

Publication in the Official Journal Yes / ~~No~~

File Number: T 514/88 - 3.2.2

Application No.: 85 200 079.3

Publication No.: 0 172 586

Title of invention: Medical infusor

Classification: A61M 5/14

DECISION
of 10 October 1989

Applicant: ALZA CORPORATION

Headword: Infusor/ALZA

EPC Articles 76(1), 123(2) and (3) and Rule 88

Keyword: "Divisional application (not allowed -
extending beyond content of parent
application)"
"Deletion of essential features (not allowed)"
"Interrelated partial problems"
"Correction under Rule 88 (denied)"

Headnote

I. The content of an application in respect of Articles 76(1) and 123(2) EPC means the total information content of the disclosure (cf. Point 2.2 of the Reasons).

II. The two tests in relation to the question of broadening of claim before grant by abandoning a feature, i.e. the test for essentiality (or inessentiality) on the one hand and the novelty test on the other, are not contradictory but represent the same principle. In both cases the relevant question is whether or not the amendment is consistent with the original disclosure (cf. T 260/85, T 331/87, T 201/83, and T 194/84) (cf. Points 2.3 and 2.4 of the Reasons). This means direct and unambiguous derivability from and no contradiction to the totality of the original disclosure (cf. Point 2.7 of the Reasons).

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Case Number : T 514/88 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 10 October 1989

Appellant :

ALZA CORPORATION
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Representative :

Evans, David Charles et al,
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Decision under appeal :

Decision of Examining Division 128 of
the European Patent Office dated
30 June 1988 refusing European patent
application No. 85 200 079.3 pursuant
to Article 97(1) EPC

Composition of the Board :

Chairman : G. Szabo

Members : P. Dropmann

O. Bossung

Summary of Facts and Submissions

- I. European patent application No. 85 200 079.3, filed as a divisional application on application No. 81 300 074.2 and claiming the priority date of 18 January 1980 from US application No. 113 224, was refused by the decision of the Examining Division dated 30 June 1988. The decision was based on Claims 1 to 5 filed on 27 November 1987.
- II. The reason given for the refusal was that the subject-matter of the divisional application extended beyond the content of the earlier (parent) application as filed, contravening Article 76(1) EPC.
- III. The Appellant lodged an appeal against this decision on 24 August 1988. The Statement of Grounds was filed on 26 September 1988 together with an amended page 11 of Claim 1.
- IV. Claim 1 reads as follows:

"An infusor (11) dispensing a liquid to an infusion site under pressure at a predetermined flow rate, comprising a tubular housing (12), a plug (13) fixed in one end of the housing having an aperture therethrough, an axially slidable piston (14) within the housing, a tubular elastomeric bladder (15) for receiving and holding liquid under pressure, the ends of which are sealingly attached (56,57) to the plug and piston respectively with the lumen of the bladder communicating with the plug, and a flow regulator (27) in the fluid path to permit the liquid to flow from the bladder via a conduit (17) to the site at a predetermined rate;

characterised by at least one axial post (44, 22, 73) within the lumen of the bladder (15), said post having an axial aperture (47,25) in communication with the aperture in the plug (13), and extending on deflation of the bladder, between the plug (13) and the piston (14), whereby the deflated bladder applies an axial force to drive the piston toward the plug thereby to cause the post to come into axial abutment so that the posts substantially fill the deflated lumen."

- V. The claim differs from Claim 1 of the parent application as filed, which claim reads as follows:

"An infusor for dispensing a liquid under pressure at a predetermined flow rate comprising a tubular housing, a plug fixed in one end of the housing having an aperture extending therethrough, an axially slidable piston within the housing, a tubular elastomeric bladder for receiving and holding the liquid under pressure, the ends of which are sealingly attached to the plug and piston, respectively, with the lumen of the bladder communicating with the aperture in the plug, a conduit extending from the aperture in the plug to the infusion site and a flow regulator in the fluid path for permitting the liquid to flow from the bladder to the infusor site at the predetermined rate characterized in that

- (a) there is at least one axial post within the lumen of the bladder that substantially fills said lumen when the bladder is deflated, said post(s) having an axial aperture and extending between the inner side of the piston and the inner side of the plug whereby when the bladder is deflated and axial force is applied to the piston in the direction of the plug, the force is transmitted via the post(s) to the plug;

- (b) the piston has an axial aperture that communicates with the axial aperture of said post(s), said apertures together defining a filling passageway adapted to receive a filling needle; and
- (c) there is a septum or one way, self sealing valve in the filling passageway."

VI. In the Statement of Grounds and during the oral proceedings held on 10 October 1989 at the Appellant's request, the Appellant made the following points:

- Two problems were to be solved by the parent application, the first problem being to achieve complete discharge of liquid from the tubular axially expansible bladder, the second problem being to refill the bladder without puncturing it while leaving the infusor attached to the patient. The first problem was solved by feature (a) and the second problem was solved by features (b) and (c) specified in Claim 1 of the parent application as filed.
- It was clear from a reading of the parent application and as a matter of use of the English language that there was some doubt as to whether or not features (a), (b) and (c), which are mentioned in the description and in Claim 1 of the parent application as filed and which are linked by the word "and", were to be taken together or were to be considered as each presenting a separate invention.
- A correct application of Rule 88 EPC would have allowed to replace the word "and" linking features (a), (b) and (c) with "or" in the parent application. In view of the

decision J 04/85 (cf. "Correction of drawings/Etat Français", OJ EPO 1986, 205) it was permissible to look at the priority document when applying Rule 88 EPC to resolve an ambiguity. The priority document US-113 224 was silent as to features (b) and (c) in its Claims 1 and 2 and corresponding text and discussed only feature (a).

- Deletion of features (b) and (c) should also be allowable in view of the decision T 151/84 (dated 28 August 1987, unreported) wherein an inessential feature had been removed from Claim 1.
- Based on an Affidavit sworn by senior Patent Attorney Steven F. Stone and filed on 20 September 1989, the Appellant argued that, when filing the parent European patent application at the beginning of 1981, an ambiguity had existed about the real meaning of Rule 29(1)(b) EPC. The Applicant having no experience of the EPC at that time had been of the opinion that, in agreement with the United States patent practice, the features (a), (b) and (c) could all be included within Claim 1, but nevertheless might later be claimed individually depending upon the result of the search report. Because of this ambiguity, it would also be justified to look at the priority document in the present circumstances.

During the oral proceedings, the Board also discussed decisions T 401/88 (dated 28 February 1989, to be published) and T 331/87 (dated 6 July 1989, to be published).

- VII. The Appellant requested that the decision to refuse the divisional application be set aside and a patent be granted on the basis of Claim 1 as mentioned under point IV. In an alternative, he wanted the application be returned to the Examining Division for further consideration.

Reasons for the Decision

1. The appeal is admissible.
2. The broadening of claims
 - 2.1 The question to be decided in this appeal is whether or not the present divisional application complies with the provision of Article 76(1) EPC, i.e. whether the application is filed only in respect of subject-matter which does not extend beyond the content of the earlier (parent) application as filed. An examination under Article 76(1) EPC thus corresponds to that under Article 123(2) EPC.
 - 2.2 When carrying out the examination under Article 76(1) EPC, the subject-matter of the divisional application has to be compared with the content of the parent application as filed. The important question to be answered is what is the content of the application.

According to the practice of the EPO, the content of an application comprises the whole disclosure, express or implied, that is directly and unambiguously derivable from this application including information which is implicit and immediately and unambiguously apparent to a person skilled in the art reading the application. Thus, the content of the application means the total information content of the disclosure. This includes the original statements as to the problem to be solved implying certain aims and effects. Although it is possible to replace notionally such statements by more precise considerations for instance in respect of some newly cited close state of the art for the assessment of the inventive step (cf. T 1/80, "Carbonless copying paper/BAYER", OJ EPO 1981, 206), the so reformulated problem would not be accepted as

an amendment, if this involves additional information content. Thus the original statements, including the implied functions of the invention, remain part of the disclosure as filed, from the point of view of Art. 123(2) EPC.

It is to be mentioned, on the other hand, that the content of the application as filed does not include any priority documents in this respect (cf. T 260/85, "Coaxial connector/AMP", OJ EPO 1989, 105, cf. point 3).

- 2.3 The above decision T 260/85 also emphasised that it should not be permitted to delete from an independent claim a feature which the application as originally filed consistently presented as being an essential feature of the invention. Supplementing this principle, the decision T 331/87 ("Removal of a feature/HOUDAILLE", dated 6.7.89, to be reported) indicated, on the other hand, that there are certain situations where the feature to be omitted may be inessential. By implication, a test for essentiality was suggested comprising any one of the following three criteria. According to this test removal of a feature from a claim is at least not permissible under Art. 123(2) EPC if (1) the feature is presented as essential in the original disclosure, or (2) it is indispensable for the function of the invention in the light of the technical problem it serves to solve according to the original disclosure, or (3) the removal requires a modification of other features to compensate for the change. Of course, the first criterion is not only satisfied in the presence of express reference to essentiality, since the applicant's conduct in the presentation of the invention may also indicate that he considers a feature as essential.

- 2.4 In view of the relevance of the information content of the original disclosure and the relation to any amendment to

it, it has also been suggested that a novelty test should be applied to determine the allowability of the amendment (cf. T 201/83, "Lead alloys/SHELL", OJ EPO 1984, 481, Point 3). The standards for examining novelty should therefore also apply for the allowability of amendments and are also relevant to the present case. The decision in case T 194/84 ("Cellulose fibres/GENERAL MOTORS", 22.9.88, to be reported) confirmed the position and added that in the case of broadening by generalisation or omission of a feature, the test must be applied to the additional subject-matter generated by the amendment. This consideration is independent of the scope for claims, since the addition of a new, neither expressly nor by implication disclosed feature is normally considered as an extension of the content of an application, whether added conjunctively (narrowing) or disjunctively (broadening the scope of a claim).

It is the opinion of the Board that the considerations so far suggested in relation to the question of broadening before grant by abandoning a feature, i.e. the test for essentiality (or inessentiality) on the one hand, and the novelty test on the other, are not contradictory but represent the same principle. In both cases the relevant question is whether or not the amendment is consistent with the original disclosure.

- 2.5 If the addition of a new feature is an unallowable extension, it appears then that the abandonment of features is *prima facie* itself a reduction of information content. However, it could well be, at least implicitly, that simultaneously new matter is thereby added. If, for instance, it is evident to the skilled person that the disclosure involved, expressly or by implication, a condition which inextricably linked the feature in question to the rest, any removal thereof would mean the

introduction of a new condition, i.e. new information according to the novelty test, contradicting the validity of the original condition. Unless the necessity for the linkage never really existed, the amendment would be inconsistent with the original disclosure.

2.6 It also stands to reason that the removal of essential features involves such a contradiction, i.e. inconsistency. No such situation may, however, arise with the abandonment of inessential features from (conjunctive) combinations, since the embodiments generated in this manner may then be "anticipated" by the original disclosure (cf. T 194/84 *ibid.*). This is because the skilled reader would recognise the subcombination as serving the disclosed purposes in line with the criteria suggested above in case T 331/87. The same normally applies also to the deletion of an embodiment or variant from an alternative (disjunctive) list of possibilities, provided the remaining set represents no new selection invention representing a novel solution of different technical problems. In neither of such situations is the essence of the invention affected, since the basic function remains the same. The recognition and claiming of particular units, having clearly defined specific functions within the working of the whole combination may also normally satisfy the same criteria provided such characteristics were clearly within the content of the disclosure.

2.7 It is, therefore, the view of the Board that a claim broadened during prosecution of the patent application must, in addition to having all features or elements of the claim formally supported by the original disclosure, be consistent with that disclosure as a whole. This means direct and unambiguous derivability from and no contradiction to the totality of the original disclosure. There should be such basis for the broadened claim in the

original (or parent) application (cf. T 66/85, "Connector/AMP", OJ EPO 1989, 167, cf. point 2). The basis need not be presented in express terms but it must be sufficiently clear to a person skilled in the art to be directly and unambiguously recognisable as such and not of a vague and general character.

- 2.8 In the present case, Claim 1 of the divisional application differs from Claim 1 of the parent application as filed inter alia in that Claim 1 of the divisional application does not contain features (b) and (c) defining the piston/filling port assembly. These features read "(b) the piston has an axial aperture that communicates with the axial aperture of said post(s), said apertures together defining a filling passageway adapted to receive a filling needle; and (c) there is a septum or one way, self sealing valve in the filling passageway".

Deletion of these features means that present Claim 1 also includes infusors which, for example, can be filled via the plug assembly or, alternatively, the bladder can be prefilled on manufacture for one-way use of the device (cf. page 2 of the Statement of Grounds).

- 2.9 In order to decide whether the omission of features (b) and (c) has led to subject-matter which extends beyond the content of the parent application as filed, the relevant parts of this application will be considered in the following in order to define the content of the parent application as filed.

The introductory paragraph of the description refers to prior art infusors comprising a replaceable cartridge assembly and a housing and states that these infusors are complex and cannot be easily manufactured in an automated manner and are thus costly. Following this introduction and

introduced by the expression "Accordingly to the present invention", Claim 1 is repeated on pages 2 and 3 of the description, features (a), (b) and (c) being linked by the connecting word "and" indicating conjunction of these features.

The "basic elements of the preferred embodiment of the infusor" are depicted in Figures 1 and 2 and are mentioned on page 3, line 22 to page 4, line 5 and comprise the piston/filling port assembly 14. The axial post(s) 22, 44, which are defined by feature (a) and substantially fill the lumen of the bladder 15 when it is deflated, and the piston/filling port assembly 14 comprising a septum 48 and a piston having an axial aperture 47 that communicates with the axial aperture of the post(s) (features (b) and (c)) are explained in more detail on pages 4 and 5. On page 5, lines 23 to 26, it is stated that "these features contribute to the complete discharge of liquid from the bladder and the ease with which the bladder may be charged with liquid".

At the bottom of page 5 a filling operation of the bladder is described using a syringe 59 having a needle 62. It is pointed out that the force applied to the piston/filling port assembly 14 "to puncture septum 48 is transmitted to fixed plug/flow control assembly 13 via the abutting posts 22, 44. Piston/filling port assembly is thus supported during this initial step in the filling operation. Further, post 44 guides needle 62 after the septum is punctured and shields the bladder from being punctured."

- 2.10 It can be seen from the statements under point 2.9 that the features disclosed in the parent application as filed result in complete discharge of liquid from the bladder as well as in easy refilling of the bladder without puncturing it.

Hence, the person skilled in the art, when reading the parent application as filed, will immediately and unambiguously recognise that the problem underlying the parent application was to develop an infusor to be easily manufactured that can be both completely discharged and thereafter easily refilled. These two partial problems are sought to be solved in the parent application in a single device.

- 2.11 In view of this clear linkage between the partial problems to be solved in the parent application and in view of the following reason, the Board is of the opinion that, contrary to the Appellant's view, it is not permissible to separate the two partial problems in the present case and consequently to consider features (a), on the one hand, and (b) and (c), on the other, presenting separate inventions. In fact, when defining the content of the parent application as filed, also the technical problem as originally indicated has to be considered (cf. point 2.2 above).

Moreover, as clearly set out in the description and Claim 1 of the parent application, a functional interrelationship exists between features (a) and (b). As shown under point 2.9, features (b) and (c) defining the piston/filling port assembly are not functionally independent from feature (a) defining the post(s). The piston/filling port assembly requires the post(s) for supporting the piston/filling port assembly during the initial step in the filling operation and the axial aperture in the piston communicates with the axial aperture in the post(s).

- 2.12 The omission of features (b) and (c) would not comply with criteria (1) and (2) set forth above under point 2.3. As has been shown under points 2.9 and 2.10, features (b) and (c) are both (1) essential in the disclosure and (2) indispensable for the function of the invention in the

light of the technical problem it serves to solve. It also appears that when features (b) and (c) were to be omitted, the construction of the device would have to be somewhat modified to adapt the system to filling and discharge (criterion (3)), except in the extreme situation when the infusor is of the throwaway kind only to be filled once in advance by the manufacturer. This would not be consistent with the presentation of the invention by the applicant.

- 2.13 The general statement on page 8, lines 13 to 16 of the parent application as filed cannot serve as a basis for broadening the scope of a claim and to justify deletion of features (b) and (c). Page 8, lines 13 to 16 read:
"Modifications of the embodiments shown in the drawings and described above that are obvious to those of skill in the mechanical device and/or mechanical arts are intended to be within the scope of the following claims." Such a vague statement cannot be considered as disclosing variations in an application in a manner clear enough to satisfy Article 83 EPC, since it does not indicate how the embodiments may have to be modified.
- 2.14 Case T 151/84 (ibid.) cited by the Appellant is not analogous to the present case because the application which led to decision there contained sufficient information to the effect that the feature (permanent magnets) to be deleted from the claimed device was not indispensable for its function, whilst this is not the case in the present application under appeal.
3. Correction under Rule 88 EPC
- 3.1 The Board cannot share the Appellant's opinion that it was clear as a matter of use of the English language that the skilled person, from a reading of the parent application as

filed, was left in some doubt as to whether the features (a), (b) and (c) were to be taken together or were to be regarded as each presenting a separate invention. The Appellant has contended that it was acceptable in the English language to view these three features as alternatives and to read the word "and" connecting features (a), (b) and (c) as "or".

However, there is no support for such a contention in the parent application as filed. In view of the clear, unequivocal disclosure of the parent application as set out under point 2.9 above and the fact that features (a), (b) and (c) are linked by the connecting word "and" indicating conjunction and not disjunction, there is no doubt that all these features are disclosed in combination and are characteristic of the invention.

An amendment under Rule 88 of the word "and" linking features (a), (b) and (c) in the parent application to "or" as hypothetically considered by the Appellant would not have been justified to resolve the question. A correction requested under Rule 88, second sentence, EPC is not admissible if the requested amendment is not permissible under Article 123(2) EPC (cf. point 2.2 of the Reasons of the Decision T 401/88 dated 28 February 1989, to be published).

- 3.2 The Appellant argued that it would, in the present case, be permissible to look at the priority document in order to find a basis for the deletion of features (b) and (c). It is true that the priority document US-113 224, in its Claims 1 and 2 and its corresponding text, is silent as to features (b) and (c). However, the Board cannot accept the Appellant's argument for the following reason. Article 76(1) EPC, being under consideration in the present case, refers to "the content of the earlier application as

filed". As stated in Decision T 260/85 (ibid., cf. point 3 of the Reasons), for the purpose of Article 123(2) EPC, the content of an application as filed does not include any priority documents. Thus the abandonment of any particular subject-matter in the European application in comparison with the priority document is irreversible and binding. This also applies to Article 76(1) EPC. Hence, the priority document cannot serve to support the Appellant's contention that deletion of features (b) and (c) in the European proceedings would not lead to subject-matter which extends beyond the content of the parent application as filed.

- 3.3 Based on Mr Stone's Affidavit, the Appellant submitted that, when filing the parent European patent application at the beginning of 1981, an ambiguity had existed about the real meaning of Rule 29(1)(b) EPC and that, therefore, it should be justified to look at the priority document. There was no ambiguity in that Rule since any presentation of claims must have been considered in the light of other express provisions in the Convention, limiting the freedom of amendment at later stages. Such an ambiguity, had it really existed, should have led the representatives of the applicant formulating a European patent application to choose a secure way, i.e. not to restrict the content of this application in comparison with the priority application, rather than to limit it expressly to a combination of conditions. However, when formulating the European patent application, which now forms the parent application, the Applicant obviously deliberately restricted the subject-matter of the priority application to embodiments which comprise features (a), (b) and (c) in combination, i.e. to a particular embodiment of a piston/filling port assembly, and abandoned the earlier broader presentation in the priority document. This can clearly be seen from the fact that the Applicant deleted the statement on page 8, lines 20 and 21 of the priority

document, this statement relating to other bladder filling means such as a radial inlet to a post aperture.

4. After taking the Appellant's arguments into consideration, the Board is of the opinion that the subject-matter of the divisional application extends beyond the content of the parent application as filed, contravening Article 76(1) EPC.

Order

For these reasons, it is decided that:

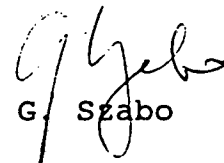
The appeal is dismissed.

The Registrar:


The Chairman:



S. Fabiani



G. Szabo

 21.12.89