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**Datasheet for the decision
of 3 April 2008**

Case Number: T 1396/07 - 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:

EPC Art. 123(2), (3), 111

Relevant legal provisions (EPC 1973):

EPC Art. 54(1), (2), 84

Keyword:

"Novelty - no (main request and auxiliary requests 1 to 3)"

"Added subject-matter - yes (auxiliary request 4)"

"Remittal to the first instance (auxiliary request 5)"

Decisions cited:

G 0002/88

Catchword:

-



Case Number: T 1396/07 - 3.2.02

DECISION
of the Technical Board of Appeal 3.2.02
of 3 April 2008

Appellant I: Modiano, Micaela Nadia
(Opponent) Modiano, Josif, Pisanty & Staub Ltd.
Baaderstrasse 3
D-80469 München (DE)

Representative: Johnson, Terence Leslie
Marks & Clerk
90 Long Acre
London WC2E 9RA (GB)

Appellant II: Carmel Pharma AB
(Patent Proprietor) P.O. Box 5352
SE-402 28 Göteborg (SE)

Representative: Inger, Lars Ulf Bosson
Valea AB
Lindholmospiren 5
SE-417 56 Gothenburg (SE)

Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
27 June 2007 concerning maintenance of European
patent No. 0948371 in amended form.

Composition of the Board:

Chairman: T. Kriner
Members: R. Ries
A. Pignatelli

Summary of Facts and Submissions

- I. By its interlocutory decision posted on 27 June 2007, the opposition division decided to maintain the European patent No. 0 948 371 in amended form according to the second auxiliary request then on file. The claims as granted had been refused for lack of novelty of the claimed subject matter, whereas the first auxiliary request was not admitted to the proceedings as it was held late filed.
- II. The patentee (appellant I) lodged an appeal against this decision by notice received on 27 August 2007 and paid the appeal fee on the same day. A statement setting out the grounds of appeal was filed on 29 October 2007.
- III. Notice of appeal against this decision was also lodged by the opponent (appellant II) on 22 August 2007, and the appeal fee was paid on the same day. A statement setting out the grounds of appeal was submitted on 22 October 2007.
- IV. On appeal, essentially the following documents have been relied upon by the parties:
- D5: SE-B-437 700 & EP-A-0 126 718
D6: US-A-3 822 700
D7: US-A-4 857 068
- V. As to acceding to the patent proprietor's request for accelerated prosecution of the case set out in its letter dated 29 October 2007, oral proceedings as

requested by both parties were held before the Board on 3 April 2008.

The following requests were made:

The patentee requested that the decision under appeal be set aside and the patent be maintained as granted (main request), or on the basis of one of the auxiliary requests 1 to 4 filed on 3 March 2008 or of auxiliary request 5 filed during the oral proceedings.

The patentee's former request to disregard document D6 was withdrawn at the oral proceedings.

The opponent requested that the decision under appeal be set aside and that the European patent No. 0 948 371 be revoked.

VI. The single claim as granted (main request) reads:

"Device for administering a toxic fluid, comprising an infusion device (10) for connection to an infusion bag, which 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 administered, **characterized in, that** the connection is provided with at least one membrane (17), which is air tight and penetrable by an injection needle."

Compared thereto, the claims set out in the first to fourth auxiliary requests read (amendments in bold letters):

First auxiliary request:

"... that the connection is provided with at least one **uninterrupted** membrane (17), which..."

Second auxiliary request:

...needle, **the said connection (16) constituting the sole connection for supplying fluid to the ventilating duct (14) from outside of the infusion device (10) via the infusion device.**"

The claim of the third auxiliary request includes the amendments of those of the first and second auxiliary requests.

Fourth auxiliary request:

"...air tight, **thereby preventing any air flow both in a direction from the outside of the device to the inside of the device and from the inside of the device to the outside of the device when the device is connected to the bag,** and penetrable by an injection needle."

Fifth auxiliary request:

"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 administered to the infusion bag by penetrating said at least one membrane (17) by the injection needle."

VII. The arguments of the appellant I are summarised as follows:

The patent addressed the problem of eliminating the risk of contaminating the ambient breathable air by a toxic drug, such as cytotoxic drugs or antiviral antibiotics, when the drug was supplied to a flexible infusion bag of standard type prior to its use. This was achieved by the single connection (16) which was closed at its end with an airtight membrane and

attached to the insertion portion (11) of the device depicted in Figure 1 of the patent. Any kind of fluid supplied to the infusion liquid was injected through this single access point i.e. membrane (17), via a needle mounted on a syringe piercing the membrane. When the needle was withdrawn, the membrane re-sealed and closed the connection. Contrary to the solution dispenser shown in D6, the claimed device did not include an additional air-inlet nipple that was closed with a ball check valve for admitting air to the infusion bottle as shown in Figure 2 of D6. If, however, a flexible collapsible infusion bag of standard type was used, pressure could be exerted on the bag by pressure cuffs forcing the toxic liquid to seep through the ball check valve and to come into contact with breathable air. The risk of seepage or leakage through the ball check valve was specifically referred to in document D7, column 7, lines 49 to 52. To overcome this problem, D7 advocated the use of a replaceable sealing tab member (18) to be used in combination with a check valve to prevent leakage or seepage of fluid from collapsible containers. Hence any dispenser comprising two ports, as did the infusion dispenser of D6, was not suitable for supplying a toxic fluid of the type identified in the patent, since it did not reliably solve the problem. Consequently the claimed subject matter was novel over D6.

The amendments to the claim of the fourth auxiliary request were unambiguously derivable from the application documents as a whole and by the function of the airtight membrane. Therefore the claim of the fourth auxiliary request satisfied the requirements of Article 123(2), (3) EPC.

As to the fifth auxiliary request, the following was noted: At the time of D6 only infusion bottles were known, before the advent of the collapsible and flexible fluid containers used today. An essential difference between the method for using the claimed device and the usage of the device described in D6 resided in that the claimed apparatus for administering a toxic drug was connected to a collapsible (standard) infusion bag. Such a flexible bag always comprised two pierceable stoppers, one for being connected to the infusion device and another e.g. for supplying additive drugs or even air. The claimed method eliminated the need for administering toxic additives through one stopper of the bag and the problems of leakage associated therewith. Another difference to D6 was brought about by administering the toxic drug to the infusion bag prior to infusion rather than when the device was already in use, as set out in D6, column 2, lines 21 to 23.

As regards in particular the passages [0010] and [0011] of the patent specification describing the use of the claimed device including two membranes, the patent proprietor, by referring to document D5, explained that piercing the membrane by the injection needle was carried out in that embodiment in combination with the specific sealing device depicted in Figures 1 and 2 of D5 and also comprising a membrane. In so doing the safety level when administering toxic fluid was further enhanced.

VIII. The arguments of the appellant II are summarised as follows:

Document D6 related to an intravenous solution dispenser which solved the same technical problem as it was addressed in the patent specification, i.e. supplying drugs to a standard infusion bag or bottle through a pierceable re-sealable diaphragm. The known device was provided with an insertion portion (18) for connecting the device to the stopper of a bag or bottle. Spike (16, 18) comprised a liquid conduit (2) allowing flow of the infusion liquid from the bottle to the drip chamber and a passage for air (26) (ventilating duct) ending (a) in connection (34) (air inlet nipple 28) and (b) passageway (36) closed at its end by a pierceable re-sealable and air-tight diaphragm through which additives could be made via a syringe having a needle thereon. In its use, the known device was not restricted to any type of drug, toxic or non-toxic. Depending on the patient's needs, the physician could supply whatever additive to an infusion liquid stored in any kind of infusion container. Hence, the subject matter of the claims according to the main and first to fourth auxiliary requests lacked novelty over the disclosure of document D6.

By the amendments to the claim of the fifth auxiliary request, the focus of the opposed patent was shifted to "another invention" that was neither discussed in the opposition proceedings nor reflected in the impugned decision. However, the device known from D6 worked in the same way and could be used either prior or after the infusion at any stage. Moreover, collapsible standard infusion bags did not necessarily comprise two

stoppers, as alleged by the patentee at the oral proceedings. Contrary thereto, collapsible bags with only one stopper existed.

Reasons for the Decision

1. The appeals are admissible.
2. Main request, first to third auxiliary requests;
novelty (Article 54(1), (2) EPC 1973)
 - 2.1 Like the patent at issue, document D6 relates to a device for administering a fluid (in particular an intravenous injection dosing device in the field of surgery and health care; see D6, column 1, paragraph 1). The perspective view of the embodiment that is depicted in Figure 2 and described in the corresponding passage in D6, column 3, lines 15 to 60 discloses that this device comprises
an infusion device (10, 12, 14) provided with an insertion portion in the form of a piercing pin or spike (16, 18) suitable for connecting the device 10 to a standard infusion bottle or bag (not shown),
an infusion chamber (drip chamber 22) for dosing a fluid flow via a flow duct (20) in the insertion portion (spike 16) from the bottle or bag to an outlet arranged on the chamber (12, 14, 22),
the insertion portion also comprising a ventilating duct (passage for air 26 in the spike 16) extending between the infusion bottle or bag and the outside of the infusion device and ending among other things in a connection (injection nipple 34) arranged on the side of the infusion device (attached to the body 10) for

supplying fluid to be administered, whereby the end of the connection is closed with a cap (38) including a pierceable, re-sealable membrane (diaphragm 40 made of rubber) thereon.

Due to the nature of the rubber diaphragm in the cap, the fact that the ingress of air, if any, is admitted through the separate air inlet nipple (28), and by the absence of any information to the contrary, the air-tightness of diaphragm (40) is duly assumed. If additives, albeit of toxic, non-toxic or whatever nature (e.g. an emergency drug; see D6, column 2, line 47), for modifying the solution are to be made when the device is in use, they can readily be supplied by piercing the diaphragm with a needle mounted on a syringe. Withdrawing the needle from the diaphragm (40) re-seals passageway (36).

2.2 The patent proprietor argued that the intravenous injection device of D6 was not suitable for supplying a toxic fluid since it included a ball check valve for admitting air. He pointed in this context to document D7, column 3, lines 30 to 40 and 49 to 52 showing that ball check valves run the risk of seepage and leakage of toxic fluid from rigid or collapsible containers thereby contaminating the breathable air and leading to health problems of the exposed personnel. To eliminate this problem, the claimed device did not comprise a ball check valve which was superfluous anyway when using a collapsible standard fluid dispensing bag which did not require pressure compensation.

2.3 To the Board these arguments are not convincing. As for the question of novelty, the claimed device has to be

considered per se, independently from the type of standard infusion container the device could be connected to.

Moreover, the check valve in D7 is located in the vent passage for exactly the same reason as in D6, i.e. in order to prevent fluid from leaking or seeping out of the dispensing container when the air filter is removed. In the exceptional case when external pressure is exerted on the collapsible fluid container by employing a pressure cuff, fluid could be forced by the high pressure past the check valve, and only in this case is an additional sealing tab used. Contrary to D7, the device of D6 is described as being used essentially in combination with an (incompressible) bottle, and since no pressure is exerted on the liquid, the ball check valve could admit air to the bottle and prevent fluid flow from the bottle without running the risk of seepage (see D6, column 3, lines 35 to 37).

Moreover, and contrary to the patentee's allegations, an adjustable port for supplying air (as for instance shown in D6) could also be mounted on the connection attached to the ventilating duct of the claimed device. As the patent teaches in paragraph [0009], this makes it possible to obtain a controllable supply of air to the bag so that the infusion fluid can evacuate from the bag in a controllable way. It can therefore be concluded that the claimed device is or at least would also be provided for use in combination with rigid fluid containers such as standard infusion bottles which require pressure compensation by supplying air to the device.

The Board also notes that the (toxic or non-toxic) drug is supplied to the injection dosing device of D6 in exactly the same manner as described in the patent: in both cases the rubber membrane is penetrated with an injection needle and the drug is supplied. Upon withdrawing the needle, the membrane (or the two membranes) reseal(s) and close(s) the injection duct (see the patent specification paragraphs [0006], [0011]). Nothing is found anywhere in document D6 which leads to the conclusion or implication that the device depicted in Figure 2 is restricted to particular types of drugs or would be totally unsuited for supplying a "toxic" fluid.

Given that a distinction between the claimed and the known device is not discernable, the device set out in the claim as granted is completely anticipated by the disclosure of D6.

The subject matter of the single claim according to the main request therefore lacks novelty over D6.

- 2.4 Due to the absence of any contrary information, the membrane or diaphragm used in D6 satisfies the requirements of being "uninterrupted" and "constituting the sole connection for supplying fluid to the ventilating duct", as set out in the claims according to the first to third auxiliary requests.

It is noted in this context that the term "fluid" featuring in the characterizing part of the single claim of the second and third requests is understood as being the toxic drug or additive that is supplied to

the ventilating duct rather than any other fluid, as for instance air.

Hence the subject matter of these claims also lacks novelty over D6.

3. Fourth auxiliary request:

3.1 The feature added to the characterizing part of the single claim of the fourth auxiliary request (see bold letters in section VI above) is not described anywhere in the documents as originally filed. Contrary to the patentee's allegation it is not unambiguously and clearly derivable from the patent specification as a whole that the supply of air to the device from the outside is totally excluded.

3.2 In the Board's understanding, it also remains unclear whether the feature should relate exclusively to the membrane or to the device as a whole. In the first case, no difference in function is seen to the rubber membrane of the device known from D6 which, like in the patent at issue, re-seals the injection port 36 upon withdrawing the needle. If, on the other hand, the ingress of air into and out of the device as a whole is meant, the feature is contradictory to the explanations of Figure 1 given in paragraph [0009] of the patent specification and describing a "ventilating duct" which makes it possible to obtain a controllable supply of air to the infusion container.

Hence, the addition of this feature to claim 1 of the fourth auxiliary request contravenes the requirements of Articles 123(2) EPC and 84 EPC 1973.

4. Fifth auxiliary request:
 - 4.1 The claim of the fifth auxiliary request relates to a method for administering a drug to the infusion liquid contained in an infusion bag by using the claimed device, as it is described in the passages [0010] and [0011] of the patent specification. Having regard to considerations given in the Enlarged Board decision G 2/88, the change of category from a product claim to a use claim does not contravene the requirements of Article 123(3) EPC.
 - 4.2 However, based on the explanations of the patent proprietor, the amended claim shifts the focus of the patent specification from an infusion device comprising an air-tight penetrable and re-sealable membrane to a method for using the device in combination with a (collapsible) infusion bag, and the problems associated therewith, rather than with a (rigid) infusion bottle of standard type as in D6. These hitherto unknown problems are neither elucidated anywhere in the specification nor immediately apparent to the skilled reader. This aspect of the patent at issue has not been considered in the impugned decision either. Thus, the amendments to the claim of the fifth auxiliary request made at the appeal stage have changed the factual framework of the contested decision.
 - 4.3 For these reasons and to guarantee rights of the parties to appeal against the decision based on new facts, the Board exercises its power under Article 111(1) EPC to remit the case to the first instance for further prosecution on the basis of this request.

Order

For these reasons it is decided that:

The case is remitted to the department of first instance for further prosecution.

The Registrar:

The Chairman:

V. Commare

T. Kriner