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Datasheet for the decision of 17 January 2023

Case Number: T 2046/19 - 3.3.04

Application Number: 13707113.0

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Language of the proceedings: EN

Title of invention:
Prediction of outcome in patients with chronic obstructive pulmonary disease

Patent Proprietor:
B.R.A.H.M.S GmbH

Opponent:
Radiometer Medical ApS

Relevant legal provisions:
EPC Art. 83

Keyword:
Sufficiency of disclosure - (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 2046/19 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 17 January 2023

Appellant: (Opponent)	Radiometer Medical ApS Akandevej 21 2700 Bronshoj (DK)
Representative:	Maiwald GmbH Elisenhof Elisenstraße 3 80335 München (DE)
Respondent: (Patent Proprietor)	B.R.A.H.M.S GmbH Neuendorfstrasse 25 16761 Hennigsdorf (DE)
Representative:	Tomerius, Isabel Lang & Tomerius Patentanwaltspartnerschaft mbB Rosa-Bavarese-Strasse 5 80639 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 29 April 2019 rejecting the opposition filed against European patent No. 2823314 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairwoman	M. Pregetter
Members:	R. Hauss
	L. Bühler

Summary of Facts and Submissions

I. European patent No. 2 823 314 was granted with a set of 15 claims. Claim 1 reads as follows:

"1. A method for the prognosis and/or risk assessment and/or monitoring of therapy and/or management of patients with COPD the method comprising the steps of:

i) providing a sample of a bodily fluid from said patient,

ii) determining in said sample the level of at least one biomarker, selected from the group consisting of proadrenomedullin (proADM), pro-natriuretic peptide, pro-Vasopressin (proAVP) and Procalcitonin (PCT) or fragments thereof of at least 12 amino acids in length,

iii) determining the BODE-index parameters according to one of the following steps:

iii-a) determining the BODE-index parameters body-mass index (BMI, parameter B), degree of airflow obstruction (FEV_1, parameter O), and dyspnea (parameter D), omitting the BODE-index parameter exercise capacity (parameter E);

iii-b) determining the BODE-index parameters body-mass index (BMI, parameter B) and dyspnea (parameter D), omitting the BODE-index parameters exercise capacity (parameter E) and degree of airflow obstruction (FEV_1, parameter O);

iv) correlating said level of said at least one biomarker determined in step ii), in combination with said BODE-index parameters determined in step iii-a) or in step iii-b) to the prognosis and/or risk assessment

and/or monitoring of therapy and/or management of patients with COPD."

II. The patent was opposed under Article 100(a), (b) and (c) EPC on the grounds that the claimed subject-matter lacked an inventive step, was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art and extended beyond the content of the application as filed.

III. The decision under appeal is the opposition division's decision rejecting the opposition, announced in oral proceedings on 13 March 2019 and posted on 29 April 2019.

IV. According to the decision under appeal:

- Claim 1 as granted was based on claims 1 to 3 as filed and did not contain added subject-matter (Article 100(c) EPC).
- The requirement of sufficiency of disclosure was met as the opposed patent disclosed at least one way of performing the claimed invention (Article 100(b) EPC).
- The claimed subject-matter also involved an inventive step (Articles 100(a), 52(1) and 56 EPC).

VI. The opponent (appellant) appealed against this decision.

VII. In its reply to the appeal, the patent proprietor (respondent) requested that the appeal be dismissed and that the patent be maintained as granted (main request).

By letter of 26 April 2022, the respondent filed an auxiliary request (claims and amended description pages).

Claim 1 of the auxiliary request corresponds to claim 1 of the main request, except that steps iii) and iv) were amended as follows:

"iii) determining the BODE-index parameters body-mass index (BMI, parameter B) and dyspnea (parameter D), omitting the BODE-index parameters exercise capacity (parameter E) and degree of airflow obstruction (FEV_1, parameter O);

iv) correlating said level of at least one biomarker determined in step ii), in combination with said BODE-index parameters determined in step iii) to the prognosis and/or risk assessment and/or monitoring of therapy and/or management of patients with COPD."

VIII. Oral proceedings before the board were held on 17 January 2023, the outcome being that the board revoked the opposed patent for insufficiency of disclosure.

IX. The appellant's arguments relating to sufficiency of disclosure may be summarised as follows.

The claimed method was not enabled over the whole breadth of the claims, for several reasons.

To put the claimed method into practice, a predictive model was needed for carrying out step iv). In order to arrive at a functioning model, a relationship between several parameters and the prediction of the clinical outcome had to be established and the model had to be validated on that basis.

The opposed patent failed to disclose a general relationship between biomarker levels, BODE-index parameters and patient outcomes. Without a general concept to apply, the person skilled in the art would not have been enabled, without undue burden,

to correlate levels of the biomarkers in step ii) of claim 1 in combination with the BODE-index parameters of step iii) for patient outcome prediction according to step iv).

The only information that could be used by the person skilled in the art to put the claimed method into practice were the biomarker threshold levels and scores indicated in table 5 of the opposed patent for one particular embodiment (prediction of mortality within two years, one biomarker and BODE-index parameters as categorical variables).

Beyond that, the skilled person, when attempting to deviate from this embodiment, was left with the task of collecting new patient data and calculating new models.

This would even be required if, while relying on the same model considering the same end point of death within two years, the skilled person merely wished to carry out the method with a different balance between clinical sensitivity and specificity. The opposed patent disclosed neither raw data from the clinical study that the appellant had conducted, nor the Cox regression models based on this data that would permit the variation of the threshold levels and scores that would be required for such a modified purpose.

Furthermore, it had not been established that all four purposes recited in claim 1, step iv, could be achieved by the claimed method, and how this could be done. These purposes were defined very broadly and encompassed, for example, the prediction of all kinds of events involving a worsening or improvement of a variety of symptoms. It had not been established that all these potential end points could be correlated to parameter combinations according to claim 1, let alone

that the single correlation model disclosed in the patent was applicable to all these situations.

Obtaining new sets of data and calculating relevant models from this data would constitute an undue burden. As a consequence, the method of claim 1 was not enabled across the entire scope claimed. With every deviation regarding threshold levels or outcomes to be considered, the person skilled in the art would have to rework the invention from scratch to establish a meaningful correlation between a number of parameters (permutations of the selected BODE parameters combined with the level of at least one selected biomarker) and the chosen pertinent clinical outcome.

X. The respondent's arguments relating to sufficiency of disclosure may be summarised as follows.

The invention did not lie in the provision of specific threshold levels but in the general teaching that the determined levels of specific biomarkers and BODE parameters could advantageously be used together for the claimed uses of prognosis, monitoring and patient management.

Beyond that, the general framework regarding possible approaches that was provided in the patent would have been sufficient for the skilled person to put the claimed method into practice. General guidance for carrying out the claimed method was provided in paragraphs [0035], [0036] and [0050] to [0054] of the opposed patent. The patent also provided data showing the correlation of the levels of single biomarkers for the prediction of death within two years (paragraph [0072] and figures 9 to 12).

In the examples, the opposed patent described at least one way of carrying out the invention. This was enough to establish sufficiency of disclosure. The burden of

proof for showing insufficient disclosure across the claimed scope was on the opponent (appellant), who had not provided experimental evidence of this.

Even if, in order to attain a specific practical object, further studies might be desired to obtain threshold levels different from those disclosed in the patent, the work necessary to collect patient data and to recalculate the regression model was within the skilled person's abilities and would not amount to an undue burden. The collection of patient data was a standard procedure that could be carried out in the course of a hospital's routine services.

The collection of further data in such a context would not serve the purpose of finding a new solution to the technical problem, but merely that of adapting the known solution to a different starting position involving varied requirements. A smaller study would suffice as there were no given quality requirements for thresholds to be fulfilled.

However, to implement the method of the invention, it would not always be necessary to make use of specifically calculated threshold levels as derived in the model created from the underlying study described in the opposed patent.

Firstly, the patent taught that it was also possible to use the biomarker levels as continuous variables. This embodiment did not require threshold levels.

Secondly, it would in any case not be necessary to conduct specific studies for putting the claimed method into practice. A comparison of biomarker levels with generally available physiologically normal levels of the general population would be enough. Several patients could be compared to determine, on the basis of their biomarker levels, which patients had a better,

or worse, prognosis. A less robust statistical model could also be used, obviating the need for a full-scope study. Data obtained from two patients might well be enough to work with. The method could also be implemented by comparing data obtained at different times from one patient.

In principle, it was not necessary to rely on a predetermined rule or pre-collected knowledge for the purpose of establishing the required correlations.

The meaning of the terms "prognosis", "risk assessment", "therapy monitoring" and "patient management" overlapped and these embodiments had a strong impact on each other. Contrary to the appellant's assertions, the experimental results presented in the patent therefore covered all variants of claim 1, and no insufficiency of disclosure could be construed from the different embodiments of claim 1.

XI. The appellant (opponent) requested that the decision under appeal be set aside and the patent be revoked.

The appellant furthermore requested that documents D17 to D19 be admitted and that documents D20 to D22 as well as the auxiliary request filed by letter of 26 April 2022 not be admitted into the appeal proceedings.

XII. The respondent (patent proprietor) requested that the appeal be dismissed, or, alternatively, that the patent be maintained in amended form on the basis of the auxiliary request filed by letter of 26 April 2022.

The respondent also requested that documents D17 to D19 not be admitted, and that the appellant's lines of argument for the assessment of inventive step starting from either document D4 or document D7 not be admitted.

Reasons for the Decision

1. Sufficiency of disclosure - main request

1.1 The requirement of sufficiency of disclosure must be satisfied at the effective date of the patent, i.e. on the basis of the information provided in the patent application as filed, together with the common general knowledge then available to the person skilled in the art. In the following analysis, where the board refers to passages of the opposed patent, the same content is also found in the text of the application as filed.

Technical background

1.2 The opposed patent relates to the individual risk-assessment of patients with COPD (chronic obstructive pulmonary disease). A patient diagnosed with COPD may be in a stable or unstable (acute exacerbated) state of the disease (see also dependent claim 5). The goals of COPD assessment are to determine the severity of the disease, its impact on a patient's health status, and the risk of future events (exacerbations, hospital admission, death) in order to guide therapy (see paragraph [0004] of the opposed patent).

1.3 As set out in the opposed patent (see paragraphs [0006] and [0029]), the so-called "BODE index" was known as a tool for the prognosis of mortality and hospitalisation for COPD in patients with COPD. It combines four variables into a single score. These parameters are:

B: body-mass index

O: degree of airflow obstruction, measured by lung-function testing (FEV_1)

D: dyspnea

E: exercise capacity, measured by the six-minute walk test

Depending on the respective measurement results, scores are assigned to the patient for each parameter (see table 2 in the opposed patent). The sum of these scores is the BODE index. It reflects the impact of both pulmonary and extrapulmonary factors on prognosis and survival in COPD, with higher scores indicating greater risk.

1.4 However, determination of the BODE index is cumbersome as it requires a 6-minute walk test in the stable state of the disease, and it is not suitable for acute exacerbations (see paragraph [0006] of the opposed patent).

1.5 Thus, there had been increasing interest in using other parameters, including pulmonary biomarkers, to monitor disease severity in patients with COPD (see paragraphs [0006] to [0008]). It was known, for instance, that certain biomarkers, such as procalcitonin, are increased during exacerbations. Systemic biomarkers were also known to be of interest as a means of determining disease severity and prognosis in stable COPD. However, information was still scarce as to the prognostic value of these biomarkers.

Objective and claimed subject-matter

1.6 The opposed patent (see paragraph [0009]) seeks to provide a method for easy and reliable prognosis and/or risk assessment and/or monitoring of therapy and/or management of patients with COPD, with minimum inconvenience for the patient.

1.7 More specifically, it is suggested that such a method should replace part of the conventional determination of the BODE-index parameters, with a view to reducing the burden on the patient.

1.8 To this aim, and as defined in claim 1 as granted (see point I. above), several predictor parameters are to be determined:

- the level of at least one biomarker, selected from a specified group of eligible biomarkers, in a sample of a bodily fluid of a patient with COPD (claim 1, steps i) and ii))
- selected parameters of the BODE index (claim 1, step iii), namely:

  (a) either three parameters (BOD) are to be determined, omitting parameter E

  (b) or two parameters (BD) are to be determined, omitting both parameters O and E

These parameter values determined for the individual patient are to be combined and "correlated to" the prognosis and/or risk assessment and/or monitoring of therapy and/or patient management, which is both the purpose and the effect of the method (claim 1, step iv); see also paragraphs [0001] and [0009] to [0012] of the opposed patent).

1.9 The board understands this to mean that the assessment made for an individual patient (which is the claimed method's stated purpose), on the basis of this patient's parameter values obtained according to steps i) to iii), will be based on a known relationship (i.e. a correlation) between a combination of the specific parameters chosen and a relevant clinical outcome that is to be considered for the analysis. Hence, this general correlation, which will be applied

in step iv) to the patient's individual parameter values, must of necessity have been established before carrying out the claimed method on individual patients. Otherwise it would not be possible to determine which parameters should be measured according to steps i) to iii).

1.10 The claimed method is defined functionally by its result. This result is defined only indirectly, in a general and rather broad manner, in that the method must enable prognosis, risk-assessment, therapy monitoring and/or management of patients with COPD. The crucial step for achieving this purpose is step iv).

1.11 While there is no doubt that the person skilled in the art would know how to collect parameter values according to steps i) to iii), claim 1 does not say how step iv) is to be put into practice. In particular, the claim does not specify how to choose the contributing parameters in the first place, how to combine the parameter values in practice and how to establish and use a correlation of these combined values to a particular outcome to achieve the defined purposes of prognosis, risk assessment, monitoring of therapy and patient management.

1.12 The prognosis or risk assessment addressed in claim 1 has to relate to a specific clinical outcome. On the basis of this prognosis or assessment, measures for therapy monitoring (such as testing for particular parameters, increasing or reducing the frequency of tests) or patient management (such as decisions about medication or hospitalisation) can then be determined.

Content of the Example

1.13 One particular way of carrying out the claimed method is suggested in the example, which shows one instance of how a pertinent correlation with a specific clinical outcome was established and how the predictor parameters were combined (see paragraphs [0066] to [0077] of the opposed patent and the corresponding passages of the application as filed).

1.14 The example relates to a study involving 548 patients with COPD. The clinical outcome of interest was mortality within two years.

1.15 It appears that the BODE parameters B, O, D and E and the BODE score were determined at the beginning of this study. Furthermore, the levels of the following biomarkers were determined in serum samples of the patients:

- MR-proADM (mid-regional pro-adrenomedullin, a fragment of proADM conforming to claim 1, see paragraphs [0041] and [0042] and SEQ ID NO:7)
- MR-proANP (mid-regional pro-atrial natriuretic peptide, a fragment of proANP conforming to claim 1, see paragraphs [0038] to [0040] and SEQ ID NO:4)
- Copeptin (a fragment of a precursor of pro-AVP conforming to claim 1; see paragraphs [0043] and [0044] and SEQ ID NO: 10)
- Procalcitonin (PCT)

The patients were subsequently followed for two years and patient death was recorded as a study outcome. 43 patients (7.8%) did not survive (paragraph [0071]).

1.16 The inventors developed a scoring system by relating the biomarker levels and specific BODE parameters to the outcome "mortality within two years". The opposed patent mentions and discusses various models that are based on the data set obtained in this study.

Different statistical models were assessed, *inter alia* for correlation of BOD or BD values in combination with one biomarker level (i.e. combinations conforming to claim 1) with the outcome "mortality within two years". Different sets of Cox regression models were calculated with the parameters as continuous and/or categorical variables:

- biomarker as continuous, BODE-index parameters as categorical variable (table 4)

- biomarker and BODE-index parameters as categorical variables (table 5)

- biomarker and BODE-index parameters as continuous variables (table 6)

1.17 According to the opposed patent, these models in general showed good accuracy for predicting death within two years.

No details are provided in relation to the models according to tables 4 and 6. The data shown in the tables only pertains to the quality of prediction. The patent does not teach how to put the claimed method into practice using these models.

To use the biomarkers as categorised variables in the set of models according to table 5, two different cut-offs resulting in a score of 0, 2 or 4 were defined for each biomarker. The patent explains that the respective biomarker score is to be added to the score retrieved from the index parameters BOD or BD to obtain a combined score (see paragraph [0073] and table 5,

indicating the cut-off values needed for transforming the concentration determined for each biomarker, i.e. a continuous value, into a score, i.e. a categorical value). This also involves a weighting of the biomarker level in relation to the BODE scores. Figures 26, 27, 29, 30, 32, 33, 35 and 36 show the proportion of patients surviving in relation to three ranges of score points in each case, for the respective parameter combinations BOD/MR-proADM, BD/MR-proADM, BOD/MR-proANP, BD/MR-proANP, BOD/Copeptin, BD/Copeptin, BOD/PCT and BD/PCT (see also paragraph [0076}]).

1.18 Thus, with the biomarker scores indicated for the model according to table 5 and associated information, the opposed patent provides, in a method as claimed, a correlation which may serve to link individual patient values determined for these specific parameter combinations by scoring algorithm to the outcome of death within two years. This amounts to disclosure of one way of putting the claimed method into practice.

Criteria for sufficiency of disclosure

1.19 Both the opposition division (in the decision under appeal) and the respondent reasoned that the criterion of sufficiency of disclosure was met already because the example disclosed one way of performing the invention.

1.20 The board does not share this view.

1.20.1 According to the established jurisprudence of the boards of appeal, the disclosure of one way of performing the invention is only sufficient if it allows the invention to be performed in the whole range claimed (see Case Law of the Boards of Appeal of the European Patent Office, 10th edition 2022, II.C.5.4). This means that the person skilled in the art must be

enabled to find working embodiments over the claimed range with reasonable effort. More technical details and more examples may be necessary to support claims of a broad scope (as in the present instance, where the desired result is only defined as a desideratum or result to be achieved).

1.20.2 Thus, it must also be considered whether the patent's disclosure allows the person skilled in the art to work over the whole ambit of the claim without undue burden.

Breadth of claim, lack of guidance for further embodiments

1.21 The claimed method is not restricted to considering the outcome of death within two years for the prognosis or risk assessment, nor is it restricted to the use of the specific parameter combinations and experimental conditions mentioned in paragraphs [0073], [0076] and table 5 of the patent (the level of one particular biomarker or fragment was considered in each case, which had been determined in a serum sample). Indeed, the scope of conceivable alternatives, or range of variants, encompassed by claim 1 (with regard to purpose, parameter combinations and clinical outcomes that may be used for correlation) is considerably broader than what is covered by the embodiment according to table 5.

1.22 The disclosure in the example relates to a particular embodiment, but does not provide any guidance or generalisable technical concept that makes available further embodiments of the claimed method.

1.22.1 For instance, the risk of getting exacerbations is a risk that may also be assessed with the claimed method (see point 1.2 above). Indeed, the dependent claims distinguish between the prognosis/risk assessment of mortality, preferably within various time frames

between five years and six months (see claims 6 and 7) and the prognosis/risk assessment of getting an acute exacerbation, preferably within time frames between two years and seven days (see claims 8 and 9).

1.22.2 Establishing the likelihood of death within two years in the manner disclosed in the patent would not permit any conclusion to be drawn about the risk of exacerbations within any given time frame, e.g. within seven days, or for that matter, about the likelihood of death within time frames other than two years (such as six months or five years), or about the parameter combinations that might be suitable for a pertinent prognosis or risk assessment.

1.22.3 Such options are not covered or supported by the specific embodiment described in the patent, which is restricted to the prognosis of death within two years. While the respondent argued that all conceivable uses of the claimed method are somehow interrelated, the precise relationship (if one exists) between these different outcomes/objectives and the prognosis of death within two years is not disclosed in the patent and is not derivable from common general knowledge.

1.23 Different objectives would require the application, in step iv), of correlation algorithms other than the one disclosed in the example of the opposed patent. It would have to be determined first which parameter combinations might provide information about the likelihood of a particular clinical outcome and whether any useful correlation could be found. Predictive models would have to be researched and validated for various permutations of parameter combinations, by statistical methods based on patient data, as a

prerequisite for putting the claimed method into practice (see point 1.9 above).

1.24 Claim 1 and the opposed patent as a whole merely provide a general concept of a speculative nature, to the effect that certain biomarker levels might be combined with certain of the BODE-index parameters in the hope that this would enable prognosis or risk assessment for patients with COPD. The opposed patent does not provide any generalisable teaching that would give guidance to the person skilled in the art in finding working embodiments across the scope claimed.

1.24.1 The respondent contested this view. In particular, the respondent argued that certain passages in the description did provide general guidance, should any be required. In this context, the respondent referred to paragraphs [0034] to [0036], [0050] to [0053] and [0072].

1.24.2 This argument cannot succeed.

Paragraphs [0034] to [0036] merely mention, in a general way, some methodology that may be useful for establishing correlations, without showing any practical application in a further embodiment.

Paragraphs [0050] to [0053] mention general ranges for threshold levels of individual biomarkers, but not in the context of any correlation, parameter combination or clinical outcome to be considered.

Paragraph [0072] relates, again, to the study disclosed in the examples, linking the levels of single biomarkers to the outcome of death within two years. As this passage relates to study data in the context of the examples rather than to further correlations in relation to other clinical outcomes than death within

two years, this does nothing to prove the respondent's point.

1.24.3 With the exception of the case where the outcome of interest is "death within two years", the patent does not disclose which parameter combinations might provide a usable (i.e. reasonably accurate) prognosis of any specific relevant clinical outcome, and how the parameters should be weighted in such a combination.

1.24.4 For each embodiment of the method relating to a different outcome of interest, some research effort is therefore required to establish a combination of technical features and corresponding algorithm which solves the task of providing a reasonable prediction or risk assessment. As the person skilled in the art would have to develop the features of a new method each time, within the general framework of only a vague and speculative concept formulated as a desideratum, this amounts to an inventive effort that is required for actually implementing each further specific embodiment.

1.24.5 The point of this objection is not the amount of work that would have to be invested but that a new method and suitable predictive model would have to be developed from scratch for each new embodiment.

Concluding remarks

1.25 In view of these considerations and conclusions, it was not necessary to examine the further question as to whether adapting the method according to table 5 to be put into practice with different sensitivity/ specificity would be an undue burden.

1.26 For these reasons, the method of claim 1 is not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art

across its entire scope. As a consequence, the ground for opposition under Article 100(b) EPC prejudices maintenance of the opposed patent in the version as granted.

2. Sufficiency of disclosure - auxiliary request

2.1 Claim 1 of the auxiliary request differs from claim 1 of the main request in that alternative iii-a) has been deleted in step iii).

2.2 The reasoning set out in section 2 above in relation to claim 1 of the main request applies equally to claim 1 of the auxiliary request. The deletion of alternative iii-a) does not change anything in that respect, as the same reasoning applies to alternative iii-b).

2.3 As a consequence, the method defined in claim 1 of the auxiliary request is not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Articles 100(b) and 83 EPC), for the same reasons as the method defined in claim 1 of the main request.

2.4 In view of this outcome, it was not deemed necessary to address the appellant's request for non-admittance of the auxiliary request.

3. Requests relating to the (non-)admittance of evidence and arguments

3.1 At the oral proceedings, the board advised the parties that it saw no reason to hold document D17 (filed by the appellant with its grounds of appeal) inadmissible under Article 12(4) RPBA 2007. However, since the content of D17 was ultimately not relevant to the board's reasoning set out above and the resulting outcome of the appeal proceedings, it is not necessary

at this point to address reasons relating to its admittance.

3.2 Documents D18 and D19 were filed by the appellant with its grounds of appeal, whereas documents D21 and D22 were filed by the respondent with its reply to the grounds of appeal, in the context of the parties' respective reasoning on inventive step. As they are not relevant to the issue of sufficiency of disclosure, it was not necessary for the board to decide on the admittance of these documents. For the same reason, no decision was required on the admittance of the appellant's lines of argument for the assessment of inventive step starting from either document D4 or document D7.

3.3 D20 (filed by the respondent) is an entry from a dictionary defining "correlate" as meaning "establish a mutual or reciprocal relationship between". Its admittance would have made no difference to the board's understanding of the claim language as set out in point 1.9 above, or to the outcome of the present decision.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairwoman:

I. Aperribay M. Pregetter

Decision electronically authenticated