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D E C I S I O N
of 27 January 1998

Case Number: T 0142/93 - 3.3.4

Application Number: 85113751.3

Publication Number: 0182152

IPC: C12P 1/06

Language of the proceedings: EN

Title of invention:

Antitumor antibiotics (LL-E33288 Complex)

Applicant:

American Cyanamid Company

Opponent:

-

Headword:

Antibiotics/AMERICAN CYANAMID

Relevant legal provisions:

EPC Art. 83

EPC R. 28

Keyword:

"Microorganisms, deficiency in deposit (no)"

Decisions cited:

T 0239/87, T 0039/88, J 0013/84

Catchword:

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Chambres de recours

Case Number: T 0142/93 - 3.3.4

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 27 January 1998

Appellant: American Cyanamid Company
One Cyanamid Plaza
Wayne, NJ 07470-8426 (US)

Representative: Wächtershauser, Günter Prof. Dr.
Patentanwalt
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80331 München (DE)

Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 16 September 1992
refusing European patent application
No. 85 113 751.3 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: U. M. Kinkeldey
Members: F. L. Davison-Brunel
S. C. Perryman

Summary of Facts and Submissions

- I. European patent application No. 85 113 751.3 claiming two US priorities from 16 November 1984 and 17 October 1985 was filed on 29 October 1985 and published on 28 May 1986 with 23 claims. The description at page 11 referred to a new strain of **Micromonospora echinospora** ssp. **calichensis** and stated:

"A viable culture of this new microorganism has been deposited with the Culture Collection Laboratory, Northern Regional Research Centre, U.S. Department of Agriculture, Peoria, Illinois on August 9, 1984, and has been added to its permanent collection. It has been assigned by such depository the strain designation NRRL 15839. Access to such culture, under the strain designation NRRL 15839, during the pendency of the instant application shall be available to one determined by the Commissioner of Patents and Trademarks to be entitled thereto under 37 C.F.R. §1.114 and 35 U.S.C. §122, and all restrictions on availability to the public of such culture will be irrevocably removed upon grant of a patent on the instant application."

On page 17 a mutant (designation NRRL 15975) of culture NRRL 15839 is referred to and in respect of this mutant the same wording as above (except for the designation number) appears.

Claims 18 to 23 as filed referred to these two deposited micro-organisms.

- II. The Appellant (applicant) put forward as main request a revised set of claims referring to the deposited strains NRRL 15839 and NRRL 15975, and as auxiliary request a set of claims containing no references to these deposited strains.

In the decision under appeal the Examining Division refused the application pursuant to Article 97(1) EPC for the reason as regards the claims of the main request, that it considered that the deposits had not been converted to deposits under the Budapest Treaty until 6 September 1989, whereas Rule 28(3) EPC required this to be done at the latest at the filing of the application. This requirement was made clear by the publication by the EPO in the Official Journal 8/1986 of a notice dated 18 July 1986 concerning patent applications in which reference is made to micro-organisms. In relation to micro-organisms not available to the public, and which cannot be described sufficiently, this notice stated that "To meet the requirements of Article 83 in conjunction with Rule 28 EPC a culture of this new micro-organisms **must** have been deposited **with** a recognized depositary institution not later than the date of filing of the European patent application, **in accordance with the legal statute on the basis of which the institution is recognised.**" In the situation where "the deposit was made previously in accordance with a legal statute other than the Budapest Treaty or bilateral agreement (for example, in accordance with a specific national law), the deposit must be converted into a deposit in accordance the Budapest Treaty or the bilateral agreement **not later than the date on which the European patent application is filed**". Accordingly the deposits were not made in accordance with Rule 28 EPC, and the application did not disclose the invention

in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, and the main request was not allowable under Article 83 EPC.

As regards the auxiliary request the Examining Division indicated that this too was not allowable under Article 83, because the description did not contain any information identifying a microorganism available to the public at the filing date, which microorganism would meet the requirements of the claims, namely a particular positive reaction in a biochemical induction assay.

III. A notice of appeal was filed against this decision. The Appellant argued inter alia as follows:

- The micro-organisms had been deposited with the NRRL which was a recognized depositary institution for the purpose of Rule 28 EPC, earlier than the date of filing of the application. The relevant information on the micro-organisms was provided in the description of the patent application as originally filed. By putting in the references to the NRRL deposit number in a European application, the applicant gave his consent to the deposited material being available under the provisions of Rule 28(2)(c) EPC. At the time of filing, all of the requirements of Rule 28 EPC, as they were then understood to be, were fulfilled.

- The clarifying Notice of the EPO dated 18 July 1986 merely stated that a conversion to the Budapest Treaty at or before the date of filing of the application was mandatory. The notice was published too late for the applicant to take such action. The notice contained no clarification of what, if anything, someone in the Appellant's position should do by any particular date. The

Appellant understood the notice as not requiring anything of applicants in respect of applications already on file at the time the clarifying Notice was issued, for whom the previous practice prior to the publication of the notice would continue to apply.

- The Appellant further provided evidence that a request had been made to the EPO by a third party pursuant to Rule 28 EPC, and this request had been fulfilled in 1987 by the NRRL depository institution, after checking with the applicant. The Appellant had confirmed to the depository institution that it was bound by Rule 28 EPC and that the request was to be fulfilled. This confirmation was made merely because the depository authority seemed confused as to the status of the deposits. As on the evidence, the deposited material was made available to the only requester under Rule 28 EPC, it should be deemed that the Appellant had complied with Rule 28 EPC.

IV. The Appellant requested that the decision of the Examining Division be set aside and that a patent be granted on the basis of the main or auxiliary request annexed to the decision under appeal.

Reasons for the Decision

1. As stated by the Appellant in relation to the main request, the explicit requirements of Rule 28 EPC had been met in the application by the references to biological material deposited under references NRRL 15839 and NRRL 15975 at a recognized depository institution not later than the date of filing of the application. The name of the depository institution and

the accession numbers given by the deposit institution were stated and the application contained the relevant information known to the applicant on the characteristics of the microorganism. In view of Rule 28(2)(c) EPC stating "... The communication of this information shall be considered as constituting the unreserved and irrevocable consent of the applicant to the deposited biological material being made available to the public in accordance with this Rule" it was not wholly unreasonable for the applicant at the time of filing to assume that nothing more was required. The wording in the application, taken over from the US priority applications, that "restrictions on availability to the public of these deposited cultures will be irrevocably removed upon grant of a patent on the instant application" on the evidence did not prevent at least one requester from asking for and obtaining such biological material prior to grant of any of the European patent or the US patents.

2. The deposits were not however accompanied by a written statement indicating that they were made under the Budapest Treaty (as required under Rule 6.1(a)(i) of that treaty) or under Rule 28 EPC (as required under the special agreement referred to under paragraph 2 above) between the depositary and the EPO.
3. The relevant case law of the Boards of Appeal dealing with circumstances analogous but not identical to the present case is to be found in decisions T 0239/87 of 11 February 1988 and T 0039/88 (OJ EPO 1989, 499). In both these cases, European applications had been filed before the Notice of 18 July 1986, claiming specific micro-organisms. The micro-organisms had been deposited in accordance with the US regulations in connection with the filing of the US applications from which priority was claimed. The deposits had not been converted to deposits under the Budapest Treaty at the

date of filing of the EP-application. The micro-organisms had become available only after the publication date of the European patent, but were already available, as a result of the grant of the corresponding US patent, at the time the Notice of the EPO dated 18 July 1986 was published. In both cases, it was held that the deposits could nevertheless be recognized and examination procedure continued on this basis, on the reasoning that the European applications had been filed at a time when the situation was still unclear as how to cope with deposits originally filed for other purpose than the EP-patent applications and that it would be unfair to let the Applicants bear the whole risk of this lack of clarity.

4. In the specific circumstances of the cases, the question did not arise whether deposits made in accordance with a national law, in connection with a patent application filed before the Notice of 18 July 1986, ought to have been converted to deposits under the Budapest Treaty or the bilateral agreement immediately after publication of the Notice.
5. While the Notice of 18 July 1986 is clear as to what should be done in respect of the patent applications filed after the publication of the notice (see para. II, supra), it contains no provisions on what, if anything, needed to be done in relation to deposits which were made in relation to applications which had already been filed before the 18 July 1986.
6. As in decisions T 0239/87 and T 0039/88 the failure to convert the deposits into ones meeting the Budapest Treaty or the bilateral agreement between the depositary institution and the EPO prior to the filing of the European application was not considered to be an absolute bar to the deposits being relied on, and as on the evidence the Appellant considered itself bound by

Rule 28 EPC to allow the provision of deposited samples to any requester, and such sample was actually provided, the Board holds that the failure of the Appellant to act after publication of the Notice of 18 July 1986 does not prevent the deposits from being relied on as being in accordance with Rule 28 EPC for the purposes of the present application. The notice of 18 July 1986 did not give clear and unambiguous instructions as to what applicants in the situation of the present Appellant should do, and by what time limit this should be done. In these circumstances the lack of action by the Appellant is excusable, and the requirements of Rule 28 EPC are met in relation to the strains referred to as deposited under strain designations NRRL 15839 and 15975.

7. Since no examination has yet taken place whether the claims of the main request fulfil the other requirements for patentability, the case must be referred back to the Examining Division for further prosecution.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the first instance for further prosecution.

The Registrar:

The Chairwoman:

D. Spigarelli

U. Kinkeldey