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**Datasheet for the decision  
of 13 April 2010**

**Case Number:** T 0057/09 - 3.3.08

**Application Number:** 99918188.6

**Publication Number:** 1076824

**IPC:** G01N 33/68

**Language of the proceedings:** EN

**Title of invention:**

Antenatal screening for Down's syndrome

**Patentee:**

Wald, Nicholas John

**Opponents:**

PerkinElmer, Inc.  
Maternal Fetal Medicine Foundation  
Bauer, Wulf  
Media Innovations Limited

**Headword:**

Antenatal screening/WALD

**Relevant legal provisions:**

EPC Art. 54, 84, 111(1), 112(1) (a), 123(2) (3)  
EPC R. 80

**Relevant legal provisions (EPC 1973):**

-

**Keyword:**

"Main request - clarity (no) - added subject-matter (yes)"

"Admission of first and second auxiliary requests into the proceedings (yes)"

"First auxiliary request - clarity (no)"

"Second auxiliary request - novelty (no)"

"Third auxiliary request - admission (yes) - basis in the application as filed (yes) - clarity (yes) - novelty over document E3 (yes)"

"Request for referral to EBA (not granted)"

"Remittal to the opposition division"

**Decisions cited:**

T 0762/07, T 0782/07, T 1483/07, T 1108/08

**Catchword:**

-



Case Number: T 0057/09 - 3.3.08

**D E C I S I O N**  
**of the Technical Board of Appeal 3.3.08**  
**of 13 April 2010**

**Appellant:** Wald, Nicholas John  
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**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted 27 November 2008  
revoking European patent No. 1076824 pursuant  
to Article 101(3)(b) EPC.**

**Composition of the Board:**

**Chairman:** L. Galligani  
**Members:** M. R. Vega Laso  
R. Moufang

## **Summary of Facts and Submissions**

- I. European patent No. 1 076 824 with the title "Antenatal screening for Down's syndrome" was granted on European patent application No. 99 918 188.6 (published as WO 99/56132), which was filed as PCT/GB99/01341 on 29 April 1999 claiming the priority of two earlier British applications.
- II. Four oppositions were filed against the grant of the patent. The oppositions by opponents 01, 02 and 04 were based on the grounds for opposition mentioned in Article 100(a), (b) and (c) EPC 1973, in particular that the subject-matter of the claims as granted lacked novelty and/or inventive step (Articles 54 and 56 EPC 1973), and extended beyond the content of the application as filed, and that the claimed invention was contrary to morality (Article 53(a) EPC 1973) and not sufficiently disclosed in the patent. Opponent 03 based its opposition on the grounds mentioned in Article 100(a) in conjunction with Articles 54, 56 and 52(1), (4) EPC 1973.
- III. By a decision posted on 27 November 2008, the opposition division revoked the patent under Article 101(3)(b) EPC. The opposition division found that the subject-matter of the claims according to the main request or the first auxiliary request then on file lacked novelty, and that the claims according to the second auxiliary request did not conform to Article 84 EPC. The amendments introduced into the claims according to the third auxiliary request were considered to offend against Article 123(2) EPC.

- IV. The patent proprietor (appellant) lodged an appeal against the adverse decision of the opposition division. Together with its statement of grounds of appeal, the appellant submitted four sets of amended claims as its main request and first to third auxiliary requests. The set of claims according to the main request on appeal was identical to the set of claims of the second auxiliary request before the opposition division. All other requests on which the opposition division had decided were not pursued further. The appellant requested oral proceedings if the board did not intend to allow the main request.
- V. The respondents (opponents) were given the opportunity to submit comments on the grounds of appeal. Only respondent I (opponent 01) filed observations and additional documentary evidence. It also requested oral proceedings under Article 116(1) EPC.
- VI. The parties were summoned to oral proceedings. In a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA), the board drew the attention of the parties to some of the issues to be discussed during the oral proceedings, in particular the question whether or not the fresh auxiliary requests filed on appeal should be admitted into the proceedings, and issues in connection with Articles 123(2) (3), 84 and 54 EPC.
- VII. The appellant replied to the board's communication and filed further documentary evidence. The representative of respondents I (opponent 01), II (opponent 02) and IV (opponent 04) submitted additional comments.

VIII. At the oral proceedings held on 13 April 2010 respondents II and IV, which had been duly summoned, were not represented. During the discussion of the second auxiliary request, respondent III (opponent 03) put forward the following question of law for referral to the Enlarged Board of Appeal:

"Is an independent method claim that starts with the instruction to perform method step A and/or method step B and in a further instruction positively excludes method step B in accordance with the EPC, especially with Art. 84?"

IX. During the oral proceedings, the appellant replaced the third auxiliary request then on file with a fresh third auxiliary request (amended claims 1 to 14 and pages 2 to 5 of the patent specification). Respondent I requested that the fresh third auxiliary request not be admitted into the proceedings because it had been filed late. The board decided to admit the request which was then discussed with the parties.

X. The sets of claims on which the appellant's final requests were based, are as follows:

**Main request (claims 1 to 18)**

Independent claims 1 and 13 read:

"1. A method of determining whether a pregnant woman is at an increased risk of having a fetus with Down's syndrome, the method comprising the steps of:

measuring the level of at least one screening marker from a first trimester of pregnancy by:

(i) assaying a sample obtained from the pregnant woman at said first trimester of pregnancy for at least one biochemical screening marker; and/or

(ii) measuring at least one ultrasound screening marker from an ultrasound scan taken at said first trimester of pregnancy;

measuring the level of at least one screening marker from a second trimester of pregnancy by:

(i) assaying a sample obtained from the pregnant woman at said second trimester of pregnancy for at least one biochemical screening marker; and/or

(ii) measuring at least one ultrasound screening marker from an ultrasound scan taken at said second trimester of pregnancy,

the at least one screening marker from the second trimester of pregnancy being different from the at least one screening marker from the first trimester of pregnancy; and

determining, using a computer program executed on a computer, a quantitative estimate of the risk of Down's syndrome by comparing the measured levels of both the at least one screening marker from the first trimester of pregnancy and the at least one screening marker from the second trimester of pregnancy with observed relative frequency distributions of marker levels in Down's syndrome pregnancies and in unaffected pregnancies.

13. A computer program which when executed on a computer causes the computer to perform a process for determining a pregnant woman's risk of having a fetus



with Down's syndrome, the process comprising the steps of:

inputting a measurement of the level of at least one screening marker from a first trimester of pregnancy obtained by:

- (i) assaying a sample obtained from the pregnant woman at said first trimester of pregnancy for at least one biochemical screening marker; and/or
- (ii) measuring at least one ultrasound screening marker from an ultrasound scan taken at said first trimester of pregnancy;

inputting a measurement of the level of at least one screening marker from a second trimester of pregnancy obtained by

- (i) assaying a sample obtained from the pregnant woman at said second trimester of pregnancy for at least one biochemical screening marker; and/or
- (ii) measuring at least one ultrasound screening marker from an ultrasound scan taken at said second trimester of pregnancy,

the at least one screening marker from the second trimester of pregnancy being different from the at least one screening marker from the first trimester of pregnancy; and

determining a quantitative estimate of the risk of Down's syndrome by comparing the input levels of both the at least one screening marker from the first trimester of pregnancy and the at least one screening marker from the second trimester of pregnancy with observed relative frequency distributions of marker levels in Down's syndrome pregnancies and in unaffected pregnancies."

Dependent claims 2 to 12 concern specific embodiments of the method of claim 1. Dependent claims 14 to 17 concern various embodiments of the computer program of claim 13. Claim 18 is directed to a computer program recording medium storing a computer program according to any one of claims 13 to 17.

**First auxiliary request (claims 1 to 12):**

Independent claim 1 reads:

"1. A method of determining whether a pregnant woman is at an increased risk of having a fetus with Down's syndrome, the method comprising the steps of:

selecting at least one screening marker for a first trimester of pregnancy that has the ability to discriminate between Down's syndrome pregnancies and unaffected pregnancies at said first trimester of pregnancy

measuring the level of the selected at least one screening marker for said first trimester of pregnancy by:

- (i) assaying a sample obtained from the pregnant woman at said first trimester of pregnancy for at least one biochemical screening marker; and/or
- (ii) measuring at least one ultrasound screening marker from an ultrasound scan taken at said first trimester of pregnancy;

selecting at least one screening marker for a second trimester of pregnancy that has the ability to discriminate between Down's syndrome pregnancies and

unaffected pregnancies at said second trimester of pregnancy;

measuring the level of the selected at least one screening marker for said second trimester of pregnancy by:

- (i) assaying a sample obtained from the pregnant woman at said second trimester of pregnancy for at least one biochemical screening marker; and/or
- (ii) measuring at least one ultrasound screening marker from an ultrasound scan taken at said second trimester of pregnancy; and

determining, using a computer program executed on a computer, a quantitative estimate of the risk of Down's syndrome by comparing the measured levels of both the at least one screening marker for the first trimester of pregnancy and the at least one screening marker for the second trimester of pregnancy with observed relative frequency distributions of marker levels in Down's syndrome pregnancies and in unaffected pregnancies."

(Differences between claim 1 of the first auxiliary request and the corresponding claim of the main request are shown underlined; an additional difference is the deletion of the feature "*the at least one screening marker from the second trimester of pregnancy being different from the at least one screening marker from the first trimester of pregnancy*" in claim 1 of the first auxiliary request)

Dependent claims 2 to 12 are identical to the corresponding claims of the main request.

**Second auxiliary request (claims 1 to 14):**

Claim 1 differs from the corresponding claim of the main request in that the feature "*the at least one screening marker from the second trimester of pregnancy being different from the at least one screening marker from the first trimester of pregnancy*" has been deleted, and that the screening markers from the first and second trimesters are specified as follows:

"1. A method [...] comprising the steps of:  
measuring the level of at least one screening marker from a first trimester of pregnancy by:

[...]

measuring the level of at least one screening marker from a second trimester of pregnancy by:

[...]

wherein the screening markers from the first and second trimesters consist of one of the following combinations:

- 1) the at least one screening marker from the first trimester of pregnancy consists of NT and PAPP-A, and the at least one screening marker from the second trimester of pregnancy consists of AFP, uE<sub>3</sub>, total hCG and inhibin-A;
- 2) the at least one screening marker from the first trimester of pregnancy consists of NT, PAPP-A and free  $\beta$ -hCG, and the at least one screening marker from the second trimester of pregnancy consists of AFP, uE<sub>3</sub> and inhibin-A;
- 3) the at least one screening marker from the first trimester of pregnancy consists of NT and PAPP-A, and the at least one screening

- marker from the second trimester of pregnancy consists of AFP, uE<sub>3</sub> and total hCG;
- 4) the at least one screening marker from the first trimester of pregnancy consists of NT, PAPP-A and free  $\beta$ -hCG, and the at least one screening marker from the second trimester of pregnancy consists of AFP and uE<sub>3</sub>;
  - 5) the at least one screening marker from the first trimester of pregnancy consists of PAPP-A, free  $\beta$ -hCG or both, and the at least one screening marker from the second trimester of pregnancy consists of AFP, uE<sub>3</sub>, inhibin-A, free  $\beta$ -hCG, free  $\alpha$ -hCG, total hCG or any set thereof; and
- determining [...]"

Independent claim 9 corresponds to claim 13 of the main request in which the same amendments as in claim 1 have been introduced. The remaining claims differ from those of the main request in that claims 6 to 9 have been deleted, claims 10 to 12 and 14 to 18 renumbered as claims 6 to 8 and 10 to 14, and the dependencies amended accordingly.

**Third auxiliary request (claims 1 to 14)**

Independent claim 1 reads as follows:

"1. A method of determining whether a pregnant woman is at an increased risk of having a fetus with Down's syndrome, the method comprising the steps of:

measuring the level of at least one screening marker from a first trimester of pregnancy by:

- (i) assaying a sample obtained from the pregnant woman at said first trimester of pregnancy for at least one biochemical screening marker; and/or
- (ii) measuring at least one ultrasound screening marker from an ultrasound scan taken at said first trimester of pregnancy;

measuring the level of at least one screening marker from a second trimester of pregnancy by:

assaying a sample obtained from the pregnant woman at said second trimester of pregnancy for at least one biochemical screening marker,

wherein the screening markers from the first and second trimesters consist of one of the following combinations:

- 1) the at least one screening marker from the first trimester of pregnancy consists of PAPP-A, and the at least one screening marker from the second trimester of pregnancy consists of AFP, uE<sub>3</sub>, total hCG and inhibin-A;
- 2) the at least one screening marker from the first trimester of pregnancy consists of PAPP-A and free  $\beta$ -hCG, and the at least one screening marker from the second trimester of pregnancy consists of AFP, uE<sub>3</sub>, and inhibin-A;
- 3) the at least one screening marker from the first trimester of pregnancy consists of NT and PAPP-A, and the at least one screening marker from the second trimester of pregnancy consists of AFP, uE<sub>3</sub>, total hCG and inhibin-A;

- 4) the at least one screening marker from the first trimester of pregnancy consists of NT, PAPP-A and free  $\beta$ -hCG, and the at least one screening marker from the second trimester of pregnancy consists of AFP, uE<sub>3</sub>, and inhibin-A;
- 5) the at least one screening marker from the first trimester of pregnancy consists of PAPP-A, and the at least one screening marker from the second trimester of pregnancy consists of AFP, uE<sub>3</sub> and total hCG;
- 6) the at least one screening marker from the first trimester of pregnancy consists of PAPP-A and free  $\beta$ -hCG, and the at least one screening marker from the second trimester of pregnancy consists of AFP and uE<sub>3</sub>;
- 7) the at least one screening marker from the first trimester of pregnancy consists of NT and PAPP-A, and the at least one screening marker from the second trimester of pregnancy consists of AFP, uE<sub>3</sub> and total hCG;
- 8) the at least one screening marker from the first trimester of pregnancy consists of NT, PAPP-A and free  $\beta$ -hCG, and the at least one screening marker from the second trimester of pregnancy consists of AFP and uE<sub>3</sub>;
- 9) the at least one screening marker from the first trimester of pregnancy consists of PAPP-A, and the at least one screening marker from the second trimester of pregnancy consists of AFP, uE<sub>3</sub> and inhibin-A;  
and

determining, using a computer program executed on a computer, a quantitative estimate of the risk of

Down's syndrome by comparing the measured levels of both the at least one screening marker from the first trimester of pregnancy and the at least one screening marker from the second trimester of pregnancy with observed relative frequency distributions of marker levels in Down's syndrome pregnancies and in unaffected pregnancies."

Independent claim 9 corresponds to claim 13 of the main request in which the same amendments as in claim 1 have been introduced. Dependent claims 2 to 8 and 10 to 14 are identical to the corresponding claims according to the second auxiliary request.

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

E3: EP 0 800 085 A2, published on 8 October 1997;

E6: N.J. Wald and A.K. Hackshaw, *Prenatal Diagnosis*, 1997, Vol. 17, No. 9, pages 821 to 829;

E9: Nicholas J. Wald et al., *Journal of Medical Screening*, 1997, Vol. 4, pages 181 to 246;

E67: Mark I. Evans et al., *American Journal of Obstetrics & Gynecology*, March 2007, pages 198 to 205;

E68: Unknown author, *Antenatal and neonatal screening*, 1984, ed. N.J. Wald, Oxford University Press, pages 5 to 10.



XII. The submissions made by the appellant, as far as they are relevant to this decision, may be summarized as follows:

*Main request*

*Articles 84 and 123(2) EPC*

Contrary to the view of the opposition division, the limitation introduced into claim 1 was clear within the meaning of Article 84 EPC. The limitation referred to "the at least one screening marker from the first trimester" and "the at least one screening marker from the second trimester". As these terms were used earlier in the claim earlier, the word "the" made clear that the limitation was referring back to those identical sets of markers as an antecedent.

The two antecedent phrases "*measuring the level of at least one screening marker from a first trimester of pregnancy*" and "*measuring the level of at least one screening marker from a second trimester of pregnancy*" in claim 1 each defined an activity ("measuring") carried out on the product feature of "*at least one marker*". In the context of this activity, the skilled person did interpret this to mean that, when the product feature of "*at least one marker*" consisted of plural markers, the activity was performed on each individual marker. However, in the limitation introduced into claim 1 there was an additional condition of "*being different*" in respect of the two product features "*at least one marker*". This additional condition did not necessarily mean that all the markers were different, even if the activity performed on the

product features in the antecedent phrase was performed on each marker. Since the words "*at least one screening marker*" defined a set of one or more markers, the limitation of being "*different from*" simply required that the set of one or more markers from the first trimester be different from the set of one or more markers from the second trimester. This requirement was met if any one of either set was different, because then the sets as a whole were different.

Both paragraph [0019] and claims 6 and 7 of the opposed patent (corresponding to claims 8 and 9 as originally filed) suggested the same interpretation, namely that some of the markers in the two sets of "*at least one marker*" may be the same. Claims 6 and 7 covered many combinations of markers including a combination of free  $\beta$ -hCG as a marker from the first trimester and free  $\beta$ -hCG as a marker from the second trimester. This supported the idea that the requirement for difference was met even if one of the markers was the same. The passage in paragraph [0019] on which the opposition division relied started with the word "Preferably", which meant that the feature was optional and hence it was within the scope of the invention in its broadest sense to use markers from both trimesters which were correlated.

The inclusion of free  $\beta$ -hCG in both the list of markers for the first trimester set out in claim 6 and the list of markers for the second trimester set out in claim 7 was fully supported by the description. On page 4, line 46 of the patent specification, it was clearly taught that "*any markers that are effective at each particular stage may be selected*". Furthermore, free

$\beta$ -hCG was present in both Tables 2a/b and Tables 3a/b which respectively listed examples of markers that were effective in the first and second trimesters. This disclosure that free  $\beta$ -hCG was a marker which was effective in each semester combined with the teaching to select markers which were effective at each particular stage directly and unambiguously taught that the selection of free  $\beta$ -hCG both as a marker measured in the first trimester and as a marker measured in the second trimester was within the scope of the invention. Thus, like claims 6 and 7, the description also supported the interpretation that the invention did not require all the markers measured in the second trimester to be different from all the markers in the first trimester.

The amendments introduced into claim 1 had a basis in the statements on page 4, lines 6ff.; page 8, lines 12 to 15; page 12, lines 28 to 34; as well as in claims 8 and 9 and the tables of the application as filed.

*Admission of the first and second auxiliary requests into the proceedings*

The board should exercise its discretionary power to admit the auxiliary requests filed together with the statement of grounds of appeal. The actual events of the opposition proceedings had been such that the need for additional requests could not have been predicted earlier. It came as a surprise when a passage of document E3 describing a bivariate probability density function technique which was prejudicial to novelty was mentioned for the first time by the chairman of the opposition division during the oral proceedings.

Neither the patent proprietor nor, by inference, the opponents had noticed it before the oral proceedings. The auxiliary requests were a legitimate reaction to the situation, filed at the first opportunity following the oral proceedings before the opposition division.

*First auxiliary request*

*Article 84 EPC*

The limitations introduced into claim 1 had a basis in the application as filed in the paragraph on page 4, lines 6 to 14 and also the text on page 8, lines 12 to 15.

The amended claim 1 conformed to Article 84 EPC. A person skilled in the art knew that no single marker or combination of markers provided perfect separation into affected and unaffected pregnancies. Thus, he/she would not understand the term "discriminate" as meaning perfect separation between the two groups, but simply providing a useful degree of separation that enabled risk of having an affected pregnancy to be calculated and so categorising women into high and low risk groups. This was described clearly in document E68 which was a standard text from a textbook and reflected the common general knowledge of the skilled person.

In this context, the skilled person understood a direct relationship between the "ability to discriminate" and the "effectiveness" of a marker, this relationship being made explicit on page 1, lines 28 to 30 of the application as filed.

It was part of the common general knowledge of the skilled person which markers did or did not have the ability to discriminate at either trimester. An individual marker was judged to be sufficiently discriminatory for use in screening practice if its use or its addition to a panel of existing markers resulted in a clinically significant improvement in screening performance.

*Second auxiliary request*

*Article 54 EPC*

Combination (5) in amended claim 1 included a sub-combination of using free  $\beta$ -hCG in both trimesters. This sub-combination was novel over document E3. Although E3 disclosed the use of the same marker in both trimesters, the teachings of this document imposed a specific requirement to select a marker that was effective in one of the stages of pregnancy but was ineffective in the other stage of pregnancy.

The marker free  $\beta$ -hCG did not meet this requirement and was, therefore, not a marker that could be used with the method of E3. Free  $\beta$ -hCG was most effective in the second trimester, but it was also discriminatory in the first trimester. This fact was part of the general knowledge of the skilled person and was evident from documents E9, E67 and E6. Thus, even though E3 contained express mention that free  $\beta$ -hCG was a marker that could be used with the method, a person skilled in the art, on the basis of its common general knowledge, immediately understood that the mention of free  $\beta$ -hCG must be an error. Accordingly, the mention of free

$\beta$ -hCG failed to meet the standard of being "direct and unambiguous disclosure" necessary to establish a lack of novelty. Hence, all embodiments encompassed by claim 1 were novel over document E3.

*Third auxiliary request*

*Article 123(2) EPC*

The combinations numbered (1) to (4) had express basis in the description as originally filed on page 12, lines 32 to 34 and in Tables 4a and 4b on pages 14 and 15. The combinations numbered (5) to (8) corresponded to the combinations (1) to (4) but omitting inhibin-A, this having a basis on page 8, lines 25 to 31. Combination (9) had a basis in the description of Figure 1 on page 16, lines 15 to 17.

*Article 54 EPC - Document E3*

The holding of lack of novelty was overcome by the amended claims. Each of the combinations (1) to (9) were combinations of markers in which all the markers from the first trimester were different from all the markers from the second trimester, such that there was clearly novelty over E3 which related to the measurement of the same marker in both trimesters.

XIII. The submissions made by respondent I, as far as they are relevant to this decision, may be summarized as follows:

*Main request*

*Articles 84 and 123(2) EPC*

The wording of the feature introduced into claim 1 was ambiguous. The fact that, as regards that feature, diametrically opposed interpretations of the language of claim 1 were possible, indicated that the claim must be unclear. Granted claims 6 and 7, which both referred to "free  $\beta$ -hCG" as a possible screening marker for the first and second trimesters, were in contradiction with the interpretation that each of the screening markers from the first trimester must be different from each of the screening markers from the second trimester. Since it was stated in the application as filed that any markers which are effective at each particular stage may be selected, starting from the teaching of dependent claims 6 and 7, namely that free  $\beta$ -hCG was effective at the first and second trimesters, a person skilled in the art would conclude that any of the markers could be used in any stage, provided that said marker was suitable for the intended purpose. In other words, a person skilled in the art derived from said teaching that a specific screening marker could be used at two different trimesters, and not that each of the screening markers from the first trimester must be different from each of the screening markers from the second trimester.

Amended claim 1 had no basis in the application as filed. The passage on page 4, lines 6 to 14 on which the appellant relied, did not disclose a combination of different screening markers from the first and second trimesters. It merely disclosed the known fact that

individual screening markers, when measured at different stages of pregnancy, vary in their ability to discriminate between Down's syndrome pregnancies and unaffected pregnancies. Also the passage on page 8 indicated by the appellant referred only to stages of pregnancy.

*Admission of the first and second auxiliary requests into the proceedings*

The fresh requests could and should have been filed in opposition proceedings. It was apparent from the minutes of the oral proceedings before the opposition division that the proprietor chose to not react to the arguments put forward by the opponents with respect to the disclosure content of document E3, in particular the statements on page 8, lines 15 to 17, by filing amended claims.

*First auxiliary request*

*Article 84 EPC*

The meaning of the feature introduced into claim 1, which required that the screening marker by itself be discriminatory, was ambiguous. The passages of the application as filed indicated by the appellant as support for the amended claim 1 were exactly the same as cited as support for a completely different feature in claim 1 of the main request.



*Second auxiliary request*

*Article 54 EPC*

As apparent from the passage on page 4, lines 3 to 5 of E3, the content of this document was not restricted to the measurement of one marker in two different trimesters. Rather, the skilled person was taught by E3 to combine different markers, including first trimester and second trimester markers. Thus, several embodiments falling under claim 1 lacked novelty over E3.

*Third auxiliary request*

*Article 123(2) EPC*

At least options (1) to (8) of claim 1 were not supported by the application as filed. The specific combination of markers disclosed in Tables 4a and 4b were only disclosed in the context of a simultaneous correction for maternal age. However, claim 1 did not include the requirement of a correction for maternal age. While maternal age was neither a biochemical nor an ultrasound screening marker, it nonetheless had a functional relationship with these markers that significantly affects the estimation of risk of Down's syndrome. In view of this functional relationship, the specific combination of markers without a correction for maternal age violated Article 123(2) EPC.

*Article 54 EPC - Document E3*

The use of the first trimester markers PAPP-A and free  $\beta$ -hCG in combination with the second trimester markers

AFP, uE3, inhibin-A, free  $\beta$ -hCG, free alpha-hCG and total hCG was disclosed in document E3. Thus, the subject-matter of claim 1 lacked novelty.

XIV. The submissions made by respondent III, as far as they are relevant to this decision, may be summarized as follows:

*Main request*

*Articles 84 and 123(2) EPC*

While the meaning of the feature introduced into claim 1 was unambiguous if the claimed method was applied to only one screening marker from each trimester, clarity became an issue when two or more screening markers were used. The passage of the application as filed corresponding to paragraph [0030] of the patent could not be considered as a basis for the introduced feature because the passage concerned different screening tests, rather than different screening markers.

*Admission of the first and second auxiliary requests into the proceedings*

The fresh sets of claims filed with the statement of grounds of appeal had been submitted late and should not be admitted into the proceedings. In the communication accompanying the summons to oral proceedings, the opposition division had already expressed the provisional view that the subject-matter of claim 1 as granted lacked novelty in view of document E3. Being aware of the novelty objection, the

proprietor could have filed the amended sets of claims prior to the oral proceedings before the opposition division.

*First auxiliary request*

*Article 84 EPC*

The amended claim offended against Article 84 EPC because the question whether or not a screening marker was discriminatory could not be answered with certainty.

*Second auxiliary request*

*Article 54 EPC*

Free  $\beta$ -hCG was not the only marker disclosed in document E3. On page 8 of this document also the use of PAPP-A as screening marker was disclosed.

*Third auxiliary request*

*Article 84 EPC*

Claim 1 lacked clarity within the meaning of Article 84 EPC because it specified that the level of at least one screening marker from the first trimester was measured by method step (i) and/or method step (ii), but in the further features method step (ii) was positively excluded.

- XV. The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or the

first auxiliary or the second auxiliary request, all these requests filed with the statement of the grounds of appeal dated 6 April 2009, or the third auxiliary request filed at the oral proceedings. As a procedural request, the appellant requested to remit the case to the opposition division for further prosecution with respect to the issues of exclusion of computer programs as such from patentability, novelty vis-à-vis documents other than E3, inventive step and enabling disclosure.

XVI. Respondents I and III (opponents 01 and 03) requested that the appeal be dismissed.

XVII. Respondent III (opponent 03) furthermore requested that a question of law be referred to the Enlarged Board of Appeal and that, if the board decided to set aside the decision under appeal, the case be remitted to the opposition division for further prosecution with respect to the issues of exclusion of computer programs as such from patentability, novelty vis-à-vis documents other than E3, inventive step and enabling disclosure.

## **Reasons for the Decision**

*Main request (claims 1 to 18)*

*Articles 84 and 123(2) EPC*

1. Claim 1 according to the present main request, which is identical to the corresponding claim of the second auxiliary request in opposition proceedings, differs from claim 1 as granted, *inter alia*, in that it includes the additional feature "..., *the at least one*

*screening marker from the second trimester of pregnancy being different from the at least one screening marker from the first trimester of pregnancy;...*". A similar amendment has been introduced into the independent claim 13, which is derived from claim 14 as granted.

2. In the decision under appeal, the opposition division found that the feature introduced into claim 1 could have two different meanings: (i) none of the screening markers from the first trimester test is identical to any one from the second trimester test, or (ii) at least one marker from the second trimester test is different from the markers used in the first trimester test. Both meanings were found to make technical sense in the context of the invention, and to be relevant to the assessment of the scope of the claims. Since in the view of the opposition division the opposed patent as a whole did not give any hint on how the feature should be interpreted, it concluded that claim 1 lacked clarity within the meaning of Article 84 EPC (see the passage from page 16, second paragraph to page 17, second paragraph of the decision under appeal).
  
3. On appeal, the appellant maintained on the one hand that in the light of the patent specification the sole possible interpretation of the feature introduced into claims 1 and 13 was that at least one marker from the second trimester test must be different from the markers used in the first trimester test. In support of this line of argument, the appellant pointed to paragraphs [0019] and [0030] of the patent specification, and claims 6 and 7 as granted.

4. On the other hand, the appellant asserted that the wording "*the at least one screening marker*" in the introduced amendment referred back to the same wording used in claims 1 and 13 for defining the first and second steps of the claimed screening method. It also admitted that, in the context of these steps, "*measuring the level of at least one screening marker*" meant "measuring the level of **each** of one or more screening markers", since measuring the level of the set of screening markers as a whole would not make technical sense when the set consisted of more than one screening marker. However, the appellant contended that, in the context of the introduced amendment the wording "*the at least one screening marker*" had to be construed differently, namely as "a set of screening markers" (see the appellant's arguments in paragraph XII above).
5. In view of the decision of the opposition division and the arguments put forward by the appellant, the issue to be decided by the board is not only whether or not the amendment introduced into claims 1 and 13 renders these claims unclear within the meaning of Article 84 EPC - as the opposition division held - but also whether or not the amendment at issue has a basis in the application as filed (cf. Article 123(2) EPC). The answer to these questions revolves around the meaning of the wording "*the at least one screening marker*" in the introduced feature.
6. According to the jurisprudence of the Boards of Appeal concerning claim construction, when identical wording is used in a claim, the same meaning is assumed, unless the claim so construed is technically illogical. In the context of the first two steps of the method of claim 1

("measuring the levels..."; see paragraph X above), the sole interpretation of the wording "*the at least one screening marker*" which makes technical sense is - as the appellant admitted - "each of one or more screening markers". The same applies in the context of the further step of comparing the levels measured in the first and second steps with observed relative frequency distributions of marker levels in Down's syndrome pregnancies and in unaffected pregnancies, because it is evident that what is compared in this step is not the level of the set of markers as a whole, but the level of each of the screening markers measured in the preceding steps.

7. There is, in principle, no reason to give the same wording used in the feature introduced into claims 1 and 13 a different meaning. The feature at issue is then construed as "each of one or more screening markers from the second trimester of pregnancy being different from each of one or more screening markers from the first trimester of pregnancy". This interpretation makes perfect technical sense in the context of the invention, and the amended claims are, in themselves, clear and free of contradiction.
  
8. In its submissions on appeal, the appellant nevertheless relied on a different interpretation of the feature introduced into claims 1 and 13. In its view, this feature should be construed as meaning that "**at least one** screening marker of the set of screening markers from the first trimester **is different** from the markers of the set from the second trimester" (see paragraph XII above). While the board considers that, from the technical point of view, there is no cogent

reason for giving different meanings to the wording "*the at least one screening marker*" depending on whether this wording is used in the introduced feature or elsewhere in the claim, it must be acknowledged that the interpretation on which the appellant relied is, in principle, possible and makes technical sense in the context of the claimed invention.

9. Consequently, the introduced feature has, in fact, two possible meanings, which - as the opposition division stated in its decision - are relevant to the scope of the claim, since it seems that, if the feature at issue is interpreted as the appellant submitted, the amended claim would encompass embodiments of the screening method which would not be encompassed based on the narrower alternative interpretation.
10. It was submitted by the appellant that, having regard to the patent as a whole, there was no ambiguity as to how the introduced feature must be interpreted, because the sole meaning supported by the patent specification was that at least one screening marker of the set of screening markers from the first trimester must be different from the markers of the set from the second trimester. The board is, however, unable to find in the passages of the patent specification indicated by the appellant any clear support for this interpretation.
11. As regards paragraph [0019] of the patent specification, in particular the statement "*Any markers which are effective at each particular stage may be selected*" (see page 4, line 46 of the patent as granted), the board is unable to identify in it any indication, either explicit or implicit, which supports the



appellant's interpretation. In the board's view, this passage does not provide any hint as to whether one or more selected markers from the two stages could be the same, as long as one marker differs between the two sets, or whether all markers must be different. Paragraph [0030] of the patent specification, which is concerned with the performance of different screening **tests** which were either known in the art at the filing date or described for the first time in the application as filed, does not give any hint either.

12. The appellant relied further on claim 7 as granted, which, as far as it depends on claim 6, is directed to screening methods in which PAPP-A, free  $\beta$ -hCG or both are measured in the first trimester of pregnancy, and AFP, uE<sub>3</sub>, inhibin-A, free  $\beta$ -hCG, free  $\alpha$ -hCG, total hCG or any combination thereof in the second trimester of pregnancy. In the appellant's view, there would be a contradiction between this claim and the amended claim 1, if the feature introduced into the latter were construed to mean that each of the one or more screening markers from the first trimester is different from each of the one or more screening markers from the second trimester.
  
13. This argument is not persuasive. It is true that claim 7 as granted appears to encompass methods using combinations of screening markers which include free  $\beta$ -hCG as a screening marker from each of the first and the second trimesters, this being in contradiction to the feature introduced into claim 1 if the feature is interpreted as "each of one or more screening markers from the second trimester of pregnancy being different from each of one or more screening markers from the

first trimester of pregnancy". However, the board notes that claim 7 as granted appears to encompass also a method in which free  $\beta$ -hCG is used as the **sole** screening marker from each of the first and the second trimesters, which is clearly in contradiction to the feature introduced into claim 1 if interpreted as the appellant submitted. Thus, contrary to the appellant's view, claims 6 and 7 as granted cannot support conclusively either of the two possible interpretations of the feature introduced into claim 1.

14. In view of the above, the board concludes that the opposition division's finding that the amended claim 1 does not conform to Article 84 EPC is correct. The finding of lack of clarity applies, *mutatis mutandis*, also to amended claim 13.
  
15. In the decision under appeal, the opposition division did not decide the question whether or not the amendment introduced into claims 1 and 13 offends against Article 123(2) EPC. However, in the board's judgement, the application as filed does not provide a proper basis for the subject-matter defined in the amended claims 1 and 13, irrespective of the interpretation given to the introduced feature. None of the passages of the application as filed to which the appellant pointed (see, in particular, page 4, lines 6 to 9 and page 8, lines 14 and 15 of the application as filed) discloses, clearly and unambiguously, that at least one - or all - screening markers from one trimester of pregnancy must be different from the marker(s) from the other trimester. Thus, the amendment introduced into claims 1 and 13 is considered to contravene Article 123(2) EPC.

16. In view of the findings above concerning Articles 84 and 123(2) EPC, the patent cannot be maintained on the basis of the set of claims according to the main request.

*Admission of the first and second auxiliary requests into the proceedings*

17. The sets of claims according to the first and second auxiliary requests, which were filed together with the statement of grounds of appeal, are regarded as an attempt to overcome the objections of lack of novelty raised by the opponents in respect of claim 1 as granted. While it is true that an adverse provisional opinion with respect to novelty in view of document E3 was expressed in the communication attached to the summons to oral proceedings before the opposition division, it was only during the oral proceedings that the opposition division brought to the attention of the parties a passage in document E3 which was regarded as highly relevant to the assessment of novelty. It appears from the minutes of the oral proceedings before the opposition division that this came as a surprise not only to the present appellant, but also to the other parties who requested a short adjournment of the proceedings in order to evaluate the content of the passage indicated by the opposition division (see paragraph 2.3 of the Minutes).
18. In fact, the passage in question had not been mentioned, let alone discussed in the written proceedings. The board considers that, under these circumstances, it would be unreasonable to demand from the proprietor an

immediate reaction in the form of amended claims. Since the amended claims were filed together with the statement of grounds of appeal, i.e. at the earliest opportunity once the appellant had become aware of the relevance of the passage in question, the procedure has not been delayed and the respondents had ample time to study the claims and submit their comments.

19. As regards the decisions of this board of appeal in different compositions which were cited by respondent I in support of its objection to the admission of the fresh sets of claims into the proceedings (T 1108/08 of 11 May 2009, T 1483/07 of 7 July 2009, T 782/07 of 4 February 2009, T 762/07 of 24 February 2009), the board observes that decisions on the admission of fresh requests must always take into account the specific circumstances of each case. As the circumstances of the cases underlying the cited decisions differ from the very specific circumstances of the present case, the conclusions reached in those cases do not prejudice the admission into the proceedings of the fresh sets of claims filed by the appellant together with the statement of grounds of appeal.

20. Thus, the board, exercising its discretionary power to admit or disregard requests submitted for the first time on appeal, decided to admit the sets of claims according to the first and second auxiliary requests into the proceedings.

*First auxiliary request (claims 1 to 12)*

*Article 84 EPC*

21. The method of claim 1 differs from that of the corresponding claim as granted in that each of the steps of measuring the level of at least one screening marker from a first/second trimester of pregnancy, is now preceded by the step of selecting at least one screening marker from the first/second trimester of pregnancy that has the ability to discriminate between Down's syndrome pregnancies and unaffected pregnancies at the corresponding trimester.
22. In the board's judgement, claim 1 does not conform to Article 84 EPC because, in view of the ambiguity of the functional feature defining the screening marker(s) to be selected, the scope of the protection sought cannot be determined with certainty.
23. As the appellant admitted, no single marker or combination of markers provides perfect discrimination between affected and unaffected pregnancies. Thus, the question arises whether or not there is a generally accepted quantitative definition of the standard of discrimination to be applied.
24. The appellant pointed to documents E68 and E9 (see paragraph XI above) as evidence of the common general knowledge of the skilled person concerning the discriminatory power of a particular screening marker or set of markers. In the appellant's view, these documents showed that an individual marker was judged to be sufficiently discriminatory for use in screening

practice if its use or its addition to a panel of existing markers resulted in a clinically significant improvement in screening performance, that is, a clinically useful increase in the proportion of true positives (detection rate) for the same false-positive rate.

25. The board notes that there is no unequivocal indication in the documents cited by the appellant for what is meant to be - from the quantitative point of view - a "clinically significant improvement in screening performance" or a "clinically useful increase in the proportion of true positives". Nor does the description provide such an indication. It is stated in the description that "*... the ability of different screening markers to discriminate between Down's syndrome pregnancies and unaffected pregnancies varies according to the stage of pregnancy*" (see page 4, lines 6 to 9 of the application as filed), and that "*The discriminatory power of a test is usually specified in terms of the detection rate achieved for a given false-positive rate, or in terms of the false-positive rate required to achieve a given detection rate*" (see page 1, lines 30 to 34 of the application as filed). However, no cut-off value whatsoever, either for the detection rate or for the false-positive rate is indicated, from which a person skilled in the art could learn the extent of the scope of protection.
26. In view of the lack of clarity of claim 1, the board concludes that the set of claims according to the first auxiliary request cannot form a basis for the maintenance of the patent.

*Second auxiliary request (claims 1 to 14)*

*Article 54 EPC*

27. In the decision under appeal, the opposition division found that all the steps defining the method of claim 1 as granted were disclosed, either explicitly or implicitly, in document E3. In the amended claim 1 according to the present second auxiliary request, particular combinations of screening markers from the first and second trimesters are specified which, in the appellant's view, impart novelty to the claimed subject-matter.
28. Even though further objections under Articles 123(2) and 84 EPC were raised by the respondents in respect of this request, the decisive issue is, in the board's view, whether or not a method using the marker combination (5) specified in claim 1 (see paragraph X above) is new with regard to document E3.
29. On appeal, the appellant admitted that the marker combination (5) specified in claim 1 included the sub-combination of using free  $\beta$ -hCG as a screening marker in both the first and the second trimesters of pregnancy. Furthermore, the appellant admitted that free  $\beta$ -hCG was expressly mentioned in document E3 as a screening marker that can be used in both trimesters of pregnancy for determining whether a pregnant woman is at an increased risk of carrying a fetus with Down's syndrome, applying the method described in the same document. However, the appellant contested the finding of lack of novelty in the decision under appeal, arguing that a person skilled in the art, on the basis

of his/her common general knowledge, immediately understood that the mention of free  $\beta$ -hCG must be an error because free  $\beta$ -hCG was not a marker that could be used in the method of E3. As evidence of the common general knowledge of the skilled person at the priority date, the appellant relied on documents E9, E67 and E6 (see paragraph XI above).

30. The arguments and evidence put forward by the appellant in this respect fail to persuade the board. First, there was, in the board's view, no reason for a person skilled in the art reading document E3 to doubt that the method described therein could be applied using free  $\beta$ -hCG as a screening marker for both the first and second trimesters of pregnancy, as expressly stated in the document. It is noted that, according to the method described in E3, the concentration of the marker is determined at two points in time during pregnancy, preferably in different trimesters (see page 3, lines 43 to 46). At one time, the marker's ability to discriminate between affected and unaffected pregnancies is low, i.e. the marker does not function **effectively** as a marker (see page 3, lines 38 to 40).

31. Contrary to the appellant's contention, this statement cannot be interpreted to mean that the screening marker does not "function" at all, but rather that, if the difference in the concentration of the marker between affected and unaffected pregnancies is relatively small (less than 20%), the inter-subject variation may strongly influence the ability to discriminate. This is in fact the problem purportedly solved by the method described in E3, which provides a correction to remove



or reduce the influence of the inter-subject variation (see page 3, line 27).

32. As it is apparent from Figure 7.2 of document E9, the ability of the free  $\beta$ -hCG marker to discriminate between affected and unaffected pregnancies in the first trimester of pregnancy varies strongly between the different studies, suggesting that inter-subject variation may be influential. This is in contrast to the free  $\beta$ -hCG values in the second trimester (see Figure 3.5 in document E9), which allow a much more reliable discrimination. Since this is precisely the situation addressed in document E3, a person skilled in the art reading this document would have no reason to suspect that free  $\beta$ -hCG was erroneously mentioned as a marker which could be used in the described method. Thus, the board regards the appellant's contention relying on document E9 as ill-founded.
  
33. No other conclusion can be reached having regard to documents E67 and E6. In any case, the content of these two scientific publications cannot normally be regarded as forming part of the common general knowledge of a person skilled in the art, all the more so if it is considered that document E67 was published in 2007, i.e. almost ten years after the priority dates claimed in the patent.
  
34. For the reasons given above, the board is persuaded that the objection of lack of novelty prejudices the maintenance of the patent on the basis of the second auxiliary request.

*Third auxiliary request (claims 1 to 14)*

*Admission into the proceedings*

35. The set of claims of the present third auxiliary request was filed in response to a clarity issue raised by respondent III in respect of the set of claims of the previous third auxiliary request which was later withdrawn. It should be noted that, even though the previous claims had been on file from the outset of the appeal proceedings, the clarity objection was raised for the first time during the oral proceedings. Thus, the present third auxiliary request, which was filed as a reaction to the objection, could not have been submitted earlier.

36. The amendment introduced into claims 1 and 9 of the third auxiliary request consists in the deletion of one alternative step. Since no new substantial formal issues which might have required adjournment of the oral proceedings arose from this amendment, the board, exercising its discretion, decided to admit the set of claims into the proceedings.

*Rule 80 and Article 123(2)(3) EPC*

37. The board is persuaded that the amendments introduced into the claims have been occasioned by the grounds for opposition under Article 100(a) in conjunction with Article 54 EPC.

38. As concerns Article 123(2) EPC, the basis in the application as filed for the particular combinations of

screening markers specified in claims 1 and 9 is as follows:

- Combination (1): Tables 4a and 4b, first column;
- Combination (2): Tables 4a and 4b, second column;
- Combination (3): Tables 4a and 4b, third column;
- Combination (4): Tables 4a and 4b, fourth column;
- Combinations (5) to (8): like (1) to (4) in conjunction with page 8, lines 25-31; and
- Combination (9): page 16, lines 15-17; Figure 1.

39. The board cannot accept respondent I's argument that Article 123(2) EPC is contravened because, whereas claims 8 and 9 of the application as filed specified that the screening markers were assayed in a **serum** sample from the pregnant woman, the present claim 1 does not include the serum limitation. The board notes that on page 7, line 3ff. of the application as filed, it is disclosed that the measurements carried out on biochemical samples may include assaying one or more of, *inter alia*, PAPP-A, AFP and uE<sub>3</sub> **in maternal serum or plasma**. In particular in view of this passage, there is no reason for a person skilled in the art reading the application as filed to assume that the invention disclosed therein is limited to methods in which the biochemical screening markers are assayed only in maternal serum.

40. As concerns respondent I's objection to the use of the term "trimester" in the present claims, it is true that the claims as filed only specified a "first stage" and a "second stage". However, since in the description of the application as filed the terms "trimester" and "stage" are used interchangeably (see, for instance, the paragraph bridging pages 3 and 4 of the application as filed), the board has no doubts that, in this respect, Article 123(2) EPC is met.

41. Respondent I maintained that the subject-matter of claim 1 extended beyond the content of the application as filed, because in Tables 4a,b and 5a,b of the application, which were allegedly the sole basis for the amended claim, the specific combinations of screening markers were disclosed only in the context of simultaneous correction for maternal age, while this correction was missing in the claim. The board observes that, even though the disclosure of the application focuses on screening methods using biochemical and ultrasound screening markers, it is also stated in the application that:

*"Information on one or more of these biochemical or ultrasound markers (collectively called screening markers) **can** be combined with the age-related risk of Down's syndrome, to form the basis of a screening test."* (see page 1, lines 13 to 16 of the application as filed; emphasis added by the board).

42. In the board's judgement, a person skilled in the art reading the quoted passage of the application would understand that, even though maternal age **may** be used as a further parameter in combination with biochemical

and ultrasound screening markers, this does not represent an essential feature of the invention, but rather a further option or embodiment.

43. No objections were raised by the respondents under Article 123(3) EPC, and the board has none of its own.

*Article 84 EPC*

44. Respondent III raised an objection of lack of clarity in respect of claims 1 and 9, arguing that there was a contradiction between the general definition of the markers or combination of markers measured in the first and second steps, and the particular combinations (1) to (9) specified in the contested claims.
45. The board cannot accept respondent III's objection. Claims 1 and 9 specify that at least one biochemical screening marker **and/or** at least one ultrasound screening marker is assayed at the first trimester of pregnancy, and that at least one biochemical screening marker is assayed at the second trimester of pregnancy. Each of the particular combinations of screening markers (1) to (9) specified in claim 1 is covered by this general definition. In combinations (1), (5) and (9) a single biochemical screening marker (PAPP-A) is assayed at the first trimester and several biochemical screening markers are assayed at the second trimester. In combinations (2) and (6), two biochemical screening markers (PAPP-A and beta-hCG) are assayed at the first trimester, and two or more biochemical screening markers at the second trimester. Each of these combinations is covered by the alternative term "or". In combinations (3), (4), (7) and (8), an ultrasound

screening marker (NT) and, additionally, one or two biochemical screening markers are assayed at the first trimester, and several biochemical screening markers at the second trimester. This is covered by the term "and".

46. It is true that there appears to be a slight inconsistency within the claim because at the first trimester ultrasound screening markers alone (i.e. not in combination with a biochemical screening marker) are not assayed in any of the particular combinations specified in claims 1 and 9. However, this does not necessarily render the claims unclear within the meaning of Article 84 EPC. The board has no serious doubt that a person skilled in the art reading the claim would understand the particle "or" linking the two types of marker as meaning that either type **could**, but not necessarily must be part of a combination of markers. In the board's view, forcing the appellant to reformulate the claims only for the sake of utmost consistency would be contrary to the principle of procedural efficiency, as the amendments would possibly give rise to other formal objections.

*Article 54 EPC - Document E3*

47. Contrary to respondent I's view, the board is unable to find in document E3 a clear and unambiguous disclosure of the use of the first trimester markers PAPP-A and free  $\beta$ -hCG in combination with the second trimester markers AFP, uE3, inhibin-A, free  $\beta$ -hCG, free alpha-hCG and total hCG. While it is true that these markers are mentioned in document E3 (see page 4, lines 3 to 6), this is done only in the context of a method as described in the prior art document, in which one and

the same marker is measured at two points in time separated by several weeks. None of the embodiments of the method of claim 1 defined by the marker combinations (1) to (9) involves measuring the same screening marker both at the first and second trimesters of pregnancy. Thus, with regard to document E3 novelty is acknowledged.

*Request for referral of a question of law to the Enlarged Board of Appeal*

48. Pursuant to Article 112(1)(a) EPC, the boards of appeal shall refer a question to the Enlarged Board of Appeal if this is necessary for ensuring uniform application of the law or if a point of law of fundamental importance arises. In the present case, neither requirement is fulfilled.
49. Respondent III submitted its request for referral of a question of law during the discussion of appellant's second auxiliary request, against which it had raised a clarity objection (see paragraph VIII above). Since the board refused the second auxiliary request for lack of novelty, i.e. for reasons unrelated to the issue raised by respondent III in its request for referral, no decision of the Enlarged Board of Appeal is required in so far as the second auxiliary request is concerned.
50. Respondent III nevertheless argued that the third auxiliary request, albeit amended by the proprietor in order to overcome respondent III's corresponding objection (see paragraphs 35 and 36 above), still suffered from a similar lack of clarity so that the

question to be referred was relevant for deciding the present case.

51. However, the board's finding on Article 84 EPC with respect to claim 1 of the third auxiliary request (see paragraphs 45 and 46 above) does not contradict earlier decisions of the boards of appeal. The issue on which respondent III based its request for referral concerns the interpretation of a particular term in the context of a specific claim. The board is not aware of any decision taken under circumstances corresponding to those of the present case - nor did respondent III cite any - from which the board might have departed.

52. In addition, the board fails to see in the question formulated by respondent III a point of law of fundamental importance that would justify a referral. As stated above, the issue to be decided in the context of assessing the conformity of claim 1 to Article 84 EPC is how a person skilled in the art would interpret and understand the claim, having regard to a slight inconsistency between the general definition of the markers or sets of markers to be assayed at a certain point in time, and the particular embodiments specified in the claim. This issue is a very specific one and does not raise any legally important point.

53. Consequently, the request for referral cannot be granted.

*Remittal to the opposition division*

54. Both the appellant and respondent III requested remittal of the case to the opposition division for



further prosecution with respect to issues not yet considered by the opposition division (i.e. novelty vis-à-vis documents other than E3, inventive step and sufficiency of disclosure), or issues which had been discussed in the decision under appeal (exclusion of computer programs as such from patentability), but were the subject of a referral for opinion to the Enlarged Board of Appeal at the time when the present decision was taken. Respondent I did not object to the remittal.

55. The board considers that in the present case a remittal to the opposition division is justified. Thus, exercising the discretion conferred by Article 111(1) EPC, the board decides to remit the case to the opposition division for further prosecution on the basis of the third auxiliary request filed at the oral proceedings before the board.

**Order**

**For these reasons it is decided that:**

1. The decision under appeal is set aside.
2. The request to refer a question of law to the Enlarged Board of Appeal is refused.
3. The case is remitted to the opposition division for further prosecution on the basis of the third auxiliary request filed at the oral proceedings.

The Registrar:

The Chairman:

A. Wolinski

L. Galligani