked, for example 99.99%. However, the first situation would be produced by any channel wall, which intrinsically pushed away the edges of the incision from the middle of the channel to at least some extent. The second situation was anyhow practically excluded, since body tissue in the region of the excision would be under tension and could not be in contact with the whole periphery of the channel. For these reasons the skilled person would not know which meaning should be given to the claimed feature.

Novelty - Article 54 EPC

The subject-matter of claim 1 of the main request was not novel over E3. Figures 1 and 2 disclosed a lance in the form of a triangular penetration probe 12. In view of the broadness of the scope of the claim, this lance, which comprised a first sharpened end point at one vertex of the triangle and a second end point at the broadest lance section opposite to that vertex, could be interpreted as building up the claimed lancing element, separation element and connector. In particular, the connector was in the region of open channel 14.

E4 was also novelty-destroying for the subject-matter of claim 1 of the main request. In particular, the body of the lance in figure 1 comprised a lancing element with a first sharpened end point (the tip of the lance), a separation element and a connector within the meaning of the claim.

E16 was also novelty-destroying for the subject-matter

of claim 1 of the main request. Similar to the disclosure of E4, the body of lance 6 in figure 1A comprised a lancing element with a first sharpened end point (tip 24), a separation element in the form of the steep channel walls of channel 22 and a connector within the meaning of the claim.

Inventive step - Article 56 EPC

The subject-matter of claim 1 of the main request was not inventive over the combination of E16 with E15. If E16 was considered not to disclose a separation element and its claimed function of holding the incision open, the objective technical problem solved by these features would be to prevent blockage of the channel. E16, in particular paragraph [0072], taught that any kind of lancing element could be used in the embodiment of figure 2. Moreover paragraph [0082] taught that it was important to maintain an unhindered capillary flow through the channel. In view of this teaching and seeking a solution to the objective technical problem the skilled person would also consider lances in other fields, like catheters and cannulas, and come across E15. This document, which disclosed a separation element of a cannula in particular in the form of a bottom member described in the passage starting from column 5, line 56, discussed in detail the problem of the blockage of the channel of the cannula. As a result, the skilled person would implement the separation element of E15 in the lance of E16 and arrive at the subject-matter of claim 1 of the main request in an obvious way. In the same context, also E4 could be considered as the closest prior art.

Starting from E15, this document disclosed all the features defined in claim 1 of the main request except

the hydrophilic coating. In view of figures 1 and 2 of the patent in suit, which showed a channel which was partially closed in the region of working electrode 36 and insulating substrate 18, claim 1 did not require that the channel should be open along its whole length. The claimed hydrophilic coating addressed the objective technical problem of improving the flow through the channel. E15 taught that it was important to find out early whether a blood vessel had been punctured by the insertion of the cannula (column 2, lines 4 to 8). This teaching alone would prompt the skilled person to improve the flow through the channel of the cannula. In view of one or more of E3, E4, E6, E8 and E16, which all described the advantages of a hydrophilic coating for the channel of a lance, it would be obvious for the skilled person to provide the channel of the cannula of E15 with a surface coating as claimed.

XII. The respondent's arguments, as far as relevant for the present decision, may be summarised as follows:

The appellant stated that the objections submitted in the notice of opposition were valid, despite the fact that the patent had been amended and upheld in amended form. The situation at the time of filing of the notice of opposition differed significantly from the situation in appeal. According to the established case law of the boards of appeal, a statement of grounds which merely referred generally to previous submissions was not sufficient. All the appellant's references in the statement of grounds to earlier submissions should be discounted as inadmissible, because they were insufficiently substantiated.

Added subject-matter - Articles 76(1) and 123(2) EPC

The amendment replacing "channel" with "open channel" in claim 1 of all requests was based on the passage at page 2, lines 14 to 16 of the application. As also noted by the Opposition Division in the impugned decision, this passage, although in the section "Problem to be Solved", defined a function that the invention had to fulfil. Moreover, the feature of the channel being open was not inextricably linked to the other features, in particular to those of the lancing element being a flat or partially curved piece, as described in that passage. Therefore it was permissible to introduce only the feature of the open channel into the claim.

Similarly, the features that the "separation element (24) is for holding an incision open when the lancing element (22) is in the incision and preventing the edges of the incision from closing on the lancing element (22) and partially or fully blocking the open channel", based on the same passage on page 2, lines 14 to 16 of the application, were not inextricably linked to the other features described in that passage. As a result it was permissible to independently introduce them into the claim.

As regarded claim 7 of the main request, there was ample support for it at page 7, lines 20 to 22.

Extension of protection - Article 123(3) EPC

The newly introduced expression "partially or fully" in claim 1 of the main request did not extend the scope of the claim. More particularly, partial blocking was a form of blocking, as also was full blocking. Both these

forms were encompassed by the broader concept of "blocking" as defined in claim 1 of the patent as granted, since this concept had to be interpreted as an observable, significant hindrance of the flow through the channel, in accordance with the disclosure in column 2, lines 4 to 10 and 17 to 24 of the patent.

The definition in claim 1 of all requests that the separation element was "for holding an incision open when the lancing element is in the incision" made it abundantly clear that the incision held open was the one created by the lancing element, as was the case for claim 1 of the patent as granted. Arguing that this wording contemplated that the incision could be created by a separate lance was a wilful misinterpretation of the claim in order to arrive at an objection. However, the skilled person would interpret the claim with a mind willing to understand.

Clarity - Article 84 EPC

The word "blocking" was commonly understood to refer to the action of obstructing or hindering. Such a meaning was in accordance with the description. In context, if bodily fluids were prevented from flowing to the proximal end of the channel or the amount of fluid which could flow was limited in some way, then "blocking" of the open channel occurred. It followed that the word "blocking" was clear. The expression "partially or fully blocking" had to be interpreted the same way and was, therefore, also clear. In particular, the appellant's submission that partial blocking encompassed a situation when the edges of the incision extended into the channel to occupy 0.001% of its cross-sectional area was wrong, since such a situation would not constitute an obstruction or hindrance to

flow.

Novelty - Article 54 EPC

The subject-matter of claim 1 of all requests was novel over the cited prior art. In particular, that subject-matter required two distinct elements: a lancing element for creating an incision and a separation element for holding the incision open. None of the cited documents disclosed a separation element as claimed.

E3 disclosed a lance with a penetration probe (12 in figure 1) formed by two spaced-apart triangular-shaped sheets. The penetration probe formed a lancing element for creating an incision. The point where the penetration probe transitioned into surface 34 (figure 1), identified as the "second point" according to the claim language, was merely part of the lance which created the incision and could not represent the claimed separation element. It followed that no separation element was disclosed in E3.

E4 disclosed a lancing element with a U-shaped open channel 15 (figure 1A). What the appellant had identified as a separation element was part of the sloped cutting surface of the lancing element and performed a lancing function to create an incision, rather than a separation function. There was no element preventing the edges of the incision from closing on the lancing element and blocking open channel 15. Hence, E4 did not disclose a separation element as claimed.

E16 did not disclose a separation element either. In particular, the walls of channel 22 in figure 1A formed

the edge of the channel and could not be considered as the claimed separation element.

Inventive step - Article 56 EPC

The subject-matter of claim 1 of all requests was also inventive over the cited prior art.

In particular, E15 disclosed a closed emergency medical needle for rapid cannulation of blood vessels. It did not disclose an open channel as claimed. Such a needle had a different purpose and involved technical considerations different from the invention, which was concerned with a lance having an open channel for taking small samples from skin by capillary action. E15 would not be considered by the skilled person trying to improve configurations for lances of the claimed kind.

Reasons for the Decision

1. The appeal is admissible.
2. Although duly summoned by communications dated 18 July 2016 and 5 August 2016, the appellant was not present at the oral proceedings, as announced by letter dated 22 August 2016.

In accordance with Rule 115(2) EPC and Article 15(3) RPBA, the oral proceedings were continued without this party.

3. The invention

The invention relates to a lance for making an incision in a patient's tissue, typically used for drawing out

bodily fluids for analysis. The claimed lance comprises a lancing element with a first sharpened end point, a separation element for holding the incision open and a connector element forming an open channel. The lancing element, the separation element and the open channel are made from a single sheet of metal and a portion of the open channel is treated with a hydrophilic surface coating.

The claimed features help to promote the flow of bodily fluids through the open channel, enabling them to better reach for example a sensor strip connected to the lance and intended to perform the fluid analysis.

4. Main, first and second auxiliary requests - Articles 84 and 123(2) EPC
- 4.1 Compared with claim 1 of the patent as granted, claim 1 of the main and the first and second auxiliary requests have been amended so as to define a separation element "for preventing the edges of the incision from [...] partially or fully blocking the open channel".
- 4.2 The introduction of the expression "partially or fully" renders the claim unclear as it does not allow clear delimitation or the defined function of the separation element with respect to the open channel.

The Board agrees with the respondent that the concept of "blocking the channel", present in claim 1 of the patent as granted, has to be interpreted in context and cannot be limited to a complete obstruction of the channel but also includes situations in which a significant hindrance of the fluid flow through the channel takes place. However, the respondent's argument that "partially or fully blocking" should be

interpreted in the same way as simply "blocking" is not convincing. Confronted with an amendment of a claim the skilled person will try to give it a technical content unless there is a clear indication to the contrary, for example in the light of the specification as a whole. In the present case, also in view of the description and drawings of the patent, the precise meaning of a partial blockage of the open channel cannot be ascertained, or that it is the same as that of a blockage of the channel. The skilled person will therefore assume that there is a difference, but will not be able to quantify it. More particularly, the skilled person is left in doubt as to which degree of fluid-flow hindrance constitutes partial as opposed to full blockage.

- 4.3 The fact that less significant hindrance is now encompassed in the scope of claim 1 of the main and the first and second auxiliary requests also implies that this scope has been extended compared to that of the patent as granted.
- 4.4 It follows that the main and the first and second auxiliary requests cannot be allowed because they do not comply with Articles 84 and 123(3) EPC.
- 4.5 Since these requests cannot be allowed the Board does not need to consider other appellant's objections, in particular those under Article 83 EPC to the same expression "partially or fully".

5. Third auxiliary request

5.1 In claim 1 of the third auxiliary request the expression "partially or fully" has been deleted. The non-compliance with the EPC which rendered the higher-ranking requests not allowable has been removed.

5.2 In the statement of grounds of appeal the appellant raised a number of objections to the main request, which may also apply to the third auxiliary request, merely by general references to submissions made in the first-instance proceedings, before the impugned decision was notified to the parties.

These objections do not take into account the reasons given in the impugned decision by the Opposition Division, which explained why they were found unsuccessful. It follows that such objections do not enable the Board and the other party to immediately understand, without having to carry out investigations of their own, why the decision under appeal should be set aside. Therefore, they do not serve the main purpose of the appeal procedure, which is the revision of the impugned decision in view of the arguments of the appealing party. For this reason the Board considers that such general references to submissions made in the first-instance proceedings do not constitute "reasons why it is requested that the decision under appeal be reversed, amended or upheld [...] specify[ing] expressly all the facts, arguments and evidence relied on" in order to present a party's complete case, according to Article 12(2) RPBA. Consequently, they are disregarded.

5.3 *Added subject-matter - Articles 76(1) and 123(2) EPC*

Except for some editorial changes in the claims of the application as originally filed, as far as the respondent's objections under Articles 76(1) and 123(2) EPC are concerned the parent and the present application as originally filed have the same technical content. For ease of understanding, the Board refers below only to the relevant passages of the parent application as originally filed.

5.3.1 The subject-matter of claim 1 of the third auxiliary request finds a basis in claims 1, 3 and 5, and page 2, lines 12 to 16 of the parent application as originally filed.

5.3.2 The appellant argued that the passage on page 2, lines 12 to 16 belonged to a section entitled "Problem to be Solved" and, therefore, was not a disclosure of the invention.

The Board does not share this view. As also concluded by the Opposition Division in the impugned decision (point 3.1 of the Reasons), the section "Problem to be Solved" sets out the functions that the invention should fulfil. This is made clear, in particular, by the beginning of the passage mentioned, which reads:

"It would, therefore, be advantageous to design a lancing device where the lancing element is a flat or partially curved piece including an open channel and the lancing element includes a separation element for holding the incision open when the lancing element is in the wound and preventing the edges of the incision from closing on the lancing element and partially or fully blocking the open

channel."

It is therefore concluded that, implicitly, the functional features of the described advantageous design of the lancing device are achieved by the device of the invention.

- 5.3.3 The appellant further argued that extracting only the features of the *"open channel"* and the *"separation element for holding the incision open when the lancing element is in the wound and preventing the edges of the incision from closing on the lancing element and blocking the open channel"* constituted a non-allowable intermediate generalisation.

However, as the respondent also observed, the Board notes that the other features of the passage mentioned above are not technically inextricably linked to the claimed features. In particular, the Board does not see why a flat or partially curved lancing element should be technically necessary in order to obtain the claimed open form of the channel. Similarly, the described construction of the lancing element cannot be necessary for the claimed function of the separation element, i.e. a different element.

As a result, the skilled person is not presented with the fresh information that features originally disclosed as necessary for the invention no longer are.

- 5.3.4 The appellant further argued that according to the passage on page 2, lines 12 to 16 of the parent application as originally filed the open channel and the separation element were part of the lancing element, which was in contradiction with claim 1 of the main request, according to which the lance comprised

three elements in the form of a lancing element, a separation element and a connector, the latter forming the open channel.

The Board however notes that the skilled person would read that passage in context, in the light of the embodiments described and the lance defined in claim 1 of the parent application as originally filed. In such a context there is no necessary relationship between the claimed open form of the channel and the function of the separation element on the one hand, and the specific form of the lancing element comprising two or three different elements on the other hand.

- 5.3.5 It is therefore concluded that claim 1 of the third auxiliary request complies with both Articles 76(1) and 123(2) EPC.
- 5.3.6 The subject-matter of claim 7 of the third auxiliary request is additionally based on page 7, lines 20 to 22 of the parent application as originally filed.
- 5.3.7 The appellant argued that since the passage on page 7, lines 20 to 22, concerned a specific embodiment of a lance produced by bending a metal sheet, extracting from that passage only the geometry of the "gap" formed by the lancing element and the separation element, while omitting the necessary manufacturing technique, was not allowable.

Again the Board notes that the claimed geometry of the gap, from a technical point of view, is not necessarily related to a single manufacturing technique of the lance. Hence, the introduction of only the gap geometry described in that passage does not present the skilled person with information which was not directly and

unambiguously derivable from the parent application as filed.

5.3.8 It is therefore concluded that also claim 7 of the third auxiliary request complies with both Articles 76(1) and 123(2) EPC.

5.4 *Extension of protection - Article 123(3) EPC*

5.4.1 The appellant argued that the amendment in claim 1 of the third auxiliary request according to which the separation element was "for holding an incision open" extended the scope of protection with respect to claim 1 of the patent as granted, which additionally required that the incision be made by the lance.

5.4.2 The Board does not share this view. Whether the incision to be held open by the separation element is made by the claimed lance or otherwise has no effect on whether the defined functional feature of the separation element is suitable for holding such an incision open. Furthermore the suitability of the lance for making an incision, expressly stated by the wording "made by the lance" in claim 1 of the patent as granted, is retained in claim 1 of the third auxiliary request by the definition of the "sharpened end point (38)". Additionally, the fact that the claim recites that the incision is to be held open "*when the lancing element [...] is in the incision*" implies, in the context of the invention, that the incision is performed by the lancing element itself and, hence, by the lance, as was defined in claim 1 of the patent as granted.

5.4.3 The Board therefore concludes that claim 1 of the third auxiliary request complies with Article 123(3) EPC.

5.5 *Novelty - Article 54 EPC*

5.5.1 The appellant formulated novelty objections based on E3, E4 and E16.

5.5.2 In the Board's view, E3 does not disclose in particular a separation element as defined in claim 1 of the third auxiliary request. According to the claim three distinct elements - a lancing element, a separation element and a connector - are required, each with its specific structural and/or functional features. The skilled person trying to make technical sense out of the claim wording will understand that these features have to be individually fulfilled by the respective elements defined. In the case of the triangular penetration probe (12 in figures 1 and 2) of E3, which the appellant argued could be interpreted as building up all these three elements, it is not possible to identify individual entities or parts, each fulfilling their specific features as claimed. Even assuming that the penetration probe was suitable for performing the claimed function of the separation element, it would be the probe as a whole, acting concurrently as lancing element and connector. For example, the second end point identified by the appellant at the broadest lance section of the triangular penetration probe opposite to the vertex making up the first sharpened end point is also necessarily involved in the incision of tissue and conveyance of fluid to channel 14 (figure 2). As a result, an individual separation element as claimed is not disclosed in E3.

5.5.3 For similar reasons, E4 and E16 do not disclose a separation element according to claim 1 of the third auxiliary request either. More particularly, the whole body of capillary structure 11 in figure 1 of E4, and of lance 6 in figure 1A of E16, which the appellant identified as forming the claimed lancing element, separation element and connector, performs the incision of tissue, the conveyance of fluid through channel 15 and, allegedly, the separation of tissue according to the definition of claim 1 of the third auxiliary request. As a result, an individual separation element as claimed is not disclosed in E4 or E16 either.

5.5.4 Consequently, the Board concludes that the requirement for novelty (Article 54 EPC) does not prejudice the maintenance of the patent according to the third auxiliary request.

5.6 *Inventive step - Article 56 EPC*

5.6.1 The appellant raised inventive-step objections based on the combination of E16 or E4 with E15, and starting from E15.

5.6.2 Turning to E15, the Board notes that this document is concerned with a needle for rapid cannulation of arteries and veins (column 1, lines 4 to 14). It is not concerned with a lance incision of tissue and ensuring that the edges of the incision do not close on the lancing element of the lance, thereby blocking an open channel of the lance within the meaning of claim 1 of the third auxiliary request. The technical considerations behind a lance as claimed, typically used to slowly extract minor amounts of bodily fluid from a patient's tissue, are completely different from those behind a needle of the kind disclosed in E15,

typically involved with large fluid flows. The Board is convinced that the skilled person in the field of lances, when starting from documents of this field like E16 or E4, would not consider E15 at all.

For the same reasons, the skilled person would not consider E15 as the closest prior art when following the problem-solution approach. In any case there is no apparent reason for providing the interior of a needle for rapid cannulation of the kind disclosed in E15 with a hydrophilic coating and transforming such a needle into a lance within the meaning of claim 1. E15 does not mention any specific problem related to the interior surface of the needle and the detection of back flow when a blood vessel is punctured. The passage in column 2, lines 4 to 8, referred to by the appellant, is generally concerned with needle plugging. E3, E4, E6, E8 and E16, mentioned by the appellant, all concern lances for sampling bodily fluids, with different purposes.

5.6.3 The Board therefore concludes that the requirement for inventive step (Article 56 EPC) does not prejudice the maintenance of the patent according to the third auxiliary request either.

5.7 It follows that the patent can be maintained on the basis of the third auxiliary request.

Under these circumstances, there is no need for the Board to consider the fourth to the ninth auxiliary requests.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance, with the order to maintain the patent on the basis of:
 - claims 1 to 7 of the third auxiliary request, filed on 21 September 2016;
 - description, columns 1 to 10 filed on 21 November 2011; and
 - figures 1 to 3 of the patent as granted.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated