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

**Case Number:** T 1128/07 - 3.3.08

**Application Number:** 95100149.4

**Publication Number:** 0655501

**IPC:** C12N 15/49

**Language of the proceedings:** EN

**Title of invention:**  
HIV-2 virus variants

**Patentees:**  
QIAGEN GmbH, et al

**Opponent:**  
Institut Pasteur

**Headword:**  
HIV-2 variants/QIAGEN

**Relevant legal provisions:**  
EPC Art. 54, 56, 76(1), 83, 123(2)(3)  
EPC R. 82(1)

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

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**Keyword:**

"Main request: added matter (yes)"  
"Auxiliary request 1: added matter (yes)"  
"Auxiliary request 2: compliance with the EPC (yes)"

**Decisions cited:**

T 0219/83, T 0329/88

**Catchword:**

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Case Number: T 1128/07 - 3.3.08

**DECISION**  
of the Technical Board of Appeal 3.3.08  
of 30 June 2009

**Appellant:** Institut Pasteur  
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**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted  
9 May 2007 concerning maintenance of European  
patent No. 0655501 in amended form.

**Composition of the Board:**

**Chairman:** L. Galligani  
**Members:** T. J. H. Mennessier  
C. Rennie-Smith

## Summary of Facts and Submissions

- I. The opponent (appellant) lodged an appeal against the interlocutory decision of the opposition division dated 9 May 2007, whereby European patent No. 0 655 501, which had been granted on European application No. 95 100 149.4, a divisional application filed on the earlier application 89 710 057.4, was maintained in an amended form on the basis of auxiliary request II (claims 1 to 23) filed on 16 February 2007. The main request (claims 1 to 24 as granted) and auxiliary request I (claims 1 to 24) filed on 16 February 2007 had been refused for non-compliance with Article 123(2) EPC.
- II. The patent had been opposed on the grounds as set forth in Articles 100(a), (b) and (c) EPC that (i) the invention was neither new (Article 54 EPC) nor inventive (Article 56 EPC), (ii) the invention was not sufficiently disclosed (Article 83 EPC) and (iii) the patent contained subject-matter which extended beyond the content of the application as filed (Article 123(2) EPC).
- III. Claims 1 and 3 of auxiliary request II filed on 16 February 2007 on the basis of which the patent was maintained by the opposition division read as follows:
- "1. A virus isolate HIV-2 D205 (ECACC V 87122304), which prefers cells which are derived from myeloidic cells for in vitro replication."
- "3. cDNA differing from the nucleotide sequence of the virus isolates according to claim 1 by up to 5%."

- IV. The statement of grounds of appeal was filed on 7 September 2007. The appellant argued that the claims as maintained by the opposition division (auxiliary request II of 16 February 2007) did not comply with the requirements of Articles 54, 56, 83, 84 and 123(2) EPC.
- V. The patent proprietors (respondents) replied with a formal letter dated 20 January 2008 in which it was simply requested to reject the appeal, no comments being made on the grounds of appeal.
- VI. The board issued a communication dated 17 February 2009 pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) with an outline of the issues to be discussed at the upcoming oral proceedings.
- VII. In reply to that communication, the respondents made on 29 May 2009 some submissions and filed an auxiliary request (claims 1 to 8), to be referred to hereafter as auxiliary request 1. In the same letter, it was requested that, nevertheless, the appeal be terminated without a decision on the substantive issues, the reason being that on 13 June 2009 the patent would in any case expire. In this context, reference was made to decision T 329/88 of 22 June 1993. The respondents also indicated that they would not attend the scheduled oral proceedings.
- VIII. Claims 1 and 2 of the auxiliary request 1 were identical to claims 1 and 3 of the main request (see Section III *supra*).

- IX. In reply to the board's communication and to the subsequent respondents' letter, the appellant in its letter dated 3 June 2009 argued that the respondents' request that the appeal be terminated without a decision on the issues should be refused, the present situation differing from that of the case T 329/88 (see *supra*). The appellant also indicated that it would not attend the scheduled oral proceedings.
- X. In a communication pursuant to Article 17(1) RPBA faxed on 5 June 2009, the board informed the parties that the oral proceedings were maintained as scheduled and refused the respondents' request that the appeal be terminated without a decision on the issues. As the appellant had confirmed that it maintained its request for revocation of the patent, the rationale of decision T 329/88 (see *supra*) was not applicable in the present case. The board also informed the parties that, at the oral proceedings, in addition to all the issues listed in the communication of 17 February 2009, the board intended to deal with the issue of added matter in respect of both claim 3 of the set of claims maintained by the opposition division and claim 2 of the auxiliary request filed with the letter of 29 May 2009 (present auxiliary request 1) (see Section VIII *supra*) which were both identical to claim 3 as granted.
- XI. While the appellant did not file any comments, the respondents replied on 17 June 2009 by filing a letter which was accompanied by a further auxiliary request, to be referred to hereafter as auxiliary request 2. An adapted description was also filed with that request.

XII. Auxiliary request 2 consisted of 6 claims which read as follows:

"1. A virus isolate HIV-2 D205 (ECACC V 87122304), which prefers cells which are derived from myeloidic cells for in vitro replication."

2. Viral RNA differing from the nucleotide sequence of the virus isolates according to claim 1 by up to 5%.

3. RNA according to claim 2, wherein the RNA is present as hybrid with complementary labelled RNA strands.

4. A process for detecting HIV-related nucleic acids (DNA and RNA) in biological samples, cells and in isolated form by using the nucleic acids according to claims 2 or 3.

5. Isolated cells which have been transformed with nucleic acids according to claims 2 or 3.

6. Isolated cells which have been infected with the virus isolate according to claim 1."

XIII. The following document is referred to in the present decision:

(D2) EP 0 239 425 (publication date: 30 September 1987)

XIV. Oral proceedings took place on 30 June 2009 in the absence of the parties.

XV. The position of the appellant may be summarised as follows.

Although the issue of the non-compliance of granted claim 3 with the provisions of Article 123(2) EPC had been raised in the opposition phase (see the notice of opposition, page 12, item B1), the appellant did not make submissions in respect of claim 3 of the set of claims as maintained by the opposition division as well as in respect of claim 2 of auxiliary request 1 (both being identical to claim 3 as granted) nor did it comment on the board's communication raising this issue (see Section X *supra*).

No submissions were made in respect of auxiliary request 2. Nevertheless, the following comments which were made as regards the claims as maintained by the opposition division also apply to auxiliary request 2.

*Sufficiency of disclosure (Article 83 EPC)*

The feature "*which prefers cells which are derived from myeloidic cells for in vitro replication*" could not be determined as the patent was silent on the culture conditions suitable for the claimed isolate. Therefore, claim 1 was not sufficiently disclosed.

*Inventive step (Article 56 EPC)*

In document D2, which represented the closest state of the art, a number of new isolates had been characterised and, thus recognised as the members of a definite new group of viruses, named HIV-2. The technical problem solved by the invention could be regarded as the provision of an alternative isolate of HIV-2.

As the alleged properties of the HIV-2 isolate D205 which would have marked it as a tool of interest for the diagnostic of a HIV-2 infection were not supported by any experimental results, claim 1 did not contribute to the state of the art and, therefore, lacked inventive step.

XVI. The position of the respondents may be summarised as follows.

No submissions were made in reply to the board's communication which had indicated that both claim 3 of the set of claims as maintained by the opposition division and claim 2 of auxiliary request 1 had a problem of support in the application as filed (see Section X *supra*).

During the opposition proceedings, in reply to the objection made by the opponent/appellant against claim 3 as granted, the respondents had argued that the last paragraph of page 3 of the application as filed provided an appropriate support.

No submissions were made in respect of auxiliary request 2. Nevertheless, the following comment on inventive step was made as regards the claims as maintained by the opposition division and it applies also to present auxiliary request 2: the contribution to the art of the invention was the provision of a search tool from which the skilled person could derive expression products using routine methods of the fields of immunology and virology.



- XVII. The appellant (opponent) requested that the decision under appeal be set aside and the patent be revoked.
- XVIII. The respondents (patent proprietors) requested in writing that the appeal be terminated without a decision on the issues or that the appeal be dismissed or that the decision under appeal be set aside or the patent be maintained on the basis of auxiliary request 1 filed on 29 May 2009 or auxiliary request 2 filed on 17 June 2009.

## **Reasons for the Decision**

### *Procedural aspects*

1. In the letter of 29 May 2009, the respondents have requested that the appeal proceedings be terminated without a decision on the substantive issues for the reason that the patent will have lapsed on 13 June 2009 in all the designated contracting states. In support of the request, reference to decision T 329/88 of 22 June 1993 was made.
2. In decision T 329/88 (see *supra*) the board of appeal applied Rule 60(1) EPC 1973 (see Rule 84(1) EPC 2000) by analogy to appeal proceedings and terminated the proceedings without any decision on the issues, since during the appeal proceedings the European patent had expired in all the designated contracting states, account being taken of the fact that the opponent/appellant had not requested continuation of the appeal proceedings.

3. In the present case, as the appellant still requests continuation of the appeal proceedings, the rationale of decision T 329/88 (see *supra*) is not applicable and the appeal must be examined as to its merits.

Claim 3 as maintained and claim 2 of auxiliary request 1

*Compliance with Article 123(2) EPC*

4. Claim 3 of the request as maintained by the opposition division and claim 2 of auxiliary request 1 are both directed to a cDNA differing from the nucleotide sequence of the HIV-2 isolate D205 (ECACC V 87122304) by up to 5% (see Sections III and VIII, *supra*). The two claims are identical to claim 3 as granted against which the opponent/appellant had raised an objection under Article 123(2) EPC.
5. The second sentence of the last paragraph of page 3 is the only place in the application as filed where a difference of up by 5% between nucleotide sequences is referred to. Said sentence reads as follows: "*Moreover, the virus isolates [sic] comprise variants which are distinguished from the viruses and proviruses described above in that they are different in their nucleotide sequences from the above-described viruses only by up to 5%, and preferably by 2%, particularly preferred by 1%.*"
6. A reading of the sentence shows readily that it refers to variants of the HIV-2 isolate D205 which differ therefrom by up to 5% in terms of the nucleotide sequence of their genomic RNA and their proviral DNA. This passage provides no support for a cDNA differing

from the nucleotide sequence of the HIV-2 isolate D205 by up to 5%. Thus, both claims do not comply with the requirement of Article 123(2) EPC and the respective requests cannot form a basis for the maintenance of the patent in an amended form.

Auxiliary request 2

*Compliance with Article 123(2) and (3) EPC*

- 7. Support is found in the application as filed as follows:
- 7.1 With respect to claim 1, in the first paragraph of page 1 (description of the HIV-2 isolate D205) taken together with the sentence bridging pages 8 and 9 (description of the optional feature of the isolate).
- 7.2 With respect to claim 2, in the last paragraph of page 3 (see points 5 and 6 *supra*).
- 7.3 With respect to claim 3, in claim 6 as filed taken together with the support mentioned at point 7.2 (description of the viral RNA) and the third paragraph of page 4 (description of hybrids).
- 7.4 With respect to claim 4, in claim 19 as filed taken together with the support mentioned at point 7.2 (description of the viral RNA).
- 7.5 With respect to claim 5, in claim 24 as filed taken together with the support mentioned at point 7.2 (description of the viral RNA).

- 7.6 With respect to claim 6, in claim 25 as filed taken together with the support mentioned at point 7.1 (description of the HIV-2 isolate D205).
8. In conclusion, auxiliary request 2 as a whole complies with Article 123(2) EPC. Moreover, the amendments introduced do not raise issues of Article 123(3) EPC as the extent of protection is unchanged in comparison with the claims as granted.

*Compliance with Article 76(1) EPC*

9. Corresponding support is found for each and every claim in the earlier application as filed, the content of which is the same as the divisional application as filed, insofar as it relates to the HIV-2 isolate D205 and variants thereof. Thus, auxiliary request 2 complies with Article 76(1) EPC.

*Compliance with Article 83 EPC*

10. The appellant argued that the patent fails to disclose cells which, as referred to in claim 1, are derived from myeloidic cells and are suitable for the in vitro replication of the HIV-2 isolate D205, as well as the appropriate culture conditions of such cells.
11. Claim 1 refers to a specific virus isolate the availability of which (and thus the possibility to reproduce it) has been ensured by way of a deposit made pursuant to Rule 28 EPC 1973 (see Rule 31 EPC 2000). The said isolate is further characterised in claim 1 by a feature referring to its preference for *in vitro* replication in cells which are derived from myeloidic

cells. This latter feature can be regarded as being redundant for the purposes of reproducibility of the isolate because - as said above - this is warranted by the deposit. The feature merely points to a preferred way of *in vitro* replication of the isolate and is thus not essential to ensure its reproducibility. Thus, the isolate of claim 1 is to be regarded as being disclosed as prescribed in Article 83 EPC. The same conclusion applies to the rest of claims which are directed to RNAs defined with reference to claim 1 (see claims 2 and 3), the use thereof (see claim 4), cells transformed with the same (see claim 5) and cells infected by the isolate of claim 1 (see claim 6). Therefore, auxiliary request 2 as a whole complies with Article 83 EPC.

*Compliance with Article 54 EPC*

12. None of the prior art documents on file, including document D2 (EP 0 239 425), describes the HIV-2 isolate D205 and/or viral RNA which differs from the RNA of the isolate by up to 5%. Therefore, claims 1 to 3 are new. The same conclusion applies to claim 4, as it is directed to a process using the nucleic acids of claim 2 or 3, as well as to claims 5 and 6, as they are directed to respectively cells transformed with such a nucleic acid (claim 5) and cells infected with the HIV-2 isolate D205 (claim 6). Thus, auxiliary request 2 as a whole complies with Article 54 EPC.

*Compliance with Article 56 EPC*

13. As indicated in the decision under appeal, document D2 represents the closest state of the art. It describes a

number of isolates (see page 6) which are recognised as members of a definite new group of viruses collectively named HIV-2.

14. In view of that state of the art, the technical problem may be regarded as the provision of an alternative HIV-2 isolate, the solution to that problem being represented by the HIV-2 isolate D205 of claim 1.
  
15. The question to be answered for the assessment of inventive step is whether a skilled person would have had any reason to predict the existence of the specific HIV-2 isolate D205. Whereas he/she might have suspected that HIV-2 strains other than those described in document D2 existed, the finding of that particular isolate in reality was only a matter of chance as confirmed by paragraph 0009 on page 2 of the patent which reports the isolation of the HIV-2 isolate D205 from a clinically asymptomatic patient. Thus, by no means could such a finding have somehow been anticipated.
  
16. The disclosure of the invention has made available to the public a further new strain of HIV-2 which as such constitutes a valuable contribution to the art as it paves the way for a more reliable diagnostic of HIV-2 infections using nucleic acids derived therefrom (see claims 2 to 4) and cells transformed or infected with the same (see claims 5 and 6). Thus, auxiliary request 2 as a whole complies with Article 56 EPC.

Adaptation of the description

17. Although a description said to be adapted to auxiliary request 2 was filed on 17 July 2009, the opponent has had less opportunity to assess the correctness of the adaptation than is usually permitted if (as in the present case) it cannot be dealt with at oral proceedings (see Rule 82(1) EPC and decision T 219/83, OJ EPO 1989, 189, Reasons, points 13 to 16). The board therefore regards it as appropriate to remit the case to the first instance for the purpose of performing that task.

**Order**

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

1. The decision under appeal is set aside.
2. The case is remitted to the first instance with the order to maintain the patent on the basis of the auxiliary request 2 filed with the letter of 17 June 2009 and a description and drawings to be adapted thereto.

The Registrar

The Chairman

A. Wolinski

L. Galligani