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Bezeichnung der Erfindung: Catheter introducer with flexible tip

Title of invention:

Titre de l'invention :

Klassifikation / Classification / Classement : A61M 25/06

ENTSCHEIDUNG / DECISION

vom / of / du 9 November 1990

Anmelder / Applicant / Demandeur : Mallinckrodt, Inc.

Patentinhaber / Proprietor of the patent /
Titulaire du brevet :

Einsprechender / Opponent / Opposant :

Stichwort / Headword / Référence :

EPÜ / EPC / CBE PCT Article 17(3)(a); PCT Rules 13 and 40

Schlagwort / Keyword / Mot clé :
"Lack of unity a priori between the independent
claims"
"No clear case for lack of unity a posteriori
for dependent claims"

Leitsatz / Headnote / Sommaire

Europäisches
Patentamt
Beschwerdekammern

European Patent
Office
Boards of Appeal

Office européen
des brevets
Chambres de recours



Case Number : W 26/90 - 3.2.2
International Application No. PCT/US 89/03266

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 9 November 1990

Appellant : Mallinckrodt, Inc.
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St. Louis, Missouri 63134
United States of America

Representative : BERNARD, Eugene L.
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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 two additional fees) of the European Patent Office (branch at The Hague) dated 26 January 1990.

Composition of the Board :

Chairman : G. Szabo

Members : P. Dropmann
F. Benussi

Summary of Facts and Submissions

- I. International patent application PCT/US 89/03266 was filed on 19 July 1989.
- II. On 26 January 1990 the EPO, acting as International Searching Authority (ISA), sent to the Applicant an invitation pursuant to PCT Article 17(3)(a) and Rule 40.1 to pay, within 45 days, two additional search fees. The said invitation indicated that the ISA considered that the above mentioned application related to the following groups of subject-matter which did not meet the requirements of unity of invention as set forth in PCT Rule 13:
- | | |
|--|---|
| 1. Claims 1, 3-4 and 6-9: | Introducer with soft tip. |
| 2. Claims 2 and 12-14
(a posteriori): | Introducer with valve seal means in proximal end. |
| 3. Claims 5, 10 and 11 (a posteriori)
and 15-18 (a priori): | Introducer coated with hydrogel. |

The ISA argued that it was directly evident that there was no common inventive concept between the subject-matter of Claims 1, 3-4 and 6-9 on the one hand and Claims 15-18 on the other (lack of unity a priori). Furthermore, the ISA added that it was apparent from the state of the art as known from documents EP-A-0 232 994 and DE-A-2 140 755 that the subject-matter of Claims 1, 3-4 and 6-9 lacked novelty and that, therefore, in the absence of any common inventive

concept, lack of unity a posteriori existed between the subject-matters listed above.

III. The Applicant paid the two additional search fees under protest and argued that, in view of PCT Rules 13.3 and 13.4, the application complied with the requirement of unity of invention and that the division by the ISA of the claims into three groups was arbitrary and improper, and the invitation to pay additional fees was erroneously issued. The telecopies of the letter of protest and of the appropriate payment order were received by the ISA on 7 March 1990 and the original letter and payment order were received on 13 March 1990.

Reasons for the Decision

1. The invitation to pay additional search fees meets the requirements of PCT Rule 40.1.
2. Admissibility of the protest

In the invitation to pay additional fees a time limit provided for in PCT Article 17(3)(a) of 45 days from the date of mailing (26 January 1990) was set in accordance with PCT Rule 40.3. This time limit expired on 12 March 1990.

Whilst the telecopies of the letter of protest and of the cheque were already received by the ISA on 7 March 1990, the original letter and cheque were only received from the U.S.A. on 13 March 1990, i.e. after expiry of the time limit. However, both the letter and the cheque are to be considered to have been submitted in time, the former in view of PCT Rule 92.4(a); the latter in view of PCT Rule 82.1(a) and (b), since the Applicant succeeded in

proving that he had mailed, by registered mail, the original letter with the cheque on 7 March 1990, i.e. five days prior to the expiration of the time limit (Rule 82.1(a)). Since this letter from the U.S.A. arrived on 13 March 1990, it follows that the mailing must have been by airmail.

Hence, the protest complies with the formal requirements of PCT Rules 40.2(c) and 40.3 and is accordingly admissible.

3. Lack of unity a priori between the independent claims

3.1 PCT Rule 13.1 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Lack of unity of invention may be directly evident a priori, i.e. before considering the claims in relation to any prior art, on the basis of common general knowledge of the person skilled in the art.

3.2 The Board is of the opinion that, in the present case, lack of unity a priori exists between the subject-matter of independent Claim 1 and that of independent Claim 15 for the following reason.

Claim 1 relates to a catheter introducer of the kind as indicated in the prior art portion of Claim 1. Said introducer is characterised by a tip portion attached to the body portion of the introducer and including a polymer material rendering the tip portion substantially more flexible than the tube forming the body portion. The subject-matter of independent Claim 15 having almost the same prior art portion as that of Claim 1 is characterised by a coating of lubricious hydrogel on the interior and/or exterior surface of the tube of the catheter introducer.

As mentioned on pages 4 and 5 of the description, the object underlying the subject-matter of Claim 1 and its effects were to construct a new and improved catheter introducer with reduced tendency to split or buckle or to abrade or traumatise a vessel wall during use, whereas the object and effects of the subject-matter of Claim 15 were to reduce strength and rigidity requirements of the introducer to withstand forces during insertion in a blood vessel and during placement of a catheter.

Consequently, neither the objects and effects nor the structural features of the characterising portions of Claims 1 and 15 create a unifying link between the subject-matter of Claim 1 and that of Claim 15. The only link can be recognised in the structural features of the prior art portions of these claims. This link or single general concept, however, clearly is not inventive since catheter introducers as mentioned in the prior art portions of Claims 1 and 15 belong to the common general knowledge of the skilled person as admitted by the Applicant (cf. pages 1 and 2 of the description). Thus, the subject-matter of independent Claims 1 and 15 do not meet the requirement of unity of invention prescribed by PCT Rule 13.1.

- 3.3 In his letter dated 7 March 1990, the Applicant argued that, in view of PCT Rule 13.3, Claims 15-18 should be permitted in the same international application as Claim 1 and should be included in the search report with Claim 1. However, PCT Rule 13.3, which indeed allows to include in the same international application two or more independent claims of the same category, contains the proviso that the requirement of Rule 13.1 must be met. As reasoned above, this is clearly not the case.

3.4 Accordingly, the a priori lack of unity objection raised by the ISA against Claims 1 and 15 was correct and the invitation to pay an additional search fee for Claim 15 was justified.

4. No clear case for lack of unity a posteriori for dependent claims

4.1 According to Chapter VII, point 9 of the PCT Guidelines for International Search, lack of unity of invention may become apparent a posteriori, i.e. after taking the prior art into consideration, e.g. a document discovered in the international search shows that there is lack of novelty in a main claim, leaving two or more dependent claims without a single general inventive concept.

4.2 In its Decision G 1/89 of 2 May 1990 (to be published), the Enlarged Board of Appeal of the EPO made the following statement (cf. point 8.2):

"It may be added that the consideration by an ISA of the requirement of unity of invention should, of course, always be made with a view to giving the applicant fair treatment and that the charging of additional fees under Article 17(3)(a) PCT should be made only in clear cases. In particular, in view of the fact that such consideration under the PCT is being made without the application having had an opportunity to comment, the ISA should exercise restraint in the assessment of novelty and inventive step and in border-line cases preferably refrain from considering an application as not complying with the requirement of unity of invention on the ground of lack of novelty or inventive step."

- 4.3 The Board takes the view that the present application is not such a clear case in which charging of an additional search fee on the basis of lack of unity a posteriori is justified.
- 4.3.1 The a posteriori objection of lack of unity raised by the ISA is based on the grounds that the subject-matter of the bridging Claim 1 and dependent Claims 3, 4 and 6 to 9 appears to lack novelty with respect to document EP-A-0 232 994 or DE-A-2 140 755 cited as X-documents in the partial international search report, thus leaving dependent Claims 2 and 12 to 14, on the one hand, and dependent Claims 5, 10 and 11, on the other, without a single general inventive concept.
- 4.3.2 Document EP-A-0 232 994 discloses in Claim 1 a catheter introducer for use with a guide wire and comprising a tubular body having an inwardly tapered tip, said tip having a flexible snout adapted to follow the path of a guide wire. It follows from the wording of this claim, from the statements in column 1, lines 4-16 and column 2, lines 18-22 and 46 and from the figures (see reference numerals 12, 14, 24, 30, 36, 40, 44) of the EP-document that the tubular body of the catheter introducer known from this document corresponds to the dilator (22, 90, 92) of the catheter introducer according to the present application, whilst the sheath of the prior art catheter (see reference numeral 16 and the above-mentioned passages of the EP-document) corresponds to the body portion (24) and its attached soft tubular tip portion (26), which together form the sheath (36), of the claimed catheter introducer.

When deciding on novelty of the claimed catheter introducer in comparison with the prior art catheter introducer, only corresponding parts may be compared. Consequently, since the sheath (16) of the prior art

introducer does not comprise the features of the sheath (36), i.e. the body portion (24) and the tip portion (26), of the claimed introducer, EP-A-0 232 994 clearly does not deprive the subject-matter of Claim 1 of novelty.

Furthermore, no clear reason can be seen why, in view of the prior art known from EP-A-0 232 994, it should be obvious to provide the sheath of the prior art introducer with the features characterising the dilator (30, 40, 44) of the prior art introducer.

4.3.3 Similarly, it is not obvious whether document DE-A-2 140 755 clearly destroys novelty or inventive step of the catheter introducer according to Claim 1 of the application. The DE-document discloses a plastic tube portion and a needle-cannula-assembly comprising a tube having a tip portion which, similar to the claimed catheter introducer, includes a polymer material rendering the tip portion more flexible than the remaining tube (see in particular Claims 1 and 13). The DE-document does not disclose a catheter introducer as specified in Claim 1 of the application. Therefore, when assessing novelty, the question arises whether the prior art tube portion or cannula would, without any modification, be suitable for use as a catheter introducer. There may be doubts about that. At least, this particular question should not be answered in the affirmative (this would mean that the subject-matter of Claim 1 would not be novel in comparison with the prior art known from the DE-document) without the Applicant having an opportunity to comment on this point. This, however, is not possible during the search stage of the application. The same reservation applies to the question of inventive step.

4.4 Hence, in the above circumstances, the present case is, in the Board's view, certainly not a clear case in which the a posteriori lack of unity objection by the ISA against

dependent claims and charging of an additional search fee on this basis have been justified.

5. It follows from the above findings that the charging of additional search fees was justified only in one case (see point 3.4). The other additional search fee should be reimbursed.

Order

For these reasons, it is decided that:


Refund of one additional search fee is ordered.

The Registrar:

The Chairman:



S. Fabiani


G. Szabo 13.11.90

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