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Datasheet for the decision of 23 July 2024

Case Number: T 1423/22 - 3.3.08

Application Number: 14842603.4

Publication Number: 3041576

IPC: G01N33/68, G01N33/70

Language of the proceedings: EN

Title of invention:
Methods for detecting renal disease

Patent Proprietor:
IDEXX Laboratories, Inc.

Opponent:
Immundiagnostik AG

Headword:
Renal disease/IDEXX

Relevant legal provisions:
EPC Art. 52(2), 56, 100(a)
RPBA 2020 Art. 12(2), 12(4), 12(6)

Keyword:
Patentable invention - technical and non-technical features - technical character of the invention
Inventive step - (yes)
Grounds for opposition - fresh ground admitted (no)
Late-filed evidence and late-filed objection - admitted (no)

Decisions cited:
G 0010/91, G 0001/19, T 0641/00

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Case Number: T 1423/22 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 23 July 2024

Appellant: (Opponent)	Immundiagnostik AG Stubenwald-Allee 8a 64625 Bensheim (DE)
Representative:	Benedum, Ulrich Max Nebens IP Patente Marken Designs Oberföhringer Strasse 172 81925 München (DE)
Respondent: (Patent Proprietor)	IDEXX Laboratories, Inc. One Idexx Drive Westbrook, ME 04092 (US)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 7 April 2022 rejecting the opposition filed against European patent No. 3041576 pursuant to Article 101(2) EPC**

Composition of the Board:

Chair	M. Montrone
Members:	A. Schmitt
	L. Bühler

Summary of Facts and Submissions

I. The appeal of the opponent (appellant) is against the opposition division's decision to reject the opposition filed against European patent No. 3 041 576 (the patent). The patent was granted on the basis of European patent application No. 14 842 603.4, which had been filed as an international application published as WO 2015/035155 (the application).

II. The opposition proceedings were based on the grounds for opposition under Article 100(a) EPC in relation to novelty (Article 54 EPC), inventive step (Article 56 EPC) and exclusion from patentability (Article 52(2)(a) EPC).

III. With the statement of grounds of appeal, the appellant submitted, *inter alia*, a document designated "E1".

IV. In reply to the appeal, the patent proprietor (respondent) submitted, *inter alia*, sets of claims according to auxiliary requests 1 to 14. The set of claims as granted (main request) consists of 14 claims; claim 1 is the only independent claim.

Claim 1 of the main request reads as follows:

"1. A method for estimating glomerular filtration (GFR) rate in an animal subject, the method comprising:
measuring the concentration of free symmetrical dimethylarginine (SDMA) in a blood sample from the subject;
measuring the concentration of creatinine in a blood sample from the subject; and

comparing a value resulting from an equation comprising the product of the concentration of creatinine and the concentration of free SDMA to one or more standard values that correlate to glomerular filtration rate in the animal subject."

V. The board summoned the parties to oral proceedings in accordance with their requests and, in a communication under Article 15(1) RPBA, expressed its preliminary opinion on some of the matters raised.

VI. Oral proceedings were held as scheduled.

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

D1 M. B. Nabity *et al.*, J. Vet. Intern. Med. 27, 2013, 733

D2 R. J. MacAllister *et al.*, Nephrology Dialysis Transplantation 11, 1996, 2449-2452

D6 US 2010/0035274 A1

D8 A. Koch *et al.*, article ID 413826, Mediators of Inflammation, 2013, 1-8

E1 Print-out of a Wikipedia article on the coefficient of determination

VIII. The appellant's arguments, where relevant to the decision, are summarised as follows:

Main request (patent as granted)
Admittance of a fresh ground for opposition

The new ground for opposition under Article 100(c) EPC that was raised in the statement of grounds of appeal was *prima facie* relevant and should therefore be considered by the board under Article 114(1) EPC.

Admittance of an objection based on document D8 (Article 12 RPBA)

The fact that document D8 was mentioned in the notice of opposition but was not relied on during the opposition proceedings did not constitute a reason for not admitting it into the proceedings. The content of document D8 reflected common general knowledge and demonstrated the typical actions of the skilled person in the relevant technical field. It supported the same line of argument as document D2.

Inventive step (Article 100(a) EPC and Article 56 EPC)

Document D1 (see the figure, for example) and document D6 (see paragraphs [0005], [0006], [0008], [0009], [0011], [0069] to [0071], [0189] and [0190], and Figures 2 and 3) were both suitable starting points for the assessment of inventive step as they both concerned methods for assessing the glomerular filtration rate (GFR) in an animal. Both documents disclosed steps of measuring free symmetric dimethylarginine (SDMA; "step (i)" of claim 1) and serum creatinine (sCr; "step (ii)" of claim 1) in a blood sample from an animal and disclosed that both parameters correlated with the GFR.

The claimed method differed from this disclosure in that it comprised a further step of comparing a value resulting from an equation comprising the product of the concentration of sCr and the concentration of SDMA to one or more standard values that correlated to the GFR in the animal subject ("step (iii)" of claim 1).

This distinguishing feature was not a technical feature, and it did not contribute to the technical character of the alleged invention either, as it was limited to feeding the results of measurement steps (i) and (ii) into an equation and comparing the resulting value to one or more standard values. There was no interaction of step (iii) with steps (i) and (ii) as the measurement steps were not affected by the result of step (iii).

The mere comparison of a calculated value to one or more standard values that correlated to the GFR did not contribute to an estimation of the GFR since no instruction was given in the claim as to how the estimation of the GFR was obtained from this comparison.

Claim 1 stipulated that the GFR could be estimated in an animal subject by comparing the product of measured concentration values of sCr and SDMA to one or more standard values that had been obtained by the same measurements and calculations in the same animal subject. The claimed method hence contained a mathematical circular reasoning.

Moreover, the patent did not teach a general range of standard values that correlated with a particular GFR; nor did the claim provide technical instructions on how to accurately determine these standard values, which were in any case specific to each individual and/or were affected by factors other than the GFR, as was evident from paragraphs [0006] and [0008] of document D6, for example.

Like the standard values, the weighting factors P and Q could also only be determined if the GFR had been

measured by a different method. This was a further reason why step (iii) of claim 1 was non-technical and instead merely a mathematical circular reasoning. No explanation was presented in the patent as to why the weighting factors P and Q differed between Examples 6 and 7.

Examples 6 and 7 of the patent merely plotted measured sCr and SDMA concentration values and their products against the GFR measured by iohexol clearance (see paragraph [0139] and Figures 5 to 7 of the patent) and employed weightings of the measured concentration values (see Figure 8 of the patent) by regression analysis, a method that was possible only if the actual GFRs were known. Hence, these examples did not relate to the claimed method of estimating the GFR in an animal subject but to a retrospective analysis of measured data, i.e. the opposite of the claimed method.

The objective technical problem was thus the provision of an alternative way of mathematically treating results obtained from measurements of blood samples from animal subjects.

The solution proposed in the claim, i.e. the multiplication of the sCr and SDMA concentration values, was obvious for two reasons. Firstly, it was an arbitrary mathematical transformation and a basic arithmetic operation. The multiplication of probabilities was a typical operation when combining independent probabilities.

Secondly, the ratio of the two measured concentration values was encompassed by the term "product" as used in the claim, because it was possible for the weighting factors P and Q, which were also encompassed by the

term "product" (see dependent claim 4, for example), to be negative (see, for example, paragraphs [0055], [0144] and [0149] of the patent). If one of these weighting factors was positive and the other one negative, the result of the product was a ratio of the two values. The provision of ratios of measured values when aiming at higher levels of sensitivity and specificity was a standard procedure in clinical diagnostics, as was evident from Figure 2 on page 2451 of document D2, for example.

The claimed method did not involve an inventive step over the teaching of document D1 or document D6 combined with that of document D2.

IX. The respondent's arguments, where relevant to the decision, are summarised as follows:

Main request (patent as granted)
Admittance of a fresh ground for opposition

Introducing a new ground for opposition after the notice of opposition has been filed was not allowed. Filing such a new ground for opposition for the first time on appeal was an abuse of procedure and therefore it should not be admitted into the appeal proceedings.

Admittance of an objection based on document D8 (Article 12 RPBA)

Document D8 had been filed with the notice of opposition but was only mentioned in the list of cited documents. It was hence not clear under which ground for opposition document D8 had been cited, nor what exactly it disclosed. In view of this, none of the arguments based on document D8 should be admitted into

the appeal proceedings. The assertion that document D8 reflected common general knowledge was a new argument presented for the first time during the oral proceedings before the board and therefore should not be admitted. It was also incorrect, as document D8 was not a textbook. Nor was document D8 *prima facie* relevant, as the line of argument based thereon was the same as that based on document D2.

Admittance of document E1 and the line of argument under the heading "Digression" (Article 12 RPBA)

No reasons were apparent as to why document E1, a Wikipedia article, could not have been filed during the opposition proceedings. The same was true for the new line of argument under the heading "Digression", which had been raised for the first time on appeal and which was based, *inter alia*, on document E1. Neither document E1 nor this line of argument should be admitted into the appeal proceedings.

Inventive step (Article 100(a) EPC and Article 56 EPC)

Document D1 contemplated the use of both SDMA and sCr for the assessment of renal function (see the figure and the last paragraph) and was the most suitable closest prior art. The claimed method differed from that disclosed in document D1 in that a value resulting from an equation comprising the product of the concentrations of sCr and SDMA was compared to one or more standard values that correlated to the GFR in the animal subject ("step (iii)").

In combination with steps (i) and (ii), step (iii) of the claimed method provided the estimated GFR value and hence contributed to the technical character of the

claim and the desired technical effect. Comparing (the product of) measured values to standard values that correlated to the GFR allowed the estimated GFR to be read out. This procedure was common to all diagnostic methods and had to be taken into account for the assessment of inventive step.

Paragraph [0056] of the patent described how standard values could be obtained. The preparation of standard curves and the weighting of measured values in a regression analysis were part of the skilled person's common general knowledge. The appellant's objections in this regard were disguised objections relating to sufficiency of disclosure.

The technical effect of the distinguishing feature was higher precision when estimating the GFR, as was evident from Examples 6 and 7 of the patent, in which this effect was demonstrated for two different animal species (dogs and cats). There was no evidence on file indicating that the results shown in these examples were incorrect.

Document D1 measured both concentration values but lacked any teaching as to how they should be combined in order to estimate the GFR, and merely speculated that SDMA might be a useful addition to sCr. It was not obvious to the skilled person on the basis of this disclosure that a product of the concentration values could be obtained in order to solve the technical problem of providing an improved method for estimating the GFR.

Document D2 was not relevant to the claimed method as it did not disclose that the concentration values of SDMA and sCr should be multiplied together to obtain a

product. Instead, it employed ratios of the two concentration values. These ratios were the result of a different mathematical operation and did not fall under the term "product". Hence, the claimed method was not obvious when the disclosure in document D1 was combined with that in document D2.

Similar considerations applied with respect to document D6 as the closest prior art. In fact, document D6 lacked any incentive to combine the two parameters sCr and SDMA in order to estimate the GFR, as it was merely concerned with finding an alternative for sCr (see, for example, paragraphs [0006] and [0046]) in view of the known disadvantages associated therewith (see paragraphs [0005] and [0006]). The claimed method was therefore not obvious based on document D6 alone or in combination with document D2.

X. The parties' requests, where relevant to the decision, were as follows:

The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked. It also requested that document E1 and the objection against claim 10 under the ground for opposition according to Article 100(c) EPC be admitted into the appeal proceedings.

The respondent (patent proprietor) requested that the appeal be dismissed, i.e. that the patent be maintained as granted (main request). The respondent further requested that the new ground for opposition according to Article 100(c) EPC not be admitted into the appeal proceedings, that documents D8 and E1, arguments and objections based on document D8 and the new line of

argument denominated "Digression" not be admitted into the appeal proceedings.

Reasons for the Decision

Main request (patent as granted)
Admittance of a fresh ground for opposition

1. In the statement of grounds of appeal, the appellant raised, for the first time, an objection based on the ground for opposition under Article 100(c) EPC (see also section II. above). The respondent argued that this ground for opposition should not be admitted into the appeal proceedings.

2. According to decision G 10/91 of the Enlarged Board of Appeal (OJ 1993, 420, Headnote 3), fresh grounds for opposition may only be considered in appeal proceedings with the approval of the patentee. Since in this case the respondent, i.e. the patentee, opposed the admittance of the above-identified objection into the appeal proceedings (see point 1. above), there is no scope for considering this objection.

3. The board therefore decided not to take into consideration the objection raised on appeal based on the ground for opposition under Article 100(c) EPC.

Admittance of an objection based on document D8
(Article 12 RPBA)

4. Document D8 was filed with the notice of opposition, i.e. within the time limit pursuant to Article 99(1) EPC, and therefore forms part of the opposition proceedings. The opposition division

therefore had no discretionary power under Article 114(2) EPC not to admit this document.

5. However, in the opposition proceedings document D8 was not used to substantiate any objections that had been raised. The appellant's assertion in the statement of grounds of appeal that the claimed method lacked an inventive step in view of the disclosure in either of documents D1 or D6 combined with the disclosure in document D8 therefore represents an amendment of the appellant's case that may only be admitted into the appeal proceedings at the discretion of the board (Article 12(2) and (4) RPBA).

6. The appellant did not provide any reasons why it had not submitted this objection until the appeal proceedings. In fact, since document D8 had been submitted with the notice of opposition and a similar objection had been made in relation to the disclosure of document D2, the board cannot see any reason why the appellant had not raised the objection based on document D8 in the opposition proceedings, nor can it identify any particular circumstances of the appeal case that would justify the admittance of the objection on appeal. Contrary to the appellant's allegation, document D8, a research article, does not reflect common general knowledge.

7. Consequently, and in line with the provisions under Article 12(6) RPBA stipulating that a board must not admit, *inter alia*, objections or evidence which should have been submitted in the proceedings leading to the decision under appeal, the board decided not to admit into the appeal proceedings the objection based on document D8.

Admittance of document E1 and the line of argument under the heading "Digression" (Article 12 RPBA)

8. With the statement of grounds of appeal, the appellant submitted a new document (E1) and a new line of argument based on this document, under the heading "Digression", in which it questioned whether, as considered in the decision under appeal, Examples 6 and 7 of the patent demonstrated an improvement when estimating the glomerular filtration rate (GFR) using the product of the measured free symmetrical dimethylarginine (SDMA) and serum creatinine (sCr) concentration values compared to using either measured concentration value alone. The appellant did not provide any reasons why it had not submitted this objection until the appeal stage.

9. It was asserted in the patent that Examples 6 and 7 do demonstrate an improvement in the estimation of the GFR as a result of combining sCr and SDMA values by multiplication compared to using either value alone (see paragraphs [0143] and [0148] of the patent). Consequently, document E1 and the objection under the heading "Digression" do not constitute a response to a new development of the case triggered by the decision under appeal; rather, they should have been presented in the opposition proceedings.

10. In view of this and in line with the provisions under Article 12(6) RPBA (see point 7. above), the board decided not to admit document E1 or the objection under the heading "Digression" into the appeal proceedings.

Inventive step (Article 100(a) and Article 56 EPC) - claim 1

11. The claim concerns a method for estimating the GFR in an animal subject and comprises the technical steps of measuring the concentration of free SDMA and that of sCr in a blood sample from the subject ("step (i)" and "step (ii)"), and a step of "comparing a value resulting from an equation comprising the product of the concentration of creatinine and the concentration of SDMA to one or more standard values that correlate to glomerular filtration rate in the animal subject" ("step (iii)").

12. Step (iii) of the claimed method hence relates to a mathematical operation (multiplication of two measured values together) and to a mental act (comparing the value of the resulting product to one or more standard values), i.e. is non-technical. The claim therefore consists of a mixture of technical and non-technical features.

13. Documents D1 and D6 were proposed as the closest prior art.

Document D1 as the closest prior art

14. Document D1 discloses measuring concentration levels of both sCr and SDMA in dogs and demonstrates their correlation with the GFR measured by iohexol clearance (see the figure and the second to fourth paragraphs). The document concludes that SDMA "*correlates well with GFR ... and might be a useful addition to sCr in the assessment of renal function*" (see the last paragraph).

15. The claimed method differs from that proposed in document D1 in step (iii) (see point 11. above), i.e.

in that a value resulting from an equation comprising the product of the sCr and SDMA concentration values is compared to one or more standard values that correlate to the GFR in the animal subject. This was not contested.

16. However, the appellant contested that this distinguishing feature, which was non-technical, contributed to the technical character of the claimed method.

17. If a claimed invention consists of a mixture of technical and non-technical features, as is the case with the present claim 1 (see points 11. and 12. above), and has a technical character, i.e. solves a technical problem, all of the features that contribute to that technical character, i.e. that solve a technical problem by providing a technical effect, are to be taken into account in the assessment of inventive step, even if these features are non-technical *per se* (T 641/00, Headnote 1, and Reasons 5 and 6; G 1/19, OJ EPO 2021, A77, Reasons 140).

18. The claimed method has a technical character as it solves the technical problem of estimating the GFR, a clinical parameter relevant in renal diseases, based on measuring the blood concentrations of two markers (SDMA and sCr). Step (iii), which is non-technical, contributes to solving this technical problem, together with measurement steps (i) and (ii), because the GFR estimated for an animal subject is determined by the recited calculation of a product of measured SDMA and sCr concentration values and a comparison of this product to one or more standard values that correlate to the GFR in the animal subject.

19. It is noted that the claim lacks an explicit link of step (iii) to the actual estimation of the GFR as it does not recite that by comparing the product of the sCr and SDMA concentration values to one or more standard values that correlate to the GFR in the animal subject the value of the correlated GFR is read out, and that this correlated GFR represents the GFR estimated for the animal subject. However, despite this deficiency, the skilled person immediately understands from the wording of the claim that the comparison to standard values, which correlate to a particular GFR, directly and necessarily leads to the estimation of the GFR in the animal subject for which the blood markers were measured. The missing explicit link of how the steps of the claimed method result in the estimation of the GFR can thus be implicitly understood from the method steps.

20. Indeed, if the claimed method were to be interpreted as nothing more than a mere comparison of the product of the measured sCr and SDMA concentration values to one or more standard values that correlate with the GFR in the animal subject, without linking this comparison to the estimated GFR in the animal subject, the purpose of the claimed method - estimating the GFR in an animal subject - would not be achieved.

21. However, since this purpose of the claimed method is expressed in the claim as a functional feature, not achieving this effect by the steps of the claimed method would result in a lack of sufficiency of disclosure. Yet no objection on sufficiency of disclosure was raised by the appellant (see also section II. above).

22. Contrary to the appellant's view, step (iii) hence contributes, together with the technical steps (i) and (ii) of measuring the blood sCr and SDMA concentrations, to providing a method for estimating the clinical parameter GFR in an animal subject and hence contributes to the technical character of the claimed method.

Technical effect and objective technical problem

23. According to the patent, the product of the concentration values of sCr and SDMA allows for an improved estimation of the GFR compared to either concentration value alone (see paragraphs [0143] and [0148], Examples 6 and 7, and Figures 7 and 11 of the patent). However, as document D1 already suggests measuring the concentration values of both sCr and SDMA for the assessment of renal function (see the last paragraph of document D1 and point 14. above), an improvement over the method proposed in document D1 cannot be acknowledged.

24. The objective technical problem is therefore the provision of an alternative method for estimating the GFR.

25. The appellant contested that the objective technical problem could be formulated in this manner. The claim required that the standard values must be obtained in the same (individual) animal subject for which the GFR was to be estimated by the same measurements and calculations, which resulted in a "circular mathematical reasoning". According to the appellant, the objective technical problem was thus the provision of an alternative way of mathematically treating

results obtained from measurements of blood samples from animal subjects.

26. The appellant's claim construction cannot be followed however. The expression "standard values that correlate to glomerular filtration rate in the animal subject" defines that these values are applicable to the animal subject for which the GFR is to be estimated, but not that these standard values have to be determined, first, in the same (individual) animal subject.

27. The appellant's assertion in this context that neither the claim nor the patent disclosed how the standard values recited in the claim could be obtained is not persuasive either, as the determination of such standard values lies within the skilled person's common general knowledge. Indeed, standard values for markers are commonly used in methods in which the concentration of a clinical marker is determined in a subject's sample and then compared to standard values of that clinical marker. The standard values are obtained from a population of healthy and/or diseased subjects, as is also described in paragraphs [0056] and [0057] of the patent, for example.

28. In this context, the appellant also referred to individual variations in the concentration of the markers, influenced by external factors, for instance. However, this fact is routinely taken into account by establishing the standard values from a representative population of subjects and expressing them as ranges and does not hinder the skilled person from establishing standard values for the product of the sCr and SDMA concentration values correlating to the GFR for a given animal species.

29. Moreover, Figure 7 of the patent discloses a standard curve that correlates the value of this product with GFR and that was established for the population of dogs analysed in Example 6. Example 7 of the patent discloses the same analysis for a population of cats (Figure 11). It is therefore incorrect that the patent does not teach the skilled person how to accurately determine standard values or that, as also asserted by the appellant, the standard values for the product of the sCr and SDMA concentration values are specific to each individual animal subject. According to Examples 6 and 7 of the patent, these standard values are species-specific, as would have been expected by the skilled person, and no evidence to the contrary was submitted by the appellant.

30. In this context, the appellant also objected to the fact that the patent did not explain why weighting factors P and Q (also recited in dependent claim 4) differed between Examples 6 and 7. However, since in these examples different species were analysed (dogs and cats), this difference is not surprising.

31. The appellant also pointed to the fact that Examples 6 and 7 of the patent disclose a retrospective analysis of measured data and do not assess the GFR in an animal subject that had not been used for establishing the standard curve. The board fails to understand how this observation is relevant to the assessment of inventive step of the claimed method. Examples 6 and 7 demonstrate that the product of the sCr and SDMA concentration values correlates better with the GFR than either concentration value alone and therefore provide proof of concept of the claimed method. It is not necessary for a patent's working examples to carry out the claimed method.

32. The appellant's assertions that the claim was based on a "circular mathematical reasoning", that the skilled person could not establish the required standard values for the product of the sCr and SDMA concentration values, and that the objective technical problem was the provision of an alternative way of mathematically treating results obtained from measurements of blood samples from animal subjects are therefore not persuasive.

Obviousness

33. Document D1 teaches that SDMA "*might be a useful addition to sCr in the assessment of renal function*" (see the last paragraph) and therefore proposes assessing renal function based on the serum concentrations of both sCr and SDMA. Document D1 is silent, however, on what the addition of SDMA to sCr could look like.

34. The sCr and SDMA concentration values are measured parameters, and not, contrary to the assertion of the appellant, probabilities. The board therefore cannot see how the theory of probabilities could be relevant to the measured parameters in the claim. The appellant's argument that it was obvious to use the product of the sCr and SDMA concentration values for estimating the GFR as these values were independent probabilities that could be multiplied together is speculative since it lacks any support from the prior art and is thus not persuasive.

35. Moreover, the board is not persuaded by the appellant's assertions that a ratio of SDMA and sCr concentration values fell under the expression "product" used in the

claim and that the provision of the ratio of sCr and SDMA concentrations was obvious from Figure 2 on page 2451 of document D2, for example. The reason for this is that a ratio is the result of a division, which is a different mathematical operation than a multiplication resulting in a product. According to the common meaning of these expressions, the "ratio" of two values is hence not encompassed by the "product" of two values.

36. It is true that the patent discloses that weighting factors P and Q could be negative (see, for example, paragraph [0055]) and that the patent contemplates the relationship of the inverse of the product of the sCr and SDMA concentration values to the GFR (see, for example, Figure 8). However, paragraph [0055] merely teaches that both weighting factors can be negative, in which case the inverse of the product is obtained, but not that one weighting factor could be negative and the other one positive. The patent's description therefore does not teach that the expression "product" used in the claim could be a "ratio", contrary to the common meaning of these terms.

37. Consequently, document D2, which discloses the ratio but not the product of SDMA and sCr concentration values, cannot support the notion that it was obvious to estimate the GFR in an animal subject based on the product of the SDMA and sCr concentration values measured in a blood sample from the animal subject.

38. Thus, none of the appellant's arguments as to why the claimed method was obvious when selecting document D1 as the starting point for the assessment of inventive step are persuasive.

Document D6 as closest prior art

39. Similar considerations apply when selecting document D6 as the closest prior art instead of document D1. Document D6 discloses SDMA as an alternative diagnostic marker for sCr (see paragraphs [0006] and [0064], for example), but does not propose combining the SDMA and sCr blood concentrations in order to estimate the GFR and assess renal disease.

40. In view of this teaching in document D6 and the disclosure in paragraphs [0143] and [0148] of the patent that the product of the concentration values of sCr and SDMA allows for an improved estimation of the GFR compared to either concentration value alone (see also point 23. above), the technical effect of the claimed method compared to that in document D6 is an improved estimation of the GFR.

41. The technical problem to be solved thus resides in the provision of an improved method for estimating the GFR in an animal subject.

42. In view of the experimental data in Examples 6 and 7 of the patent, the board is satisfied that the method of claim 1 solves this problem.

43. Furthermore, as regards obviousness the employment of the product of the sCr and SDMA concentration values in order to achieve this effect was not obvious for the same reasons as those outlined above with respect to document D1 as the closest prior art (see points 34. to 37. above).

44. The claimed method hence involves an inventive step irrespective of whether document D1 or document D6 is

used as the starting point and whether or not the teaching of document D2 is taken into account as well (Article 56 EPC).

45. None of the grounds for opposition that were admissibly raised by the appellant prejudices the maintenance of the patent as granted.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

L. Malécot-Grob M. Montrone

Decision electronically authenticated