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**Datasheet for the decision  
of 30 July 2009**

**Case Number:** T 0231/08 - 3.2.02

**Application Number:** 00942919.2

**Publication Number:** 1192269

**IPC:** C12Q 1/00

**Language of the proceedings:** EN

**Title of invention:**

Mass transport limited in vivo analyte sensor

**Applicant:**

Abbott Diabetes Care Inc.

**Opponent:**

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**Headword:**

-

**Relevant legal provisions:**

EPC R. 103  
RPBA Art. 11

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

EPC Art. 52(1), 54, 96(2), 113(1)  
EPC R. 51(3)

**Keyword:**

"Novelty (yes, after amendment)"  
"Substantial procedural violation (yes)"  
"Reimbursement of the appeal fee (yes)"

**Decisions cited:**

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**Catchword:**

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Case Number: T 0231/08 - 3.2.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.02  
of 30 July 2009

**Appellant:** Abbott Diabetes Care Inc.  
1360 South Loop Road  
Alameda, CA 94502 (US)

**Representative:** Andrae, Steffen  
Andrae Flach Haug  
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**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 6 August 2007  
refusing European application No. 00942919.2  
pursuant to Article 97(1) EPC 1973.

**Composition of the Board:**

**Chairman:** M. Noël  
**Members:** S. Chowdhury  
A. Pignatelli

## Summary of Facts and Submissions

- I. This appeal is against the decision of the examining division dated 6 August 2007 to refuse European patent application No. 00 942 919.2.
- II. The application was filed as an international application and published under the number WO 00/78992. The application as filed and published included 41 claims.

Subsequently an International Search Report (ISR) and an International Preliminary Examination Report (IPER) were drawn up by the EPO, acting as the International Search and Preliminary Examining Authority, respectively. In the IPER an objection of lack of novelty was raised against claims 1-4, 6-9, 11, 12, 15, 17-24, 26-28, 33-36, 38, 40, and 41 on the basis of six documents cited in the ISR.

As regards the novelty of the subject-matter of claim 19 the IPER merely stated the following:

"19(not new): ..... The subject-matter of this claim is for example anticipated by DX1 (Fig.2,3)".

The application then entered the regional phase, in which the applicant limited the claims to claims 1 to 13, corresponding to original claims 19 to 31.

An official communication pursuant to Article 96(2) EPC was issued by the examining division on 31 March 2005, which is cited below in full and without amendment:-

"Claims 1-13 are identical with claims 19-31 as originally filed and almost identical with claims 19-31, on which the International Preliminary Examination Report was based. The deficiencies mentioned in that report with respect to claims 19-31 give rise to objections under the corresponding provision of the EPC with respect current [sic] to claims 1-13".

In response to this communication the applicant filed a revised set of claims numbered 1 to 12, an analysis of the documents DX1, X2, DX3, X4, X5, and PX6 which were cited in the IPER, and detailed arguments as to why the revised claims related to subject-matter which was novel and inventive. Claim 1 of the new set of claims was based on claim 1 of the set filed on entry into the regional phase, which in turn was based on claim 19 as originally filed and included some new features (listed in point 3.4 below).

The examining division thereafter refused the application for lack of novelty of the subject-matter of claim 1, based on the disclosure of the document DX3 (US-A-4 650 547).

III. On 5 October 2007 the appellant lodged an appeal against the decision and paid the prescribed fee on the same day. On 14 December 2007 a statement of grounds of appeal was filed.

Thereafter, in a telefax received on 28 July 2009, the appellant requested that the decision be set aside and a patent be granted on the basis of claims 1 to 12 of the auxiliary request filed on 14 December 2007.

IV. Claim 1 of this request reads as follows:

"An electrochemical sensor for glucose sensing comprising:  
a planar sensor body having a top layer impervious to glucose and a base layer impervious to glucose, the body having a peripheral edge;  
a working electrode present between the top layer and the base layer;  
an analyte-responsive sensing layer comprising glucose oxidase and a redox polymer proximate the working electrode and exposed for contact with an analyte only at either:  
the peripheral edge of the body, or  
through a channel extending through the top layer to the working electrode such that the sensor signal is limited, at least in part, by mass transport of the analyte glucose to the sensing layer".

### **Reasons for the Decision**

1. The appeal is admissible.
2. *Novelty*
  - 2.1 Claim 1 specifies that an analyte-responsive sensing layer comprises glucose oxidase and a redox polymer proximate the working electrode. Document DX3 makes no mention of a redox polymer and consequently the subject-matter of claim 1 is novel having regard to DX3.

2.2 Since the subject-matter of claim 1 is novel over the disclosure of DX3 the decision of the first instance must be set aside.

3. Fundamental deficiencies are apparent in the first instance proceedings, as follows:

3.1 Claim 1 is based on claim 19 as originally filed, against which the only objection raised under Article 52(1) EPC during the examination procedure at the EPO was by reference to the IPER in the following terms:

"19(not new): ..... The subject-matter of this claim is for example anticipated by DX1 (Fig.2,3)".

3.2 In the context of the examination procedure, Article 113(1) together with Article 96(2) and Rule 51(3) EPC 1973 aim at giving the applicant, before a decision is taken, the possibility of knowing on which legal and factual reasons the decision will be taken and to comment on and amend its case accordingly. These provisions of the EPC, therefore, impose a duty on the examining division to send a reasoned communication as often as necessary.

3.3 Rule 51(3) EPC 1973

In the present case the solitary communication under Article 96(2) EPC 1973 from the examining division, dated 31 March 2005, gave very meagre reasons why the claims were objectionable under Article 52(1) EPC 1973. The communication contains no claim analysis (a feature-by-feature comparison of the claim with DX1)

and merely refers to the International preliminary examination report dated 5 July 2001, which report itself also does not contain a claim analysis but merely refers to Figures and passages of the cited documents.

While mere references to Figures and passages of the cited documents may be acceptable in some cases, for example where the subject-matter is very simple, in the present cases more detail is necessary in order to understand the objection under Article 52(1) EPC. This was provided for the first time in the decision to refuse, for example, the explanation why DX3 is considered to disclose a top layer impervious to glucose is mentioned for the first time in the decision to refuse (point 1. of "reasoning").

Therefore, neither the IPER nor the official communication dated 31 March 2005 fulfils the requirements that a reasoned communication must be sent to the applicant.

As regards the matter of inventive step, no technical problem is identified in the IPER and no discussion of the prior art with this problem in mind is presented.

The communication pursuant to Article 96(2) EPC does not meet the requirement of Rule 51(3) EPC 1973 accordingly. Thus, a substantial procedural violation has occurred.

3.4 Article 113(1) EPC 1973

Article 113(1) EPC 1973 states that the decisions of the European Patent Office may only be based on grounds or evidence on which the parties concerned have had an opportunity to present their comments.

The impugned decision is based on legal and factual reasons which were not mentioned in the communication pursuant to Article 96(2) EPC, they were presented for the first time to the applicant in the decision itself, so that the applicant had no opportunity to comment on them or to produce counter-arguments.

The decision states, for the first time during the examination procedure, that DX3 anticipates the subject-matter of claim 1 (corresponding to original claim 19) then on file. The IPER only mentions that DX1 anticipates the subject-matter of claim 19. It is noted that the applicant itself provided an analysis of DX3 in its letter of 28 September 2005, but was never informed by the examining division that DX3 anticipated the subject-matter of claim 1.

Moreover, claim 1 refused by the examining division includes the following new features upon which the examining division had not commented prior to the decision:

- a planar sensor body
- having a top layer impervious to glucose and a base layer impervious to glucose, the body having a peripheral edge

- the working electrode is present between the top layer and the base layer, and
- the analyte-responsive sensing layer is proximate the working electrode and exposed for contact with an analyte only at the peripheral edge of the body.

The applicant was not informed that DX3 disclosed these features prior to issue of the decision to refuse.

Since these are reasons which were never communicated to the party before the decision was issued, Article 113(1) EPC 1973 is violated. This is a further instance of substantial procedural violation.

4. In the circumstances of the case, the Board remits the case to the department of first instance for a full substantive examination on the basis of the EPC under Article 11 RPBA.
5. Since the applicant's right to be heard has been violated and substantial procedural violations have been committed, the Board considers it equitable to refund the appeal fee in accordance with Rule 103 EPC.

For these reasons the Board considers it appropriate to remit the case to the department of the first instance for re-examination of the application, and in particular whether the claims define novel subject-matter in view of the other cited documents, meet the inventive step requirement of Article 52(1) EPC, and fully meet the requirement of Article 123(2) EPC.

**Order**

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

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance for further prosecution on the basis of claims 1-12 of the auxiliary request filed on 14 December 2007.
3. The appeal fee is refunded.

The Registrar

The Chairman

D. Sauter

M. Noël