

Veröffentlichung im Amtsblatt	Ja/ Nein
Publication in the Official Journal	Yes/ No
Publication au Journal Officiel	Oui/ Non



Aktenzeichen / Case Number / N° du recours : T 31/84

Anmeldenummer / Filing No / N° de la demande : 80 102 614.7

Veröffentlichungs-Nr. / Publication No / N° de la publication : 19 253

Bezeichnung der Erfindung: Test device, composition and method for the
Title of invention: determination of triglycerides
Titre de l'invention :

Klassifikation / Classification / Classement : C 12 Q

ENTSCHEIDUNG / DECISION
vom / of / du 4 May 1985

Anmelder / Applicant / Demandeur :

Patentinhaber / Proprietor of the patent / Miles Laboratories (appellant)
Titulaire du brevet : Boehringer Mannheim (respondent)

Einsprechender / Opponent / Opposant :

Stichwort / Headword / Référence :

EPÜ / EPC / CBE Art. 54, 111(1)

Kennwort / Keyword / Mot clé :

Novelty - the consideration of an additional document
in the evaluation of a citation

Leitsatz / Headnote / Sommaire

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Anmeldenummer / Filing No / N^o de la demande : 80102614.7

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Stichwort / Headword / Référence :

EPÜ / EPC / CBE Art.54,111(1)

"Novelty - anticipation proven by later document"

"Remittance to Opposition Division - lack of full first-
instance examination"

Leitsatz / Headnote / Sommaire

Europäisches
Patentamt
Beschwerdekammern

European Patent
Office
Boards of Appeal

Office européen
des brevets
Chambres de recours



Case Number: T 31 / 84

DECISION
of the Technical Board of Appeal 3.3.1
of 4 May 1985

Appellant:
(Proprietor of the patent)

Miles Laboratories Inc.
1127 Myrtle Street
Elkart Indiana 46514
U S A

Representative:

Dr. Erwin Dill
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Respondent:
(Opponent)

Boehringer Mannheim GmbH
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Representative:

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Patentanwälte Dipl.-Ing. H. Weickmann et al.
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Decision under appeal:

Decision of the Opposition Division of the European Patent Office
dated 1 December 1983 revoking European patent No.
19253 pursuant to Article 102(1) EPC

Composition of the Board:

Chairman: K. Jahn
Member: F. Antony
Member: F. Benussi

Summary of Facts and Submissions

- I. European patent application No. 80 102 614.7, which had been filed on 12.05.80, claiming USA priority of 21.05.79, was granted as European patent No. 19 253 on 12.05.82, with nine claims. Claim 1 reads :

"An enzymatic method for determining the amount of tri-glycerides present in an aqueous fluid by hydrolysis of the triglycerides and then by determination of the amount of triglycerides present based on the amount of glycerol produced, characterized in contacting the fluid with a mixture of a lipase and cholesterol esterase for a time sufficient to hydrolyze the triglyceride to glycerol and free fatty acids."

Independent Claims 8 and 9 relate to, respectively, a composition for such determination comprising such enzyme mixture and a glycerol assay system, and to a test device for such determination comprising a carrier incorporated with such composition.

- II. On 11.02.83, Opponents (Respondents) lodged opposition against the patent granted, requesting complete revocation thereof, for lack of novelty and inventive step, based on the following documents :

- (1) Biochim. Biophys. Acta 231 (1971), 15-22;
- (2) Technical Service Bulletin 1, "LIPASE-MY" (Meito Sangyo Co. Ltd);
- (3) DE-C-2 229 849;
- (4) DE-A-2 162 325;
- (5) DE-C-2 315 501;
- (6) DE-C-2 535 953;
- (7) Agr. Biol. Chem. 39(7), 1511-1512(1975);
- (8) Biochem. J. 117(2), 1970, 38p-39p;

- (9) DE-B-2 512 605;
- (10) Package insert "Test-Combination Triglyceride ..."
(Boehringer Mannheim GmbH).

III. By a decision of 01.12.83, the Opposition Division revoked the patent. It considered the invention claimed in Claim 1 novel because, in its view, none of the citations described the use of a mixture of lipase and cholesterol esterase for a triglyceride determination. However, it held that Claim 1 lacked inventive step, because it was known from citation (5), dealing with cholesterol determination, that *Candida cylindracea*, widely used in industry for its lipase activity, contains not only a lipase, but also a cholesterol esterase. Having thus learned that it is such an enzyme mixture which makes this micro-organism so useful, it would be obvious for the expert to use such a mixture for triglyceride determination.

In independent Claims 8 and 9 - directed, respectively, to the composition and test device of the invention - the Opposition Division recognized no patentable feature either.

IV. A notice of appeal was filed by the Appellants against the decision of the Opposition Division on 26.01.84. The fee for appeal was paid. The Statement of Grounds for appeal submitted on 31.03.84 argued essentially as follows : Citation (5) relates to a cholesterol assay only, without suggesting use of its techniques for a triglyceride assay. It is to be emphasized that this citation does not disclose any additive or synergistic effect of the two enzymes contained in *C. cylindracea*. In response to a Communication from this Board suggesting that, as proven by (5), citation (1) would appear to destroy the novelty of the patent, the Appellants contend that (1) teaches nothing concerning triglyceride assays; does not mention involvement of

cholesterol esterase, but suggests presence of an isomerase; and is absolutely worthless to an expert for providing a rapid and economical method of triglyceride determination.

The Respondents have contested the Appellants' arguments. They have pointed out that (1), as evidenced by the first paragraph of section "Quantitative Determination of Esters and Acids", describes quantitative colorimetric determination of glycerol liberated by enzymatic hydrolysis of triglycerides, utilizing as an enzyme the trade product "Lipase MY", which is explicitly referred to as unpurified (page 16, section "Lipase Sources") and must therefore have contained cholesterol esterase. Citation (5) utilizes the same "Lipase MY".

They have further argued that - as proven by the package insert (10), mentioning a "mixture of lipase and esterase" as components of their own trade product - such mixtures were commonly used for triglyceride determination prior to the invention. According to the Respondents, the "esterase" mentioned on the package insert is a cholesterol esterase, which they say the expert could easily verify from the commercial product, and is in fact cholesterol esterase from Lipase MY.

VI. In the Oral Proceedings of 04.06.85, the Appellants have submitted a fresh set of Claims 1 to 7. New Claim 1 reads as follows :

"An enzymatic method for determining the amount of triglycerides present in an aqueous fluid by hydrolysis of the triglycerides and then by determination of the amount of triglycerides present based on the amount of glycerol produced characterised in contacting the fluid with a mixture of a lipase and cholesterol esterase for a time sufficient to hydrolyze the triglyceride to glycerol and

free fatty acids, wherein the lipase is produced from a microorganism selected from the group consisting of Rhizopus delemar, Rhizopus arrhizus and Chromobacterium viscosum and the cholesterol esterase is obtained from the microorganism Pseudomonas aeruginosa or from beef pancreas, and 0,01 to 5 U cholesterol esterase per 10 U lipase are present."

The Appellants (Patentees) request that the decision under appeal be set aside and the patent be maintained in an amended form on the basis of the new claims.

The Respondents, in turn, request dismissal of the appeal.

Reasons for the Decision

1. The appeal is in accordance with Articles 106 to 108 and Rule 64 EPC; it is thus admissible.
2. There can be no formal objection to the new claims, because they do not extend the scope of the patent as granted (Art. 123, para. 3, EPC). New Claim 1 corresponds literally to the granted version of Claim 1, with the features of granted Claims 2 and 7 incorporated therein. New Claims 2 to 5 correspond to granted Claims 3 to 6, respectively; new Claims 6 and 7, by reference to Claim 1, are limited accordingly, and otherwise correspond to granted Claims 8 and 9, respectively.
3. While Claim 1 as granted could be considered to have been anticipated by citation (1), as proven by citation (5), it is undisputed, and thus requires no lengthy explanations, that new Claim 1 does possess novelty : The combination of lipase from one of the three sources mentioned therein, with cholesterol esterase of one of the two sources set forth in

the new Claim 1, has not been disclosed by any of the cited documents, nor has the ratio of cholesterol esterase to lipase defined in the new Claim 1 been so disclosed.

4. Final conclusions as to inventive step are not possible without further substantive examination and, perhaps, evidence :

4.1 Concerning the closest prior art, the only literature reference with which the Decision under appeal deals in any detail is (5). It can thus be concluded that (5) was considered the closest prior art. This document relates to a process for determining the total cholesterol content of the body serum, wherein the ester groups of esterified cholesterol are enzymatically removed, utilizing cholesterol esterase from *Candida cylindracea*, already known to contain a lipase. Without reference to (1) - which is not discussed in the Decision - or possibly to another reference relating to a triglyceride determination, it can hardly be seen how (5) could be relevant at all, and certainly not how it could be the most relevant prior art.

4.2 Starting from what is considered the most relevant piece of prior art, the object of the invention is to be established, considering the achievement of the invention beyond such most relevant art, such achievement including any submitted effect. The Decision of the Opposition Division defines the object ("task") of the invention by almost literally quoting from page 1, lines 60 to 61, of the granted specification, without - apparently - an objective analysis in the above sense.

4.3 Further, it is to be assessed, on the basis of the prior art, whether or not the solution provided by the invention was obvious in the light of the underlying

problem. The Decision under appeal, while mentioning a problem ("task"), does not seem to so analyse the solution.

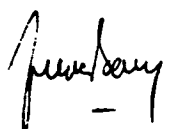
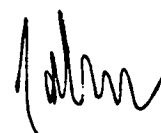
- 4.4 In view of the above, it is observed that a full first-instance examination of the opposition on the basis of the principles developed by this Board, i.e. on the basis of the problem (object) and solution (see: "Carbonless Copying Paper", OJ EPO 7/1981, 206; "Metal Refining", OJ EPO 4/1983, 133), has not yet taken place. This alone must have the consequence that the Decision under appeal is to be set aside and the case remitted to the first instance, without decision of this Board on the merits of the case.
5. In addition to the above, new Claim 1, by inclusion of the features of granted Claims 2 and 7 into granted Claim 1, has been so drastically restricted that any previous relevant considerations concerning inventive step would no longer be applicable. This restriction became necessary in order to overcome lack of novelty, a defect of the granted claim not raised by the Opposition Division, but for the first time by the Board's Communication of 26.09.84. Although no unexpected effect of the invention is presently recognizable, the Board cannot, under these circumstances, refuse Appellants' request based on the new claims. Rather, equity dictates that the Board make use of its power under Article 111(1) EPC to remit the case to the Opposition Division, for proper examination without loss of instance.
6. In reconsidering the case, the Opposition Division will have to :
- (i) determine the most relevant piece of prior art, whether it be citation (1) or (3) or possibly a new document;

- (ii) define the object of the invention on the basis of an objective analysis considering the difference or surplus of the results of the invention (effect) beyond such most relevant art;
- (iii) satisfy itself that the so defined object will be achieved by the solution of the invention;
- (iv) assess whether in the light of such object, such solution involved an inventive step, taking into account the prior art.

Order

For these reasons, it is decided that :

1. The Decision of the Opposition Division is set aside.
2. The case is remitted to the Opposition Division for further substantive examination on the basis of Claims 1 to 7 and description as submitted during the Oral Proceedings.



GD3
Geschäftsstelle

³München, den 22.10.1986

Verteiler: Bezieher der Entscheidungen der Beschwerdekammer

Betr.: Entscheidung T 31/84 vom 04.05.1985

Die vorgenannte Entscheidung wird nachträglich veröffentlicht (ohne Leitsatz aber mit geändertem Stichwort).

Sie werden daher gebeten, das ursprüngliche Vorblatt gegen das beiliegende auszutauschen.


J. Rückerl