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Datasheet for the decision of 28 June 2012

Case Number: T 2266/10 - 3.3.08

Application Number: 94110658.5

Publication Number: 657532

IPC: C12N 7/00

Language of the proceedings: EN

Title of invention:
HIV-3 retrovirus strains and their use

Patentee:
N.V. INNOGENETICS S.A.

Opponents:
Bio-Rad Innovations
Institut Pasteur

Headword:
HIV-3/INNOGENETICS

Relevant legal provisions:
EPC Art. 76(1), 83, 111(1), 123(2)(3)

Relevant legal provisions (EPC 1973):
EPC Rule 28a

Keyword:
"Added matter - (no)"
"Sufficiency of disclosure - deposit/redeposit of claimed virus - (yes)"
"Remittal for further prosecution"

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 2266/10 **-** 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 28 June 2012

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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 26 August 2010 revoking European patent No. 657532 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman: M. Wieser
Members: B. Stolz
R. Moufang

Summary of Facts and Submissions

I. The appeal lies against the decision of the opposition division to revoke European patent No. 657532.

II. Two oppositions had been filed against the patent on the grounds of Articles 100(a), (b) and (c) EPC.

III. The opposition division found that the main request before it did not comply with the provisions of Article 76(1) EPC, and decided not to admit auxiliary request I, filed at the oral proceedings held on 18 December 2007, because it was late filed and gave rise to new objections under the provisions of the EPC.

IV. The patent was granted with two sets of claims for the contracting states of AT, BE, CH, LI, DE, FR, GB, IT, LU, NL, SE, and ES and GR, respectively. It is based on European patent application 94110658 which is a divisional application of European patent application 88109200 (the parent application).

V. With letter dated 10 November 2010, and in view of the importance of the figures for the decision under appeal, appellant I requested that the files of the parent and the divisional application be made available for inspection in their original form.

VI. In a communication dated 15 April 2011, the board informed the parties that the figures contained in the original files of the parent and the divisional patent applications were available for file inspection on the premises of the EPO in Munich.

VII. In a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) annexed to a summons to oral proceedings, the board informed of its preliminary, non-binding opinion on some of the issues to be discussed at the upcoming oral proceedings, in particular issues concerning Articles 76(1), 123(2) and 83 EPC.

VIII. The appellant and opponent I (respondent I) made further submissions in response to the board's communication.

IX. Oral proceedings were held on 28 June 2012, in the absence of opponent II (respondent II), who had informed the board that it would not participate in oral proceedings and had not made any further submissions.

X. Appellant's main request consists of two sets of claims for the contracting states of AT, BE, CH, LI, DE, FR, GB, IT, LU, NL, SE, and ES and GR respectively. Claims 1 to 8 for the contracting states of AT, BE, CH, LI, DE, FR, GB, IT, LU, NL, SE read as follows:

"1. A nucleic acid molecule portion of the cDNA corresponding to the entire RNA genome of the HIV-3 retrovirus strain deposited under ECACC N° V88060301 or the complementary strand thereof and which specifically hybridizes with the nucleotide sequence of said HIV-3 strain under stringent hybridisation conditions.

2. A probe comprising the nucleic acid molecule of claim 1, which is optionally labeled.

3. A vector comprising the nucleic acid molecule of claim 1 or 2.

4. The vector of claim 3 which is an expression vector.

5. A host cell transformed with a vector of claim 3 or 4.

6. A kit comprising the probe of claim 2.

7. A method for the detection of an HIV-3 retrovirus strain or of its RNA in a biological liquid or tissue, characterized by
(a) contacting nucleic acids contained in said biological liquid or tissue with the probe of claim 2 under stringent conditions,
(b) washing the hybrid formed with a solution preserving said stringent conditions, and
(c) detecting the hybrid formed.

8. Use of a nucleic acid molecule of claim 1, a probe of claim 2 or a kit comprising said nucleic acid molecule or probe for the in vitro detection of HIV-3 or in vitro diagnosis of HIV-3 infection."

XI. The following documents are cited in this decision:

D7 ANNEX BRaI of OPPONENT 1 (O1)
Letters and e-mails between BIO-RAD, the EPO and the ECACC, concerning the request for the furnishing of a sample of the microrganism deposited at the ECACC under V88060301 (strain ANT7O), comprising:

- D7A: mail of O1 dated 18 March 2004 to the EPO (sample request),
- D7B: EPO Communication to O1, advising that the request has been sent to the Depositary Institution (EPO Form 1143a dated 27 April 2004),
- D7C: O1's reminder e-mails and reminder mails to ECACC (e-mail of 1 June 2004; mail of 3 June 2004; facsimile and mail of 15 June 2004, reminder by DHL on 30 June 2004),
- D7D: e-mail of 5 July 2004 from ECACC (Ms. Cheryl Saffery) to O1, advising that "*deposit V88060301 need's to be re-deposited, and that they are currently in contact with the depositor to arrange this*",
- D7E: O1's mail to ECACC of 9 July 2004, asking for confirmation that the deposit is not available,
- D7F: mail of 27 July 2004 from ECACC confirming that the deposit is not available, and that the ECACC is "*waiting for the Depositor to confirm if [they] are able to rebank this line*".

D21 Declaration Dr Vanden Haesevelde

D23 Re-deposit of HIV_{ANT7O} strain V88060301

D33 e-mail from ECACC to Ms Vanden Haesevelde dated 08/10/2004, submitted with Patentee's letter of 27 February 2006

D34 e-mails from ECACC to innogenetics.com dated 16/08/04 and 17/08/04, submitted with Patentee's letter of 27 February 2006

D35 Experimental data provided by OPPONENT 1 with O1's letter dated 23 February 2006 (O1's reference D7), accompanied by a reference document marked "D45" (declaration signed by Ms Bussfeld, which has been filed at the EPO in the Opposition Proceedings relating to another HIV patent, i.e., EP 591 914 B1)

D36 Declaration of Ms Vanden Haesevelde, submitted to the EPO with Patentee's letter dated 18 October 2007

D37 Experimental data provided by the Patentee with its letter dated 18 October 2007

D45 Letter of Patentee to EPO dated 27 January 1993 (parent case)

D48 BLAST alignment of the envelope sequence shown on page 24 of the divisional patent application, provided by appellant with its letter of 25 May 2012

D51 e-mail from ECACC to Dr Haesevelde dated 12 November 2004, cited as D3 in the oppostion division's communication dated 17 October 2005

XII. The arguments of the appellant, as far as relevant for the present decision can be summarized as follows:

Article 123(2) EPC

Claims 1 to 8 corresponded to claims 5 to 9, and 13 to 15 as granted and did not contain any reference to the

contested Figure 13. The basis for the feature "specifically hybridizing" could be found on page 12 of the description.

Article 83 EPC

The virus was deposited by Mr Robert De Leys on behalf of the patent proprietor, Innogenetics N.V./S.A., which had full power over the deposited strain. The redeposit of strain HIV_{ANT70} (ECACC V88060301) after the originally deposited strain was no longer available was in compliance with the requirements of the EPC.

XIII. The arguments of the respondents as far as relevant for the present case can be summarized as follows:

Article 76(1) EPC

Figures 4, 10 and 13 of the divisional application differed from the respective figures of the parent application. Therefore, the divisional application as a whole violated the requirements of Article 76(1) EPC.

Article 123(2) EPC

The term "specifically hybridizes" in claim 1 was vague and had as such no basis in the application documents as filed.

Article 83 EPC

Strain HIV_{ANT70} (ECACC V88060301) had not been deposited by the patent proprietor. The address and the name of the company given by the depositor, Mr Robert De Leys,

differed from those of the patent proprietor. Moreover, the redeposit, after the originally deposited strain was no longer available, did not comply with the requirements of the EPC. Firstly, the conditions of Rule 28a(1)(b) EPC 1973 were not met, and secondly, the redeposited strain lacked a characterizing feature of the originally deposited strain.

XIV. The final requests of the parties were as follows:

The appellant requested that the decision under appeal be set aside and the patent be maintained on the basis of its main request (originally filed as auxiliary request II with its grounds of appeal). It requested that the case be remitted to the first instance for further prosecution should the board arrive at the conclusion that the request met the requirements of Articles 76(1), 123(2)(3) EPC, and of Article 83 EPC as far as the redeposit of HIV_{ANT70} was concerned.

Respondents I and II requested that the appeal be dismissed.

Reasons for the decision

1. Two sets of claims have been granted for the contracting states of AT, BE, CH, LI, DE, FR, GB, IT, LU, NL, SE, and ES and GR, respectively. The present decision equally applies to both sets of claims.

Admissibility of the request

2. After the opposition division had decided that the main request before it violated the provisions of Article 76(1) EPC, and had not admitted the auxiliary request, the patent proprietor (appellant) explicitly stated that it did not wish to file any further requests (see points 6 and 7 of the minutes of the oral proceedings before the opposition division).

3. The current request was filed with the grounds of appeal, and respondent I considered it inadmissible because the appellant had deliberately missed the opportunity to present it to the opposition division.

4. The appellant argued that it did so because the figures of the patent were of crucial importance, and at the time of the oral proceedings before the opposition division, it was not clear what exactly was shown by the figures contained in the original files. Thus, it would not have been reasonable to file further requests before the opposition division.

5. According to the records of the opposition proceedings, the figures contained in the original file were neither available to the opposition division nor to the parties. In view of the importance of the figures to the present case, the board considered appellant's behaviour at the oral proceedings comprehensible and, exercising its discretion under Article 12(4) RPBA, decided to admit the request.

Article 76(1) EPC

6. The descriptions of both the parent application and the divisional application as originally filed are

literally identical, except that some paragraphs have been rearranged. Therefore, as far as the basis for the claimed subject matter depends on the disclosure of the description as filed, any conclusion reached in respect of Article 123(2) EPC leads to the same conclusion in respect of Article 76(1) EPC. Respondents' objections as far as they refer to claims 1 to 8 will be dealt with in the section on Article 123(2) EPC.

7. Respondent I raised an objection under Article 76(1) EPC against the patent as a whole because it held that Figures 4, 10, and 13 of the divisional application as filed differed in their technical content from the respective Figures of the parent application.

8. Since the claims of the present request do not refer to any of these figures, the board sees no need to decide on this issue before the claims have been found to meet all requirements of the EPC (see point 33, below).

Article 123(2) EPC

9. The nucleic acid molecule portion of claim 1, as well as the probe of claim 2 comprising such nucleic acid molecule portion, are disclosed on page 12, lines 23 to 41, of the description as filed. The recited paragraphs refer to nucleic acids, optionally labelled, which are derived in part, at least, from RNA of the HIV-3 (HIV_{ANT70}) virus and to their use as hybridization probes for the specific detection and diagnosis of HIV-3 infection. As also disclosed on page 12, lines 47 to 58, the specific detection of HIV-3 requires stringent hybridization conditions.

10. The board is thus satisfied that the requirements of Article 123(2) EPC (and of Article 76(1) EPC) are met.

Article 83 EPC

11. Respondent I raised several objections against the validity of the deposit and redeposit of strain ECACC No. V88060301.

It raised questions whether the patentee was at all times in full control of the deposited strain, whether the redeposit after exhaustion of the original deposit was made within the time period set by Article 4 of the Budapest treaty and by Rule 28a(1)(b) EPC 1973, and whether the redeposited virus was identical with the originally deposited virus.

Who was in control of deposit ECACC No. V88060301?

12. The viral isolate was originally deposited by Mr De Leys on behalf of Innogenetics S.A., located in B-2000 Antwerpen. The original patent application was however filed by Innogenetics N.V., located in B-9052 Ghent. Based on the different company designations and locations, respondent I concluded that the deposit of the claimed virus was not made by the patent applicant (appellant) and was therefore not in compliance with Rule 28 EPC 1973.

13. In a declaration on file (document D21), the appellant confirmed that Innogenetics N.V./S.A. had offices in both locations and that both offices belonged to the same legal entity.

The board is therefore satisfied that the original deposit of the claimed virus met the requirements of Rule 28 EPC 1973.

The redeposit of strain ECACC No. V88060301

14. The redeposit of biological material deposited in accordance with the Budapest Treaty has to occur within three months of notification of the depositor by the depositary institution and has to be accompanied by a statement signed by the depositor that the newly deposited biological material is the same as that originally deposited (Article 4(1)(c) and (d) Budapest Treaty, and Rules 28a(1)(b) and 28a(4)(5) EPC 1973). A copy of the receipt of the (re)deposit issued by the depositary institution has to be forwarded to the European Patent Office within four months from the date of the new deposit (Rule 28a(1)(b) EPC 1973).

15. As a first step, the board will establish when the depositor was first notified of the non-availability of the deposited virus.

16. Document D7 shows several unsuccessful attempts of respondent I (Bio-Rad) to obtain samples of the deposited strain. The e-mails and letters reproduced in document D7 show that respondent I could not obtain samples of the strain deposited under ECACC No. V88060301 at least between March 2004 and July 2004. In reply to a purchase order, ECACC informed respondent I that the strain deposited with number V88060301 needed to be redeposited (letter of 5 July 2004). Respondent I was also informed by the same letter that ECACC was

"currently in contact with the depositor to arrange this".

Based on this last statement, respondent I concluded that the depositor was notified of the interruption of the deposit on 5 July 2004 at the latest.

17. This conclusion was contested by the appellant on the basis of evidence submitted as documents D33 and D34.

Document D34 shows an e-mail from the depositary institution, ECACC, to the depositor (appellant) with an earliest mailing date of 16 August 2004 which contains an inquiry of the depositary institution about the whereabouts of Mr De Leys and a statement that further samples of the HIV-3 strain deposited under number V88060301 were requested.

Document D33 is an e-mail from ECACC to the depositor, carrying the date of 8 October 2004, and comprising an explicit request for a redeposit of the HIV-3 strain deposited under number V88060301.

18. On the basis of the available evidence the board concludes that 16 August 2004 (document D34) is the earliest date that can be established with reasonable certainty as the date on which the depositor was informed of the need for a redeposit. Earlier evidence submitted as document D7 merely shows that Respondent I could not obtain samples of the deposited strain and that ECACC was in the process of contacting appellant I.

19. The next question to be answered is whether the redeposit was made within the period of three months

set by Article 4(1)(d) Budapest Treaty and Rule 28a(1)(b) EPC 1973, and whether the European Patent Office was informed within four months from the redeposit as required by Rule 28a(1)(b) EPC 1973.

20. Document D48, an e-mail from the depositary institution to the depositor carrying the date of 12 November 2004, states that the (re)deposit was "received in good condition on 10 November 2004". Document D23 shows a copy of the international form of the Budapest Treaty which also mentions a date of receipt of 12 November 2004.

The time lapsed between 16 August 2004 and 12 November 2004 (at the latest) is thus shorter than the three months limit set by Article 4(1)(d) Budapest Treaty and Rule 28a(1)(b) EPC 1973.

Furthermore, the new deposit had to be accompanied by a statement signed by the depositor which confirmed that the redeposited material was the same as that originally deposited (Article 4(1)(c) Budapest Treaty and Rule 28(1)(d) EPC 1973). Document D36 provides evidence that the depositor confirmed identity with a letter dated 4 November 2004.

21. Finally, the European Patent Office received a letter from the depositor on 2 March 2005, informing it of the redeposit (document D23). This is within the time period of four months from the date of redeposit which was either 10 November 2004 or 12 November 2004 (Rule 28a(1)(b) EPC 1973).

22. The Board is thus satisfied that the redeposit met the formal requirements laid down in Article 4 Budapest Treaty and in Rule 28a EPC 1973.

Was the newly deposited material the same as the originally deposited material?

23. In addition to objections concerning the formal aspects of the redeposit, respondent I provided experimental data as evidence that the originally deposited virus and the redeposited virus were not the same.

24. Respondent's objections concern the presence or absence, respectively, of a DNA sequence which was described as being part of the envelope gene sequence of the originally deposited HIV-3 virus (see page 8 of the divisional patent application or paragraph [0044] of granted patent EP 657532).

25. An annex to document D35, labelled as D45 (declaration by Dr Bussfeld dated 7 January 2004, not to be confused with document D45 submitted by the appellant), confirms that said envelope sequence could be amplified from the original deposit of the HIV-3 strain (cf. in particular the last paragraph of Dr Bussfeld's declaration).

On the other hand, document D35, the technical report submitted by respondent I, provides also data that said envelope sequence could not be amplified from the redeposited strain, and this result is confirmed in document D37 provided by the appellant.

Thus, there was agreement between the parties as far as the absence of the "envelope sequence" from the

redeposited viral isolate was concerned. There was however disagreement about the significance of this result.

26. The appellant pointed out that the examining division was informed as early as 1993 (see document D45 relating to the prosecution of the parent application), that the so called "envelope sequences" were of non-viral origin. Throughout the opposition and appeal proceedings the appellant maintained this position and provided additional evidence as document D48. This document demonstrates that the sequences most closely related to the "envelope sequence", found in a BLAST search, are 96% identical and originate from Mycoplasma fermentans.

27. The original deposit comprised Molt-4 cells (cf. page 3, lines 17-19, of the application document) infected with the claimed HIV-3 virus and apparently also comprised a contaminant. In the light of document D48, the board has no reason to doubt that the sequence disclosed in paragraph [0044] of the patent is of non-viral, and in particular of Mycoplasma origin. Mycoplasma is a contaminant often found in cultured cells.

28. Biological material which is not available to the public can be deposited according to the provisions of Rule 28(1) EPC 1973 (Rule 31(1) EPC 2007) in order to meet the requirements of Article 83 EPC. In the present case, the claimed biological material is the HIV-3 strain deposited under ECACC No V88060301. For the board, the presence or absence of a contaminating Mycoplasma sequence is therefore not decisive as long

as the redeposit and the original deposit contained the same HIV-3 virus.

29. Since the original deposit is no longer available, a direct comparison of the original deposit and the redeposit is not possible. The only evidence that the deposit and the redeposit contained the same virus is available in the form of a declaration from the appellant (document D36) and technical data also provided by the appellant (document D37).

30. The technical data of document D37 show that it is possible to amplify a HIV-3 specific sequence from the redeposited sample using primers derived from the DNA sequence shown on page 22 of the application document. According to the experimental report, the amplified sequence differs from known ANT70 (HIV-3) sequences in 3 out of 355 positions (> 99% identity). Matches to other HIV isolates showed at most 92% sequence identity.

31. It is correct that due to the 3 base difference, the data of document D37 are no absolute proof that the same strain was redeposited. However, HIV viruses are known to rapidly change their nucleic acid sequences and it cannot be ruled out that the original deposit (which is no longer available for analysis) already showed the three base difference found in document D37. According to a well established legal principle, the burden of proof in opposition proceedings is on the party raising the objection and any conclusion has to be based on facts or evidence submitted to the board. As no such evidence has been provided by the respondents, the board has no reason to doubt that the redeposit contained the same virus as the original

deposit, and it is satisfied that the requirements of Article 83 EPC are met as far as the deposit and redeposit of the claimed virus are concerned.

Remittal to the first instance

32. Because objections under Articles 54 and 56 EPC had not been examined by the opposition division and objections under Article 83 EPC have now only been examined as far as the deposit and the redeposit of the claimed virus were concerned, the appellant requested remittal to the first instance for further examination.

In view of the considerable number of objections under Articles 54, 56 and 83 EPC not yet examined by the first instance, the respondent agreed with this request.

33. Under these circumstances, the board decides to remit the case to the opposition division for further prosecution (Article 111(1) EPC), including, if necessary, the adaptation of the description (see points 3 and 4 above).

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 to 8 of two sets of claims for different contracting states of the main request, filed as auxiliary request II with letter dated 5 January 2011.

The Registrar: The Chairman:

A. Wolinski M. Wieser