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Datasheet for the decision of 2 October 2012

Case Number: T 1650/08 - 3.3.08

Application Number: 96933140.4

Publication Number: 871459

IPC: C12N 15/86, C12N 7/01, A61K 35/76, A61K 48/00

Language of the proceedings: EN

Title of invention:
Vector and method of use for nucleic acid delivery to non-dividing cells

Patentee:
THE SALK INSTITUTE FOR BIOLOGICAL STUDIES

Opponent:
OXFORD BIOMEDICA (UK) LTD.
Medawar Centre

Headword:
Pseudotyped HIV-based retrovirus/OXFORD BIOMEDICA

Relevant legal provisions:
EPC Art. 112(1)
RPBA Art. 13(1)

Keyword:
"Main request and Auxiliary requests I-III - late filed - not admitted"
"Referral to the Enlarged Board of Appeal - no"

Decisions cited:
G 0009/91, G 0001/93, T 0384/91, T 0033/07, T 0321/07, T 1168/08, T 1634/09

Catchword:
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Case Number: T 1650/08 - 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 2 October 2012

Appellant: (Patent Proprietor)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 24 June 2008 revoking European patent No. 871459 pursuant to Article 101(3)(b) EPC.

Composition of the Board:

Chairman: R. Moufang
Members: B. Stolz
T. J. H. Mennessier

Summary of Facts and Submissions

I. European Patent No. 0 871 459 was granted with a set of 19 claims on the basis of European patent application No. 96933140.4, filed on 26 September 1996. The mention of the grant was published on 3 March 2004.

II. A notice of opposition was filed on the grounds of Article 100(a), (b), and (c) EPC.

III. Claim 1 as granted referred to a replication defective recombinant retrovirus comprising:

(a) a lentiviral GAG protein;

(b) a lentiviral POL protein;

(c) a non-lentiviral ENV protein; and

(d) a retroviral genome comprising: a heterologous nucleic acid sequence operably linked to a regulatory nucleic acid sequence; at least one lentiviral cis-acting nucleic acid sequence necessary for reverse transcription and integration; a lentiviral packaging nucleic acid sequence, wherein said lentiviral packaging nucleic acid sequence comprises a lentiviral 5' splice donor sequence, a psi sequence, wherein the nucleic acid sequence is devoid of lentiviral sequences both upstream and downstream from the splice donor site to a gag initiation site. (emphasis added).

IV. In its statement of grounds of opposition, the opponent objected to claim 1 under Article 123(2) EPC. It objected inter alia to features (c) and (d). Regarding feature (d), it had several objections, the most prominent being that the last half sentence (underlined above) represented added matter. Not only was this added matter but it was also technically incorrect and non-sensical because it created a contradiction within the definition of feature (d) itself.

V. In its response to the grounds of opposition, the patentee acknowledged that the last half sentence of feature (d) referred to properties of a different nucleic acid (point 4.2 of the letter dated 23 December 2005) and requested the correction of an obvious error under the provisions of Rule 88 EPC 1973 (Rule 139 EPC 2000).

VI. Oral proceedings in opposition were held on the basis of a new main request and 6 auxiliary requests. The opposition division decided that an error in claim 1 was obvious but that the requested correction did not meet the requirements of Rule 88 EPC 1973, second sentence, because it was not immediately evident that nothing else would have been intended than what was offered as the correction. Moreover, none of the requests before it met the requirements of Article 123(2) and 123(3) EPC. Consequently, it revoked the patent.

VII. The appellant (patentee) filed an appeal against the decision of the opposition division. With its grounds of appeal it filed a new main request and a new auxiliary request. The amendment in claim 1 of the main

request was said to consist of the correction of an obvious error. The auxiliary request was limited to a set of claims directed to methods of producing a replication deficient retrovirus.

VIII. 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 the parties of its preliminary, non-binding opinion on some of the issues to be discussed at the upcoming oral proceedings, in particular issues concerning Rule 88 EPC 1973, and Article 123(2) and(3) EPC.

IX. With letter dated 31 August 2012, the appellant submitted further arguments and filed a new main request and a new auxiliary request which replaced the previous main and auxiliary requests.

X. Oral proceedings were held on 2 October 2012. During these proceedings, the appellant filed a second and a third auxiliary request.

XI. Appellant's main request consisted of 11 claims. Independent claim 1 of the main request reads as follows:

"1. A replication defective recombinant pseudotyped HIV-based retrovirus comprising:

(a) an HIV retroviral GAG protein;

(b) an HIV retroviral POL protein;

(c) a ENV protein selected from the group consisting of Moloney murine Leukemia virus (MoMuLV), Harvey murine sarcoma virus (HaMuSV), murine mammary tumor virus (MuMTV), gibbon ape leukemia virus (GaLV), Rous Sarcoma Virus (RSV) and Vesicular stomatitis virus (VSV); and

(d) a retroviral genome comprising: a heterologous nucleic acid sequence operably linked to a regulatory nucleic acid sequence; at least one HIV retroviral cis-acting nucleic acid sequence necessary for reverse transcription and integration; and an HIV retroviral packaging nucleic acid sequence, wherein said HIV retroviral packaging nucleic acid sequence comprises an HIV retroviral 5' splice donor sequence, and a psi sequence, wherein the nucleic acid sequence is devoid of lentiviral sequences both upstream and downstream from the splice donor site to a gag initiation site." (emphasis added)

XII. Auxiliary requests I to III related to the same subject matter and differed from the main request only by feature (d) of claim 1.

In claim 1 of auxiliary request I the last half sentence of feature (d) of the main request, referring to the lack of sequences upstream and downstream from the splice donor site (underlined in item XI), was deleted.

In claim I of auxiliary request II a further feature reading "and wherein said HIV-based retrovirus is

produced by a suitable packaging host cell" was added to feature (d) of claim 1 of the main request.

In claim I of auxiliary request III the amendments of auxiliary requests I and II were combined.

XIII. The following documents are cited in this decision:

D10: WO 91/19798

D11: Lusso et al., 1990, Science vol. 247, 848-852.

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

Admissibility of the requests (Article 13(1) RPBA)

The requests submitted with the grounds of appeal specifically addressed the objections raised in the decision of the opposition division. The respondent did not file a response to the grounds of appeal and did not raise any objections to these requests. New requests were then filed in response to the preliminary opinion expressed by the board in its communication accompanying the summons to oral proceedings. There was thus a consecutive history of amendments which always concerned the same features which had already been the subject of the decision under appeal. The amendments could therefore not result in a fresh case.

With its grounds of appeal, the appellant could only address issues under Article 123(2) EPC because these were the only issues which the opposition division had

decided. In decision G 9/91, the Enlarged Board of Appeal emphasized the judicial nature of inter partes appeal proceedings and concluded that their purpose was mainly to give the losing party an opportunity to challenge the decision under appeal. Novelty and inventive step of the claimed subject matter over prior art document D10 should therefore be irrelevant for the board when exercising its discretion under Article 13(1) RPBA. This view found support in decisions T 384/91 and G 1/93, where it was stated that a comparison with prior art documents had to be avoided when addressing issues under Article 123(2) and (3) EPC.

The purpose of these appeal proceedings was not to predict the outcome of the opposition proceedings as far as novelty and inventive step were concerned. For this purpose, the case had to be remitted to the first instance. Not doing so would lead to procedural uncertainty for the appellant because it would be deprived of the opportunity to present its complete case in both instances.

XV. The arguments of the respondent, as far as they are relevant for the present decision, can be summarized as follows:

The requests were inadmissible under Article 12(4) RPBA because they could have been presented in the first instance proceedings. In the alternative, the Board should exercise its discretion under Article 13(1) RPBA and decide not to admit the requests.

The opposition brief included objections under Article 123(2) EPC relating inter alia to the feature

defined in the last half sentence of claim 1 as granted. This issue remained the same throughout the proceedings. The appellant's immediate response to the opposition brief was a shift from claims directed to a retrovirus to claims directed to compositions comprising the virus and a second nucleic acid. All the requests in opposition proceedings were directed to this subject matter and claims to retroviruses per se had been abandoned. With its grounds of appeal, the appellant returned to claims directed to retroviruses per se defined inter alia by a product by process feature. This represented a fresh case because the new requests were not obtained by merely combining independent and dependent claims of existing requests.
The claims of these requests still comprised features which had been objected to under Article 123(2) EPC from the beginning of the opposition proceedings and lacked novelty over document D10.

XVI. The requests of the parties were as follows:

The appellant requested that the decision under appeal be set aside and the case be remitted to the opposition division for further prosecution on the basis of the main request or, in the alternative, of the first auxiliary request, both filed with letter dated 31 August 2012, or of the second or third auxiliary request, both filed at the oral proceedings. The appellant furthermore requested that a question of law as submitted in the course of the oral proceedings be referred to the Enlarged Board of Appeal if the board were not inclined to accept the appellant's arguments that issues of novelty and inventive step should not be

considered when deciding whether to admit the main and the auxiliary requests into the proceedings.

The proposed question to the Enlarged Board of Appeal was phrased as follows:

"If an appeal lies from a decision from an opposition division under Article 123(2) and/or 123(3) EPC only, is it within the discretion of the Board of Appeal to consider novelty and/or inventive step when assessing formal admissibility of amendments under Article 13(1) RPBA when the decision of the opposition division was not based on these grounds?"

XVII. The respondent requested that the appeal be dismissed and that appellant's main request and auxiliary requests not be admitted into the proceedings.

Reasons for the decision

Admissibility of the requests (Article 13(1) RPBA)

1. The main request and auxiliary request I were filed one month before oral proceedings, and auxiliary requests II and III were filed during the oral proceedings.

2. According to Article 13(1) RPBA, any amendment to a party's case after it has filed its grounds of appeal or reply may be admitted and considered at the Board's discretion. The discretion shall be exercised inter alia in view of the complexity of the new subject matter, the current state of the proceedings and the need for procedural economy.

3. The board will therefore examine whether the late filed requests are in line with these principles.

4. With regard to the procedural economy, the admission of new requests at a very late stage of the proceedings, i.e. shortly before or on the day of oral proceedings, is only in keeping with this principle if the requests are not unsuitable from the outset to overcome the objections as to the allowability of the claims. This means that there must be no doubt that the late-filed requests meet the formal requirements and that they constitute a promising attempt to counter all outstanding objections (cf. Case Law of the Boards of Appeal, 6th edition, VII.E.16.4.1, and VII.E.16.5.4; cf. e.g. also T 33/07 of 17 July 2008; T 321/07 of 23 October 2008; T 1168/08 of 10 June 2011; T 1634/09 of 30 June 2011).

The board will therefore not limit its preliminary assessment to issues under Article 123(2) and 123(3) EPC but will include issues under Articles 54 and 56 EPC.

5. The appellant argued that the board, when exercising its discretion, could only take into account issues which were dealt with in the decision under appeal, i.e. only issues under Article 123(2) and 123(3) EPC. Based on decision T 384/91 (OJ EPO 1995, 745) in connection with decision G 1/93 (OJ EPO 1994, 541), and on decision G 9/91 (OJ EPO 1993, 408), it reasoned as follows:

In decision G 1/93, the Enlarged Board of Appeal had defined the conditions under which a patent could be maintained unamended despite it containing subject matter extending beyond the content of the application as filed. Based on point 13 of the reasons in decision G 1/93, the competent board in decision T 384/91 concluded that the assessment whether the exception provided for in the Enlarged Board's decision applies in a particular case should only rely on the technical relationship of the added feature with the content of the application as originally filed. The assessment could not depend on considerations of the prior art.

The same conclusion could be derived from decision G 9/91 of the Enlarged Board of Appeal, where the purpose of an appeal procedure was described as mainly giving a losing party the possibility of challenging the decision of the opposition division on its merits, and where it was explicitly stated that it would not be in conformity with this purpose to consider grounds of opposition on which the decision of the opposition division had not been based (cf. Reasons, point 18).

Since the decision under appeal dealt exclusively with issues under Article 123(2) and 123(3) EPC, the board was barred from including considerations of other grounds of opposition when assessing the admissibility of appellant's requests.

6. The board is not convinced by these arguments.

Decision G 1/93 addressed the specific problem of the relationship between the provisions of Article 123(2) and (3) EPC, and analysed the conditions under which it

was possible to maintain a granted claim containing subject matter extending beyond the content of the application as filed. When discussing the relationship between these provisions (cf. points 5 and 13 of the reasons), the Enlarged Board stated that both were mutually independent of each other and of equal weight, and that there was no room for an interpretation of this relationship depending on the facts of the individual case, i.e. depending on prior art considerations.

In the present case, the board is not examining appellant's argument that the last half sentence of feature (d) of claim 1 as granted represented a limiting feature according to Headnote 2 of decision G 1/93. The question addressed by the board is that of the admissibility of late filed requests, and in this respect, decision G 1/93 is silent.

Decision G 9/91 was concerned with the question if the power of an opposition division or a board of appeal to examine and decide on the maintenance of a patent depended on the extent to which the patent was opposed in the notice of opposition. Regarding the purpose of appeal proceedings as mainly giving the losing party an opportunity to challenge a decision from an opposition division, and in view of the judicial nature of appeal proceedings, the Enlarged board decided that it would in principle not be justified to introduce fresh grounds for opposition at the appeal stage (cf. Reasons, point 18).

In the present case, novelty and inventive step were grounds of opposition from the beginning of the

procedure, and the board is assessing a different question, i.e. the admissibility of late filed requests. The conclusions drawn in decision G 9/91 do not relate to the present case.

Thus, there is no legal reason preventing the board, when exercising its discretion under Article 13(1) RPBA, from taking into consideration the issues of novelty and inventive step on which the opposition was based from the very beginning.

7. When deciding on the admissibility of late filed requests, the board does not consider it as a necessary prerequisite that the proposed amendments overcome all outstanding objections with certainty but that they result at least in an arguable case. The board sees no reason in admitting amendments which would result in clearly non-allowable requests as this would only lead to unnecessary delays.

8. The appellant submitted that the late filed requests represented promising attempts to overcome all outstanding issues.

9. In its communication accompanying the summons to oral proceedings (cf. point 6), the board had expressed its preliminary opinion that the last half sentence of part (d) of claim 1 referred to a property of a packaging vector but did not further specify the technical properties of the claimed retrovirus. In view of this preliminary opinion, the appellant argued that the last half sentence of part (d) should be simply ignored when determining whether the main request and auxiliary request II met the requirements of Article 123(2) EPC.

For the same reason, the deletion of the last half sentence of part (d) in auxiliary requests I and III should have no consequences under the provisions of Article 123(3) EPC.

The board agrees that the proposed amendments to part (d) of claim 1 could be regarded as a promising attempt as far as issues under Article 123(2) and 123(3) EPC are concerned. It remains however to be established if this also applies to the objections under Articles 54 and 56 EPC.

10. The subject matter of claim 1 of the main request is a replication defective pseudotyped HIV-based retrovirus. It comprises a HIV GAG protein (feature (a)), a HIV POL protein (feature (b)), an ENV protein selected from the group of ENV proteins listed in feature (c), among others from a Moloney Murine Leukemia virus, and a retroviral genome comprising a heterologous nucleic acid linked to a regulatory nucleic acid sequence, at least one HIV cis-acting nucleic acid sequence necessary for reverse transcription and integration, and a HIV retroviral packaging site comprising a 5' splice donor sequence and a psi sequence (feature (d)).

11. From the beginning of the opposition procedures, the respondent had argued that the claimed retrovirus lacked novelty over document D10.

12. Document D10 discloses the production of a replication deficient retroviral HIV based retrovirus comprising a HIV GAG, POL and ENV protein (features (a) to (c)) and a retroviral genome comprising cis-acting HIV sequences necessary for reverse transcription and integration,

and a packaging sequence including the 5' splice donor sequence and a psi sequence (feature (d)) (for the retroviral genome cf. Figure 2, vector "HVB(SL3NEO)", and page 16; for features (a) to (c) cf. Figure 2, vectors "HXBΔP1Δenv" and "pSVIIIenv3-2", and e.g. Table II).

The retrovirus disclosed in the examples of document D10 comprises HIV ENV and thus differs from the retrovirus of claim 1 of the main request by the nature of the ENV protein. The disclosure of document D10 is however not limited to the examples. It refers inter alia to pseudotyping as a way to increase the virus host range (cf. page 30: "in light of recent observations demonstrating that HIV can be pseudotyped with the envelope glycoproteins of other viruses, increasing the host range of these vectors is feasible"). In the same context, it also contains an explicit reference to a particular document describing the pseudotyping of a HIV virus (cf. page 13: "HIV can be pseudotyped with the envelope glycoproteins of other viruses. [(Lusso, P. et al., Science 247:848-851 (1990)]. Consequently one can prepare a vector containing a sufficient number of nucleotides to correspond to a functional env gene from a different retrovirus").

The document referred to, Lusso et al., is document D11 in the current proceedings. It discloses a HIV vector pseudotyped with an ENV protein from an amphotrophic Murine Leukemia virus (MLV) (cf. feature (c) of claim 1).

13. The respondent argued that document D10 directly affected the novelty of claim 1 because it contained an explicit reference to document D11.

14. The appellant submitted that document D10 did not affect novelty of any of the requests because it merely contained a reference to a further publication without disclosing any of the specific heterologous ENV proteins defined in part (c) of claim 1.

15. The board agrees with the appellant that the proposed amendments to claim 1 represent at least an arguable case to overcome the novelty objections but it disagrees with the appellant with regard to inventive step.

16. Document D10 suggests pseudotyping in general terms as a solution if one wishes to increase the host range of the disclosed retroviruses (cf. point 12 above), and, by reference to document D11, directly points to one of the replication defective pseudotyped HIV based retroviruses as defined in claim 1.

Therefore, the board is convinced that claim 1 of the main request is clearly unallowable under the provisions of Article 56 EPC.

17. The proposed amendments in claim 1 of auxiliary requests I to III concern the deletion of the last half sentence of part (d) (auxiliary requests I and III) and the addition of the feature "and wherein said HIV-based retrovirus is produced by a suitable packaging host cell" (auxiliary requests II and III), respectively. As explained above (cf. point 9), the last half sentence

of part (d) specifies properties of a packaging virus without affecting the technical features defining the claimed replication defective retrovirus, and removal of this feature does not alter the technical specification of the claimed retrovirus. The same is true for the addition of the new process feature to part (d). It does not alter the definition of the claimed retrovirus. Since the the technical features of the replication defective recombinant retroviruses of the main request and of auxiliary requests I to III are identical, the conclusions reached in respect of the main request equally apply to auxiliary requests I to III.

18. For these reasons the board decided not to admit any of the requests into the proceedings.

Request for a referral under Article 112(1)(a) EPC

19. The appellant requested referral of a question of law to the Enlarged Board of Appeal should the present board not accept the argument that, when exercising its discretion under Article 13(1) RPBA, legal reasons prevented it from taking into consideration issues of novelty and inventive step which had not been decided on in the decision under appeal (cf. points 5 and 6, above).

20. There is no absolute right to have an issue decided on by two instances, and the board may exercise any power within the competence of the department which was responsible for the decision appealed (Article 111(1) EPC). Since the board has the power to come to a final decision on all validly introduced grounds of

opposition including issues of novelty and inventive step, irrespective of whether those were decided on in a decision under appeal, it also has the power to take into consideration whether late filed requests are clearly unallowable in respect of any of these issues.

21. The request for referral of the question of law, cited in point XII above, to the Enlarged Board of Appeal is therefore rejected.

22. Since there is no admissible request on which the board could decide, the appeal has to be dismissed.

Order

For these reasons it is decided:

The appeal is dismissed.

The Registrar: The Chairman:

A. Wolinski R. Moufang