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**Datasheet for the decision  
of 23 January 2009**

**Case Number:** T 0005/06 - 3.3.02

**Application Number:** 96916476.3

**Publication Number:** 0825878

**IPC:** A61K 51/00

**Language of the proceedings:** EN

**Title of invention:**  
Folate complex for tumor imaging

**Applicant:**  
Purdue Research Foundation

**Opponent:**  
-

**Headword:**  
Folate complex/PURDUE RESEARCH FOUNDATION

**Relevant legal provisions:**  
EPC Art. 111(1)

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

**Keyword:**  
"Procedural violation - yes: decision not reasoned"

**Decisions cited:**  
G 0001/03, T 0939/92

**Catchword:**  
-



Case Number: T 0005/06 - 3.3.02

**DECISION**  
of the Technical Board of Appeal 3.3.02  
of 23 January 2009

**Appellant:** Purdue Research Foundation  
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Room 307  
West Lafayette  
Indiana 47907-1021 (US)

**Representative:** Bannermann, David Gardner  
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**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 8 August 2005  
refusing European application No. 96916476.3  
pursuant to Article 97(1) EPC.

**Composition of the Board:**

**Chairman:** U. Oswald  
**Members:** J. Riolo  
J.-P. Seitz

## Summary of Facts and Submissions

- I. European patent application No. 96 916 476.3 was refused by a decision of the examining division dated 8 August 2005 under Article 97(1) EPC in conjunction with Article 56 EPC (lack of inventive step).
- II. The decision was based on independent claim 1 of the set of 7 claims of the main request filed with the appellant's letter of 8 October 2004.

Claim 1 of this request reads as follows:

"1. Use of a composition comprising a diagnostic agent complexed with a ligand selected from the group consisting of folate and folate receptor-binding compounds capable of binding to folate receptors, in a pharmaceutically acceptable carrier, excipient or diluent in the preparation of a medicament for use in a method for detecting a tumor in a vertebrate species, said method comprising the steps of administering the medicament to said vertebrate species and monitoring the biodistribution of said complex."

- III. The grounds for the decision of the examining division read in full:

"The main request does not meet the requirements of Article 52(1) EPC, because the subject-matter of claims 1-7 does not involve an inventive step in the sense of Article 56 EPC.

The problem to be solved by the present application may be seen in the provision of agents that can be used in the detection of tumours.

Claim 1 lays down the following features:

1.) a composition comprising:

- a diagnostic agent
- complexed to folate or folate receptor binding compounds

2.) to be used for detection of a tumour

Therefore, feature 1 merely requires that the agent comprises a ligand selected from folate or a folate receptor binding compound that is complexed to a diagnostic agent. Folate 1251-RNASE conjugates comprise folate and a diagnostic agent. Consequently they fall within the definition of claim 1.

According to the description (page 21, lines 5-8) and to applicant's letters dated 12.09.2002 and 24.11.03, folate 1251-RNase conjugates are not sufficiently selective to afford clinical utility, due to poor tumour contrast with other non-target tissues. It is therefore clear that folate 1251-RNase conjugates, at least, are not suitable for use in the detection of tumours. Accordingly, the underlying problem is not solved over the whole scope of the claimed subject matter. The requirements of Article 56 EPC are therefore not met."

In that respect, the board notes that the "minutes" of the oral proceedings contain in the penultimate paragraph a reference to decision T 939/92 (OJ 1996, 309).

IV. The appellant lodged an appeal against this decision.

In its grounds of appeal, it submitted in substance that the examining division's decision was not reasoned, contrary to Rule 111 EPC.

It also filed a main and four auxiliary requests and provided arguments in favour of the grant of a patent.

V. In a communication dated 17 September 2008, the board expressed its view that the examining division's decision did indeed not meet the requirements of Rule 111 EPC, so that the decision under appeal should be set aside.

VI. In reply to this communication, the appellant withdrew its request for oral proceedings (appellant's letter dated 29 September 2008).

VII. The appellant requested in writing that the examining division's decision be set aside and that the case be remitted to the examining division. It also requested a refund of the appeal fee.

### **Reasons for the decision**

1. The appeal is admissible.
2. The function of appeal proceedings is to give a judicial decision upon the correctness of a separate earlier decision taken by a first-instance department. A reasoned decision issued by the first-instance department meeting the requirements of Rule 111(2) EPC is accordingly mandatory.

3. In the present case the examining division refused the application on the grounds of lack of inventive step based on the fact that "the underlying problem is not solved over the whole scope of the claimed subject matter" because it encompassed non-working embodiments.
4. In that respect, the board observes that Article 56 EPC requires that "an invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art" (see III above).

Thus, when it comes to inventive step, the examining division remains obliged by Article 56 EPC to issue a decision presenting all the legal and factual reasons for refusing the application having regard to the prior art and to the assessment of obviousness vis-à-vis the said prior art.

In the present case, the board notes that the examining division's decision is totally silent on these issues, so that the rejection under Article 56 EPC is not reasoned, contrary to the requirements of Rule 111(2) EPC.

5. The duty to provide substantiated reasons in administrative decisions is a fundamental principle in all contracting states, Rule 111(2) EPC simply being an expression of that principle. Further, from the point of view of the practical functioning of the system envisaged in the EPC, in the absence of the documents and an adequately related reasoned decision within the meaning of Rule 111(2) EPC the board cannot examine the

appeal as to its merits in an **adequate** manner (Article 110 EPC).

6. In accordance with the established case law of the boards of appeal, the case is remitted to the department of first instance for further prosecution.

The appeal is allowed to the extent that the decision under appeal is set aside and the appeal fee is reimbursed pursuant to Rule 103 EPC on account of the substantial procedural violation constituted by non-compliance with Rule 111(2) EPC.

7. General matters

- Non-working embodiments

For the further prosecution of the application attention should be paid to the Enlarged Board of Appeal decision G1/03 which stipulates that "if a claim comprises non-working embodiments, this may have different consequences, depending on the circumstances. . . . If an effect is expressed in a claim, there is lack of sufficient disclosure. Otherwise, ie if the effect is not expressed in a claim but is part of the problem to be solved, there is a problem of inventive step." (OJ, 2004, 413, point 2.5)

In the present case, as the effect is part of the claim, it appears from the above that only an objection for insufficiency can be raised under certain circumstances; these circumstances being that the application as filed would not contain sufficient information on the relevant criteria for finding

appropriate alternatives over the claimed range with reasonable effort.

- Decision T939/92

In this decision the claims under consideration related to a group of chemical compounds "per se", ie the effect is not expressed in a claim.

To that extent, this decision did not apply to the present case, which relates to a use claim. It is however worth noting that the board in this decision did not conclude that the claims were not inventive **merely** because the problem was not solved over the whole scope of the claim.

The complete reasoning of the board implied, on the contrary, that, for the compounds deemed not to solve the problem, a different problem (less ambitious) was defined and obviousness with respect to this new problem was established (see point 2.5).



**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.
3. The appeal fee is to be reimbursed.

The Registrar:

The Chairman:

N. Maslin

U. Oswald