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Aktenzeichen / Case Number / N^o du recours : W 46/90 - 3.3.2

Anmeldenummer / Filing No / N^o de la demande : PCT/GB 90/00 727

Veröffentlichungs-Nr. / Publication No / N^o de la publication :

Bezeichnung der Erfindung: Enzymes and their use in drug detection

Title of invention:

Titre de l'invention :

Klassifikation / Classification / Classement : C 12 N 9/18

ENTSCHEIDUNG / DECISION

vom / of / du 27 November 1990

Anmelder / Applicant / Demandeur : National Research Development Corporation

Patentinhaber / Proprietor of the patent /

Titulaire du brevet :

Einsprechender / Opponent / Opposant :

Stichwort / Headword / Référence :

EPÜ / EPC / CBE PCT Art. 17(3)(a), Rule 13.1, Rule 40.1

Schlagwort / Keyword / Mot clé : "Lack of unity (no) - lack of reasons in the invitation"

Leitsatz / Headnote / Sommaire



Case Number : W 0046/90 - 3.3.2

International Application No. PCT/

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 27 November 1990

Applicant : National Research Development Corporation
101 Newington Causeway
London SE 1 6BU

Representative :

Subject of the Decision : Protest according to Rule 40.2(c) of the Patent Cooperation Treaty made by the applicants against the invitation (payment of additional fee) of the European Patent Office (branch at The Hague) dated 28 August 1990.

Composition of the Board :

Chairman : P. Lançon
Member : I. Holliday
Member : C. Holtz

Summary of facts and submissions

- I. The Applicant filed international patent application PCT/GB 90/00 727.
- II. The EPO, acting as International Search Authority (ISA) sent to the Applicant an invitation to pay four additional search fees in accordance with Article 17(3)(a) and Rule 40.1 PCT.

The ISA indicated that the subject-matter claimed related to five inventions set out as follows:

1. Claims 1-4, 9-13, 26, part 27, 32 :

Acetylmorphine carboxylesterase; production by Rhodococcus; method of detecting heroin in the presence of the esterase (detecting the hydrolysis reaction); a conductrimetric biosensor containing the esterase.

2. Claims 5-8, 15-20 :

Morphine dehydrogenase; production by Pseudomonas; a method of detecting morphine.

3. Claims 14, 21-25, part 27, 29-31 :

Method of detecting heroin using an esterase to yield morphine and detecting said morphine by morphine dehydrogenase; an amperometric biosensor.

4. Claim 28 :

A sensor comprising an esterase or a dehydrogenase or both in working relationship with an optical, thermal, potentiometric or piezoelectric transducer.

5. Claims 33, 34 :

A process for preparing a 6-ketone from morphine.

III. The Applicant paid the additional search fees under protest in accordance with Rule 40.2(c) PCT. The Applicant argued that the general inventive concept concerned the detection of heroin, i.e. 3,6-diacetylmorphine. The two enzymes which were the subject-matter of claims 1 and 5 respectively were both used in the said detection process as was the sensor of claim 28. As the present application is a PCT application, the Applicant deliberately chose not to formulate "use claims" common in European practice since such claims are not acceptable in certain patent offices, e.g. the USA.

Reasons for the Decision

1. The protest is admissible.
2. Rule 40.1 PCT stipulates that the invitation provided for in Article 17(3)(a) PCT must specify the reasons why the International application is not deemed to comply with the requirements of unity of invention. The purpose of setting out reasons is to enable the Applicant and, in the case of a protest, also the appeal body to examine whether the request to pay additional fees owing to lack of unity of the invention is justified. At the least, the considerations that motivated the decision must be readily

comprehended from the reasons indicated in the invitation of the ISA.

- 2.1 In two earlier published decisions (W 04/85, OJ EPO 1987, 63 and W 07/86, OJ EPO 1987, 67) the Boards of Appeal have already expressed the view that the requirement to give reasons in an invitation pursuant to Article 17(3)(a) and Rule 40.1 PCT is so fundamental that an unsubstantiated invitation cannot be regarded as legally effective. The first mentioned decision states that in straightforward cases all that may be necessary to substantiate a lack of unity is a list of the different groups of subject-matter in the application. However, in the latter decision, it was deemed appropriate to add that such is rarely the case.
- 2.2 The invitation to the Applicant sets out as "reasons for requiring the additional fees", merely the five groups of subject-matter listed above together with the following passage:
- "The subjects of the invention are three methods of detecting heroin and/or morphine using two different enzymes, claimed as independent products; and a process for preparing a 6-ketone from morphine or a 3-ether thereof. We don't see a sufficient technical relationship or interaction so as to form a single general inventive concept."
- 2.3 The fact that the ISA "did not see" a technical relationship between the said groups of subject-matter cannot be regarded as adequate reasoning as required by Rule 40.1 PCT. In accordance with the decisions referred to in Point 2.1 above, the lack of reasoning is sufficient grounds to deprive the invitation to pay the additional fees of its legal effect. The Applicant is at least

entitled to a short resumé of why the ISA could not see any technical relationship. The lines quoted in Point 2.2 amount in fact to nothing more than a listing of subject-matter (cf. W 04/85).

3. Since the ISA made no reference to the prior art in the sheet accompanying Form PCT/ISA 6, it is apparent that an objection "a priori" is intended. In the case of a protest under Rule 40(2) PCT where an objection a priori is raised, no examination of the merits of the claim in comparison with the state of the art has been carried out. The only way to determine the technical problem (in contradistinction to the normal approach) is to rely on the description of the application and the provisional acknowledgement of the prior art therein, if given.

- 3.1 The present application makes no introductory reference to specific prior art documents. However, it is apparent from the passage on page 2, lines 7-19 that the problem underlying the application is to provide an improved method for the detection of heroin by enzyme reactions. A one-step method is claimed in claim 9 and a two-step in claim 21; both, however, rely on the detection of morphine. It is also apparent from the description, especially from the reaction scheme which appears on page 5, that the most advantageous method is to employ the two-step process. In the first step the acetyl groups of the heroin are hydrolysed to yield morphine and in the second step the morphine is oxidised to morphinone, i.e. the corresponding 6-ketone. The first stage hydrolysis reaction is catalysed by the acetylmorphine carboxylase (AMCE) whilst the second stage oxidation is catalysed by the morphine dehydrogenase (MDH). Both these reactions can be monitored, as indicated in the description, by means of a biosensor related to either enzyme. It is also to be

noted that the MDH catalysed oxidation reaction is in fact a process for preparing a 6-ketone from morphine.

- 3.2 According to Rule 13.2 PCT, in addition to an independent claim for a given process, the same application may also claim means specially adapted to carry out the said process. In the opinion of the Board, the enzymes AMCE and MDH can be regarded together with the biosensor as such means. As indicated above, the second stage of the two-stage detection process for heroin is, in fact, a process for preparing a 6-ketone from morphine. Accordingly, the method of detecting heroin (claim 14) provides a unifying link between the enzymes of claims 1 and 5, the sensor of claim 28, the preparatory process of claims 33 and 34 and also the method for detecting morphine (claim 15). It is also worthy of note that Rule 13.3 PCT permits the inclusion of two or more independent claims of the same category in an international application which cannot readily be covered by a single generic claim. Thus, at the present stage, the requirements of Rule 13.1 PCT appear to be satisfied.
4. The invitation was accordingly issued incorrectly since it violated the obligation to specify reasons laid down in Rule 13.1 PCT. Consequently, it is not legally effective and the additional fees paid by the Applicant cannot be retained.

Order

For these reasons, it is decided that:

Reimbursement of the additional fees to the Applicant is ordered.

The Registrar:

The Chairman:

M. Beer

P. Lançon