BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARD OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

A		B	X	C	

File Number: T 576/91 - 3.3.2

Application No.: 86 304 900.3

Publication No.: 0 208 468

Title of invention: pTR2030, a conjugal plasmid and derivatives thereof that confer phage resistance to group N streptococci

Classification: C12N 15/00

D E C I S I O N

of 18 May 1993

Applicant: North Carolina State University

Headword: Plasmid pTR2030/NORTH CAROLINA STATE UNIVERSITY

EPC Art. 54(2)

Keyword: "Novelty (yes) - state of the art-enabling disclosure (no) - micro-organism - availability to the public (no)"

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number : T 576/91 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 18 May 1993

Appellant : North Carolina State University
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Decision under appeal : **Decision of the Examining Division of the European Patent Office dated** 20 February 1991 **refusing European patent application No.** 86 304 900.3 **pursuant to Article 97(1) EPC.**

Composition of the Board :

Chairman : P.A.M. Lançon
Members : L. Galligani
E.M.C. Holtz

Summary of Facts and Submissions

I. European patent application No. 86 304 900.3 filed on 25 June 1986 and published under No. 0 208 468, claiming priority from a US application filed on 25 June 1985, was refused by the Examining Division on 20 February 1991.

The decision was taken on the basis of Claims 1 to 8 filed in a letter dated 2 November 1989.

Claim 1 reads as follows:

"The plasmid pTR2030 characterized by a molecular weight of 30.0 + 3.0 megadaltons, having the following sensitivity to restriction endonucleases:

Enzyme	# sites
HindIII	16
HaeIII	4
EcoRI	8
XbaI	5
HpaI	3
NcoII	5
AvaI	2

and carrying one or more genetic determinants for phage resistance in group N streptococci (lactococci) and exhibiting phenotypes of Tra^+, Clu^-, Hsp^+ and Hrp^+, the said plasmid being obtainable from **S.Lactis** TRSI-a (ATCC 53146) or **S.Lactis** TEK1 (ATCC 53167)."

Claims 5 and 6 relate to an N group streptococcus containing the said plasmid.

II. The Examining Division refused the application under Article 97(1) EPC on the grounds that the subject-matter of Claims 1, 5 and 6 lacked novelty within the meaning of Article 54 EPC, having regard to the article by Klaenhammer et al. in J.Gen. Microbiol., Vol. 131, No. 6, pp. 1531-1942, published on 5 June 1985 (hereinafter (1)).

The main reasons given for the decision are as follows:

(a) the plasmid pTR2030 which forms the subject-matter of Claim 1 is also disclosed in document (1), together with all the technical information necessary for its preparation by conjugal mating of **S.Lactis** ME2 with **S.Lactis** LM0230 and for its isolation from the resulting phage resistant strains;

(b) the two parent strains are regarded as freely available to the public because they were repeatedly the subject of scientific publications. It is an ethical rule of the scientific community that specimens of published micro-organisms must be released;

(c) even in the absence of a deposit, the skilled person could reproduce plasmid pTR2030 starting from said parent cells, by following the description in (1);

(d) the firm Miles Laboratories, which provided specimens of the strain **S.Lactis** ME2 to the present Appellant, was a member of the "public" to which document (1) was directed and which could reproduce the quoted plasmid;

(e) in view of points (a)-(d), document (1) has a novelty-destroying effect vis-à-vis the present application. The additional features cited in Claim 1 are immaterial with regard to novelty.

The Examining Division objected, furthermore, that the subject-matter of Claims 2-4 and 7-8 did not comprise any inventive features vis-á-vis (1).

III. The Appellant lodged an appeal against this decision and paid the appeal fee. A series of exhibits in support of the appeal was filed in a letter dated 9 March 1993.

The Appellant's arguments are essentially as follows:

(a) the donor strain **S.Lactis** ME2 was an industrial strain owned and controlled by Miles Laboratories and made available to the present Appellant for research purposes under an agreement dated 1 March 1983 whereby it could not be released to third parties. The said strain was therefore not available to the public;

(b) in view of (a), a skilled reader of (1) was not able to reproduce the conjugal mating described therein and reliably select plasmid pTR2030. Document (1) does not therefore constitute an anticipation under Article 54 EPC having regard to T 206/83 (OJ EPO 1987, 5);

(c) even if there were an obligation on the authors of (1) to make the strain available to the scientific community on request, they would have not been in a position to do so without Miles' approval. In any case, no requests were received, and there is no evidence that anyone other than Miles and the present Appellant had access to the donor strain;

(d) Miles Laboratories could not be considered as part of the "public" because of the contractual research relationship with the NCARS (North Carolina Agricultural Research Service) at North Carolina State University.

IV. The Appellant requested that the above decision be set aside and that a patent be granted on the basis of Claims 1 to 8 on file.

Reasons for the Decision

1. The appeal is admissible.

2. The question at issue is the novelty of the subject-matter of Claims 1, 5 and 6.

2.1 According to established Board of Appeal case law, a document can be used for a lack-of- novelty objection only if it contains an enabling disclosure.

EPO case law has also established that the criteria for examining the reproducibility of a particular technical teaching should be the same in cases where the disclosure of a prior art document or a disclosure of a patent application in question has to be assessed (see, for example, T 206/83 OJ EPO, 1987, 5 and T 81/87 OJ EPO, 1990, 250).

2.2 In the present case, document (1) disclosing plasmid pTR2030 was published before the priority date of the application which claims, inter alia, the same plasmid pTR2030. The Appellant does not deny that the two products are identical.

The question therefore arises whether publication (1) contains an enabling disclosure of plasmid pTR2030 and is therefore admissible prior art within the meaning of Article 54(2) EPC. If so, document (1) would have a novelty-destroying effect vis-à-vis the present Claims 1, 5 and 6 under the terms of Article 54(1)(2) EPC.

This issue poses two further questions:

(a) whether publication (1) can be considered intrinsically enabling merely by virtue of an **unwritten** ethical rule whereby the authors of (1) would have been prepared to supply - upon request - samples of plasmid pTR2030 to each and every person interested in obtaining it;

(b) whether the reproduction of plasmid pTR2030 was in any case possible for the skilled person on the basis of the technical information provided in (1) which, in this case, amounts to the question whether the starting materials, namely the parent microorganisms **S.Lactis** LM0230 and **S.Lactis** ME2, were available to the public.

2.3 This section is concerned with question a) in section 2.2.

It is generally recognised that the aim of a scientific publication is to inform the public in writing about a teaching or a discovery which has been made. In the scientific community the free exchange not only of technical information, but also of biological material is generally encouraged. Some scientific journals have already adopted this principle by including it in their instructions to authors (see, for example, the "Instruction to authors" in Applied and Environmental

Microbiology, January 1992, submitted by the Appellant as Exhibit E).

Despite the fact that this **unwritten** rule appears to be generally accepted within the scientific community, the Board is unable to conclude that it amounts to an obligation, so that any biological material which is the subject of a publication can in effect be considered publicly available.

The situation in question has already been examined by this Board in the case of decision T 815/90 of 26 February 1993 (to be published in the OJ EPO, see especially section 3.2), in the context of a question relating to Article 83 and Rule 28 EPC. In this case the Board had to decide whether a viral strain disclosed in a prior publication could be regarded as "available to the public" on the basis of the declared favourable attitude of researchers toward the free exchange of biological materials. Although the Appellant submitted an affidavit and documents testifying to the research institution's policy of supporting and encouraging the free exchange of biological material among research workers and the general public, the Board took the view that the strain described in the prior publication could not be considered publicly available. The Board's reasons were essentially that:

(i) it was apparent from the documents submitted with the affidavit that, where patent rights had to be respected, the release of biological material was subject to various restrictions specified in the grant regulations and contract;

(ii) the research institution was under no obligation to ensure that the biological material was cultured and kept alive;

(iii) the research institution could change at any time the policy of releasing the material to third parties.

The same considerations apply, mutatis mutandis, to the present case. Given the absence of evidence to the contrary and especially in the light of the presumption of patent rights together with the contractual obligations and the grant regulations involved (see also section 2.4 below), the conclusion must be drawn that the plasmid in question **was not** made available to the public within the meaning of Article 54(2) EPC, despite the existence of document (1). The presumed positive attitude of the researchers toward the free exchange of specimens does not suffice to ensure availability of the public of the plasmid.

The Board's answer to question (a) is therefore negative.

2.4 This section is concerned with question (b) in section 2.2.

2.4.1 The description in document (1) is workable in that it enables the skilled person to prepare plasmid pTR2030 **provided** that the starting strains, namely **S.Lactis** LM0230 and **S.Lactis** ME2, are available.

The public availability of **S.Lactis** LM0230 is not disputed by the Appellant.

As regards strain **S.Lactis** ME2, it is owned by Miles Laboratories, a private company.

This strain was the subject of several scientific publications prior to the present application and to document (1).

The Examining Division understandably assumed that the said strain was part of the prior art and that it was freely available among the scientific community, having regard to the criteria set forth in section 2.3, second paragraph.

During the appeal proceedings, however, the Appellant has provided concrete evidence that, notwithstanding the scientific publications quoting it, strain **S.Lactis** ME2 was owned and controlled by Miles Laboratories and made available to the present Appellant for research purposes under an agreement by which the Appellant could not release it to third parties (Exhibit A: Memorandum from one of the inventors, T.R. Klaenhammer, dated 1 April 1991, and Exhibit B: Copy of the agreement dated 1 March 1983 between the Biotechnology Division of Miles Laboratories and the North Carolina Agricultural Research Service (NCARS) at North Carolina State University).

The publications quoting strain **S.Lactis** ME2 referred to by the Examining Division are all authored by, inter alia, one of the present inventors, namely T.R. Klaenhammer, and all relate to work carried out at the North Carolina State University under the said agreement.

It is observed that the quoted agreement did not explicitly exclude the possibility of Miles making the strain available to other licensed parties or to parties with which Miles had a contract for outside research.

However, no proof is available that, despite the said scientific publications, a release of specimens of strain **S.Lactis** ME2 took place outside the contractual obligations between Miles and the present Appellant. On the basis of the evidence submitted by the Appellant relative to the mutual contractual obligations between the present Appellant and Miles, it should be assumed that access to the said strain was deliberately restricted to a group of persons bound either by a research contract or a licence. The consequent bar of confidentiality necessarily restricted the use or dissemination of the strain.

Under these circumstances, it cannot be concluded that the strain was "available to the public" under the terms of Article 54(2) EPC.

A similar conclusion was reached in case T 300/86 of 28 August 1989 (not published in OJ EPO), in which it was decided that "if access to a document is deliberately restricted to certain persons it is by that token not available to the public, even if the group of persons able to gain knowledge of the content of the document is large" (see section 2.5).

2.4.2 The Examining Division also put forward the argument that Miles Laboratories, as a member of the "public" to which document (1) was directed, could have arrived at the invention by using the strain **S.Lactis** ME2. Firstly, however, there are no indications that this has actually occurred. Secondly, in the Board's view, Miles cannot be considered part of the "public" within the meaning of Article 54(2) EPC. As the owner of the strain in question, Miles Laboratories was bound, vis-á-vis the present Appellant, by a research contract which implied, in view of possible patent rights, restrictions to the use or dissemination of biological

materials and information. Thus, although Miles was neither the inventor nor the applicant, the company cannot - for the above reasons - be considered as a "third party" to which the invention was available before the priority date of the present application.

For the above reasons, the answer to question b) is also negative.

2.5 In conclusion, publication (1) does not contain an enabling disclosure in respect of plasmid pTR2030. Consequently, it cannot have a novelty-destroying effect vis-à-vis Claims 1, 5 and 6 of the present application.

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 Chairman:

P. Martorana P.A.M. Lançon