BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS | BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE | CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

**Internal distribution code:**
(A) [ ] Publication in OJ
(B) [X] To Chairmen and Members
(C) [ ] To Chairmen

# D E C I S I O N
## of 20 October 1997

**Case Number:** T 0815/90 - 3.3.4

**Application Number:** 85904746.6

**Publication Number:** 0196316

**IPC:** C12N 7/08

**Language of the proceedings:** EN

**Title of invention:**
Hepatitis A virus purified and triply cloned

**Applicant:**
THE UNITED STATES OF AMERICA as represented by the Secretary United States Department of Commerce

**Opponent:**
-

**Headword:**
Hepatitis A virus II/UNITED STATES OF AMERICA

**Relevant legal provisions:**
EPC Art. 123(2)
EPC R. 28, 28(1)(c), 28(2)(a)
PCT R. 13$^{bis}$

**Keyword:**
"Subject-matter other than accession number added in relation to deposited material - not allowable under Article 123(2) EPC or Rule 28 EPC"

**Decisions cited:**
G 0002/93, J 0008/87, T 0815/90 of 26 February 1993

**Catchword:**
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

**Case Number:** T 0815/90 - 3.3.4

# D E C I S I O N
## of the Technical Board of Appeal 3.3.4
## of 20 October 1997

**Appellant:** THE UNITED STATES OF AMERICA as represented by the Secretary United States Department of Commerce
National Technical Information Service
Office of Government Inventions and Patents
5285 Port Royal Road
Springfield
Virginia 22161 (US)

**Representative:** Daley, Michael John
F.J. CLEVELAND & COMPANY
40-43 Chancery Lane
London WC2A 1JQ (GB)

**Decision under appeal:** **Decision of the Examining Division of the European Patent Office posted 12 July 1990 refusing European patent application No. 85 904 746.6 pursuant to Article 97(1) EPC.**

**Composition of the Board:**

**Chairman:** U. M. Kinkeldey
**Members:** R. E. Gramaglia
S. C. Perryman

## Summary of Facts and Submissions

I. European patent application No. 85 904 746.6 filed on 18 September 1985, claiming priority of 19 September 1984 was published under No. WO-A-86/01826 with seven claims.

II. The text of the application as filed contained the following passages:

"Statement of deposit

The HM-175 strain of hepatitis A virus has been deposited in the American Type Culture Collection under the patent procedures prior to the filing of this application, thus affording permanency of the deposit and ready availability to the public upon issuance of a patent."

(appearing immediately before **Example 1** three lines reading as follows:)

"The HM-175 strain of human hepatitis A virus was imported into this country and is described in Infection and Immunity, 32(1), April 1981, pages 388-393."

"Example 3

....Clone #1 (TC passage 20 or 21) infected 11 of 15 susceptible chimpanzees inoculated intravenously or by mouth and produced a mild hepatitis in only two of these. The 11 infected chimpanzees responded with protective antibody 3-8 weeks after vaccination. Clone #2 (TC passage 20) was inoculated intravenously into 4 susceptible chimpanzees. Only 1 of the 4 animals had a very mild borderline hepatitis. All four developed protective antibody. Similarly, 1 of 2 susceptible

chimpanzees inoculated intravenously with clone #4 (TC passage 9) was infected without hepatitis but with the development of protective antibody."

The claims as originally filed read:

"1. A method of producing a protective antibody response in higher primates by injecting said primate with a hepatitis A live attenuated virus injection which is of uniform virus composition.

2. The method of claim 1, wherein the uniform virus composition is triple cloned material of passage level at least 10-30.

3. The method of claim 1, wherein the live attenuated virus is strain HM-175.

4. The method of claim 1, wherein the injection of a higher primate is a form of vaccination that confers protection against type A hepatitis caused by unmodified (wild type) hepatitis A virus.

5. A method of claim 1, wherein the live attenuated hepatitis A virus is administered by percutaneous injection.

6. A method of claim 1, wherein live attenuated hepatitis A virus is administered by mouth.

7. An improved vaccine for mammals comprising a triple cloned hepatitis A virus, strain HM-175, that is useful after attenuation as a vaccine."

The cited passages of the text and claims were the same in the US priority document and in the PCT application published under number WO 86/01826 resulting in the present European application.

III. During further prosecution the appellant submitted new claims and also by letter dated 16 February 1987, received on 20 February 1987, a certificate from the American Type Culture Collection reading inter alia:

"

| Identification reference by depositor | ATCC designation |
|---|---|
| Hepatitis A Virus: Strain HM-175, Clone 5 | VR 2097 |
| Hepatitis A Virus: Strain HM-175, Clone 6 | VR 2098 |
| Hepatitis A Virus: Strain HM-175, Clone 7 | VR 2099 |

.....

The deposits were received October 5, 1984 by this International Depositary Authority and have been accepted.

....

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains.

..."

IV. The Examining Division issued a communication objecting to the claims then put forward on the grounds of lack of novelty and inventive step, in response to which 9 new claims were filed with letter of 2 February 1989, claim 1 of which read as follows:

"1. A uniform hepatitis A live attenuated virus composition adapted to produce a protective antibody response in higher primates, characterized in that the composition is triple cloned material of strain ATCC VR2097, VR2098, or VR2099."

A further communication objecting to this claim as contravening Article 123(2) EPC was issued and the appellant replied thereto.

V. In the decision under appeal the Examining Division refused the application on the basis of the claims filed with letter of 2 February 1989. The Examining Division came to the conclusion that the application did not meet the requirements of Article 123(2) EPC because the introduction of the information about the deposit numbers of three clones (VR2097, VR2098 and VR2099) constituted added subject-matter.

VI. The appellant appealed against this decision and filed a written statement setting out the grounds of appeal. With a letter dated 21 August 1991, the appellant filed a set of new claims 1 to 7, claims 1 and 6 of which read as follows:

"1. A uniform hepatitis A live attenuated virus composition adapted to produce a protective antibody response in higher primates, characterized in that the composition is triple cloned material of strain HM-175 (VR2093), in that the material is of a passage level of at least 10 to 30, and in that the triple cloning is effected by terminal dilution."

"6. A method for the production of a uniform hepatitis A live attenuated virus composition which comprises the step of serially diluting uncloned hepatitis A virus HM-175 (ATCC VR 2093), and inoculating each dilution into a respective mammalian cell culture, culturing the same, harvesting cloned virus particles and repeating said step at least twice more, thereby to produce a master seed lot therefrom for the formation of a vaccine composition."

An amended description was also filed at the same time, referring for the first time in the application proceedings to the HM-175 strain of hepatitis A virus being deposited in the American Type Culture Collection under the number ATCC VR 2093 on 14 August 1984.

VII. Board of Appeal 3.3.2 issued on 26 February 1993 interlocutory decision T 815/90 (OJ EPO 1994, 389), referring to the Enlarged Board of Appeal the question:

"May the information concerning the file number of a culture deposit according to Rule 28(1)(c) EPC be submitted after the expiry of the time limit set out in Rule 28(2)(a) EPC?"

VIII. By its decision G 0002/93 (OJ EPO 1995, 275) the Enlarged Board of Appeal answered this question as follows:

"The information concerning the file number of a culture deposit according to Rule 28(1)(c) EPC may not be submitted after expiry of the time limit set out in Rule 28(2)(a) EPC."

In point 14 of its decision it also commented "Whether the 'Guidelines for Examination in the EPO', Part A, Chapter IV, No. 4.2, a general practice of the EPO based thereupon or other special circumstances of the case may have given rise to legitimate expectations on the part of the appellant, to the effect that the time limit under Rule 28(2)(a) EPC could be extended, is left to the referring board of appeal to consider on the basis of supporting facts, evidence and arguments that may be submitted to it."

IX. The following further documents were submitted during the continuance of the appeal proceedings before the present Board 3.3.4:

- Mrs. Brandon's affidavit dated 14 June 1994

- ATCC deposit receipt dated 5 December 1995 (submitted at the oral proceedings) reading:

"Identification reference by depositor | ATCC designation

Hepatitis A Virus: Strain HM-175, HM-175 Pass 20 uncloned | VR 2093

.....

The deposit was received August 14, 1984 by this International Depositary Authority and has been accepted.

AT YOUR REQUEST:

....

The strain is available to the scientific public upon request as of December 29, 1985.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains.

..."

- ATCC Catalogue of Animal Viruses and Antisera, Chlamydiae and Rickettsiae, 6th edition, pages 109 and 210 (1990).

X. In a communication accompanying the summons to oral proceedings, Board of Appeal 3.3.4 pointed out the most important points to be discussed at the oral proceedings. In response to this communication, the Applicant submitted new claims 1 to 11, of which claim 1 reads as follows:

"1. A live attenuated hepatitis A virus composition derived from any one of the following HM-175 hepatitis A viruses deposited at the American Type Culture Collection (ATCC):

A. uncloned HM-175, wherein the derivation of said composition includes triple cloning;

B. Clone No. 1;

C. Clone No. 2; and

D. Clone No. 4."

Oral proceedings were held on 18 February 1997, during which the appellant submitted, as first auxiliary request, claims 1 to 9. Claims 1 and 8 of this request read as follows:

"1. A live attenuated hepatitis A virus composition derived from uncloned HM-175 hepatitis A virus deposited at the American Type Culture Collection (ATCC), wherein the derivation of said composition includes triple cloning."

"8. A method for the production of a live attenuated hepatitis A virus composition which comprises the step of serially diluting a virus derived from uncloned HM-175 hepatitis A virus deposited at the ATCC and

inoculating each dilution into a respective mammalian cell culture, culturing the same, harvesting cloned virus particles and repeating said step at least twice more, thereby to produce a master seed lot therefrom for the formation of a vaccine composition."

XI. In support of his requests, the appellant submitted essentially that the requirements of the second part of Rule 28(1)(c) relating to the accession number were satisfied and thus it did not amount to undue burden for a skilled person to obtain and identify the deposited material because:

- The ATCC maintained the cloned and uncloned deposits separate from each other and was able to identify the requested sample based on the depositor's designation (see Mrs. Brandon's affidavit)

- It was not decisive that the accession number be given because the depositor's designation is cross indexed (see ATCC Catalogue)

It was also argued that Rule 28 EPC in its previous version did not require the accession number and that the failure of the EPO to raise the deposit question within the time limit provided by Rule 28(2) conferred a legitimate expectation to the applicant that the application as filed satisfied the requirements of Rule 28(1) EPC.

XII. The appellant requested that the decision under appeal be set aside and that a patent be granted as main request on the basis of claims 1 to 11 and amended pages 2 and 2a filed with letter dated 17 January 1997, or as first auxiliary request, on the basis of the set of claims 1 to 9 submitted at the oral proceedings on 18 February 1997.

XIII. At the end of the oral proceedings after deliberation by the Board the chairwoman gave the following decision:

1. The debate on the issues discussed at the oral proceedings is closed.

2. The board will give its decision in due course in writing.

## Reasons for the Decision

1. *Main request*

1.1 Article 123(2) EPC

1.1.1 The wording of Claim 1 of this request refers to live attenuated hepatitis A virus composition derived from one of the following HM-175 hepatitis A viruses deposited at the American Type Culture Collection (ATCC):

A. uncloned HM-175, wherein the derivation of said composition includes triple cloning;

B. Clone No. 1;

C. Clone No. 2; and

D. Clone No. 4;

To the original information in the application as filed, namely that the HM-175 strain of hepatitis A had been deposited in the American Type Culture Collection

under the patent procedures, there is now added by newly filed page 2 (lines 1 to 2) the information that it was "under the designations: HM-175 uncloned, HM-175 clone #1, HM-175 clone #2 and HM-175 clone #4 on 14th August 1984".

1.1.2 While these identifications of the clones are mentioned in Example 3 as originally filed, and there is a reference before Example 1 to HM-175 imported into the USA, presumably uncloned, there is no clear and unambiguous disclosure in the application as originally filed that these particular clones were the ones referred to as deposited with the ATCC in the Statement of deposit in the originally filed description (see above, point II of the Facts and Submissions) or that the uncloned material is of passage 20 as now appears from the evidence submitted. The originally filed statement of deposit might with at least equal probability be taken as referring to unpassaged material.

1.1.3 That there is no clear basis for identifying the material now referred to as being that meant originally, is also evidenced by the actions of the appellant. Before the Examination Division the appellant was seeking to refer to other deposited material, namely HM-175 clones 5, 6 and 7.

1.1.4 This claim 1 does not comply with Article 123(2) EPC forbidding the addition of subject-matter not appearing in the application as filed.

1.2 Rule 28(2) EPC

1.2.1 The accession number of the depositary institution is **not** now stated in Claim 1. This avoids the problem that the accession number was not provided within the time limit set in Rule 28(a) EPC, which time limit the

answer of the Enlarged Board in decision G 0002/93 has indicated as binding. However the omission of the any reference to the accession number raises an even worse problem, namely whether claim 1 can be regarded as relating to biological material **deposited** in accordance with Rule 28 EPC.

1.2.2 The appellant has argued that Rule 28 EPC requires only that the internal house reference number of the applicant be stated, not the file reference number of the depositary institution. This is not the case for Rule 28 EPC as now worded. Nor does the Board see that there was any doubt that under the previous wording of Rule 28 EPC the term "file number" referred to anything other than the file number of the depositary institution. At the time the original Rule 28 EPC was drafted "accession number" was not yet a standard term in treaties, but in its context the term "file number" could only refer to the file number of the depositary institution, as there would be no reason to give an applicant extra time to state his own in-house reference number. Further the appellant made his application pursuant to the Patent Cooperation Treaty and this in its Rule 13$^{bis}$: Microbiological Inventions states:

"13$^{bis}$.2 References (General)

Any reference to a deposited microorganism shall be made in accordance with this Rule and, if so made, shall be considered as satisfying the requirements of the national law of each designated State.

13$^{bis}$.3 References: Contents; Failure to Include Reference or Indication

(a) A reference to a deposited microorganism shall indicate,

(i) the name and address of the depositary institution with which the deposit was made;
(ii) the date of deposit of the microorganism with that institution;
(iii) the **accession** number given to the deposit by that institution;..."
(emphasis by the board)

Rule 13$^{bis}$.4 requires the information to be provided within sixteen months of the priority date.

1.2.3 The Board sees no case for Rule 28 EPC providing a justification for the filing at a later date than the application any information other than an accession number in relation to material that has been deposited. The amendments put forward must thus be assessed for fair basis only on the text of the original application. As already concluded in Section 1.1 above there is no such basis.

1.3 Principle of legitimate expectations

1.3.1 There remains to be investigated whether in the circumstances some application of the principle of legitimate expectations could nevertheless be relied on to allow the claim 1 now put forward. However this principle has been used only to allow applicants to escape the consequences of not complying with procedural requirements or the payment of fees. Here the claim put forward is not acceptable under Article 123(2) EPC, and the Board cannot see its way to using this principle to allow the addition of subject-matter outside the ambit of Rule 28 EPC, which subject-matter is not fairly based on the original application.

1.3.2 The appellant relies on decision J 0008/87 of 30 November 1987 (OJ EPO 1989, 009) to support the application of the principle of legitimate expectations to this case. This decision, whose rationale has now been disapproved of by the Enlarged Board in its decision G 0002/93, was not published until some eighteen months after the filing date of the present application, too late to have been the cause of any misunderstanding. Not even any principle that applicants in similarly exceptional situations should be treated equally favourably, assists the appellant here. The applicant concerned in decision J 0008/87 had provided the accession number only two months out of time, and there was a single deposit clearly correlated with the description. Here the case is much worse, in that the appellant is seeking to introduce many years after the application date a reference to deposited material in a form not permitted by Rule 28 EPC. This is not something the Board can find any justification for, whether by reliance on the principle of legitimate expectations or otherwise.

1.3.3 The Board accordingly finds that the main request does not comply with Article 123(2) EPC.

2. *First auxiliary request*

2.1 Article 123(2) EPC

2.1.1 Claim 1 of this request is restricted as against Claim 1 of the main request to live attenuated hepatitis A virus composition derived from uncloned HM-175 hepatitis virus deposited at the American Type Culture Collection. However, as already stated in connection with Claim 1 of the main request, there is no clear and unambiguous disclosure in the application as originally filed that it was this material which was

deposited. For the reasons stated above in connection with the main request, neither Rule 28 EPC nor the principle of legitimate expectations can serve to make this added subject-matter acceptable. The Board finds that the auxiliary request contravenes Article 123(2) EPC and is not allowable, and that the appeal must be dismissed.

3. *Article 83 EPC*

3.1 In view of the quantity of evidence filed the Board would remark that the requests were considered unacceptable also under Article 83 EPC, and whereas deletions of the added subject-matter referring to specific material having been deposited at the ATCC could have avoided the Article 123(2) EPC objection, the objection under Article 83 EPC would have remained. The claimed subject-matter cannot benefit from the provision of Rule 28(1) that deposited material is disclosed for the purposes of Article 83 EPC. The evidence shows that the subject-matter of the respective claims 1 was not in fact available to the public at the filing date of the application. Without the benefit of the deeming provision of Rule 28(1) EPC for duly deposited and timely identified biological material, the invention as claimed was not disclosed in a sufficiently complete manner to be carried out by a person skilled in the art. The Board wholly agrees with the comment by the Enlarged Board in its decision G 0002/93 that indication of the file number (accession number) is substantive because it is instrumental in enabling a person skilled in the art to carry out the invention. If Rule 28 EPC is not complied with, there

can be no deemed compliance with the provisions of Article 83 EPC for deposited material. This deemed compliance is a special privilege conferred by Rule 28(1) EPC only on correctly and timely identified deposited material.

**Order**

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

The appeal is dismissed.

The Registrar: The Chairwoman:

D. Spigarelli U. M. Kinkeldey