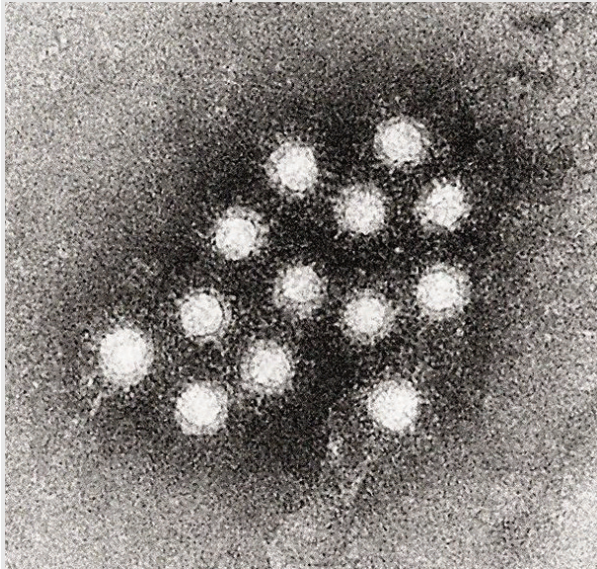


Enlarged Board of Appeal EPO, 21 December 1994, Hepatitis A virus - USA

Hepatitis A virions



From: http://en.wikipedia.org/wiki/Hepatitis_A

PATENT LAW

Sufficient disclosure

- **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 the case of an invention referred to in Rule 28(1) EPC, the primary function of a culture deposit is to complete an otherwise insufficient written disclosure. The culture deposit constitutes then an essential part of the disclosure.**

9. Rule 28(1) EPC refers to Article 83 EPC and serves to substantiate and to supplement the general requirements of Article 83 EPC for a specific group of inventions for which a mere written description is not sufficient to enable a person skilled in the art to carry out the invention. Therefore, the provisions of Rule 28 EPC are subordinate to the requirements of Article 83 EPC. For microbiological inventions making use of living matter which is not available to the public and which cannot be described in a reproducible way, these provisions set out a reliable framework for determining which indications are necessary in a European patent application and under which conditions the public may have access to a culture deposit. Consequently, the disclosure of an invention referred to in Rule 28(1) EPC has not only to comply with the provisions under Rule 28(1) EPC, but also with the requirements of Article 83 EPC.

10. Sufficiency of disclosure under Article 83 EPC requires inter alia that the subject-matter claimed in a European patent application be clearly identified. This requirement must be complied with as from the date of filing because a deficiency in a European patent application as filed, consisting in an insufficient identification of the subject-matter claimed, cannot

subsequently be cured without offending against Article 123(2) EPC which provides that the subject-matter content of a European patent application as filed may not be extended.

11. A sufficient identification under Article 83 EPC of an invention referred to in Rule 28(1) EPC implies that the culture deposit of the micro-organism, as an essential part of the disclosure (see paragraph 8 supra), be identified in the patent application as filed. If the file number (accession number) of the culture deposit given by the depositary institution is not already indicated in the application as filed, the micro-organism must be identified in such a way that the later submitted file number (accession number) can be linked back without ambiguity. This can normally be done by indicating the identification reference given by the depositor to the micro-organism within the meaning of Rule 6.1(iv) of the Budapest Treaty or of Point 12(a)(iv) of the 'Model Agreement' (published in OJ EPO 1982, 454, 457) as well as the name of the depositary institution. This reference is already known to the applicant on or before the filing date even if the depositary institution has not yet attributed the corresponding file number (accession number). The receipt of the depositary institution issued to the depositor contains both the identification reference given by the depositor to the micro-organism and the accession number given by the depositary institution to the culture deposit (see Rule 7.3(iv) and (v) of the Budapest Treaty and Point 17(b)(iv) and (v) of the 'Model Agreement' [OJ cit., 459]).

- **In order to be sufficient under Article 83 EPC, the disclosure of an invention in a European patent application must further enable a person skilled in the art to carry out the invention.**

This requirement is satisfied under Rule 28 EPC by making a deposited culture available to the public. This availability is brought about by stating the depositary institution and the file number (accession number) of the culture deposit in the European patent application (Rule 28(1)(c) EPC), because, under Rule 28(2) EPC, the "communication of this information" is regarded as constituting the unre-served and irrevocable consent of the applicant to the deposited culture being made available to the public within the meaning of Rule 28 EPC. The mere indication of the identification reference given by the depositor to the micro-organism (see paragraph 11 supra) does not bring about this legal effect.

- **The indication of the file number (accession number) of a culture deposit in a patent application is thus substantive because, under the EPC, it is instrumental in enabling a person skilled in the art to carry out the invention.**

Source: epo.org

Enlarged Board of Appeal EPO, 21 December 1994
(P. Gori, W. Moser, G. Gall, G.D. Paterson, J.-C. Saisset, K. Jahn, P. van den Berg)
Decision of the Enlarged Board of Appeal

dated 21 December 1994

G 2/93

Composition of the board:

[...]

Applicant: The United States of America as represented by the Secretary, United States Department of Commerce

Headword: Hepatitis A virus/UNITED STATES OF AMERICA II

Summary of Facts and Submissions

I. In case J 8/87 (OJ EPO 1989, 9), the Legal Board of Appeal held that an applicant who failed to submit the information relating to a culture deposit within the time limit of sixteen months provided for in Rule 28(2)(a) EPC must be given an opportunity to remedy that deficiency within a further period. The reason given was that there was an analogy between this situation and the situation in which priority documents had not been filed within the sixteen months period provided for in Rule 38(3) EPC (in the version valid until 31 May 1991), because in both cases the deficiency existed only at the expiration of the time limit. The Legal Board of Appeal considered therefore that, notwithstanding the fact that the time limit provided for in Rule 28(2)(a) EPC was not mentioned in Article 91 EPC, a similar solution should be applied in both cases. Furthermore, the Legal Board of Appeal pointed out that, according to the Guidelines for Examination in the EPO, Part A, Chapter IV, No. 4.2, the Receiving Section had to notify the applicant when the information to be furnished pursuant to Rule 28(1) EPC was deficient or was not supplied within the specified period.

II. In case T 815/90, the competent Technical Board of Appeal 3.3.2 considered that a decision was required whether or not lack of sufficiency of disclosure due to the fact that the information concerning the file number relating to hepatitis A virus strain HM-175, Pass. 20 uncloned, ie number ATCC VR 2093, was not filed until almost seven years after the priority date of the present European patent application can be remedied.

Since Technical Board of Appeal 3.3.2 was not inclined to follow the rationale of decision J 8/87 of the Legal Board of Appeal (see paragraph I supra), it decided in its interlocutory decision T 815/90 (OJ EPO 1994, 389) to refer the following point of law to the Enlarged Board of Appeal:

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

III. Technical Board of Appeal 3.3.2 made in that decision the following comments:

- The contextual position of Rule 28 within the EPC was such that it prescribed certain conditions which had to be fulfilled in order to ensure sufficient disclosure in the case of live material and thus was subordinate to the very principle of the European Patent Convention that an invention had to be described in such a manner that it could be carried out by a skilled person.

- There was no scope for remedying lack of disclosure of the originally filed European patent application, with

the sole exception of the 16-month time limit given in Rule 28(2)(a) EPC.

- It subscribed in particular to the detailed reasoning of the purpose of Rule 28 EPC in the decision of an examining division dated 14 November 1989 (OJ EPO 1990, 156) where it was stated that the deficiency consisting in the number of the culture deposit not being submitted within the period according to Rule 28(2)(a) EPC could not be remedied. Any attempt to neglect the stringency of this period could make insufficient disclosure a remediable deficiency and ignore thereby the intent of the legislator and the purpose of Rule 28 EPC, which was not a mere formal requirement, but a provision to be interpreted in the light of Article 83 EPC.

- From the 'travaux préparatoires' it was evident that the time limit of 16 months given in Rule 28(2)(a) EPC had been introduced to ensure and guarantee that the information about the deposit was filed before the public was informed, in all cases. Therefore, if an invention could only be carried out by a skilled person within the meaning of Article 83 EPC by using live material deposited with a recognised depository and only identifiable by the file number of the culture deposit, this was a precondition for sufficiency of disclosure of a European patent application, which had already to be fulfilled at the date of filing of the European patent application, and not a mere formal requirement of a European patent application.

IV. Under Article 11a of the Rules of Procedure of the Enlarged Board of Appeal, the President of the EPO submitted comments to the Enlarged Board, essentially, as follows:

- The non-submission of the file number of a culture deposit before the end of the sixteenth month after the date of filing (priority) is not to be treated as a formal deficiency, which the applicant must be invited to correct, once that period has expired.

- The legal consequence of the non-submission of the file number of the culture deposit at the expiry of the sixteen-month period can only be drawn at the stage of substantive examination. Hence, it is only if the deposited micro-organism is actually necessary to carry out the invention that the insufficiency of the disclosure will be established.

- The requirements of Article 83 EPC must be fulfilled for the application as filed. This can be derived from Article 123(2) EPC. If the disclosure is seriously insufficient, such a deficiency cannot be cured subsequently by adding examples or features without offending Article 123(2) EPC.

- If an invention concerns a microbiological process or the product thereof and involves the use of a micro-organism which is not available to the public and which cannot be described in the European patent application in such a manner as to enable the invention to be carried out by a person skilled in the art, there is already a situation in which a priori the requirements of Article 83 EPC cannot be satisfied.

- Rule 28 EPC provides for a fiction of sufficiency of disclosure, or an exception to the rule that the invention

must be disclosed in the application, if a certain number of requirements are fulfilled.

- Rule 28(2) EPC can be regarded as a further exception to the requirements of Article 83 EPC, namely the setting of a time limit for the submission of an essential element of the disclosure.

- The guarantee of a full information for the public at the publication stage in all cases is indeed the reason why the time limit can be as long as sixteen months, but no longer. It cannot be admissible to extend the exception which is made to Article 83 EPC taken in conjunction with Article 123(2) EPC beyond what is necessary to achieve the purpose of informing the public.

- A micro-organism used in an invention can be regarded as subject-matter belonging to the application as originally filed via a double fiction: on the one hand an element essential for the original disclosure (the micro-organism) is regarded as fully disclosed in the application, even though it is not, on condition that it was actually deposited (not later than the date of filing) and the (formal) criterion of the time limit of Rule 28(2) EPC has been fulfilled.

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

V. In response to a communication of 14 March 1994 of the Enlarged Board of Appeal, the appellant in case T 815/90 filed observations on the referred point of law on 29 May 1994. Oral proceedings took place on 24 October 1994, Mr D.C. Evans appearing for the appellant in case T 815/90. The appellant's arguments can be summarised as follows:

- The practical steps of depositing a culture in a collection require that the culture be identified by the depositor before the deposit is accepted. Thus, at the time of making the deposit, the only file reference number for the deposited culture is the depositor's own reference. The collection number is supplied later. For the purposes of sufficiency, what is important is the fact of the deposit under the Budapest Treaty (so that the culture is available to the public) and the relevant description in the specification accompanying the application. What the deposited culture is called does not and cannot change the sufficiency of the specification in any way.

- The purpose of Rule 28 EPC is not to place an undue burden on the person skilled in the art. In the present case, such a person would know of the culture due to the presence of the previously published article in *Immun.* 32(2) 1981 or the patent specification as the case may be and would then apply to the ATCC for a sample of the culture on the basis of information available to him at the time. The presence of the ATCC file number is not necessary.

- Thus the practice of giving an ATCC number in a document is a means of verifying to the interested public that the culture concerned is genuine and has been accepted by the ATCC. Where however there is no ATCC number given, provided the interested member

of the public knows where the culture is deposited and has some description then that will in practice be sufficient to identify the culture.

- If there is sufficient information within the specification to enable the cell line to be identified in a collection, then the specification is de facto sufficient. In view of Rule 28(1)(c) EPC, in order to be de jure sufficient, a file number must be included in the specification.

- The supply of the official file number issued by the culture collection in respect of that culture is nothing more than a convenience required by Rule 28 EPC. It is not in these circumstances "new matter" within the meaning of Article 123(2) EPC, since it does neither repeat nor add anything to the technical information contained in the specification that was present in the specification in the first place. The lack of a file number, and more particularly an "official" file number, is simply a deficiency of the specification in the formal sense.

- The commonsense approach of the EPO to date has been that the lack of a file number is simply a "deficiency" and can and should be remedied as such. This approach was supported by the Legal Board of Appeal in its decision J 8/87, where it provided that, where the file number had not been provided within the Rule 28(2)(a) EPC period, since this was a deficiency, the applicant should be given the opportunity to remedy the deficiency. This interpretation was a correct interpretation taking into account the actual practice of the deposit of a culture sample with a depositary institution.

- The situation in the decision of an examining division dated 14 November 1989 (OJ EPO 1990, 156) is analogous to that of the present application. However, in this latter case the examining division was not invited to give consideration to the substance of the case and arrived at an erroneous decision as a result.

- It is plain that the practice of deposit of a culture supports the contention that the omission of the official deposit number issued by the deposit authority is a mere deficiency. At the date of publication of the specification, the specification is sufficient because the cell line is available as of right under Rule 11 of the Budapest Treaty. Furthermore, it is to be noted that where the applicant's own designation has been used, then this is an "official" number within the meaning of the Convention since it is a statutory requirement for the initial deposit at the time of filing of the application (see Budapest Treaty).

- The specification cannot be insufficient until the specification is published because the person skilled in the art simply cannot have access to the specification until publication. Thus, up to the date of publication, the question of insufficiency cannot arise, since the person skilled in the art cannot as of right have access to it. It follows therefore that the "fiction" of a sufficiency of disclosure provided by Rule 28 EPC as proposed by the President of the EPO is a non sequitur. It is only on publication that the right of the skilled person to obtain a sample comes into being.

- It is for the applicants to select which of the file numbers is to be employed in their specification. The wording of Rule 28 EPC permits the use of either. Furthermore, the substitution of one for the other is a permissible amendment under Article 123(2) EPC and this amendment can be made at any time until the issue of the communication under Rule 51(4) EPC, ie well after the expiration of the 16-month period from the date of filing of the application as provided for in Rule 28(2)(a) EPC.

- It is to be noted that in case T 39/88 it was stated that prior to 1986 the situation concerning the filing of deposits and micro-organisms was unclear, and that it would seem unfair to let the applicant hold the risk of this lack of clarity which was inherent in the system of deposit at that time. As the present application in suit was filed on 18 September 1985, before the decision in case T 39/88, the appellant contends that in view of the lack of clarity in the system relating to the deposit of micro-organisms at that time, the appellant should be allowed the opportunity of substituting the formal file number of the deposit of uncloned HM-175 for the file number included in the application as filed, particularly as the appellant did in fact file a deposit of uncloned HM-175 with the ATCC in good time.

- The point of law referred to the Enlarged Board of Appeal by Technical Board of Appeal 3.3.2 in its interlocutory decision T 815/90 (see paragraph II supra) is not directly relevant to the application in suit, as uncloned HM-175 was available to the public prior to the earliest priority date claimed in relation to the application in suit. In this connection, reference is made to the affidavit of Mr Adler and the appellant's letter of 16 November 1992 in case T 815/90, from which it will be apparent that uncloned HM-175 was available unconditionally from the NIH on request, uncloned HM-175 itself having been disclosed in the prior art "Infection and Immunity, 32(1), April 1981, pp. 388-393".

Reasons for the Decision

Admissibility and subject-matter of referral

1. The point of law referred to the Enlarged Board of Appeal is only related to the time limit for filing the information under Rule 28(1)(c) EPC and the effect of missing the time limit set out in Rule 28(2)(a) EPC.

2. The Enlarged Board of Appeal is not concerned with the question of whether the micro-organism has already been available to the public, eg from a deposit for the purposes of the national patent granting procedure for the US patent, whose priority has been invoked, or from any other deposit, so that no deposit under Rule 28 EPC would be required. Furthermore, it is neither concerned with the requirement that, for the purposes of the European patent granting procedure, a deposit must be made in accordance with Rule 28 EPC or the Budapest Treaty (see Notice of the EPO; OJ EPO 1986, 269, in particular 271 and 272, Nos. 7 and 8), respectively, nor with the conditions for conversion of a deposit made outside the purview of Rule 28 EPC or the Budapest Treaty to a deposit made for such purposes (see OJ EPO 1991, 461). Finally, the point of law referred to the Enlarged Board of Appeal does not

touch upon multiple deposits of virus strains under the same "house designation" as set out in paragraphs 4.3 to 4.5 of the decision of referral. The referring Board will deal with this matter as it sees fit.

3. In interlocutory decision T 815/90 (see paragraph II supra), in particular in paragraph 4.6 thereof, Technical Board of Appeal 3.3.2 set out the reasons why, under its present considerations, the point of law referred to the Enlarged Board of Appeal might be crucial in view of the final decision to be taken in case T 815/90 and that it intended to deviate from the rationale of decision J 8/87 of the Legal Board of Appeal (see paragraph I supra). Therefore, the requirements for referring such point of law to the Enlarged Board of Appeal under Article 112(1)(a) EPC are met.

Relation between Article 83 and Rule 28 EPC

4. Pursuant to Article 83 EPC, a European patent application "must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art". In order to meet the requirements of Article 83 EPC, a European patent application must therefore contain sufficient information to allow a person skilled in the art, using his common general knowledge, to perceive the technical teaching inherent in the claimed invention and to put it into effect accordingly.

5. With regard to an invention concerning a microbiological process or the product thereof and involving the use of a micro-organism which is not available to the public and which cannot be described in a European patent application in such a manner as to enable the invention to be carried out by a person skilled in the art, provisions have been included in Rule 28 EPC in order to implement the general principle of Article 83 EPC (see paragraph 4 supra) in view of the special character of such an invention.

6. Rule 28(1) EPC provides that:

(a) a culture of the micro-organism has been deposited with a recognised depository institution not later than the date of filing of the European patent application;

(b) the European patent application as filed gives such relevant information as is available to the applicant on the characteristics of the micro-organism;

(c) the depository institution and the file number of the culture deposit are stated in the European patent application.

7. As regards the file number of the culture deposit, it is clear from the wording of Rule 28(1)(c) EPC that this number represents the file number given to the culture deposit by the depository institution, and not the identification reference given to it by the depositor. The term "file number" corresponds to "accession number" given by the depository authority under the Budapest Treaty (see Rule 7.3(v)) and the "Model Agreement" (Point 17(b)(v), published in OJ EPO 1982, 454, 459).

8. In the case of an invention referred to in Rule 28(1) EPC, the primary function of a culture deposit is to complete an otherwise insufficient written disclosure. The culture deposit constitutes then an essential part of the disclosure.

9. Rule 28(1) EPC refers to Article 83 EPC and serves to substantiate and to supplement the general requirements of Article 83 EPC for a specific group of inventions for which a mere written description is not sufficient to enable a person skilled in the art to carry out the invention. Therefore, the provisions of Rule 28 EPC are subordinate to the requirements of Article 83 EPC. For microbiological inventions making use of living matter which is not available to the public and which cannot be described in a reproducible way, these provisions set out a reliable framework for determining which indications are necessary in a European patent application and under which conditions the public may have access to a culture deposit. Consequently, the disclosure of an invention referred to in Rule 28(1) EPC has not only to comply with the provisions under Rule 28(1) EPC, but also with the requirements of Article 83 EPC.

10. Sufficiency of disclosure under Article 83 EPC requires inter alia that the subject-matter claimed in a European patent application be clearly identified. This requirement must be complied with as from the date of filing because a deficiency in a European patent application as filed, consisting in an insufficient identification of the subject-matter claimed, cannot subsequently be cured without offending against Article 123(2) EPC which provides that the subject-matter content of a European patent application as filed may not be extended.

11. A sufficient identification under Article 83 EPC of an invention referred to in Rule 28(1) EPC implies that the culture deposit of the micro-organism, as an essential part of the disclosure (see paragraph 8 supra), be identified in the patent application as filed. If the file number (accession number) of the culture deposit given by the depositary institution is not already indicated in the application as filed, the micro-organism must be identified in such a way that the later submitted file number (accession number) can be linked back without ambiguity. This can normally be done by indicating the identification reference given by the depositor to the micro-organism within the meaning of Rule 6.1(iv) of the Budapest Treaty or of Point 12(a)(iv) of the 'Model Agreement' (published in OJ EPO 1982, 454, 457) as well as the name of the depositary institution. This reference is already known to the applicant on or before the filing date even if the depositary institution has not yet attributed the corresponding file number (accession number). The receipt of the depositary institution issued to the depositor contains both the identification reference given by the depositor to the micro-organism and the accession number given by the depositary institution to the culture deposit (see Rule 7.3(iv) and (v) of the Budapest Treaty and Point 17(b)(iv) and (v) of the 'Model Agreement' [OJ cit., 459]).

Legal character of the time limit under Rule 28(2)(a) EPC

12. In order to be sufficient under Article 83 EPC, the disclosure of an invention in a European patent application must further enable a person skilled in the art to carry out the invention. This requirement is satisfied

under Rule 28 EPC by making a deposited culture available to the public. This availability is brought about by stating the depositary institution and the file number (accession number) of the culture deposit in the European patent application (Rule 28(1)(c) EPC), because, under Rule 28(2) EPC, the "communication of this information" is regarded as constituting the unreversed and irrevocable consent of the applicant to the deposited culture being made available to the public within the meaning of Rule 28 EPC. The mere indication of the identification reference given by the depositor to the micro-organism (see paragraph 11 supra) does not bring about this legal effect.

13. The indication of the file number (accession number) of a culture deposit in a patent application is thus substantive because, under the EPC, it is instrumental in enabling a person skilled in the art to carry out the invention. Therefore, the Enlarged Board of Appeal cannot follow the rationale underlying decision J 8/87 (see paragraph I) that the situation of non-compliance with Rule 28(2)(a) EPC is analogous to the situation of non-compliance with the requirements concerning the filing of priority documents according to Rule 38(3) EPC. Rule 28(2)(a) EPC provides a reasonable time limit which guarantees that the culture deposit is made available to the public at the same time as the corresponding European patent application is published. The file number (accession number) must be submitted within the time limit of sixteen months after the date of filing or, if priority is claimed, after the priority date laid down in Rule 28(2)(a) EPC. If this time limit is not complied with, the requirements of Rules 28(1)(c) and 28(2)(a) EPC are not fulfilled and the invention cannot be regarded as disclosed under Rule 28(1) EPC in connection with Article 83 EPC. Whether or not in individual cases it might be de facto possible to publish the file number of the culture deposit in the patent application even if it were submitted after expiration of the sixteen-months period is irrelevant. For reasons of legal certainty, the legislator has fixed an obligatory time limit in order to guarantee that the necessary information is available in due time before publication of the patent application.

Principle of good faith and protection of legitimate expectations

14. 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.

ORDER

For these reasons it is decided to answer the point of law referred to the Enlarged Board of Appeal 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.
