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Datasheet for the decision of 10 March 2010

Case Number: T 0739/09 - 3.2.02

Application Number: 96941916.7

Publication Number: 0948371

IPC: A61M 5/162

Language of the proceedings: EN

Title of invention:
Apparatus for administrating toxic fluid

Patentee:
Carmel Pharma AB

Opponent:
Modiano, Micaela Nadia

Headword:
-

Relevant legal provisions:
-

Relevant legal provisions (EPC 1973):
EPC Art. 56

Keyword:
"Inventive step (no)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0739/09 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 10 March 2010

Appellant: (Patent Proprietor)	Carmel Pharma AB P.O. Box 5352 S-402 28 Göteborg (SE)
Representative:	Inger, Lars Ulf Bosson Valea AB Lindholmspiren 5 S-417 56 Gothenburg (SE)
Respondent: (Opponent)	Modiano, Micaela Nadia Modiano, Josif, Pisanty & Staub Ltd. Thierschstrasse 11 D-80538 München (DE)
Representative:	Johnson, Terence Leslie Marks & Clerk LLP 90 Long Acre London WC2E 9RA (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted 16 March 2009 revoking European patent No. 0948371 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: M. Noël
Members: D. Valle
A. Pignatelli

Summary of Facts and Submissions

I. The appellant (patentee) lodged an appeal on 26 March 2009 against the decision of the Opposition Division posted on 16 March 2009 revoking the European patent No. 0 948 371. The fee for the appeal was paid on the same day and the statement setting out the grounds for appeal was received on 23 June 2009.

II. The Opposition Division held that the patent in suit did not meet the requirement of Article 56 EPC, having regard to the teaching of document

D6: US - A - 3 822 700,

in combination with the following documents and the general knowledge of a person skilled in the art:

D5: SE - B - 434 700 & EP - A2 - 0 126 718,
D7: US - A - 4 857 068.

III. Oral proceedings took place on 10 March 2010.

The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of claim 1 of a main request or of an auxiliary request, both filed on 23 June 2009.

The respondent requested that the appeal be dismissed.

IV. Claim 1 of the main request reads:

"Method for administrating a drug to an infusion bag containing infusion fluid prior to infusion, comprising the steps of
connecting an infusion device (10) for administrating a toxic fluid to an infusion bag, whereby the infusion device is provided with an insertion portion (11) for connecting the bag and an infusion chamber (12) for dosing a fluid flow via a flow duct (13) in the insertion portion from the bag to an outlet arranged on the chamber, which insertion portion also comprises a ventilating duct (14) which extends between the bag and the outside of the infusion device and ends in a connection (16) arranged on the side of the infusion device for supplying fluid to be administrated, whereby the connection (16) is provided with at least one membrane (17), which is air tight and penetrable by an injection needle,
filling the infusion chamber (12) with infusion fluid,
mounting an injector that is loaded with a drug to be administered and with an injection needle connected thereto on said connection (16), and
supplying said drug to be administrated to the infusion bag by penetrating said at least one membrane (17) by the injection needle."

Claim 1 of the auxiliary request only differs from that of the main request by substituting in the first line of the claim the words "a drug" by the expression:

"a toxic fluid, such as cytotoxic drug or an antiviral antibiotic".

V. In support of his requests the appellant relied essentially on the following submissions:

The method of the invention addressed the problems of maintaining the infusion device in a closed system and designing the device for use with an infusion bag of standard type. The invention aimed at improving the safety of the personal when injecting a toxic fluid to a standard bag having two ports. In essence, the proposed solution was to ignore the second port of the standard infusion bag and to provide a non-vented spike (infusion device) to be used in the manner as claimed for administrating a toxic fluid to the bag.

Claim 1 of the main request differed from D6 in that:
- the claimed method was for administrating a drug to an infusion bag and not to a bottle;
- D6 did not disclose administrating the drug to a bag prior to infusion;
- D6 did not disclose administrating a toxic fluid;
- D6 did not disclose mounting an injector on a connection of the infusion device, the injector loaded with a drug and provided with a needle for first penetrating a membrane provided in the connection and then supplying the drug. According to paragraph [9] of the patent in suit "mounting" could also mean that the ventilating duct ended in a luer connection which could be used for "mounting" an adjustable adjusting device for supplying air to the bag. If the claim needed clarification on this point, the appellant was ready to do it at the oral proceedings and to propose further amendments.

The closest prior art should be that most suitable for the purpose of the invention, not that showing most structural similarities with the solution as claimed.

D6 was not the closest prior art because it did not recognize the problem of the invention - as was derivable from paragraph [4] of the patent in suit with reference to D5 - to administer toxic fluid without the risk of the connection to a bag of standard type coming loose and of the toxic fluid coming into contact with breathable air. As it became clear from the reading of D7, see column 1, lines 29 to 40 and column 3, lines 30 to 52, vented spikes such as those disclosed in D6 where venting took place by means of a check valve 30, were unsuitable if used together with collapsible containers (bags), because they did not guarantee against leakage of toxic fluid out of the check valve and its diffusion into breathable air. Furthermore, a check valve could not prevent air from being inadvertently supplied to the container when it was tilted, with a risk of embolism for the patient. Therefore there was a clear prejudice in D7 against using the device of D6 provided with a check valve.

Even if D6 would be considered as the closest state of the art, there was no motivation in D6 or any other document for substituting the bottle for a bag. Such substitution would be the result of an *ex-post facto* reasoning. Furthermore, further non obvious steps would have been necessary to arrive at the invention, starting from D6, in order to prevent leakage.

The use of toxic fluids such as those specified in claim 1 of the auxiliary request was subject to

stringent regulations, given the high level of aggressivity of these fluids. For this reason, devices like those described in D6 or D7 provided with ball valves were not suitable since toxic fluids were likely to contaminate the surrounding air. In this context the mounting of an injector on the connection within the meaning of the present patent appeared to be of primordial importance.

VI. The respondent contested the assertions of the appellant and maintained essentially that the subject-matter of claim 1 of the main and of the auxiliary request did not involve an inventive step having regard to the teaching of D6 together with the general knowledge in the field.

More specifically, the method as claimed was nothing more than the use of the device for administrating a drug to an infusion bag, and the device only differed from D6 by the use of a bag instead of a bottle.

The problem derivable from paragraph [4] of the patent in relation to D5, of avoiding a loose connection between an injector and an infusion bag of standard type was not the problem underlying the invention, the more so since D5 had nothing to do with toxic fluids or with standard bags provided with two ports. The problem as stated in paragraph [5] of the patent was confined to provide an injector connection for eliminating the risk of the drug coming into contact with breathable air.

There was no mention in D6 that the device described therein should not be suitable for administrating toxic

fluids to an infusion bag. The use of bags was not excluded from this document and the administration of the drug could be made prior to or during the infusion. Like the present patent, the injection of additives during the use of the device could be done with a syringe through a diaphragm. A risk of leakage or seepage was neither mentioned in D6 nor in the contested patent and could not be used to define an objective problem. Likewise, there was no suggestion in the present patent that the mounting of the injector onto the connection was of particular relevance.

Collapsible bags were known and available on the market since the 1970's. Moreover, collapsible bags did not need an air inlet. Therefore, the functioning of an infusion device with an infusion bag was identical to that with an infusion bottle using a check valve.

Reasons for the Decision

1. The appeal is admissible.

2. *Inventive step - main request*

2.1 Closest prior art

D6 is considered to be the document coming closest to the claimed subject-matter since it presents most similarities not only in terms of structural features but also in terms of steps of the method for administrating a drug to an infusion container.

The appellant submitted that D6 was not the closest prior art since an appropriate starting point should be that most suitable for the purpose of the invention, not that showing most structural similarities. However, the appellant ignores that besides the same purpose the choice of the closest prior art depends on a number of other criteria such as a similar technical problem or a most promising starting point (see jurisprudence in Case Law of the Boards of Appeal, 5th Edition I.D.3). D6 is a disclosure aiming at the same objective as the claimed invention, of providing a method for administrating a drug to an infusion container, and having the most relevant technical features in common, i.e. regarding the minimum of structural and functional modifications. For this reason the Board considers that the skilled person would start from D6 as the closest state of the art.

The appellant further submitted that the closest prior art should be constituted by a method of administrating a drug to an infusion bag such as the method laid out in paragraph [4] of the patent. This paragraph refers to D5 (correspondent to SE patent) and indicates that a drawback of the system described therein is that when used for administrating a toxic fluid to a patient by infusion, there is a risk that an injector connected to the conical connection of an infusion bag of standard type could come loose so that discharge to breathable air could take place. However this paragraph is misleading in that not only the alleged drawback is not mentioned in D5 but also the connector 32 (see Figure 4) may be attached (directly or not) to an infusion bottle (see page 4, lines 7 to 14 of the

second full paragraph). There is no mention of a bag still less of a bag of standard type, not shown anyway.

Therefore the alleged drawbacks of D5 and consequently the alleged advantages of the invention to which the appellant refers are not sufficiently supported for them to be taken into account for considering D5 as the closest prior art document (see Case Law of the Boards of Appeal, I.D.4.2).

2.2 Interpretation of D6

D6 discloses not only an infusion device for administrating a drug to a container containing an infusion fluid, but also a method for administrating the drug, using the device (see column 2, line 66).

More specifically, D6 discloses a method for administrating a drug to an infusion bottle containing infusion fluid prior to infusion (see column 2, lines 16-20), comprising the steps of connecting an infusion device (10) suitable for administrating a toxic fluid to an infusion bottle, whereby the infusion device is provided with an insertion portion (spike 16) for connecting the bottle and an infusion chamber (22) for dosing a fluid flow via a flow duct (20) in the insertion portion from the bottle to an outlet (24) arranged on the chamber, which insertion portion also comprises a ventilating duct (26) which extends between the bottle and the outside of the infusion device and ends in a connection (nipple 34) arranged on the side of the infusion device for supplying fluid to be administrated (see column 2, lines 13-15), whereby the connection is provided with at least one membrane

(diaphragm 40), which is air tight and penetrable by an injection needle, filling the infusion chamber (22) with infusion fluid (see column 3, lines 24-26), mounting an injector that is loaded with a drug to be administered and with an injection needle connected thereto on said connection (see column 3, lines 47-51), and supplying said drug to be administrated to the infusion bottle by penetrating said at least one membrane (40) by the injection needle.(see column 2, lines 21-23).

However, D6 does not disclose the use of an infusion bag. D6 discloses an infusion bottle instead.

In contrast, the appellant pointed out four distinguishing features in claim 1, namely:

(a) the drug is administrated to an infusion bag
(b) this is done prior to infusion
(c) the infusion device is specifically designed for administrating a toxic fluid
(d) the method includes the step of mounting an injector on the infusion device.

Apart from feature (a), the Board does not share the appellant's analysis for the following reasons:

(b) Prior to infusion

In the Board's view, the administration of the drug to the infusion container prior to infusion is clearly disclosed by D6. Already the fact that the additives are to be introduced into the bottle while "in use" (see column 1, line 48 and column 2, line 1) does

actually imply that the injection of additives may occur before or during flow of infusion fluid since the bottle is "in use", i.e. connected. Moreover, as specified in column 2, lines 32 to 34, the additives may be introduced into the bottle through the air passage and diluted in the bottle **before** it is injected, i.e. prior to mixing and infusion, with the words of the present patent.

(c) Toxic fluid

In D6 the check valve 30 is explicitly disclosed (see column 3, lines 35 to 37) as preventing fluid flow from the infusion bottle, whatever the nature of the fluid and the container which are used. In a normal condition of infusion by gravity the pressure at the valve would not be different when using a bottle or an infusion bag and a fluid flow would be prevented in the same way. Therefore the infusion device of D6 is regarded by the Board as being suitable also for administrating a toxic fluid.

The risk of leakage or seepage referred to by the appellant is not mentioned in D6 but only in D7, which is used by the appellant to interpret D6. Said risk is relied upon in D7 in order to justify the use of an additional sealing member (tab 18), not only for better preventing leakage or seepage of fluid from a collapsible container (non-vented spike type) when undergoing additional external pressure by means of a pressure cuff, but also flow of air entering the container (see column 2, lines 1 to 9; column 3, lines 31 to 40 and lines 49 to 52). When however a ball valve is used with a rigid container (vented-spike

type), which is also the case in D6, there is no reason why the valve should not play its role properly, that is to prevent leakage or seepage of fluid from the container. Therefore the Board does not accept that D6 be improperly interpreted in the light of D7 so as to give rise to a problem that does not actually exist in D6.

(d) Mounting

In claim 1 at issue the step of mounting an injector on the connection is broadly worded. As a consequence the manner the mounting is realised or the mounting means which are used is irrelevant for the comparison with the state of the art. In paragraphs [10] and [11] of the patent specification the word "mounted" is used indifferently for mounting the connection 16 into the luer connection 15 (see column 2, line 20) and for mounting the injector (not shown) in the connection 16 (see column 2, line 33), using a glue and a bayonet socket, respectively.

Since "mounting" within the usual technical meaning of assembling, fixing or attaching to is sufficiently clear on the basis of the patent description, there was no need for additional explanations of this word or for amendments to the claim, as proposed by the appellant at the oral proceedings. Moreover the specification in claim 1 of the mounting means would have no bearing on the method itself and there is no indication in the description that those means are of particular relevance for the administrating method. The Board, therefore, did not accept further amendments at this stage of the proceedings.

When the infusion device disclosed in D6 is used and additives are to be injected through the device, this is done by piercing the diaphragm 40 of the injection nipple 34 with a syringe having a needle (see column 2, lines 21 to 23 and column 3, lines 54 to 55). As can be seen in Figure 2 of D6, the injection nipple is provided with a conical end presumably for applying and centering, i.e. for mounting the corresponding matting end of the syringe (injector) in the nipple (connection). Since both infusion devices (in D6 as in the present patent) are used for administrating a drug from a syringe (not shown), to a container (not shown), the step of mounting the injector (syringe) on a connection of the infusion device is also necessarily disclosed in D6.

2.3 Problem and solution

The solution referred to in paragraph [6] of the contested patent of providing the connection with an air tight membrane with the view to eliminate the risk of the drug coming into contact with breathable air, in accordance with the technical problem presented in paragraph [5], is known from D6 (diaphragm 40) or from D5 (double membrane 18, 24 in Figure 4). In such a case a more specific, objective problem has to be redefined, starting from the closest prior art document in agreement with the problem-solution approach (see Case Law I.D.4.3.1).

As previously established, the subject-matter of the method claim 1 differs from the disclosure of D6 by the use of an infusion bag instead of an infusion bottle.

Hence, in agreement with the Opposition Division (decision, page 7), the objective problem may be regarded as providing an alternative procedure for the preparation of an infusion fluid.

The appellant has submitted to derive the technical problem from paragraph [4] of the patent which refers to D5, stating that when administrating (a drug) to a patient via infusion, an injector connected to the conical connection of an infusion bag of standard type could come loose. However, as mentioned in D5 (see page 4, lines 12 to 29) with reference to Figure 4, the connection 32 which is provided with membranes 18, 27 to be pierced by the syringe 15 (injector), is connected to an infusion bottle (not shown) either directly or indirectly by means of a cannula 26 having a conical end. Thus D5 does not disclose a collapsible bag let alone a standard bag having two ports, and does not mention any risk resulting from the connection to the bottle.

Moreover, the alleged problem of leakage between the connection and the bag is not the subject of the present patent and no solution is proposed thereto. In fact, the injection portion 11 (spike) of the device of the patent is "connected normally to a bag" (see column 2, line 28) without reference to any leakage difficulties.

According to the consistent established case law of the Boards of Appeal (see I.D.4.4), when determining the problem underlying the invention for the purpose of assessing inventive step, the alleged effect of a feature cannot be taken into account if it is not

clearly derivable from the application as filed considered in relation to the closest prior art. For this reason the Board does not accept that the objective problem can be derived from paragraph [4] which is presented wrongly as reflecting the background of the invention and moreover without relationship to the solution presented thereafter in the patent description.

Another technical problem was submitted by the appellant, that of avoiding unwanted ingress of air into the infusion bag. Unlike the systems disclosed in D6 or D7 which are provided with check valves, the non-vented spike according to the patent has only one fluid injection port without air supply control. In the Board's view, avoiding ingress of air is not an acceptable objective problem for the following reasons.

The risk of air entering the infusion container is relied upon as well in D6 (see column 1, lines 36 to 37 and lines 47 to 53) as in D7 (column 2, lines 7 to 8 and column 3, lines 55 to 56). However the means proposed for solving this problem differ on several counts. In D6 the solution consists in adding a separate injection passage 34 (dual flow device) for injecting liquid additives into the bottle (see column 1, line 64 to column 2, line 6) without having to remove the filter at the air inlet 28 which is provided with a ball valve (see column 2, lines 47 to 49 and column 3, lines 35 to 38). In D7 a sealing tab 18 (adhesive seal) is used to cover an air filter cap 28 (see column 2, lines 7 to 8 and column 3, lines 53 to 56). However the problem of avoiding air ingress during administration of the drug is neither mentioned

nor derivable from the contested patent and no other means than a membrane 17 is provided, which reseals when the needle is withdrawn. Such a membrane is also present in D6, with the same purpose (see column 3, lines 55 to 60).

2.4 Inventive step

When assessing the inventive step of the claimed subject-matter, the only question to be answered is whether starting from the method for administrating a drug disclosed in D6 using a device suitable for administrating a toxic fluid, the person skilled in the art would be prompted to use an infusion bag instead of a bottle. In the Board's findings such replacement appears to be obvious for the following reasons.

First, flexible plastic containers have been known since the 1970's, in particular standard bags as referred to in the background of the contested patent (see paragraphs [4] and [5]). This is confirmed by the Baxter history related in an article provided both by the respondent in its written submissions and by the appellant at the oral proceedings.

Second, the use of a collapsible bag in combination with a non-vented spike is already acknowledged in the background of D7 (see column 1, lines 17 to 33 and lines 49 to 55). In particular it is stated there that when a collapsible fluid containing container is used, spikes do not need to include a vent. In other words, the replacement of a rigid container by a collapsible bag - the two alternatives were equally practised at the filing date of D7 (see column 1, lines 29 to 33) -

implies that not only the rigid container but also the associated air duct be replaced (useless in the case of a collapsible bag), which eliminates at the same time eventual leakage problems related to the check valve. It results that the choice of a plastic bag and the suppression of a vent provided with a check valve are actually parts of the same modification.

For all these reasons, the Board is satisfied that the method claim according to the main request does not involve an inventive step within the meaning of Article 56 EPC in view of the disclosure of D6 in combination with the general knowledge of a person skilled in the art.

3. *Auxiliary request*

The replacement of "a drug" by "a toxic fluid" in claim 1 of the auxiliary request has no impact on the steps of the administrating method or the use of the infusion device, already qualified as suitable for administrating a toxic fluid in claim 1 of the main request. Therefore, although the modification made to claim 1 seems to be scope limiting, it does not actually limit the use of the device. The limitation, if any, is only of form. Stated differently, the steps of the method are not modified by the specification of the toxic character of the fluid administrated to the bag.

Moreover, it was not possible to clearly identify from the description of the patent which feature was particularly adapted to the purpose of administrating a toxic fluid. Finally, the specification of a cytotoxic

drug or an antiviral antibiotic is presented in claim 1 as optional ("such as"; "or"). These known substances, therefore, can be ignored when assessing the inventive character of the claimed solution.

It results therefrom that the above reasoning and conclusion made in relation to the main request apply similarly to claim 1 of the auxiliary request. Its subject-matter, therefore, does not involve an inventive step either.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Sauter M. Noël