Examiners' Report Paper B 2023

Purpose and extent of the examiners' report

[001] The Examiners' report sets out the expected solution, explains why this solution was expected, and shows how the marks were distributed. In addition, it highlights the most common mistakes and explains which deductions were made for these mistakes.

[002] The purpose of the Examiners' report is to enable candidates to prepare for future examinations (cf. Article 6(6) of the Regulation on the European qualifying examination for professional representatives).

General considerations

[003] It is noted that any references in this text to the Guidelines for Examination at the European Patent Office (GL) refer to the version valid at the date of the examination.

The paper

[004] This paper is concerned with medical devices for measuring blood sugar levels. These are used by medical professionals but also by patients themselves to check their blood sugar level. Often, they have to measure several times per day. The paper describes a strip that can be inserted in a device in which the measurement is performed by spectroscopy.

[005] It is described that for some people who need to measure their blood levels, it is not always easy to obtain a sufficient amount of blood from a finger prick. The present application presents a solution to this problem. Less blood is needed to perform a measurement.

[006] The paper describes a strip with a membrane that can be used for the separation of blood. Red blood cells are separated by the membrane from the blood droplet. A

preferred embodiment describes a membrane with pores that taper from a larger diameter to a smaller diameter. Different ranges are described for the pore diameters. This will lead to less cell lysis, the breaking up of red blood cells.

[007] The application has several examples which show that the tapering membranes can achieve a less destructive separation than the membranes with constant diameter. This means that these membranes can perform a separation on less blood.

[008] To measure the blood glucose levels the strip should be inserted in a device, which measures the glucose level in a spectrophotometer. A specific, more accurate, device using an array detector is described. This device works especially well with the inventive strips.

[009] The paper has two prior art documents.

[010] Document D1 shows a strip with a membrane that has a constant pore size. Document D1 also shows the claimed device for measuring the blood glucose levels, using a monochromator. Document D1 is novelty destroying for claims 1 and 3 to 5.

[011] Document D2 is prior art in accordance with Article 54(3) EPC. This document discloses a very similar strip, also with a membrane using pores that taper from a larger diameter to a smaller diameter. All claims lack novelty over D2. For the device it is mentioned that a spectrophotometer is used. The document contains a reference to D1.

[012] The range of tapering pore diameters is much broader in D2 than in the preferred embodiments of the present application. However, there is no technical effect with respect to the membranes of D2. Also D2 is trying to avoid cell lysis. In view of the version of the Guidelines valid during the examination, a narrow selection, which is sufficiently far removed from the prior art, without technical effect is novel (see Guidelines G-VI. 8(ii)). The candidates should thus claim the narrow range and argue that the range is narrow and sufficiently far removed from the prior art.

[013] The client argues that he does not understand the objection in view of D2, because the document is from himself. Of course, this is irrelevant for novelty. The candidate should, therefore, restrict the claims more than suggested by the client.

[014] It is also possible to render claim 1 novel over D2 by specifying that the membrane is a polyamide. However, this is against the wishes of the client, who indicates that they would like the claims to cover other types of membranes as well. Also, this does not establish novelty over D1.

[015] The client mentions in their letter that there is an error in the claims and in the description. This was also indicated by the examining division. Claim 3 and paragraph [017] mention that the droplet that is added to the device is 5 ml. The client argues that this should be 5 µl. This should be apparent from paragraph [017] but also from D1. Indeed, it is clear that µl is intended. The client provides a document, Blood Science and Technology, that also shows the normal volume of a droplet of blood. The candidates should argue that the change is allowable as a correction under Rule 139 EPC. The extra document should be used as evidence of the knowledge of the person skilled in the art.

[016] The examining division has also argued that the strip and the device claims do not fulfil the requirements of Rule 43(2) EPC. The candidates are supposed to amend the device claim to a device that is specifically suitable for the inventive strip (with the array detector), and they should then argue the plug-and-socket exception of Rule 43(2)(a) EPC.

[017] The amendments made by the client are not bad. However, the proposed amendment to delete the term “hydrophilic” in relation to the membrane of claim 1 violates Article 123(2) EPC, since there is no basis for this amendment. Also claim 4, directed to the device, still needs to be amended to include the array detector.

[018] Novelty over D1 is straightforward to argue. Claim 1 is novel because of the tapering pores. Claim 4 is novel because of the array detector.

[019] However, novelty over D2 is more complex. The subject-matter that should be claimed is a selection over D2, because the range is narrow and sufficiently far removed from the prior art. There is no technical effect. This is part of Guidelines G-VI. 8(ii). The criterion of purposive selection has been removed a couple of years ago, based on recent Case Law that found that this purposiveness should be part of the examination of inventive step.

[020] Inventive step is not very complex to argue. However, candidates should demonstrate a proper use of the problem-solution approach, showing all the steps. There is only one document to start from and this document is, therefore, automatically the closest prior art. It should nevertheless be argued why it is a reasonable starting point. Some candidates might argue inventive step based on D2, which would, of course, be a very serious mistake. It is also necessary to argue inventive step for independent claim 4.

[021] For the subject-matter of claim 1, the distinguishing feature over D1 is the tapered membrane pores. The technical effect resulting from this difference is that less cell lysis occurs during separation of red blood cells, meaning that the plasma obtained contains fewer impurities that can influence the measurement of glucose. As a result, a more accurate measurement can be performed on a smaller blood sample. Based on this effect the objective technical problem should be defined as the provision of a strip for measuring blood sugar levels with more efficient measurement. There is no indication in D1 to use a membrane with tapering pores. Of course, the candidates should not refer to D2 at any point in their argumentation as D2 is not prior art according to Article 54(2) EPC.

[022] For claim 4 the argumentation is the following. The distinguishing feature with respect to D1 lies in the array detector. This provides for a more accurate measurement. The objective problem is the provision of a device that is able to measure glucose in smaller blood samples. There is no indication in the prior art that this can be achieved by the array detector.

Marking

[023] As usual, when multiple solutions were offered for claims or argumentation, the worst solution was marked.

Claims (30 marks)

[024] As in previous years, 30 marks are available for the claims. Out of these 30 marks, 26 marks are available for the independent claims.

Claim 1, directed to the strip, should have the following wording:

Strip for measuring blood sugar levels, comprising:

(a) a reagent part comprising a membrane

(b) a capillary for transporting a blood sample to a reagent part

(c) an opening for measurement and putting into place the strip, the opening being present in the reagent part;

characterised in that the membrane is a hydrophilic membrane ~~having a smallest pore diameter of between 0.1 and 5 µm.~~ having pores that taper in diameter from 30 to 100 µm on the upper membrane surface to 0.3 to 1 µm on the lower.

For claim 1, 18 marks are available.

[025] As usual, a main claim that is not novel does not attract any marks. For example, if the range includes an endpoint disclosed in the prior art, the claim lacks novelty. If the main claim does not specify that the membrane is hydrophilic, 10 marks are lost. There is no basis for any other membrane than a hydrophilic membrane. Some candidates defined that the membrane was also hydrophobic. These candidates lost 15 marks. Candidates who chose narrower ranges for the range of small pores on the lower surface of the membrane lost marks, because this is considered an unnecessary limitation. The candidates lost marks based on the limitation they made: a range of 0.4 to 1.0 µm lost 4 marks, whereas a range of 0.4 to 0.6 µm lost 6 marks. A range that

excludes the preferred embodiment of 0.5 µm lost 10 marks. Some candidates also restricted the range of the large pores on the upper membrane surface. This was not needed, and 5 marks were lost for this unnecessary limitation. A range that excludes one or more of the examples described in the table on page 5 (membranes C, D and E) lost 10 marks. Further unnecessary limitations also led to a loss of 5 marks each. Candidates who claimed a single point value for the upper or lower pore diameters instead of a range lost 13 marks for each of such single point values

[026] Claims that were formally novel, but which lacked an inventive step lost 10 marks.

[027] Candidates who introduced an unallowable disclaimer lost 15 marks. This could be because the disclaimer does not fulfil the requirements of Article 123(2) EPC, but also for disclaimers that rendered the claim unclear. An example of a disclaimer lacking clarity is disclaiming a membrane thickness of *around 200 µm.* A claim in which the thickness of 200 µm was disclaimed was considered to lack novelty. D2 discloses values “around 200 µm”. Even though it is not clear what the values around 200 µm are, it is clear that there are thicknesses outside 200 µm that are disclosed in D2. The Guidelines F-IV, 4.7.1 were cited by some candidates. These Guidelines concern the interpretation of claims and not the interpretation of a prior art document.

[028] General issues of lack of clarity in the claim led to a deduction of 2 marks for each unclear feature. Further issues of Article 123(2) EPC led to a loss of 6 marks.[029] Some candidates restricted the lower side pore size to 0.3 to 1 µm, but did not include a pore size for the upper side. This is an unallowable intermediate generalisation. 6 marks were lost. Some other candidates restricted the lower side pore size to 0.3 to 1 µm, but did not include the feature that the pores are tapering. There is no basis for this amendment, nor was it considered to involve an inventive step over D1. Even though the range of pore size is quite restricted in view of D1, there is no technical effect for these non-tapering pores.

[030] Some candidates tried to render claim 1 novel by specifying that the membrane is made of polyamide. However, this feature alone does not render claim 1 novel over D1, because D1 discloses a polyamide membrane. Furthermore, if the claim were

novel over D1 by adding a further feature, the restriction to polyamide is a very strong limitation going against the wishes of the client, as they would in fact like to broaden the materials. 15 marks were lost if candidates added this feature to claim 1.

[031] Some candidates tried to render claim 1 novel by incorporating the subject-matter of dependent claims that were objected to by the examiner for lack of novelty. Such claims lacked novelty.

[032] Claim 4, directed to the device, should have the following wording:

Device for measuring blood sugar levels for use with a strip as defined in claims 1 to 34, comprising an opening for inserting the strip, and a spectrophotometer comprising an array detector, which uses a wavelength of 635 nm to perform the measurement.

For claim 4, 8 marks are available.

[033] When the claim is not novel 8 marks are lost. Candidates who introduced only the feature of multiple wavelengths without the array detector lost 4 marks, because the array detector is the only device disclosed in the application. There is no basis for a generalisation. Such a claim does not fulfil the requirements of Article 123(2) EPC. Candidates who reformulated the device claim into a use claim (or method claim) with array detector lost 4 marks, whereas a use claim without array detector lost 6 marks; in that case the use should be with the strip of claims 1 to 3, otherwise the claim would lack novelty over D1. No marks were lost for specifying an additional second wavelength. Some candidates formulated this claim as a device with the strip inside. This very restricted claim lost 6 marks.

Dependent claims

[034] For the dependent claims 4 marks are available.

[035] 2 marks are available for amending ml to µl in claim 2 (original claim 3). Candidates who did not make this change did not get these marks.

[036] Maintaining the other dependent claims and adapting the dependency could earn 2 marks. For these two marks the claims should be maintained, properly numbered with proper dependencies.

[037] As usual, drafting of additional claims did not attract any marks. In any case, drafting such claims was time not well spent.

Argumentation (70 marks)

Amendments (20 marks)

[038] Providing basis for independent claims (12 marks)

[039] For the strip claim (8 marks)

For the claim directed to the strip, the basis is claim 2 for the tapering pores. This argument can receive 4 marks. Candidates could also refer to paragraph [009] but in that case more arguments are expected concerning the combination of ranges. The range of 0.3 to 1.0 µm is based on paragraph [009]. 4 marks are available for candidates who argued this properly. If ranges are combined, for example 0.4 to 1.0 µm it should be argued why this is allowed. This argument needs to be present to obtain full marks. Candidates who had deleted the feature “hydrophilic” and presented arguments why this would be allowable will not lose any further marks than the marks deducted for the claims, because this would be considered double penalisation. Candidates who had another claim approach could achieve 8 marks if the basis was argued properly. For claims that included single point values this could go up to a maximum of 4 marks.

[040] For the device claim (4 marks)

The basis for the array detector can be found in paragraph [013]. 4 marks are available for candidates who argued this properly. Also, if the claim contains the two wavelengths this is based on the same paragraph.

[041] Dependent claims (2 marks)

It should be argued that the original dependent claims were dependent on all claims and that no new combination has been made. 2 marks are available for this.

[042] Correction under Rule 139 EPC (6 marks)

The candidates needed to ask for correction of ml to µl. It should be argued that it is immediately clear that an error has occurred and that it is also immediately clear what the correction should be. The document, Blood Science and Technology, should be used in the argumentation. A complete argumentation using the document is worth 6 marks. Not using the document resulted in a maximum of 3 marks. It is noted that some candidates did not make a request for correction. When no correction is requested no marks are available. Some candidates argued this issue in view of Article 123(2) EPC. No marks were given for such arguments.

Clarity (4 marks)

[043] Clear arguments using Rule 43(2)(a) EPC can merit up to 4 marks. The device is especially suitable for the strip. Many candidates did not refer to paragraph (a) of the rule. Some candidates argued that the claims were unitary. Such arguments were not expected, because the examiner did not raise any unity objection. Such arguments attracted no marks.

Novelty (23 marks)

[044] Claim 1:
Novelty in view of D1 should identify the difference of the tapering pores. A maximum of 5 marks is available for this argumentation.

[045] In view of D2 the arguments for novelty are worth a total of 15 marks. The arguments can be split into several sub arguments. It should be argued that the claimed range is a novel selection over D2. This is worth up to 3 marks. The criteria narrow and sufficiently far removed should be mentioned. Guidelines G-VI, 8(ii) should be cited to identify basis for these criteria or equivalent wording should be used. 4

marks are available. Finally it should be argued why the criteria are fulfilled. For both criteria 4 marks (each) are available.

[046] Some candidates amended claim 1 by specifying the opening (3) as the allegedly novel feature. The opening is considered to be implicitly disclosed in D2 and cannot render the strip novel. No marks were available for the arguments on novelty in this case.

[047] Claim 4:
In view of D1 the difference is the array detector. D2 does not describe a device in detail. It is only mentioned that a spectrophotometer is used. The difference in view of D2 is at least the array detector. 3 marks are available for these arguments. D2 has a reference to D1 and one can surmise that the same device is implicitly disclosed.

Inventive step (23 marks)

[048] Candidates who used D2 in their arguments for inventive step could not get any marks for their inventive step reasoning. This means that no marks are given when D2 is used as closest prior art, but also when used as a second document in combination with D1 or when relied upon anywhere in the inventive step argumentation. This is seen as a very serious mistake.

[049] Claim 1 (15 marks):
Identifying that D1 is the closest prior art is worth 1 mark. Even though it is the only document available as closest prior art, arguments why the document could serve as closest prior art are still expected. Identifying the difference with respect to D1 (tapering pores) is worth 1 mark. Identifying the technical effect (less cell lysis) is worth 3 marks. To show that this technical effect is actually achieved is also worth up to 3 marks. The definition of the objective technical problem (more accurate measurement on smaller blood samples) is worth 3 marks. Finally, it should be argued why the claimed subject-matter is not obvious. This is worth up to 4 marks.

[050] Claim 4 (8 marks):

Again, identifying D1 as the closest prior art is worth 1 mark. 1 mark is available for identifying the difference (array detector). The technical effect is the possibility to measure glucose more accurately. This is worth 2 marks. Defining the objective technical problem based on this technical effect (ability to measure smaller blood samples) is also worth 2 marks. Finally, the arguments why the subject-matter of claim 4 is not obvious is also worth 2 marks.