

Internal distribution code:

- (A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

**Datasheet for the decision
of 18 June 2015**

Case Number: T 1618/12 - 3.3.07
Application Number: 04798564.3
Publication Number: 1701701
IPC: A61K9/12, A61P9/14, A61M5/155,
A61M5/19
Language of the proceedings: EN

Title of invention:
METHODS OF PREPARING A FOAM COMPRISING A SCLEROSING AGENT

Patent Proprietor:
BTG International Limited

Opponents:
CHEMISCHE FABRIK KREUSSLER & CO. GMBH

Headword:
METHODS OF PREPARING A FOAM COMPRISING A SCLEROSING AGENT/BTG
International Limited

Relevant legal provisions:
RPBA Art. 13
EPC Art. 56, 123(2)

Keyword:
Admission of auxiliary requests 1-3 - (yes)
Inventive step - main request and auxiliary requests 1 and 2 -
(no)
Inventive step - auxiliary request 3 - (yes)
Amendments - added subject-matter (no)

Decisions cited:

Catchword:



Beschwerdekammern
Boards of Appeal
Chambres de recours

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 1618/12 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 18 June 2015

Appellant:
(Opponent 2)

CHEMISCHE FABRIK KREUSSLER & CO. GMBH
Rheingaustrasse 87-93
D-65203 Wiesbaden (DE)

Representative:

Von Kreisler Selting Werner - Partnerschaft
von Patentanwälten und Rechtsanwälten mbB
Deichmannhaus am Dom
Bahnhofsvorplatz 1
50667 Köln (DE)

Respondent:
(Patent Proprietor)

BTG International Limited
5 Fleet Place
London EC4M 7RD (GB)

Representative:

Finnegan Europe LLP
16 Old Bailey
London EC4M 7EG (GB)

Decision under appeal:

**Interlocutory decision of the Opposition
Division of the European Patent Office posted on
4 May 2012 concerning maintenance of the
European Patent No. 1701701 in amended form.**

Composition of the Board:

Chairwoman R. Hauss
Members: D. Boulois
P. Schmitz

Summary of Facts and Submissions

- I. European patent No. 1 701 701 based on application No. 04 798 564.3 was granted on the basis of a set of 23 claims.
- II. Two oppositions were filed under Article 100(a) and (b) EPC on the grounds that its subject-matter lacked novelty and inventive step and was not sufficiently disclosed.
- III. One of the opponents later withdrew its opposition.
- IV. The documents cited during the opposition proceedings included the following:
(1): WO 00/72821
- V. The appeal by the remaining opponent lies from the decision of the opposition division concerning the maintenance of the patent in amended form. The decision was based on the set of claims filed during the oral proceedings of 28 March 2012 as main request.

Independent claims 1, 5 and 9 of the main request read as follows:

"1. A method of making a foam comprising providing two syringes, wherein syringe one is charged with a liquid phase and syringe two is charged with a gas phase, syringe one is charged with the liquid phase and the gas phase, or both syringes are charged with the liquid phase and the gas phase; and transferring the liquid phase and the gas phase repeatedly between the syringes via a connector to form a foam, wherein

the liquid phase comprises at least one sclerosing agent and
the gas phase consists of at least one physiologically acceptable gas consisting of 60 to 90% vol/vol oxygen and 40 to 10% vol/vol carbon dioxide, together with gaseous nitrogen present in an amount ranging from 0.01% to 0.8% by volume."

"5. A method of making a foam comprising:
(a) providing a syringe comprising a barrel, a first plunger and a second plunger, the second plunger having an apertured plunger head which is adapted to be movable within the barrel independently of the first plunger, the syringe being charged with a liquid phase and a gas phase; and
(b) oscillating the second plunger to form a foam;
wherein
the liquid phase comprises at least one sclerosing agent and
the gas phase consists of at least one physiologically acceptable gas consisting of 60 to 90% vol/vol oxygen and 40 to 10% vol/vol carbon dioxide, together with gaseous nitrogen in an amount ranging from 0.01% to 0.8% by volume."

"9. A sterile pack comprising:
substantially gas-impermeable packaging containing a syringe charged with at least one liquid sclerosing agent and a gas mixture consisting of 0.01% to 0.8% by volume gaseous nitrogen and with the balance being 60 to 90% vol/vol oxygen and 40 to 10% vol/vol carbon dioxide;
wherein the gas atmosphere inside the packaging has substantially the same composition as the gas mixture in the syringe."

VI. According to the decision under appeal, the composition of the gas phase as recited in claims 1, 5 and 9 did not constitute a selection from various lists and the main request met the requirements of Article 123(2) EPC.

As claims 1 and 5 of the main request disclosed the relative amounts of the gases present and all other essential steps for producing the foam, the invention was considered to be sufficiently disclosed.

Document (1) did not disclose a gas phase having the required amounts of oxygen and carbon dioxide together with gaseous nitrogen in an amount ranging from 0.01% to 0.8% by volume. The subject-matter of the main request was thus novel.

Document (1) was chosen as closest prior art, as it was aiming at the same objectives as the claimed invention, i.e. the reduction of gas embolism in sclerotherapy by controlling the composition of the gas phase that is used for the production of the sclerosing foam. The subject-matter of claims 1, 5 and 9 differed from document (1) in the gas phase, in particular owing to the content of nitrogen in the gas phase, which ranged from 0.01% to 0.8% by volume. According to document (8) and to the submissions made by the patentee with letter dated 14 March 2011, the method according to the opposed patent provided a sclerosing foam, "Varisolve B", which reduced the occurrence as well as the number of gas bubbles in the blood stream when compared to foams of the prior art, i.e. a foam produced with air or the foam "Varisolve A". The technical problem was seen as the provision of a method for producing a foam with reduced risk of embolism for use in sclerotherapy. Having regard to the evidence provided, the problem was

considered to be solved. Since the skilled person would have found no incentive in the prior art to reduce the nitrogen content below the lowest level disclosed in document (1), the claimed subject-matter was non obvious and involved an inventive step.

VII. The opponent (appellant) filed an appeal against said decision.

VIII. With a letter dated 23 January 2013, the respondent (patent proprietor) filed auxiliary requests 1-5. Additionally, it submitted several pieces of evidence among which:

(18): Standard Handbook of Biomedical Engineering and Design (McGraw-Hill 2004), 23.1-23.13

IX. With a letter dated 19 May 2015, the respondent submitted new auxiliary requests I to III in replacement of the previous auxiliary requests. Additionally, it submitted that no grounds of appeal had been presented against the maintenance of claims 5-11.

The subject-matter of the claims of the main request was the same as the claims of the request underlying the decision of the opposition division.

The subject-matter of independent claims 1 and 2 of auxiliary request I was identical to the subject-matter of claims 1 and 5 of the main request with the following additional feature:

"and the method comprises passing a mixture of the gas and liquid phase through one or more passages having at least one cross-sectional dimension of from 0.1 to 15 μm , the ratio of gas to liquid being controlled such that a foam is produced having a density of between

0.07 g/mL to 0.19 g/mL and a half-life of at least 100 seconds".

The subject-matter of independent claim 3 of auxiliary request I was identical to the subject-matter of claim 9 of the main request.

The subject-matter of claims 1 and 5 of auxiliary request II was the same as the subject-matter of claims 5 and 9 of the main request.

The subject-matter of claim 1 of auxiliary request III was the same as the subject-matter of claim 9 of the main request.

- X. In a communication dated 1 June 2015 sent in preparation of oral proceedings, the board gave its preliminary opinion. In particular, it stated that the contested patent did not provide any evidence that the technical problem as defined by the respondent had been solved, and that there was no comparison available with the very similar process of preparation used in document (1). In the absence of the demonstration that the alleged technical effect could be reached, the problem might have to be reformulated as the provision of an alternative process of preparation of a foam.
- XI. Oral proceedings took place on 18 June 2015.
- XII. The arguments of the appellant may be summarized as follows:

Amendments

The subject-matter of all requests did not meet the requirements of Article 123(2) EPC, since no basis could be found for the gas concentrations in the

claims, in particular not the combination of the amount of gaseous nitrogen with the amounts of oxygen and carbon dioxide. Paragraph [0139] of the application WO2005/048984 as published gave 5 possibilities for the amounts of gaseous nitrogen ranging from 0.0001%-0.8% to 0.01%-0.6%, while paragraph [0083] gave 4 possibilities for the amounts of oxygen and carbon dioxide, ranging from 99% of oxygen to 50% or more of carbon dioxide. The combination of values resulted in a high number of possibilities, from which the claimed subject-matter constituted a selection, which did not meet the requirements of Article 123(2) EPC.

Inventive step

Document (1) had to be considered as the closest prior art, since this document addressed the same problem as the contested patent, namely the reduction of the amount of nitrogen in the disclosed sclerosing foam. The claimed gas composition was disclosed on page 8, where it was specified that the presence of nitrogen had to be avoided in the gas composition. Said passage mentioned that oxygen could be used to an amount of 99% or more, leaving thus the concentration of nitrogen between 0% and 1%. The choice of the claimed nitrogen concentration from 0.01% to 0.8% was therefore obvious in view of this disclosure.

It was not possible to differentiate between the processes disclosed in examples 5 or 6 of document (1) and the processes claimed by the present request, since both processes occurred in open atmosphere.

XIII. The arguments of the respondent may be summarized as follows

Amendments

A basis for the amendment of the composition of the gas phase could be found in paragraphs [0033] and [0034] of the application WO2005/048984 as published as regards the nitrogen content and [0083] as regards the oxygen and carbon dioxide content.

Inventive step

Document (1) did not enable a nitrogen content of 0.01% to 0.8% by volume. The experiments of the letter dated 23 January 2013 showed that the gas compositions of examples 1 and 2 of document (1) resulted in, at best, a nitrogen content of 2.5% by volume for a purged and pressurized canister, even when the nominal gas composition was 100% medical grade oxygen. On this basis, a purge applied to the syringe embodiment of document (1) would have resulted in a nitrogen content of about 6.5% by volume.

Document (1) did not contain any teaching that would have allowed the skilled person to identify residual nitrogen content as a potential problem, nor how to determine the nitrogen content of the foam, nor any indication of what action to take to further reduce the nitrogen content if said nitrogen level was considered too high.

The difference between the subject-matter of the main request and the teaching of document (1) was the composition of the gas in the syringe, especially with regard to the nitrogen concentration. Document (1) was silent about this feature, and the process of examples 5 and 6 was performed with a source gas, without mentioning the amount of air present in the syringe.

There was no recognition of the problem linked with the presence of nitrogen. If the skilled person could control the source gas, he would also have been able to control the final amount of gas in the final foam. By the claimed method, it was to be expected that the final amount of nitrogen would have been lower in the injectable foam. The invention lay thus in the starting product.

XIV. Requests

The appellant requested that the decision under appeal be set aside and that the patent be revoked. Additionally, the appellant requested that auxiliary requests I to III filed with the respondent's letter of 19 May 2015 not be admitted into the proceedings.

The respondent requested that the appeal be dismissed, alternatively, that the patent be maintained according to one of the sets of claims filed as auxiliary requests I to III with letter of 19 May 2015.

Reasons for the Decision

1. Main request - Inventive step
 - 1.1 The invention relates to the generation of a foam comprising a sclerosing material, particularly a sclerosing solution, which is suitable for use in the treatment of various medical conditions involving blood vessels, particularly varicose veins and other disorders involving venous malformation (see par. [0002] of the specification EP 1 701 701 B1).

It intends in particular to develop a technique for manufacturing a safe foam product. It has indeed been determined that the amount of gaseous nitrogen in the injected foam plays a paramount role in the formation and persistence of bubbles in blood and the consequent occurrence of side effects, in particular embolism. Bubbles have been observed on the left side of the heart in a patient who was subsequently shown to have a minor septal defect, or patient foramen ovale ("PFO"), i. e. a hole in the heart. It has thus been determined, that, in order to produce a product suitable for administration to patients without the need for lengthy PFO screening methodology, it is required to reduce the amount of nitrogen in the injected microfoam to upper limits that were previously unrecognised (see par. [0020]-[0031] of the specification).

The invention intends also to provide a technique for manufacturing a foam by a less expensive option than techniques using a canister product (see par. [0033]-[0034] of the specification).

- 1.2 Document (1) was seen as the closest prior art by the appellant and the respondent.

Document (1) relates to the generation of a microfoam comprising a sclerosing material, particularly a sclerosing liquid, which is suitable for use in the treatment of various medical conditions involving blood vessels, particularly varicose veins and other disorders involving venous malformation (see page 1). The foam is produced by mixing the sclerosant liquid with a blood dispersible gas.

This document recognizes that large volumes of nitrogen should not unnecessarily be introduced into patients, particularly where large vessels are being filled with foam and eliminated (see page 3). One of the preferred source gas composition disclosed in document (1) is a gas comprising 60 to 90% vol/vol of oxygen with 40 to 10% vol/vol of carbon dioxide (see page 9).

The device for manufacturing the foam can be in the form of a syringe (see page 18), comprising especially chambers comprising the liquid and the gas, which are passed through a passage of defined dimensions a desired number of times to produce the foam.

In example 5 (see pages 26-27 and Figure 3), a series of three spaced meshes is located between the plunger sealing face and luer opening. The luer of the syringe is attached to a source of undefined gas and the plunger withdrawn to admit a required amount of said gas into the syringe chamber containing the sclerosing solution. A macrofoam is produced by agitation. By depressing the plunger with even pressure, the macrofoam is converted to a microfoam. Example 5 discloses further that the microfoam can be transferred to a second syringe, and passed between the two chambers of the syringes via the meshes in order to render the microfoam more uniform in nature.

The syringe used in example 6 (see pages 27-28 and Figure 4) is a syringe comprising a plunger which defines the chamber comprising the liquid phase. Passing down the longitudinal axis of said plunger is a rod mounting a porous membrane with a handle located outside the syringe chamber, which allows the porous membrane to be moved independently of the plunger, so as to force the contents of the chamber to pass through

its pores. For the production of the foam, the luer is attached to a source of gas and the plunger withdrawn to admit the required amount of gas, which is undefined in example 6. The handle of the rod is then operated to pass the membrane up and down the chamber a number of times, causing the gas and liquid to mix and produce a foam.

This document does not mention the amount of nitrogen present in the gas phase of the microfoam to be injected.

- 1.3 The technical problem as set out by the respondent is the provision of a method able of making a sclerosing foam with reduced risk of embolism for use in sclerotherapy.
- 1.4 As a solution to this alleged problem, claims 1 and 5 of the main request propose a method of making a foam comprising the involvement of respectively two syringes or one syringe comprising a liquid phase and a gaseous phase wherein in particular the gas phase comprises gaseous nitrogen in an amount ranging from 0.01% to 0.8% by volume.
- 1.5 It has to be investigated whether there is sufficient evidence supporting the alleged effect.
 - 1.5.1 The process of claims 1 and 5 relates to the generation of a foam made originally from a liquid phase comprising a sclerosing agent and an initial gas phase consisting of at least one physiologically acceptable gas consisting of 60 to 90% vol/vol oxygen and 40 to 10% vol/vol carbon dioxide, together with gaseous nitrogen present in an amount ranging from 0.01% to 0.8% by volume.

It must therefore be determined if the claimed processes of claims 1 and 5 involving said initial gas phase are able to provide inevitably a clinically safe sclerosing foam, i.e. a final foam with a low final amount of gaseous nitrogen. A sclerosing foam with a final percentage by volume of nitrogen gas ranging from 0.01% to 0.8% by volume, thus identical to the nitrogen content in the initial gas phase, is considered to be both clinically safe and consistently reproducible.

1.5.2 The respondent mentioned examples 10-12 of the contested patent to demonstrate the existence of the alleged technical effect. In these examples, a polidocanol-filled syringe system is connected through the luer to a source of medical grade oxygen, which has a purity of at least 99.5%. In example 11, a step is performed under vacuum, after that all air has been substantially removed.

However, examples 10-12 do not show the preparation of a foam involving the source gas composition of claims 1 and 5 of the main request, and above all do not give the amount of nitrogen in the final foam obtained under open atmosphere. Said examples do not show or demonstrate that the amount of nitrogen in the final foam is inevitably low, in particular comprised between 0.01% to 0.8% by volume.

These examples and the description of the contested patent do not provide in particular any teaching on how air contamination can be avoided during the syringe process as claimed in claims 1 and 5 of the main request, especially in view of the considerations on this point in the description of the contested patent (see paragraphs [0022], [0087] and [0091] of the specification EP 1 701 701 B1). The description

mentions indeed that the potential for ingress of a small percentage of air/nitrogen during a syringe process is obvious, since the syringe(s) is filled with a medical grade gas, and must then be processed under open atmosphere to obtain the foam. It is not disclosed in the description of the contested patent, in particular in examples 10-12, how the nitrogen level might be controlled under the open atmosphere processes of claims 1 and 5 of the main request.

The processes claimed in claims 1 and 5 do furthermore not comprise any step mandatorily performed under vacuum, so that the process of example 11 cannot be seen as representative of the claimed processes.

Nor is it possible to differentiate the teaching of examples 10-12 of the contested patent from the teaching of examples 5 and 6 of document (1). The syringe systems disclosed in examples 5 and 6 of document (1) are identical to respectively the syringe systems of claims 1 and 5 of the main request, and in both cases the syringes are connected to a source gas through the luer. The control of the gas phase is in both cases only exerted by the source gas.

It is therefore not possible to conclude that the teaching of examples 10-12 provides a support for the alleged technical effect of a final low concentration of nitrogen linked to the process of preparation of the microfoam.

- 1.5.3 As to the respondent's arguments regarding examples 1 and 2 of document (1), which, according to the experiments shown in the letter dated 23 January 2013 reached a nitrogen level of respectively 25% and 2.5% in the foam, they do not appear to be relevant, since

they relate to a method of production of the foam involving a canister system and not a syringe system.

- 1.5.4 The contested patent thus does not provide any evidence that the technical problem has been solved, i.e. that a final foam with a content of nitrogen as low as 0.01 to 0.8% can inevitably be obtained with the claimed processes.

According to the case law of the boards of appeal, alleged advantages to which the patent proprietor merely refers, without offering sufficient evidence to support the comparison with the closest prior art, cannot be taken into consideration in determining the problem underlying the invention and therefore in assessing inventive step. Said technical effect must be established in a plausible way over the closest state of the art.

In the absence of proof that the alleged effect can be achieved, the presence of an improvement over the process disclosed in document (1) cannot be acknowledged, and the technical problem must be reformulated as the provision of an alternative process of preparation of a foam for use in sclerotherapy.

In view of the information found in the examples of the contested patent, the board is convinced that the problem has been solved by the claimed methods.

- 1.6 One of the preferred source gas compositions disclosed in document (1) is a gas comprising 60 to 90% vol/vol of oxygen with 40 to 10% vol/vol of carbon dioxide (see page 9). The skilled person would therefore use this preferred source gas in the syringe methods disclosed on page 18 and would also see this source gas as an gas

which could be used in examples 5 and 6 of document (1) to make a foam for use in sclerotherapy. The source gases used in sclerotherapy in document (1) as well as in the contested patent are of a medical grade, thus with a purity grade of at least 99.5%, and thus containing less than 0.5% of nitrogen (see contested patent, par. [0037], [0076], examples 10-12).

1.7 Without evidence of a specific technical effect, the solution of using the particular source gas of claims 1 and 5 containing 0.01 to 0.8% of nitrogen, must be regarded as an arbitrary variation, known from document (1).

1.8 As a consequence, the subject-matter of claims 1 and 5 of the main is not inventive and this request does not meet the requirements of Article 56 EPC.

2. Admission of auxiliary requests I-III into the proceedings

Auxiliary requests I-III have been filed with the letter dated 19 May 2015, shortly before the oral proceedings, thus late in the proceedings.

2.1 Auxiliary request I

The subject-matter of independent claims 1 and 2 of auxiliary request I is identical to the subject-matter of claims 1 and 2 of auxiliary request IV filed with the the response to the statement setting out the grounds of appeal and the subject-matter of independent claim 3 of auxiliary request I is identical to the subject-matter of claim 9 of the main request on which the decision of the opposition division was based.

The subject-matter of claims 1 and 2 of this request corresponds thus to the subject-matter of an auxiliary request filed at the earliest possible stage of the appeal proceedings. The amendments made to claims 1 and 2 are also of a simple and clear nature and *prima facie* address the issues raised by the appellant's objections. Thus, this request is admitted into the proceedings (Article 13 RPBA).

2.2 Auxiliary requests II and III

The subject-matter of claims 1-4 and 5-7 of auxiliary request II corresponds to the subject-matter of claims 5-8 and 9-11 of the main request, and the subject-matter of claims 1-3 of auxiliary request III corresponds to the subject-matter of claims 9-11 of the main request on which the decision of the opposition division was based. There is thus no reason not to admit these requests into the proceedings, since they cannot give rise to new unexpected issues (Article 13 RPBA).

3. Auxiliary request I - Inventive step

The subject-matter of the process claims 1 and 2 of auxiliary request I corresponds to claims 1 and 5 of the main request amended by the following feature:
"the method comprises passing a mixture of the gas phase and liquid phase through one or more passages having at least one cross-sectional dimension of from 0.1 to 15 μm , the ratio of gas to liquid being controlled such that a foam is produced having a density of between 0.07 g/mL to 0.19 g/mL and a half-life of at least 100 seconds".

Document (1) provides a method for producing a microfoam that comprises *"passing a mixture of a physiologically acceptable blood dispersible gas and an aqueous sclerosant liquid through one or more passages having at least one cross-sectional dimension of from 0.1 to 30 μm , the ratio of gas to liquid being controlled such that a microfoam is produced having a density of between 0.07 g/ml to 0.19 g/ml and a half-life of least 2 minutes"* (see document (1), pages 7, 14, 17). The measures added to claims 1 and 2 of this request are thus known from document (1).

The amended feature does thus not provide a further difference with regard to the teaching of document (1) and therefore cannot affect the reasoning and conclusions on inventive step as set out above for the main request. As a consequence, claims 1 and 2 of auxiliary request I do not meet the requirements of Article 56 EPC.

4. Auxiliary request II - Inventive step

Since claim 1 of auxiliary request II corresponds to claim 5 of the main request, the objection raised against claim 5 of the main request apply equally for claim 1 of this request, which therefore does not meet the requirements of Article 56 EPC.

5. Auxiliary request III

5.1 Extent of appeal

The subject-matter of claim 1-3 of auxiliary request 3 corresponds to claims 9-11 of the main request and relates to a product, namely a sterile pack comprising a syringe charged with a liquid agent and a gas mixture

in a gas atmosphere identical to the gas mixture in the syringe.

The appellant submitted that no grounds of appeal had been presented against the maintenance of these claims, since no objections against claim 9 of the main request were raised in the statement of grounds of appeal.

The Board could not follow this opinion. Given that the decision of the opposition division related to claims 1, 5 and 9 of the request as filed during the oral proceedings which corresponds to the main request submitted in the appeal proceedings (see point 8.1.2 of the decision of the opposition division) and that the request of the appellant was that the decision under appeal be set aside, the product claims 9-11 and consequently claims 1-3 of auxiliary request III are comprised in the extent of the appeal.

5.2 Article 123(2) EPC

The subject-matter of the independent claims of all requests, including auxiliary request III has been objected to by the appellant under Article 123(2) EPC with regard to the claimed gas concentrations.

A basis for the claimed gas composition is disclosed directly and unambiguously in paragraphs [0037], [0033], [0034], [0081]-[0083] and [0137]-[0140] of the application as originally filed (see WO2005/048984). More particularly, paragraphs [0037] and [0083] disclose a gas composition of 60 to 90% vol/vol of oxygen and 40 to 10% vol/vol of carbon dioxide. As regards the amount of 0.01 to 0.8% of nitrogen, this amount is disclosed directly and unambiguously in paragraphs [0137]-[0140], in particular in paragraph

[0139] of the application as originally filed, in relationship with the presence of the gas mixture. This concentration is furthermore present in original dependent claim 19 in relationship with the the syringe comprised in a sterile pack.

For these reasons, auxiliary request III meets the requirements of Article 123(2) EPC.

5.3 Inventive step

5.3.1 The claimed invention of auxiliary request III relates to a sterile pack comprising a syringe that is pre-loaded with a liquid sclerosing agent and a gas mixture consisting of 0.01% to 0.8% by volume gaseous nitrogen and with the balance being 60 to 90% vol/vol oxygen and 40 to 10% vol/vol carbon dioxide.

5.3.2 Document (1) was seen as the closest prior art by the appellant and the respondent. This document does not mention the preparation of a sterile pack comprising one of the syringe systems disclosed therein (see examples 5 or 6, Figure 3 or 4).

5.3.3 The problem as set out by the respondent may be seen in the provision of a pack which does not affect the composition of the gas loaded in the syringe.

5.3.4 As a solution to this alleged problem, claim 1 of auxiliary request III proposes a sterile pack comprising a syringe wherein in particular the pack comprises a gas atmosphere having the same composition as the said gas mixture in the syringe.

5.3.5 Since plastic syringes that are typically used in such pack are normally gas permeable, there is an exchange

between the gas composition filled in the syringe and the gas composition used as gas atmosphere of the sterile pack. This exchange obviously can affect the gas composition filled in the syringe. The use of a identical gas composition in the syringe composition and within the sterile pack annihilates any change in the gas composition filled in the syringe.

In view of this credible technical argumentation, the Board is convinced that the problem has been solved.

5.3.6 It remains to be determined if the claimed solution is obvious.

Sterile packs are not usually filled with a gas mixture comprising a high amount of oxygen, in order to avoid biological contamination and chemical oxidation. Thus, the use of a high oxygen atmosphere in a pack is not within the normal teaching in the art (see for instance document (18), sections 23.1.1 23.4.1 and Table 23.1).

Sterile packs are usually filled with an inert gas, such as nitrogen. The presence of nitrogen in the gas atmosphere of the pack would however increase the concentration of nitrogen in the gas composition of the syringe. An increased amount of gaseous nitrogen in the injected foam is undesirable in view of the possible increased consequent occurrence of side effects, in particular embolism.

The use of a gas atmosphere inside the packaging with simultaneously 60 to 90% vol/vol oxygen and 0.01% to 0.8% vol/vol gaseous nitrogen departs thus from the normal practice of the art of medical sterile packaging and adopts a solution that would normally be avoided.

The solution is therefore not obvious and auxiliary request III meets the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of the claims of auxiliary request 3 and a description yet to be adapted.

The Registrar:

The Chairwoman:



S. Fabiani

R. Hauss

Decision electronically authenticated