BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Internal distribution code:
(A) [ ] Publication in OJ
(B) [ ] To Chairmen and Members
(C) [ ] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 24 March 2009

Case Number: T 0449/08 - 3.3.08

Application Number: 97905623.1

Publication Number: 0817966

IPC: G01N 33/50

Language of the proceedings: EN

Title of invention:
Method of determining renal clearances

Applicant:
U.D. Testing, Inc.

Headword:
Renal clearance/U.D. Testing

Relevant legal provisions:
EPC Art. 123(2), 84, 83

Keyword:
"Main request - sufficiency of disclosure, clarity (no)"
"First, second and third auxiliary requests - added subject-matter (yes), clarity (no)"

Decisions cited:
T 0329/99

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0449/08 - 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 24 March 2009

Appellant: U.D. Testing, Inc.
950 N. Collier Boulevard
Suite 207
Marco Island
Florida 34145 (US)

Representative: McCarthy, Denis Alexis
MacLachlan & Donaldson
47 Merrion Square
Dublin 2 (IE)

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 4 October 2007 refusing European application No. 97905623.1 pursuant to Article 97(1) EPC 1973.**

Composition of the Board:

Chairman: L. Galligani
Members: P. Julià
C. Rennie-Smith

Summary of Facts and Submissions

I. The appeal lies from the decision of the examining division dated 4 October 2007, by which the European patent application No. 97 905 623.1 published as WO 97/27481 with the title "Method of determining renal clearances" (referred to in this decision as "the application as filed"), was refused under Article 97(1) EPC 1973.

II. The examining division considered that the main request filed on 7 January 2004 did not meet the requirements of Articles 83 and 84 EPC and that the first and second auxiliary requests, both filed on 6 September 2007 at the oral proceedings before the examining division, did not fulfil the requirements of Article 123(2) EPC (cf. point X *infra*).

III. The appellant (applicant) filed a notice of appeal, paid the appeal fee and, in a letter dated 4 February 2008, filed a statement setting out the grounds of appeal together with a third auxiliary request. As subsidiary request, oral proceedings under Article 116 EPC were also requested.

IV. Claim 1 of the **main request** reads as follows:

"1. A method of determining creatinine clearance for use in detecting and monitoring renal dysfunction comprising the steps of:

(a) obtaining spot samples of urine and blood from a person;

(b) measuring specific gravity and creatinine concentration of the urine sample;

(c) calculating the specific gravity factor (SGF) which is calculated as
[(1.030 - 1.000)/(sg - 1.000)]
where sg is the specific gravity of the urine sample;

(d) measuring creatinine concentration of plasma of the blood sample; and

(e) calculating creatinine clearance as a function of the calculated urine specific gravity factor, the measured urine creatinine concentration and the measured plasma creatinine concentration, wherein creatinine clearance is calculated in accordance with the equation

cl = v'. u . SGF /p

where cl is the creatinine clearance, v' is the urine volume production rate for persons with reasonably normal renal functions, u is the measured urine creatinine concentration, SGF is the calculated specific gravity factor, and p is the measured plasma creatinine concentration."

V. Claim 1 of all auxiliary requests was identical to claim 1 of the main request except for the definition of v' in part (e) which was amended in the auxiliary requests to read:

"*... v' is the urine volume production rate at a specific gravity factor of 1.000 for persons with reasonably normal renal functions, ...*" in the **first auxiliary request**,

"*... v' is the urine volume production rate for the most concentrated sample in the collection period with a specific gravity usually near 1.030, for the person, ...*" in the **second auxiliary request,** and

"*... v' is the mean value of v at a specific gravity factor of 1.000 derived from a population regression line plot of v versus SGF where v is the urine volume production rate for each urine aliquot collected; ...*" in the **third auxiliary request**.

VI. The examining division did not rectify its decision and the appeal was remitted to the boards of appeal (Article 109 EPC 1973).

VII. On 1 October 2008, as an annex to a summons to oral proceedings scheduled for 24 March 2009, the board sent a communication under Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) informing the appellant of its preliminary, non-binding opinion.

VIII. No comments or new requests were received within the time limit of one month before the hearing set by the board. In a letter dated 6 March 2009, the appellant requested the board to cancel oral proceedings and to issue a decision based on the current state of the file.

IX. In a letter dated 12 March 2009, the appellant was informed that the oral proceedings were cancelled.

X. In the decision under appeal the examining division stated that the main request did not meet the requirements of Articles 83 and 84 EPC because it was

not clear how the parameter v' (defined as urine volume production rate for individuals with reasonably normal renal functions) was actually determined. There was a contradiction between the information found in the description of the application as filed and the interpretation made by the applicant. It was not clear what the skilled person had to do in order to determine v'. Moreover, the advantage of using the refined formula cl = u . v' . SGF/p rather than the general formula cl = u . v/p was unclear. As regards the first and second auxiliary requests, the examining division considered that the application as filed provided two different definitions of v' identifying two different methods for measuring the urine volume production rate. The features introduced into these auxiliary requests for defining v' made the method of the amended claim 1 different from that of the application as filed and could not be derived therefrom (Article 123(2) EPC).

XI. The arguments put forward by the appellant in the statement setting out the grounds of appeal, as far as relevant to the present decision, may be summarized as follows:

Main request
Articles 83 and 84 EPC

The relationship between v, v' and SGF (v = SGF . v') was set out in the application as filed (page 17, lines 17 and 18), which described the linear relationship shown in Figure 7 of the application (v/v' versus SGF, slope 1 and intercept 0) when the urine volume production rate (v') was v' = 0.58 ml/min, and where v/v' was the urine volume production rate factor

(UVPRF), v was the actual value of urine volume production rate and SGF the specific gravity factor. The mathematical equation of a straight line was common general knowledge to a skilled person and indeed it was used throughout the application including Formula (3) at page 9 of the application as filed. The definition of the sample was not essential for defining the invention.

According to the application as filed, the general formula was cl = u . v/p (page 11, line 14), whereas cl = u . v' . SGF/p was referred to in the application as a "refined formula" (cf. page 16, line 26 and page 17, line 20). The advantages of the general formula were set out at page 11, lines 4 to 9 and lines 21 to 29 of the application as filed. The additional advantages of the refined formula were set out at page 17, line 28 to page 18, line 3 of the application as filed, wherein the data on which this refined formula was based was described at page 16, lines 27 to 34 of the application as filed. There was no contradiction in the application as filed since v' was not equal to v by definition (v' = v/SGF).

First and second auxiliary requests
Article 123(2) EPC

According to the application as filed, the general formula was cl = u . v/p (page 11, line 14), whereas the "refined formula" was cl = u . v' . SGF/p (page 16, line 26 and page 17, line 20). According to the Collins English Dictionary, the English language definition of the word "refinement" meant "the act of improving upon by making subtle or fine distinctions". It went against

the established case law of the boards of appeal to conclude that there was no basis for a connection between the general formula on page 11 and the "refined formula" on page 17. The language alone which was used to refer to the formula on page 17 clearly established that the refined formula was derived from the general formula and it followed that the parameters such as v' represented the same meaning and definitions as were used in the general formula.

The same submissions were made with regard to the second auxiliary request as for the first auxiliary request.

Third auxiliary request
Article 123(2) EPC

The amendment introduced into this request related to the slope of the regression derived from Figure 7 (which had also previously been referred to as angular coefficient of the regression line v versus SGF) and had been suggested by the examining division in an official communication.

XII. The appellant requested in writing that the decision under appeal be set aside and that a patent be granted on the basis of the main request filed on 7 January 2004, or in the alternative, on the basis of the first or second auxiliary requests filed on 6 September 2007 or on the basis of the third auxiliary request filed on 4 February 2008 with the statement setting out the grounds of appeal.

Reasons for the Decision

Main request
Articles 84 and 83 EPC

1. The application as filed contains two definitions of v', each one associated with a different formula. On page 8, lines 22 to 25, **v'** is defined as "*the urine volume production rate for the most concentrated sample in the collection period with a specific gravity usually near 1.030*" and it is associated with Formula (10) on page 11 (cl = v' . u. [2.43 . SGF - 1.43]/p). The value of v' is given as being equal to 0.44 ml/min (cf. page 9, line 34 to page 10, line 2 and page 11, line 19). On page 17, lines 22 to 24, **v'** is defined as "*the urine volume production rate for persons with reasonably normal renal functions*" and it is associated with the "refined" Formula (11) on the same page (cl = v' . u . SGF/p). The value of v' is given as being equal to 0.58 ml/min (cf. page 17, lines 12 to 13, 17 and 29). Since the formula present in claim 1(e) is identical to Formula (11) on page 17 of the description, the definition of v' in claim 1(e) rightly corresponds to that found on page 17 of the application as filed.

2. Nevertheless, the value of this second v' is empirically determined and corresponds to a specific value required for making true the formula v = SGF . v'. The value of v' is "*an arbitrary urine volume production rate*" (cf. page 9, line 20) linking - by the above mathematical relationship - the *"urine volume production rate for each aliquot collected*" (v) (cf. page 8, lines 21 to 22) and the urine specific gravity factor (SGF) (cf. page 10, lines 2 to 12 and page 11,

lines 19 to 21). Hence, the value of v' is not specific or fixed but depends upon the persons used in a particular sample studied. And, the value of 0.58 ml/min is representative only for the 96 patients followed in the renal disease clinic referred to in the application as filed (cf. page 16, lines 27 to 28).

3. From the above analysis, there is a certain ambiguity, if not an apparent contradiction, between the definition of v' required for obtaining the disclosed mathematical relationship ("*an arbitrary urine volume production rate*") and the definition of v' found on page 17, lines 22 to 24 of the application as filed and which is literally taken in claim 1(e) ("*the urine volume production rate for persons with reasonably normal renal functions*"). In the absence of an indication in the claim of the specific value(s) for the volume production rate in persons with reasonably normal renal functions or of the specific (empirical and/or mathematical) method used for its determination, the definition used in claim 1(e) renders the claimed subject-matter, to say the least, ambiguous.

4. According to the application as filed, the problem to be solved was the non-availability to physicians of the actual value of the urine volume production rate (v) under normal clinical screening situations "*due to the great effort and expense required to obtain this value by collecting a timed urine sample for ambulatory patients during normal health checkups*" (cf. page 11, lines 4 to 9). If the value of v' (0.58) disclosed in the application as filed for Formula (11), which is described as being "*based upon greater amounts of SG versus urine volume and urine concentration data ...*

and therefore offers a more reliable predictor" (cf. page 17, line 28 to page 18, line 5), cannot be readily taken by the physician and directly used in the "refined" Formula (11), then the above mentioned problem has not actually been solved, since further effort and expense is required from the physician to determine the appropriate value of v' in the "refined" Formula (11) by plotting v/v' versus SGF for each and every particular sample studied - as done in Figure 7 of the application as filed (cf. page 17, lines 12 to 15).

5. The subject-matter of claim 1 is directed to "*a method of determining creatinine clearance* ***for use in detecting and monitoring renal dysfunction***" (emphasis added by the board). The presence in the claim of a "purpose" limitation of a diagnostic nature renders the scope of the claim unclear as the claim might be read as being directed to "*a method for detecting and monitoring renal dysfunction wherein creatinine clearance is determined by the steps of ...*", i.e. a diagnostic method which is excepted from patentability.

6. In view of these considerations, the board does not see any reason to deviate from the decision under appeal and concludes that the main request does not fulfil the requirements of Articles 83 and 84 EPC.

First and second auxiliary requests
Articles 123(2) and 84 EPC

7. As stated by the appellant in the statement setting out the grounds of appeal, Formula (11) represents a "refinement" of Formula (10). The former being

connected and derived from the latter, and both describing creatinine clearance equations. Whereas in Formula (10) v is equal to (2.43 . SGF - 1.43) . v' and v' equals 0.44 ml/min (cf. page 11, lines 14 to 16), in the "refined" Formula (11) v is now equal to SGF . v' and v' equals 0.58 ml/min (cf. page 17, lines 16 to 19). Therefore, the gist of the refinement essentially lies in a "refined" nature of v' which results in a different mathematical relationship between v and v' and in different values of v' (0.44 vs. 0.58). The nature and meaning of these two v' is thus different in each one of these two formulae and, accordingly, their definitions are also different, namely "*urine volume production rate for the most concentrated sample in the collection period with a specific gravity usually near 1.030*" vs. "*urine volume production rate for persons with reasonably normal renal functions*" or "*an arbitrary urine volume production rate*" that results in Formula (11) (cf. *supra*).

8. The definitions of v' introduced into the first and the second auxiliary requests apply only to Formula (10) (even though there is no formal basis for the wording introduced into the first auxiliary request) and not to the "refined" Formula (11). Although both formulae are connected and one is derived from the other, there is no explicit or implicit disclosure in the application as filed to support the allegation that the nature, meaning and value of v' in each of those two formulae are the same and consequently, the definition used in the former formula can also be used in the latter "refined" formula. In the absence of such a disclosure, the amendments introduced into the first and the second

auxiliary requests go beyond the disclosure of the application as filed.

9. The objection raised in point 5 above for the main request applies to the subject-matter of claim 1 of these two auxiliary requests as well, since the "purpose" limitation of diagnostic nature is present in the method of determining creatinine clearance in claim 1 of both requests.

10. Thus, the first and second auxiliary requests do not fulfil the requirements of Articles 123(2) and 84 EPC.

Third auxiliary request
Articles 123(2) EPC and 84 EPC

11. The amendment introduced into the third auxiliary request does not have a formal support in the application as filed. There is no indication in the application, let alone in the context of the "refined" Formula (11), that v' represents "*the mean value of v at a specific gravity factor of 1.000 ... where v is the urine volume production rate for each urine aliquot collected*" as in claim 1(e) of this request. Moreover, it is also questionable whether the application as filed discloses that "*the mean value of v at a specific gravity factor of 1.000*" can be "*derived from a population regression line plot of v versus SGF*" (wherein v is the urine volume production rate for each urine aliquot collected).

12. In the light of the case law which requires to differentiate subject-matter rendered obvious on the basis of the content of the application from

subject-matter explicitly or implicitly disclosed in the application (cf. *inter alia* T 329/99 of 5 April 2001), the question arises as to whether the definition of v' as being "*derived from a population regression line plot of v versus SGF*" is implicitly derivable from the original disclosure or whether it is only rendered obvious by this disclosure. The more so, since there are no comments in the application as filed on the meaning and relevance of having "*a slope of one and a zero intercept*" in the plotting of Figure 7.

13. In this regard, it is also doubtful whether a simple reference to v' as being "*derived from a population regression line plot of v versus SGF*" but without any further explanation of the kind or type of this derivation, the regression line plot and the population used, etc. is sufficient to fulfil the requirements of clarity as required by Article 84 EPC.

14. The objections raised, respectively, in points 5 and 9 *supra* for the main request and for the first and second auxiliary requests, apply to the subject-matter of claim 1 of this third auxiliary request as well.

15. Thus, the requirements of Articles 123(2) and 84 EPC are not fulfilled.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

K. Götz L. Galligani