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**Datasheet for the decision  
of 13 November 2014**

**Case Number:** T 0021/09 - 3.3.08

**Application Number:** 00928969.5

**Publication Number:** 1185695

**IPC:** C12Q1/68

**Language of the proceedings:** EN

**Title of invention:**

Process for high throughput DNA methylation analysis

**Patent Proprietor:**

University of Southern California

**Opponent:**

Applera Corporation

**Headword:**

Right to be heard/UNIVERSITY OF SOUTHERN CALIFORNIA

**Relevant legal provisions:**

EPC Art. 113(1)  
EPC R. 103(1)(a), 111(2)  
RPBA Art. 11

**Keyword:**

Substantial procedural violation (yes)  
Remittal (yes)  
Reimbursement of the appeal fee (yes)

**Decisions cited:**

T 0135/96, T 0914/98, T 0048/00, T 1039/00, T 0273/04,  
T 2366/11

**Catchword:**



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Case Number: T 0021/09 - 3.3.08

**D E C I S I O N  
of Technical Board of Appeal 3.3.08  
of 13 November 2014**

**Appellant:** UNIVERSITY OF SOUTHERN CALIFORNIA  
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**Respondent:** Applera Corporation  
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**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted on 20 November  
2008 revoking European patent No. 1185695  
pursuant to Article 101(3) (b) EPC.**

**Composition of the Board:**

**Chairman** M. Wieser  
**Members:** M. R. Vega Laso  
J. Geschwind

## **Summary of Facts and Submissions**

- I. European patent No. 1 185 695 with the title "Process for high throughput DNA methylation analysis" was granted on European patent application No. 00928969.5, which was filed as international application under the PCT and published as WO 00/70090 (in the following "the application as filed"). The patent was granted with 21 claims.
  
- II. Two oppositions were filed based on the grounds that the claimed subject-matter lacks novelty and inventive step (Article 100(a) in conjunction with Articles 54 and 56 EPC), and extends beyond the content of the application as filed (Article 100(c) EPC), and that the invention as claimed is not disclosed in the patent in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(b) EPC).
  
- III. Opponent 01 withdrew its opposition during the opposition proceedings.
  
- IV. By a decision of an opposition division of the European Patent Office under Articles 101(2), (3) (b) EPC posted on 20 November 2008, the patent was revoked. The opposition division found that the subject-matter of the amended claims according to the main request then on file lacked an inventive step, and that the amendments introduced into the claims according to the second auxiliary request then on file offended against Article 123(2) EPC. A set of claims filed during the oral proceedings as first auxiliary request was not admitted into the proceedings.

- V. The patent proprietor (appellant) lodged an appeal against the decision of the opposition division. Together with its statement of grounds of appeal, the appellant submitted a new set of amended claims (claims 1 to 16) "*as the main request*". The appellant requested that the decision under appeal be set aside and the case be remitted to the opposition division on the grounds that its right to be heard had been violated in opposition proceedings. As a subsidiary request, the appellant requested that the decision under appeal be set aside and the patent be maintained on the basis of the set of claims filed with the statement of grounds of appeal.
- VI. The opponent (respondent) replied to the statement of grounds of appeal and requested that the decision under appeal be upheld, the appellant's request for remittal of the case to the opposition division be denied and the outstanding issues be heard by the board. As a subsidiary request, the respondent requested oral proceedings.
- VII. By a communication of the board pursuant to Rule 100(2) EPC, the parties were informed that, in spite of being of the provisional opinion that the opposition proceedings suffered from a fundamental procedural deficiency, the board was disinclined to remit the case to the opposition division because the remittal would probably lead to a substantial delay in the procedure. The parties were given the opportunity to submit observations on the issue of remittal.
- VIII. The appellant replied to the board's communication maintaining its request for remittal. Further, it requested oral proceedings pursuant to Article 116(1) EPC if the board intended to reject the

- request for remittal, and reimbursement of the appeal fee in accordance with Rule 103(1)a) EPC.
- IX. In its reply to the communication, the respondent submitted further arguments in support of its view that there had been no procedural violation in opposition proceedings. The respondent agreed with the board's provisional opinion that the case should not be remitted to the opposition division.
- X. The board summoned the parties to oral proceedings. In a communication under Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) attached to the summons, the board indicated that the issues to be discussed at the oral proceedings were whether or not there had been a fundamental procedural deficiency in opposition proceedings and, if so, whether or not remittal of the case was justified. It was advanced that, if either of these two issues were decided by the board in the negative, further oral proceedings would have to be scheduled for discussion of the outstanding procedural and substantive issues.
- XI. On 7 April 2014, the respondent informed the board that it would not be represented at the oral proceedings. It maintained its request that the case not be remitted to the opposition division, and relied on comments presented in writing.
- XII. The oral proceedings were cancelled.
- XIII. The following documents are referred to in this decision:
- Annex 7c: "Methylation assays in regions with mosaic CpG methylation patterns assessing

differential methylation profit[sic] from detection methods covering more than two sites", authored by Dr Jörn Lewin, filed on 25 August 2005;

Annex 8a: "Experiments related to ONCOR Patent", 2008, authored by Dr Reimo Tetzner, filed on 25 August 2005;

Annex 8b: "Application D has a higher specificity than SybrGreen™", filed on 25 August 2005; and

Annex 9: "Evidence showing inventiveness of Application B", filed on 25 August 2005.

XIV. The submissions made by the appellant in writing that relate to issues relevant to this decision, were essentially as follows:

*Violation of the right to be heard - Article 113(1) EPC*

In opposition proceedings, the patent proprietor's right to be heard had been violated. The opposition division had failed to consider not only experimental data submitted in preparation of the oral proceedings, but also a key argument with respect to one of the two embodiments claimed. Moreover, the opposition division had refused to admit a set of claims submitted as first auxiliary request during the oral proceedings.

In the decision under appeal, the opposition division had rejected the main request then on file on the grounds that the subject-matter of both claim 1 ("application B") and claim 5 ("application D") lacked an inventive step. A core argument of the opposition division in support of this finding had been that the

technical effects purportedly underlying the invention could not be taken into consideration because they had not been supported by experimental data. However, comprehensive experimental data for those technical effects (speed, reproducibility, robustness and clinical applicability) had been submitted in preparation of the oral proceedings, in particular in Annexes 9, 8a, 8b and 7c. The supportive data for "application B" (Annex 9) comprised more than 15 pages of experimental data and references to seven scientific publications, those for "application D" (Annexes 8a, 8b and 7c) references to 15 independent scientific publications and comparative experiments between application D and the closest prior art. By overlooking these comprehensive experimental data, the opposition division had violated the patent proprietor's right to be heard.

The opposition division had also failed to take into account a key argument supporting an inventive step for "application D". Contrary to the statements in the last paragraph on page 19 of the decision under appeal, the proprietor had never argued that "application D" would be associated with the same technical effects as "application B". The proprietor's key argument with regard to "application D" had always been the increase in specificity. Although this point had been stressed in the proprietor's response to the summons to the oral proceedings in opposition proceedings, the opposition division had not considered the increased specificity as a technical effect, nor provided any comment or explanation in this respect. This represented a violation of the right to be heard.

In spite of having been timely submitted, the opposition division had refused to admit the set of



claims according to the first auxiliary request into the proceedings. The decision had been based on Rule 116 EPC. However, Rule 116 EPC was not applicable in this case because its requirements were not fulfilled. The feature introduced into the claims of the first auxiliary request ("*... whereby methylation patterns in genomic DNA samples are determined*") had always played a central role in the argumentation of the patent proprietor, who had discussed it as part of the problem to be solved and submitted evidence in its support. However, the argument was addressed by the opposition division for the first time during the oral proceedings. As a reaction to the discussion the first auxiliary request had been submitted.

Given the comprehensive discussion by the patent proprietor and the experimental data submitted, it could not be argued that the amendment introduced into the first auxiliary request was "unforeseeable". The opposition division's concerns with respect to the clarity of the amended claims were unfounded. Contrary to the opposition division's view, the need to re-open the discussion of inventive step did not justify the rejection of the first auxiliary request.

*Remittal to the opposition division*

The violation of the right to be heard constituted a fundamental procedural deficiency which, pursuant to Article 11 of the Rules of Procedure of the Boards of Appeal, required remittal of the case. If the board were to take a final decision on the case, the appellant would be deprived of the right to a properly reasoned decision by the opposition division in which the arguments and experimental evidence submitted in support of an inventive step were taken into account.

- XV. The submissions made by the respondents in writing concerning issues relevant to this decision, may be summarized as follows:

*Violation of the right to be heard - Article 113(1) EPC*

The patent proprietor's right to be heard had not been violated in opposition proceedings. The issues of added matter, novelty and inventive step had been considered at length during the course of the oral proceedings before the opposition division. The experimental data submitted by the patent proprietor had not been overlooked. The proprietor had referred to these data during the course of the oral proceedings, and, as was apparent from section 5.4.1 of the decision under appeal, in particular the first full sentence at the top of page 16, and the statements on page 17, the opposition division had taken into account the data, but considered them to be of no assistance in determining inventive step. The decision under appeal was properly reasoned in that it accurately reflected the points that had been made during the course of the oral proceedings.

As was clear from the minutes of the oral proceedings, the opposition division had not been prepared to automatically admit all of the documents filed by the patent proprietor with the final written submissions, but had intended to decide on their admission as the documents became relevant. The decision under appeal did not refer to any specific document submitted with the final written submissions because the patent proprietor had not asked the opposition division during the course of the oral proceedings to admit any particular document into the proceedings, nor had it

referred to or quoted from any specific document in relation to inventive step.

The opposition division had considered properly the admissibility of the claims according to the first auxiliary request and had allowed the patent proprietor its full right to be heard. The late filing of the claims was not justified. Although in its submissions during the opposition proceedings the patent proprietor had referred to the detection of methylation patterns as a significant feature, no auxiliary request including this feature had been presented until late in the afternoon during the course of the oral proceedings. The opponent (and the opposition division) had been taken aback by the proprietor's procedural behaviour. The facts of the present case were different from those underlying decision T 273/04 (*supra*), because in the present case the opposition division had not offered a positive preliminary opinion which might have suggested to the patent proprietor that auxiliary requests need not be filed.

The amendment introduced into the claims of the first auxiliary request did not limit the scope of the claims, raised questions of clarity under Article 84 EPC and did not clearly address the objections of lack of inventive step.

*Remittal to the opposition division*

For the sake of procedural efficiency, the case should not be remitted back to the opposition division. The patent proprietor had had a proper opportunity to present its case before the opposition division. Any remittal at this stage would only cause unnecessary delay in the proceedings.

- XVI. The appellant requested that the decision under appeal be set aside and the case be remitted to the opposition division for further prosecution. Additionally, the appellant requested reimbursement of the appeal fee. As a subsidiary request, oral proceedings were requested.
- XVII. The respondent requested that the appeal be dismissed. Subsidiarily, the respondent requested that the appellant's request for remittal of the case to the opposition division be dismissed.

### **Reasons for the Decision**

#### *Violation of the right to be heard - Article 113(1) EPC*

1. The main issue to be decided is whether or not the right to be heard (Article 113 EPC) of the patent proprietor (the present appellant) was violated in opposition proceedings. The appellant substantiated its allegation of a procedural violation arguing that the opposition division not only failed to consider experimental data and a key argument on inventive step submitted with the reply to the summons to oral proceedings, but also refused to admit into the proceedings the set of amended claims filed during the oral proceedings as first auxiliary request (see section 6.3 of the decision under appeal).
2. As regards the experimental data, the appellant referred to the Annexes 9, 8a, 8b and 7c. These Annexes were submitted by the patent proprietor as a reaction to the preliminary opinion of the opposition division on inventive step expressed in the communication dated 15 April 2008 attached to the summons to oral proceedings. In the communication, the opposition

division held that none of the technical effects on which the patent proprietor relied in respect of the method of claim 6 as granted (application B) was "... supported by any corresponding experimental data which thus, pursuant established case law (cf. Case Law 5<sup>th</sup> Ed. 2006, I.D.4.2), cannot be taken into consideration for the assessment of inventive step" (see paragraph bridging pages 18 and 19 of the communication).

3. According to the appellant, Annex 9 ("Evidence showing inventiveness of Application B") showed the technical performance and the biological and clinical relevance of the claimed method by reference to independent scientific publications of third parties and publications of the patent proprietor, as well as by experimental data (see sections 1.3 and 2). *Prima facie*, Annex 9 has evidential value for the ability of the method to discriminate between neighbouring methylation levels, in particular between low methylation levels (see section 1.3.3 of Annex 9). Additionally, Annex 9 shows that, applying the method defined as "application B", small amounts of DNA can be detected independently from DNA concentration (see section 1.3.1) with good repeatability (see section 1.3.2).
  
4. The evidence in Annexes 7c, 8a and 8b relates to application D. Annex 7c presents the results of experiments aimed at the detection of methylation patterns, and Annexes 8a and 8b show the results of comparative experiments in which the claimed method is compared to methods known in the prior art, in particular the Sunrise<sup>©</sup> (Annex 8a) and the SybrGreen<sup>TM</sup> technologies (Annex 8b). *Prima facie*, the experiments show a higher specificity of the claimed method.

5. Annexes 9, 8a, 8b and 7c are not mentioned in the decision under appeal. Nor are the specific experimental data provided therein discussed in the decision in connection with the issue of inventive step. Contrary to the respondent's view, the first full sentence on the top of page 16 of the decision under appeal does not relate to the experimental evidence in the Annexes in question, but only to that in Annex I, which had been filed by the proprietor on 21 November 2007 in response to the notices of opposition. As regards the statements on page 17 of the decision ("*The other two technical effects are not supported by any corresponding experimental data ...*"), it is not clear to the board whether the opposition division, when arriving at this finding, disregarded the experimental evidence in the Annexes in question, in particular Annex 9, or whether it considered it, but found it not to support the alleged technical effects for reasons not specified in the decision.
6. The minutes of the oral proceedings before the opposition division dated 20 November 2008 do not reflect any discussion on the experimental evidence submitted by the patent proprietor in preparation of the oral proceedings. It is, however, stated in section 3 of the minutes that documents (42) to (75) - which were filed by the patent proprietor with the same submission as the Annexes - were considered to be late-filed, and that the discussion on whether or not they were admitted into the proceedings was postponed. Whether or not the same applied to the Annexes in question, which are not specifically mentioned in this passage, is unclear. In any case it is noted that a discussion on the admission of late-filed evidence - if it took place - has not been recorded in the minutes of

- the oral proceedings, and that documents (42) to (75) - like the Annexes in question - are not mentioned in the reasons given by the opposition division for its findings on inventive step.
7. Under these circumstances, two possibilities arise: either the opposition division disregarded the experimental evidence in the Annexes in question as late-filed, or it may have considered it, but failed to give proper reasons in its decision as to why this evidence does not support the technical effects on which the patent proprietor relied in its line of argument on inventive step. In the first case, not only the patent proprietor has not been heard on the issue of admission of the evidence into the opposition proceedings, but, more importantly, the decision is absolutely silent about it. In the second case, the decision under appeal suffers from a severe deficiency in the reasons given by the opposition division for the adverse findings on inventive step.
  8. In either case, the decision cannot be regarded as being in conformity with Rule 111(2) EPC. Since the opposition division refused the main request for lack of inventive step, the absence of reasoning in the decision concerning the experimental evidence filed by the patent proprietor in support of its line of argument on inventive step is, in accordance with the jurisprudence of the Boards of Appeal (see, *inter alia*, decision T 135/96 of 20 January 1997), a fundamental deficiency.
  9. The question whether or not the patent proprietor expressly requested admission of the experimental evidence during the oral proceedings is not regarded by the board as a circumstance that would mitigate the

severity of the violation. Since the evidence was submitted by the patent proprietor in preparation of the oral proceedings and in clear response to the opposition division's communication, it had to be assumed that the proprietor's intention was to have the experimental evidence admitted into the proceedings and considered by the opposition division.

10. Summarising the above, the board concludes that the opposition division's failure to either consider the experimental evidence brought forward by the patent proprietor, or give reasons as to why it was not admitted into the proceedings, or did not support the purported effects, violated the patent proprietor's right to be heard. Since there is a causal link between the procedural deficiency and the final adverse decision on inventive step, the procedural defect is decisive and hence fundamental.
11. In view of these findings, there is no need to consider the appellant's further allegation of a procedural violation based on the non-admission of the first auxiliary request filed during the oral proceedings.

*Remittal to the opposition division*

12. According to Article 11 of the Rules of Procedure of the Boards of Appeal, a board shall remit a case to the department of first instance if fundamental deficiencies are apparent in the first instance proceedings, unless special reasons present themselves for doing otherwise.
13. In the present case, the respondent argued that remittal to the opposition division would entail a delay in reaching a final decision.



14. The board shares the view of the competent board in decision T 48/00 of 12 June 2002 (see section 11 of the Reasons) that a delay of the final decision caused by the remittal is an insufficient reason not to order remittal. The fundamental right of an appellant to a fair hearing before the opposition division must outweigh any advantage that might accrue to the respondent by having the board of appeal deal fully with the case rather than remit it (see decision T 914/98 of 22 September 2000; section 3 of the Reasons).
15. For these reasons, the board decides to remit the case to the opposition division for further prosecution.

*Reimbursement of the appeal fee (Rule 103(1)(a) EPC)*

16. The appeal having been allowed, the board considers reimbursement of the appeal fee to be equitable by reason of a substantial procedural violation (see, *inter alia*, decisions T 2366/11 of 26 March 2012 and T 1039/00 of 15 January 2001).

*Request for oral proceedings*

17. Since the respondent informed the board that it would not attend the scheduled oral proceedings (see section XI above), and the appellant's request to remit the case to the opposition division has been granted, this decision can be taken without oral proceedings.

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division for further prosecution.
3. The appeal fee is to be reimbursed.

The Registrar:

The Chairman:



A. Wolinski

M. Wieser

Decision electronically authenticated