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Datasheet for the decision of 8 April 2022

Case Number: T 0611/14 - 3.3.01

Application Number: 06703925.5

Publication Number: 1844338

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Language of the proceedings: EN

Title of invention:
SCREENING METHOD

Patent Proprietor:
KING'S COLLEGE LONDON
Guy's & St Thomas' NHS Foundation Trust

Opponent:
Avidity IP

Headword:
Protein variant screening/KING'S COLLEGE

Relevant legal provisions:
RPBA Art. 12(4), 13(1), 13(3)
EPC Art. 54, 56

Keyword:

Main request and second auxiliary request - admitted (no)
First auxiliary request - admitted (yes) - novelty (yes) - inventive step (no)

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Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 0611/14 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 8 April 2022

Appellant: (Patent Proprietor 1)	KING'S COLLEGE LONDON An Institute Incorporated By Royal Charter, Strand London WC2R 2LS (GB)
Appellant: (Patent Proprietor 2)	Guy's & St Thomas' NHS Foundation Trust Lambeth Palace Road London SE1 7EH (GB)
Representative:	Tombling, Adrian George Withers & Rogers LLP 2 London Bridge London SE1 9RA (GB)
Appellant: (Opponent)	Avidity IP Merlin House, Falconry Court Baker's Lane Epping Essex CM16 5DQ (GB)
Representative:	Dehns St. Bride's House 10 Salisbury Square London EC4Y 8JD (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 15 January 2014 concerning maintenance of the European Patent No. 1844338 in amended form**

Composition of the Board:

Chairman	A. Lindner
Members:	J. Molina de Alba
	L. Bühler

Summary of Facts and Submissions

I. The decision under appeal is the opposition division's interlocutory decision which held that European patent No. 1 844 338 as amended in the form of auxiliary request 1 filed during the oral proceedings on 7 November 2013 met the requirements of the EPC.

II. The following documents are referred to in the present decision:

D1 Y.A. Daniel et al., British Journal of Haematology, 2005, 130, 635-643

D3 B.J. Wild et al., Blood Cells, Molecules, and Diseases, 2001, 27(3), 691-704

A1 E. Willekens et al., Clinical Chemistry, 2000, 46(2), 281-283

A1' Quattro II user's guide by Micromass, page 25

A2 WO 03/078962

A3 L. Anderson, J Physiol, 2005, 563(1), 23-60

III. An opposition had been filed against the patent on the grounds that the claimed subject-matter lacked novelty and inventive step and was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(a) and (b) EPC).

IV. In the decision under appeal, the opposition division held that the subject-matter of the main request was not novel. In contrast, that of auxiliary request 1 was held to be sufficiently disclosed, novel and inventive.

Claim 1 of the request held allowable by the opposition division reads as follows:

"*1. A method for detecting a known protein variant, wherein the sequence of the protein variant to be detected is known, in a sample comprising:*

(i) digesting the protein to produce a defined series of peptides;

(ii) ionising the peptides and selecting by mass spectrometry an ionised species of known mass/charge ratio indicative of the protein variant; and

(iii) subjecting the selected ionised species to collision induced dissociation and measuring a single derived ionised peptide species of known mass/charge ratio that confirm the presence of the protein variant in the sample."

V. The patent proprietors and the opponent each filed an appeal against the opposition division's decision. As both parties are appellants and respondents, in the following they will be referred to as "the patent proprietors" and "the opponent".

VI. In their statements of grounds of appeal, the parties requested that the decision be set aside.

In addition, the patent proprietors requested that the patent be maintained as granted or, alternatively, in the version held allowable by the opposition division.

The opponent filed documents A1 (including A1'), A2 and A3. It requested that the patent be revoked.

VII. In their reply to the opponent's statement of grounds of appeal, the patent proprietors replaced their previous claim requests with a new main request and a first auxiliary request.

Claim 1 of the first auxiliary request derives from claim 1 held allowable by the opposition division, with the addition of the following sentence at the end of step (i): "*and directly injecting the digested sample into a mass spectrometer*".

VIII. The board scheduled oral proceedings in line with the parties' requests. In preparation for these oral proceedings, the board issued its preliminary opinion. It noted, among other things, that the amendment introduced in claim 1 of the first auxiliary request had no apparent basis in the priority application. Consequently, document D1 would belong to the prior art of the claim.

IX. The patent proprietors replied to the board's preliminary opinion with a letter dated 24 December 2019. They re-filed the claims held allowable by the opposition division as their main request. In addition, they maintained (re-filed) their first auxiliary request and filed the claims of a second auxiliary request.

Claim 1 of the second auxiliary request reads as follows:

"*1. A method for detecting a haemoglobin S protein, wherein the sequence of the haemoglobin S to be detected is known, in a sample comprising:*

(i) digesting the haemoglobin S protein with trypsin to produce a defined series of peptides;

(ii) ionising the peptides and selecting by mass spectrometry an ionised species having a mass/charge ratio of 461.9 m/z and being indicative of the protein variant; and

(iii) subjecting the selected ionised species to collision induced dissociation and measuring a single derived ionised peptide species of mass/charge ratio 472.4 m/z that confirm the presence of the protein variant in the sample."

X. In a subsequent letter, the opponent objected to the admission of the main request and the first and second auxiliary requests.

XI. Oral proceedings were held before the board. The patent proprietors requested for the first time that documents A1 to A3 not be admitted. At the end of the oral proceedings, the board announced its decision.

XII. The opponent's arguments relevant to the present decision can be summarised as follows:

Document A1 should be admitted into the proceedings. It had been filed in response to the amended claims filed by the patent proprietors at the oral proceedings before the opposition division. Claim 1 had been amended to limit the number of derived ionic species measured in step (iii) to a single one. This limitation was unexpected since it had not been present in any of the claims in the proceedings to date. A1 was relevant on its face and had been filed at the first possible occasion.

The main request should not be admitted into the proceedings. The patent proprietors had filed it with their statement of grounds of appeal. In reply to the opponent's appeal, they chose to replace the request rather than counter the opponent's arguments. Following the board's preliminary opinion in preparation for the oral proceedings, the patent proprietors reinstated the request and once again failed to counter the opponent's arguments against it. The patent proprietors had not only failed to address the objections against the main request, especially those based on new documents A1 to A3; they had also prevented the board from giving an opinion on it. If the request were admitted, the patent proprietors' arguments on A1 to A3 would be heard for the first time at the oral proceedings. This would put the opponent at a disadvantage and an adjournment of the oral proceedings for preparation could be necessary.

D3 anticipated the method of claim 1 of the first auxiliary request. Step 5 of Figure 1 and Figure 4 disclosed the detection of a pre-characterised haemoglobin variant in a tryptic digest by electrospray ionisation tandem mass spectrometry (ESI-MS/MS). The working sample was directly injected into the mass spectrometer (page 695, right-hand column, paragraph 2). Although Figure 4 showed a complete mass spectrum, the presence of the haemoglobin variant was confirmed by measuring the shift of a single derived ionised species, namely fragment y"5; the m/z peaks that did not shift were not used to confirm the presence of the variant. According to paragraph [0032] of the patent, claim 1 did not exclude recording the whole mass spectrum. It merely required that the presence of the

protein variant be confirmed by measuring a single fragment ion.

The method of claim 1 of the first auxiliary request was not inventive starting from D3. D3 dealt with the identification of protein variants by ESI-MS/MS for their subsequent screening. It confirmed the sequence of a protein variant and identified the peptide ion and derived peptide ion which characterise that protein variant. If the method of claim 1 differed from D3 in that a single derived peptide ion is measured, the objective technical problem would be to develop a suitable method for screening, detecting or quantifying the protein variant characterised in D3.

Once the authors of D3 had identified the peptide and derived peptide ions which characterise a known protein variant in MS/MS, the obvious thing to do was to use those ions for screening. It was simply a matter of setting the MS/MS equipment in the multiple reaction monitoring (MRM) mode. This was a standard working mode on the priority date for detecting an analyte in a complex mixture with high specificity (see e.g. A1').

The second auxiliary request should not be admitted. It was a response to the lack of novelty objections based on A1 to A3 that were raised in the opponent's statement of grounds of appeal. However, the request had been filed years later, even after the board's preliminary opinion in preparation for the oral proceedings. The request was not convergent with auxiliary request 1 and, on its face, added subject-matter; it was an unallowable generalisation of an example in the application as filed. Moreover, the patent proprietors had not presented inventive step arguments in relation to the request. The arguments

would be heard for the first time at the oral proceedings.

XIII. The patent proprietors' arguments relevant to the present decision can be summarised as follows:

Document A1 should not be admitted. It could and should have been filed in the opposition proceedings. The limitation in step (iii) of claim 1 to measuring a single derived ionised species was not surprising. It was an amendment that the opponent should have been able to foresee.

The main request should be admitted into the proceedings. It was a reaction to the board's preliminary opinion questioning the validity of the priority claim. The request had been held allowable by the opposition division, so the arguments regarding the patentability thereof were on file from the opposition proceedings. With regard to the opponent's objections based on A1 to A3, there was no need for the patent proprietors to address these objections because the board had not yet decided whether to admit A1 to A3.

The method of claim 1 of the first auxiliary request was novel over D3. Figure 4 of D3 showed a complete mass spectrum and assigned each peak to its corresponding derived peptide ion. Therefore, D3 did not disclose the feature in step (iii) of claim 1 that a single derived peptide ion was measured for confirming the presence of the protein variant. The latter was confirmed by measuring all peaks and observing that one had shifted while the others had remained at their respective positions.

The method of claim 1 of the first auxiliary request was inventive. In D3, a protein variant was first identified by sequencing. Then, the protein sequence was confirmed by MS/MS. This confirmation entailed a complex and time-consuming analysis of MS data. In Figure 4 of D3, the protein variant was confirmed by the mass spectrum as a whole, namely by the shift of one peak and the maintenance of the others. The method of claim 1 differed in that a single derived peptide ion was measured for confirming the presence of the protein variant. This allowed a quick and easy detection of a known protein variant in a non-purified sample with high precision and accuracy. Therefore, the objective technical problem was to provide a quick, simple and very accurate method for identifying a known protein variant in a sample. Neither common general knowledge nor the cited prior art suggested that this problem could be reliably solved by focusing on a single derived peptide ion. In particular, there was no suggestion in D3 that its teaching could be combined with the use of MRM.

The second auxiliary request should be admitted. It was a genuine attempt to overcome the opponent's objections based on A1 to A3. The request was narrow and convergent and had clear support in the main example of the application as filed. It was not an unallowable generalisation of the example. Moreover, the request was limited to a particularly useful embodiment that was inventive at first sight: none of the cited prior art documents suggested detecting haemoglobin S by focusing on the ionic species recited in claim 1.

XIV. The parties' final requests relevant to this decision were as follows:

The patent proprietors requested that the patent be maintained in amended form on the basis of the claims of the main request or, alternatively, of the first or second auxiliary requests, all of which were filed with the letter dated 24 December 2019. They further requested that documents A1 to A3 not be admitted into the appeal proceedings.

The opponent requested that the decision under appeal be set aside and that the patent be revoked in its entirety. It further requested that the main request and the first and second auxiliary requests filed by the patent proprietors with their letter dated 24 December 2019 not be admitted into the appeal proceedings, and that documents A1 to A3 be admitted.

Reasons for the Decision

1. The appeal is admissible. It meets the requirements of Articles 106 to 108 and Rule 99(2) EPC.

2. Document A1 (including A1') - admittance

2.1 At the oral proceedings before the opposition division, the patent proprietors limited the number of derived ionised peptide species measured in step (iii) of the claimed method from "one or more" to "a single" one. The opposition division held that this limitation rendered the claimed subject-matter novel and inventive

and decided that the patent could be maintained on the basis thereof (minutes of the oral proceedings, page 3, paragraphs 5 and 6; decision under appeal, points 23.2.3 and 24.3).

2.2 The opponent stated that such an amendment could not have been foreseen. Therefore, the filing of A1, which included A1', with the statement of grounds of appeal was an appropriate reaction at the first possible occasion. The document was intended to show that the claimed subject-matter was neither novel nor inventive (opponent's statement of grounds of appeal, page 3, penultimate paragraph, to page 4, second paragraph; and page 7, last paragraph, to page 8, first paragraph). Therefore, A1 should be admitted into the appeal proceedings.

2.3 The board agrees with the opponent that the limitation introduced by the patent proprietors at the oral proceedings before the opposition division could not have been foreseen. The description did not explicitly refer to such a limitation and none of the claims previously on file contained it. In fact, the only passages of the application as filed which mention the feature "single ionised species" referred to the species selected in step (ii) rather than those measured in step (iii) (page 5, lines 30-31, and page 6, lines 10-11; and claim 7). Moreover, it was not apparent that a limitation from "one or more" to "a single" did not add subject-matter.

The content of A1 (including A1') is, on its face, relevant to the limitation at issue; it deals with the detection of a known protein in a sample using MRM, a MS/MS working mode in which a single derived ion is measured. Furthermore, A1 was filed at the first

possible occasion, namely with the opponent's statement of grounds of appeal.

Therefore, the board did not hold A1, including A1', inadmissible pursuant to Article 12(4) RPBA 2007.

3. Main request - admittance

3.1 The main request is the request held allowable by the opposition division. It was filed as auxiliary request with the patent proprietors' statement of grounds of appeal.

With its statement of grounds of appeal, the opponent filed documents A1 to A3 and raised objections relating to a lack of novelty and inventive step based on these documents. The patent proprietors replied by replacing their then pending claim requests, including the request held allowable by the opposition division, with new claim requests. In the new requests, the phrase "and directly injecting the digested sample into a mass spectrometer" had been introduced into claim 1.

In preparation for the oral proceedings, the board gave its preliminary opinion on the new claim requests. It questioned the validity of the priority claim because the phrase introduced into claim 1 could not be found in the priority application. This implied that D1 belonged to the prior art and anticipated the claimed subject-matter.

The patent proprietors then re-filed the request held allowable by the opposition division as their main request. As in their reply to the opponent's statement of grounds of appeal, they did not address the opponent's objections in relation to A1 to A3.

3.2 From the above sequence of events, it follows that the patent proprietors not only failed to address the opponent's objections in relation to the main request on two occasions, they also prevented the board from considering the request in its preliminary opinion. This behaviour put the opponent and the board in a situation in which admitting the main request would have resulted in hearing the patent proprietors' arguments in relation to A1 to A3 for the first time at the oral proceedings. This could have required an adjournment of the oral proceedings.

3.3 The patent proprietors argued that the main request had been filed as a reaction to the board's preliminary opinion that the subject-matter of the previous requests was not disclosed in the priority application. They also stated that they did not need to address the objections relating to A1 to A3 because the board had not yet decided on the admittance of these documents.

3.4 These arguments are inconsistent. The patent proprietors withdrew the request held allowable by the opposition division in reaction to the opponent's statement of grounds of appeal introducing A1 to A3 and related objections. If the patent proprietors considered it possible that the request would not withstand the objections raised by the opponent, this was still the case after the board's preliminary opinion. When the request was re-filed, A1 to A3 were still on file and the patent proprietors had not objected to their admittance. Such an objection was made for the first time at the oral proceedings before the board.

Regarding the board's preliminary opinion, it did indeed call the validity of the priority claim into question. However, this issue was triggered by the amendment introduced by the patent proprietors with their reply to the opponent's statement of grounds of appeal, i.e. the addition of the phrase "directly injecting the digested sample into a mass spectrometer" into the claims. The validity of the priority claim had been an issue since the opposition proceedings due to the citation of intermediate document D1 (decision under appeal, points 18.1 and 18.2). Nevertheless, the patent proprietors filed an amendment based on a passage from the application as filed (page 15, lines 5-9) that had no correspondence in the priority application. Thus, they could not ignore the fact that the amendment was a potential source of problems in relation to the priority claim. The board is therefore not convinced that the re-filing of the main request was a legitimate reaction to its preliminary opinion. This is even more the case considering that the patent proprietors had not addressed the opponent's objections against the main request and that they had also prevented the board from giving an opinion on it.

Lastly, the patent proprietors' contention that they did not need to counter the objections raised in relation to A1 to A3 because the board had not yet decided on their admittance must fail. First, the patent proprietors did not object to the admittance of A1 to A3 until the oral proceedings before the board. Second, the board's preliminary opinion indicated (point 9) that the issue of novelty in relation to A1 to A3 could be discussed at the oral proceedings.

3.5 Therefore, for the sake of procedural economy and given the potential risk of needing to adjourn the oral

proceedings, the main request was not admitted pursuant to Article 13(1) and (3) RPBA 2007.

4. First auxiliary request - admittance

The first auxiliary request was filed with the patent proprietors' reply to the opponent's statement of grounds of appeal. It was maintained and re-filed with the letter dated 24 December 2019. The opponent objected to the admittance of the request but did not submit proper reasons as to why the request should not be admitted.

In the board's view, the first auxiliary request was a legitimate response to the filing of A1 to A3 and the related objections raised by the opponent at the outset of the appeal proceedings. Furthermore, the request was filed at the first possible occasion. Therefore, the board did not hold the first auxiliary request inadmissible pursuant to Article 12(4) RPBA 2007.

5. First auxiliary request - novelty over D3

5.1 D3 describes a systematic approach for the rapid identification of haemoglobin variants in a digested sample (abstract; section "Optimisation of Strategy" on pages 693 and 694; and Figure 1). The approach combines the use of conventional phenotypic methods with ESI-MS/MS. It requires only a small amount of whole blood and no pre-analytical steps; the sample is introduced (i.e. injected) directly into the ESI source of the MS/MS equipment (page 694, right-hand column, paragraph 3, last sentence, and page 695, right-hand column, paragraph 2, first sentence).

At a first stage of the approach, the mass difference between normal and variant haemoglobin chains is determined (steps 2 and 3 in Figure 1, and Figure 2). The two haemoglobin forms are then digested and analysed by ESI-MS. A comparison of the two mass spectra allows the identification of the peptide ion from the haemoglobin variant which bears the mutation responsible for the mass difference in relation to normal haemoglobin (page 694, left-hand column, paragraph 3, Step 4 in Figure 1, and Figure 3). In a subsequent step, the identified peptide ion and the corresponding peptide ion from normal haemoglobin are fragmented and analysed by ESI-MS/MS. A comparison of the resulting fragmentation spectra allows the identification of the derived peptide ion carrying the mutation of the haemoglobin variant (page 694, right-hand column, paragraph 1, last sentence, Step 5 in Figure 1, and Figure 4). In the particular example illustrated in D3, the peptide ion bearing the mutation had an m/z ratio of 480.7 (Figure 3). The m/z ratio of the derived peptide ion was 602.5 (Figure 4).

5.2 The opponent argued that the method of claim 1 was anticipated by D3. It conceded that in D3 (Figure 4) the whole spectrum of derived peptide ions had been recorded, not just a single peak. However, the presence of the protein variant was confirmed by measuring a single peak, namely the one corresponding to the derived peptide ion bearing the mutation. The other peaks were not used. Moreover, in light of paragraph [0032] of the patent, step (iii) of claim 1 did not exclude recording the whole spectrum of derived peptide ions.

5.3 The board disagrees. The presence of the protein variant in Figure 4 of D3 is confirmed by two

concurrent events: the observation of a shifted peak corresponding to the derived peptide ion bearing the mutation of the protein variant, and the maintenance of the remaining peaks as in the spectrum of the non-mutated protein. In fact, Figure 4 assigns each peak to its corresponding derived peptide ion. Therefore, D3 does not disclose the feature in step (iii) of claim 1 that the presence of the protein variant is confirmed by measuring a single derived peptide ion of known m/z ratio.

With regard to paragraph [0032] of the patent, although it refers to measuring the series of ionised peptide fragments, it does not define the subject-matter of claim 1; the paragraph merely describes what may happen when the selected ionised species is submitted to collision-induced dissociation (see also paragraph [0031]).

5.4 Therefore, the method of claim 1 is novel over the content of D3 (Article 54 EPC).

6. First auxiliary request - inventive step

6.1 Claim 1 defines a method for detecting a known protein variant in a sample. It involves digesting the protein and analysing the digest by MS/MS. The method is characterised by the fact that the MS/MS equipment measures a single derived peptide ion of known m/z ratio which confirms the presence of the protein variant (step (iii) of claim 1). Hence, claim 1 requires prior knowledge of the m/z ratio of both the peptide ion and the derived peptide ion which confirm the presence of the protein variant in the sample.

As correctly stated by the opponent (statement of grounds of appeal, page 2, last paragraph), the MS/MS technique defined in claim 1 corresponds to the high sensitivity scan mode called multiple reaction monitoring, or "MRM". MRM was a standard working mode in MS/MS instruments on the priority date, and this was not disputed by the patent proprietors. The patent itself shows that MRM was a well-known technique; it repeatedly refers to MRM without needing to explain its underlying principles, and discloses the use of MRM in the examples without further ado (paragraphs [0044] to [0049], [0057] to [0059], [0078], [0088], [0090] and [0091]).

MRM is a MS/MS technique for detecting and quantifying analytes. It is based on the monitoring of a specific fragmentation reaction which characterises the analyte, the so-called "transition". In MRM, the first MS instrument ionises the sample and selects an ion which characterises the analyte, the "parent ion". The parent ion is then submitted to fragmentation and the second MS instrument measures a single fragment ion which confirms the presence of the analyte, the "product ion" or "derived ion". The parent ion/derived ion pair constitutes the monitored transition indicative of the presence of the analyte in the sample. In the patent (paragraphs [0045] to [0049]), five haemoglobin variants were identified by MRM. Their transitions are indicated in parentheses: haemoglobin S (461.9/472.4), C (694.7/694.7), D^{Punjab} (1377.8/1377.8), O^{Arab} (1249.7/1249.7) and E (916.8/916.8). These variants were subsequently screened by MRM in 200 samples (paragraphs [0068] to [0073]).

6.2 The parties did not dispute that D3 is a suitable starting point for the assessment of inventive step. Neither does the board.

6.3 The method of claim 1 differs from the disclosure of D3 in that the presence of the protein variant in the sample is confirmed by measuring a single derived peptide ion (see point 5.3 above).

6.4 It was common ground that the effect brought about by this difference is that a known protein variant can be detected in a sample in a rapid, simple and accurate manner.

6.5 Therefore, the objective technical problem to be solved by the method of claim 1 is to provide a method for the rapid, simple and accurate detection of a protein variant of known sequence in a sample.

6.6 The solution proposed in claim 1 uses MS/MS to monitor a single transition which characterises the known protein variant. In other words, claim 1 proposes analysing the sample by MRM, as illustrated in the patent examples.

The board is satisfied that the method of claim 1 solves the problem. This was not disputed by the opponent.

6.7 However, the solution proposed does not involve an inventive step.

MRM was a standard MS/MS working mode on the filing date (see point 6.1, second paragraph, above). Furthermore, it was common general knowledge on that date that the presence of a known analyte in a complex

mixture could be rapidly and accurately established by MRM. This is apparent from document A1', which underlines the higher sensitivity of MRM and states that its typical application is the rapid screening of "dirty" samples for known analytes.

A1' is the operation manual for the mass spectrometer Quatro II used for MRM in A1. Although A1' does not bear any publication date, the patent proprietors did not call into question that its content indeed reflects that of the user's manual for the spectrometer used in A1. Thus, the board considers A1' to be representative of the common general knowledge on the priority date.

It follows that, starting from D3, which establishes the transition that characterises a known haemoglobin variant in MS/MS (480.7/602.5 in the specific example of D3), the obvious way of detecting the variant in a sample in a rapid, simple and accurate manner was to work in the MRM mode.

6.8 Claim 1 of the first auxiliary request therefore does not involve an inventive step. Thus, the request does not fulfill the requirements of Article 56 EPC.

7. *Second auxiliary request - admittance*

The patent proprietors filed the second auxiliary request in response to the board's preliminary opinion and in view of documents A1 to A3 (letter of 24 December 2019, page 2, section "Allowability of the requests"). The opponent objected to the admittance of the request.

The patent proprietors could have filed the second auxiliary request with their reply to the opponent's

statement of grounds of appeal, as a reaction to the filing of A1 to A3. However, they chose to react by amending the claims with a feature taken from a passage in the description that had no correspondence in the priority application. The patent proprietors could not ignore the fact that this strategy would raise concerns regarding the validity of the priority claim. This had been an issue in the opposition proceedings due to the citation of intermediate document D1 (see the decision under appeal, points 18.1 and 18.2). As the board's preliminary opinion (point 8) merely pointed at a fact that was apparent from the beginning, the patent proprietors cannot take the board's opinion as an opportunity to change their case at a late stage of the proceedings.

Furthermore, the second auxiliary request raised concerns regarding added subject-matter at first sight. It had been taken from the example on haemoglobin S in the application as filed but left some features out, e.g. the fact that ions were produced by electrospray or that the sample was obtained from digesting whole blood with trypsin.

Consequently, the board decided not to admit the second auxiliary request into the proceedings pursuant to Article 13(1) and (3) RPBA 2007.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated