Internal distribution code:

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

Datasheet for the decision of 28 January 2015

Case Number: T 0273/11 - 3.3.07

Application Number: 01997296.7

Publication Number: 1337238

IPC: A61K9/12, A61P9/14, B65D83/16, A61M5/31

Language of the proceedings: EN

Title of invention:
GENERATION OF THERAPEUTIC MICROFOAM

Patent Proprietor:
BTG International Limited

Opponent:
CHEMISCHE FABRIK KREUSSLER & CO. GMBH

Relevant legal provisions:
EPC Art. 123(2), 56, 111(1)
RPBA Art. 12(1), 12(4)

Keyword:
Admissibility of main request (yes)
Amendments - added subject-matter (yes)
Admissibility of auxiliary request - (yes)
Inventive step - auxiliary request (yes)

Decisions cited:
J 0006/98, T 0144/09, T 1178/08, T 0040/09

Europäisches Patentamt
European Patent Office
Office européen des brevets

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 0273/11 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 28 January 2015

Appellant: (Patent Proprietor)	BTG International Limited 5 Fleet Place London EC4M 7RD (GB)
Representative:	Finnegan Europe LLP 16 Old Bailey London EC4M 7EG (GB)
Respondent: (Opponent)	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)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 14 December 2010 revoking European patent No. 1337238 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman D. Semino
Members: A. Usuelli
P. Schmitz

Summary of Facts and Submissions

I. The appeal of the patent proprietor (appellant) lies against the decision of the opposition division to revoke European patent No. 1 337 238.

II. The patent was opposed under Article 100(a) EPC on the grounds that its subject-matter lacked novelty and inventive step. The following documents were among those cited during the opposition proceedings:

D1: WO 00/66274
A3: English translation of D1
D6: US 5,071,379

III. The opposition division's decision was based on a main request and two auxiliary requests. Said requests were filed with letter dated 17 September 2010 as auxiliary requests 2 to 4. During the oral proceedings held on 18 November 2010, some pending requests were withdrawn and auxiliary requests 2 to 4 became the main request and auxiliary requests 1 and 2.

IV. In its decision the opposition division came to the conclusion that claim 1 of the main request was obvious in the light of the teaching of document D1. Claim 1 of the auxiliary requests likewise did not comply with the requirements of Article 56 EPC in view of the combined teachings of documents D1 and D6.

V. The appellant lodged an appeal against that decision. With the statement setting out the grounds of appeal filed with letter dated 22 April 2011, he submitted a set of claims as main request and three sets of claims as first to third auxiliary requests.

VI. With letter of 17 December 2014 the appellant re-submitted the main request filed with the statement setting out the grounds of appeal and filed eleven additional sets of claims as auxiliary requests I to XI. These sets of claims included previous first, second and third auxiliary requests which were renamed respectively as auxiliary requests III, VI and IX.

Claim 1 of the main request read as follows:

"A device for producing a microfoam suitable for use in scleropathy of blood vessels, comprising

a housing in which is situated a pressurisable chamber containing a solution of the sclerosing agent in a physiologically acceptable solvent;

a pathway with one or more outlet orifices by which the solution may pass from the pressurisable chamber to the exterior of the device through said one or more outlet orifices and a mechanism by which the pathway from the chamber to the exterior can be opened or closed such that, when the container is pressurised and the pathway is open, fluid will be forced along the pathway and through the one or more outlet orifices;

said housing incorporating an inlet for the admission of a pressurised source of physiologically acceptable gas that is dispersible in blood;

the gas being in contact with the solution on activation of the mechanism such as to produce a gas-solution mixture;

said pathway to the exterior of the housing including one or more foaming elements;

characterised in that

the solution of the sclerosing agent is stored in the pressurisable chamber in the presence of an inert gas comprising carbon dioxide and nitrogen in the ratio of 75:25 or greater, and

the blood-dispersible gas comprises 95%-100% vol/vol oxygen and is stored in a container provided with engaging means for the housing holding the aqueous sclerosant liquid, the engaging means comprising a connector which engages at one end with the container for the aqueous sclerosant liquid and at the other end with the container for the blood-dispersible gas, to allow the blood-dispersible gas to be introduced into the chamber holding the aqueous sclerosant liquid."

Claim 1 of auxiliary request I differed from claim 1 of the main request in that the feature:

"...comprising carbon dioxide and nitrogen in the ratio of 75:25 or greater..."

was replaced by:

"..., said inert gas being carbon dioxide and nitrogen in the ratio of 75:25 or greater...".

VII. The opponent (respondent) replied to the appellant's submissions with letters of 7 September 2011 and 23 December 2014.

VIII. On 17 December 2014 a communication pursuant to Article 15(1) RPBA was issued by the board in which several

considerations were made *inter alia* on the formulation of the technical problem (point 4.2).

IX. On 28 January 2014 oral proceedings were held before the board.

X. As far as relevant to the present decision, the appellant's arguments may be summarised as follows:

Admittance of the main request

The main request was submitted with the statement setting out the grounds of appeal. The amendments introduced in this request constituted a response to the arguments set out by the opposition division in its decision; accordingly, the appellant could not file this request during the first instance proceedings. Moreover, the amendments introduced in the main request did not determine any substantial change in the subject-matter of the proceedings. The main request was therefore to be admitted into the proceedings.

Claim 1 of the main request - Article 123(2) EPC

The passage on page 7 (lines 23 to 30) of the original application provided support under Article 123(2) EPC for the introduction of the features concerning the compositions of the blood-dispersible gas and of the inert gas. In this passage it was explained that the use of these compositions made it possible to obtain a final mixture of gas having a given content of oxygen, carbon dioxide and nitrogen. However, the features relating to the compositions of the initial gas were not tied to the features concerning their use to produce a certain final mixture. Hence, introducing in the claim the compositions of the initial gas without any reference to

the final mixture was not against the requirements of Article 123(2) EPC.

The objection concerning the basis under Article 123(2) EPC for the term "comprising" was raised by the respondent for the first time during the oral proceedings. The feature "...an inert gas comprising carbon dioxide and nitrogen..." in any case found support in the sentence "...gas mix of mainly carbon dioxide with a small amount of nitrogen..." disclosed on page 7 (lines 28-29) of the original application. The term "mainly" in this passage made it clear that the gas was not constituted only of carbon dioxide and nitrogen, but that other gases could be present.

Admittance of auxiliary request I

The amendments introduced in auxiliary request I addressed the objections raised by the respondent under Articles 84 and 123(2) EPC, with regard to the term "comprising". This request was to be admitted also in view of the fact that the objection under Article 123(2) EPC was raised for the first time at the oral proceedings.

Inventive step

Document D1 represented the closest prior art. This document did not make any reference to the possibility of storing the sclerosing agent in the pressurisable chamber. It was also not clear whether the device of D1 would have been suitable for that purpose. A device in which the sclerosing agent was supplied under an inert gas ready for use offered the advantage of reducing the number of steps required for preparing the microfoam. The idea of storing the sclerosing agent in a

pressurisable container in the presence of an inert gas was not suggested either by D1 or by any other prior-art document. The skilled person would have had no reason for replacing air with a mixture of nitrogen and carbon dioxide in the apparatus of D1. The device of the opposed patent was therefore not obvious.

XI. As far as relevant to the present decision, the respondent's arguments may be summarised as follows:

Admittance of the main request

Claim 1 of the main request included features relating to the compositions of the blood-dispersible gas and the inert gas which were not included in any of the requests submitted during the first instance procedure. Admitting this request would have deprived the respondent of the opportunity to have this subject-matter considered at two instances. Moreover, the appellant did not explain why the features introduced in the main request were not included in the requests considered during the opposition proceedings. The main request was therefore not to be admitted.

Claim 1 of the main request - Article 123(2) EPC

Page 7 of the application as filed disclosed a preferred composition of the final mixture of gas. It was explained that such a composition may have been made by introducing a gas comprising 95%-100% vol/vol oxygen into a container holding carbon dioxide and nitrogen in the ratio 75:25. Accordingly, the compositions of the initial gases were disclosed only in relation to their use to produce a specific final composition. The omission from claim 1 of any reference to the final composition was against the requirements of Article

123(2) EPC because it had the effect that the claim also included devices which could not provide the final mixture specified on page 7. In the original application there was a functional relationship between the compositions of the initial gases and the composition of the final mixture. It was therefore not admissible under Article 123(2) EPC to isolate the features relating to the initial gases from the other features disclosed in the passage on page 7.

The expression "...an inert gas comprising carbon dioxide and nitrogen..." had no basis in the original application. The sentence "...gas mix of mainly carbon dioxide with a small amount of nitrogen..." disclosed on page 7 of the original application (lines 28-29) simply indicated that the inert gas contained much more carbon dioxide than nitrogen. This sentence did not imply that the inert gas could contain in addition to carbon dioxide and nitrogen any amount of any other gas.

Admittance of auxiliary request I

In its submissions of 7 September 2011, the respondent had already raised objections under Article 123(2) EPC in relation to the features concerning the compositions of the initial gas and an objection for lack of clarity in relation to the term "comprising". More than three years later the appellant filed new auxiliary requests addressing these objections. There was no justification for such late submission. Auxiliary request I was therefore not to be admitted into the proceedings.

Inventive step

The device of the opposed patent differed from the apparatus disclosed in the closest prior art D1 in that the sclerosing agent was stored in the presence of an inert gas comprising a mixture of carbon dioxide and nitrogen in the ratio 75:25 or greater. In the device of D1 the sclerosing agent was in contact with air. The technical problem was to render the sclerosing agent stable over a longer period of time. The skilled person knew that carbon dioxide and nitrogen were inert gases. There were no effects associated with the specific ratio of inert gas recited in claim 1. Accordingly, it would have been obvious for the skilled person to replace air with a mixture of carbon dioxide and nitrogen in the device of D1. Furthermore, this measure would have not required any modification of the apparatus of document D1. Hence, the provision of the device of the patent in suit did not involve any inventive activity.

XII. The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or one of auxiliary requests I to XI filed with letter dated 17 December 2014.

XIII. The respondent requested that the appeal be dismissed.

Reasons for the Decision

Main request

1. Admittance

1.1 The main request was submitted with the statement setting out the grounds of appeal and thus according to Article 12(1) RPBA forms part of the basis of the appeal proceedings.

However, under Article 12(4) RPBA the board has a discretion to hold inadmissible a request which could have been presented in the first instance proceedings. Since in fact almost every claim request could have been presented before the first instance, the question within that context is whether the situation was such that the filing of this request should have taken place already at that stage (see for instance T 144/09 of 4 May 2011, T 1178/08 of 30 August 2012 and T 40/09 of 30 August 2012).

1.2 The main amendments introduced in claim 1 of this request in comparison to claim 1 of the main request refused by the opposition division are represented by the indication that the blood-dispersible gas comprises 95%-100% vol/vol oxygen and by the definition of the inert gas as comprising carbon dioxide and nitrogen in the ratio of 75:25 or greater.

1.3 The appealed decision and the minutes of the oral proceedings before the opposition division indicate that an important aspect of the discussion on inventive step concerned the properties of the inert gas. In particular the division came to the conclusion that it would have been obvious for the skilled person to use an inert gas in order to lower the risk of degradation of the sclerosant liquid. Accordingly, the board agrees with the appellant that amending the claim by specifying the composition of the inert gas represents the logical development of the discussion on inventive step and constitutes a reaction to the opposition division's decision to consider the main request as not inventive. Furthermore, since the operation of the claimed device requires combining the inert gas with the blood-dispersible gas, there is a functional link between the

composition of the two gases which renders it necessary also to specify the composition of the blood-dispersible gas in accordance with the composition of the inert gas.

In view of this, the board sees no reason for considering that the situation during the first instance proceedings was such that the appellant should have filed the current main request already at that stage.

1.4 In addition to the above, the board notes that the amendments introduced in claim 1 do not result in any substantial change in the factual basis on which the assessment of inventive step is to be based. In particular, the selection of the closest prior art is not affected by the specification of the compositions of the inert gas and the blood-dispersible gas.

1.5 The respondent has maintained that admitting the main request would deprive him of the right to be heard on that request by two instances of the EPO.

In this respect the board observes that according to the established case law of the boards of appeal there is no absolute "right to two instances" in the sense that a party in all circumstances is entitled to have every aspect of its case examined by two instances (see J 6/98, reasons 4). The extensive interpretation of the "right to two instances" suggested by the respondent would oblige the board either to hold inadmissible any new request filed in appeal proceedings or else to admit that request but then to remit the case to the department of first instance. This would represent a limitation of the board's discretion under Articles 12(4), 13(1) and 13(3) RPBA to decide on the admittance of a new set of claims, and of its discretion under Article 111(1) EPC to exercise any power within the

competence of the first-instance department which was responsible for the decision or to remit the case to that department.

The board considers that decisions on the admittance of a new set of claims and on a possible remittal to the department of first instance can only be taken on a case-by-case basis with due regard to the content of the new set of claims and of the particular circumstances leading to the filing of the request.

For the reasons given in points 1.3 and 1.4 above the board considers that in the present case the filing of the main request by the appellant represents a legitimate reaction to the opposition division's decision. The main request is therefore admitted into the proceedings. Furthermore, in the light of the fact that the factual basis for the assessment of inventive step is not substantially changed in comparison with the situation of the first instance proceedings, the board in the exercise of its discretion under Article 111(1) EPC does not consider it necessary to remit the case to the department of first instance.

2. Article 123(2) EPC

The objections raised by the respondent under Article 123(2) EPC focus on the following feature of claim 1:

"...in the presence of an inert gas comprising carbon dioxide and nitrogen in the ratio of 75:25 or greater, and the blood-dispersible gas comprises 95%-100% vol/vol oxygen...".

In particular, it was the respondent's position that the term "comprising" and the features defining the carbon

dioxide/nitrogen ratio and the concentration of oxygen had no valid basis in the original application.

2.1 As to the carbon dioxide/nitrogen ratio and the concentration of oxygen, the appellant indicated as a possible basis for the amendment the sentence on page 7, lines 23 to 30, of the original application.

This sentence relates to an embodiment defining a preferred composition for the final gas mixture, i.e. the mixture obtained when the blood-dispersible gas enters the container holding the sclerosing liquid in the presence of an inert gas. It is explained that such preferred final gas mixture may be made by introducing a gas comprising 95%-100% oxygen into a container holding the sclerosing liquid and a mixture of mainly carbon dioxide with a small amount of nitrogen in the ratio of 75:25 or greater.

In the respondent's opinion the introduction in claim 1 of the features concerning the oxygen concentration and the ratio between carbon dioxide and nitrogen, without any indication as to the composition of the final mixture, resulted in an extension of subject-matter beyond the content of the original application.

The board considers that the sentence on page 7 describes a preferred composition for the final mixture and provides an example of a combination of starting materials, i.e. blood-dispersible gas and inert gas, suitable for the preparation of said final mixture. The wording "Such a mixture may be made..." (page 7, line 26) clearly indicates that combining a gas comprising 95%-100% oxygen with a mixture of carbon dioxide/ nitrogen in the ratio of 75:25 or greater is not the sole possibility for obtaining the preferred gas

mixture. Moreover, in the board's opinion the sentence on page 7 cannot be read to imply that the combination of a gas comprising 95%-100% oxygen with a mixture of carbon dioxide/nitrogen in the ratio of 75:25 or greater will always result in a final mixture having the preferred composition defined on page 7. Such an interpretation would be wrong also from a technical point of view, since the composition of the final gas would also depend on the relative amounts of the initial gases (i.e. the amount of oxygen and the amount of carbon dioxide/nitrogen mixture). In other words, by explaining that the preferred final mixture may be made by combining a gas comprising 95%-100% oxygen with a mixture of carbon dioxide and nitrogen in the ratio of 75:25 or greater, the description provides a disclosure of a possible way of using the initial gases, i.e. to produce the preferred final mixture. However, the skilled reader would immediately realise that other final mixtures could be obtained from the same starting substances, e.g. by varying the amount of oxygen entering the container holding the sclerosant liquid.

It follows from the above considerations that the passage on page 7 cannot be interpreted as establishing an inextricable link between the composition of the final gas mixture and the compositions of the blood-dispersible gas and inert gas. Therefore, introducing in claim 1 the features defining the concentration of the oxygen and the ratio between carbon dioxide and nitrogen without any reference to the composition of the final mixture is an amendment which does not contravene the requirements of Article 123(2) EPC.

2.2 As to the objection concerning the word "comprising", the appellant referred to a passage on page 7, lines

28-30, of the original application as possible support. This passage reads:

"...a mix of mainly carbon dioxide with a small amount of nitrogen...".

According to the appellant, the word "mainly" in the above sentence referred to both the carbon dioxide and the nitrogen and it indicated that these gases were the main components of the mixture but that other gases could also be present.

The board agrees with the respondent that the passage referred to by the appellant would be understood by the skilled person as meaning that the mixture consists of carbon dioxide and nitrogen, the first gas being in a greater amount than the second. This issue is in any case immaterial since, even following the interpretation proposed by the appellant, the sentence quoted above cannot provide a valid basis for the term "comprising". Indeed, in view of this term, the inert gas defined in claim 1 also includes gas mixtures comprising only minor amounts of carbon dioxide and nitrogen (e.g. less than 10%), the remaining part being constituted by other inert gases. Such a gas mixture would however not be in agreement with the appellant's interpretation of the cited passage, according to which carbon dioxide and nitrogen must represent the main components of the mixture. Thus, claim 1 provides a definition for the composition of the inert gas which has no basis in the original application.

2.3 In the light of the conclusions reached in point 2.2 above, the board considers that claim 1 of the main request does not comply with the requirements of Article 123(2) EPC.

Auxiliary request I

3. Admittance

Auxiliary request I was submitted on 17 December 2014, i.e. six weeks before the oral proceedings. As explained by the appellant in the letter sent on the same day, auxiliary request I addressed an objection of lack of clarity against the term "comprising" raised by the respondent in its submissions of 7 September 2011.

The board observes that the amendment introduced in auxiliary request I at the same time also addresses the objection under Article 123(2) EPC which led to the rejection of the main request (see points 2.2 and 2.3 above). Since this objection was raised by the respondent for the first time during the oral proceedings, auxiliary request I in fact also represents a reaction to this late objection.

Under these circumstances the board considers it appropriate to admit this request.

4. Article 123(2) EPC

For the reasons discussed in point 2.1 the board considers that the features concerning the carbon dioxide/nitrogen ratio and the concentration of oxygen have a basis under Article 123(2) EPC in the application as originally filed.

The respondent did not raise any further objection under Article 123(2) EPC to the amendments introduced in auxiliary request I.

The board considers that the feature "..., said inert gas being carbon dioxide and nitrogen in the ratio of 75:25 or greater..." has a basis in the passage of page 7, lines 28-30 of the original application (see point 2.2, above).

In view of the above, the board concludes that the requirements of Article 123(2) EPC are met.

5. Inventive step

The invention underlying the patent in suit relates to an apparatus for producing a microfoam containing a sclerosing material. Said microfoam is useful in the treatment of various conditions involving blood vessels such as varicose veins (see [0001]).

Closest prior art

5.1 The parties and the opposition division considered document D1 as the closest prior art. The board has no reason to follow a different approach.

This document discloses a device for producing an injectable foam containing a sclerosing agent (page 1, lines 5 to 9 of the translation document A3). Said device includes a container and means for connecting the device to a propellant gas source (document A3, page 3, lines 26 to 32). The injectable foam is prepared by introducing a sclerosant liquid into the container and thereafter injecting the impeller gas (document A3, page 3, lines 29 to 34). Since the container needs to be opened in order to introduce the sclerosant liquid (document A3, page 3, line 30), some air must be present in the container, as observed by the opposition division. This finding was not disputed by the parties.

It was also agreed by the parties that the device according to claim 1 differs from the device of D1 in that the sclerosing agent is stored in the chamber in the presence of an inert gas, said inert gas being carbon dioxide and nitrogen in the ratio of 75:25 or greater.

Technical problem

5.2 According to the appealed decision, the technical problem was to improve the stability of the sclerosant liquid when stored in a pressurisable chamber. The arguments submitted by the parties in relation to the formulation of the technical problem were likewise focused on the issue of stabilising the sclerosing agent.

The board however is of the opinion that the formulation of the technical problem should be approached in a different manner.

5.2.1 As explained above, the method for preparing the injectable foam disclosed starting on page 3, line 29, of A3 comprises a step of introducing the sclerosant liquid into the container and hermetically closing this container. The description goes on to state that "At this point the impeller gas is injected inside the container" (page 3, line 33). This wording indicates that the gas is introduced into the container shortly after the introduction of the sclerosant liquid. Accordingly, the sclerosant liquid remains in the container for a short time before being mixed with the gas to form the foam. This aspect of the invention of D1 was not disputed by the parties.

5.2.2 The concept of storing in stable conditions the sclerosing liquid is therefore absent in the invention of D1. Accordingly, formulating the technical problem as e.g. improving the stability of the sclerosing agent would mean introducing a pointer towards the idea of stablizing the sclerosing agent, which is part of the contribution provided by the invention underlying the opposed patent over D1.

5.3 As discussed in the communication sent to the parties on 17 December 2014 (see point VIII above), the board considers that the fact of storing the sclerosing agent in a chamber in the presence of an inert gas results in a different way of using the device of the opposed patent as compared to the device of document D1. In particular, while in D1 it is necessary to fill the container with the sclerosant liquid and then close it hermetically just before the injection of the gas, with the apparatus of the opposed patent the sclerosant liquid is pre-loaded in a pressurisable container in the presence of an inert gas. The foam is prepared when desired by connecting the sclerosing agent container with a further container loaded with a blood-dispersible gas.

In view of this, the board considers that the objective technical problem can be formulated as the provision of a device for preparing a sclerosing foam which can be operated in a procedure requiring fewer handling steps.

The need to simplify the operations for preparing the sclerosing foam is discussed in the description of the patent (see [0011]).

Obviousness

5.4 As observed in point 5.1 above, the main distinguishing feature of the device of claim 1 over the device of D1 is represented by the sclerosing agent being stored in the chamber in the presence of an inert gas, said inert gas being carbon dioxide and nitrogen in the ratio of 75:25 or greater.

5.5 The board notes that there is no document disclosing a device in which the sclerosing agent is stored in a container in the presence of an inert gas consisting of carbon dioxide and nitrogen. This finding was not disputed by the respondent.

5.6 Moreover, the skilled person would find no reason in D1 for modifying the device disclosed therein by introducing an inert gas instead of air into the sclerosing agent container. Such a modification would also appear illogical considering the way in which the device of D1 is to be used.

Indeed, in view of the short residence time of the sclerosing agent in the container, the skilled person would have no reasons for fearing problems of stability. This appears to be confirmed by the fact that no mention is made in D1 of any particular measure to be adopted in order to prevent any possible degradation of the sclerosing agent due to contact with air. Thus, while in the context of the patent in suit the stability of the sclerosing agent is a concern because said agent is to be stored in the pressurisable chamber in which it is supplied, this is not the case when the invention of D1 is considered, because there the sclerosing agent is introduced into its container immediately before use. Accordingly, the issue of stabilising the sclerosing agent does not even arise in D1. Thus, in the absence of any motivation to introduce an inert gas into the

sclerosing agent container, the skilled person would regard this operation as unnecessary and therefore avoidable.

In the light of the above, the board concludes that the subject-matter of claim 1 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 I and a description yet to be adapted.

The Registrar: The Chairman:

S. Fabiani D. Semino

Decision electronically authenticated