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**Datasheet for the decision  
of 13 February 2014**

**Case Number:** T 0620/10 - 3.3.07

**Application Number:** 00931445.1

**Publication Number:** 1180015

**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

**Headword:**

**Relevant legal provisions:**  
EPC Art. 100(a)

**Keyword:**  
Novelty - (yes)  
Inventive step - (yes)

**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 0620/10 - 3.3.07

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.07**  
**of 13 February 2014**

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

**Representative:** von Kreisler Selting Werner  
Deichmannhaus am Dom  
Bahnhofsvorplatz 1  
50667 Köln (DE)

**Respondent:** BTG International Limited  
(Patent Proprietor) 5 Fleet Place  
London EC4M 7RD (GB)

**Representative:** Dolan, Anthony Patrick  
BTG International Limited  
5 Fleet Place  
London EC4M 7RD (GB)

**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted on 8 February 2010  
rejecting the opposition filed against European  
patent No. 1180015 pursuant to Article 101(2)  
EPC.**

**Composition of the Board:**

**Chairman:** D. Boulois  
**Members:** D. Semino  
W. Ungler

## **Summary of Facts and Submissions**

- I. The appeal of the opponent lies against the decision of the opposition division announced at the oral proceedings on 7 December 2009 to reject the opposition against European Patent 1 180 015.
- II. The granted patent comprised 39 claims, including independent claims 1, 20 and 36.

Claim 1 read as follows:

"1. A method for producing a microfoam of a physiologically acceptable blood dispersible gas capable of being substantially completely dissolved in or absorbed by blood and an aqueous sclerosant liquid suitable for use in sclerotherapy of blood vessels characterised in that it comprises passing a mixture of a physiologically acceptable blood dispersible gas and an aqueous sclerosant liquid through passages having at least one cross-sectional dimension of from 0.1 to 30 $\mu$ m provided as multiple openings in one or more elements placed across the flow and comprising a perforated sheet or membrane, a mesh, screen or sinter, the ratio of gas to liquid being controlled such that, on flow through the passages, a microfoam is produced having a density of between 0.07g/ml to 0.19g/ml and has a half-life of at least 2 minutes."

Claim 20 was directed to a device for producing a microfoam of a physiologically acceptable blood dispersible gas and an aqueous sclerosant liquid and claim 36 to a device for delivering microfoam to a syringe from a microfoam generating device.

III. A notice of opposition was filed against the granted patent requesting revocation of the patent in its entirety on the grounds of lack of novelty and lack of inventive step in accordance with Article 100(a) EPC.

IV. The decision of the opposition division was based *inter alia* on the following documents:

D1: H. Mayer et al., "Angiologie - Zur Ätiologie und Behandlung der Varizen der unteren Extremität",  
Chirurgische Praxis, 1957, Heft 4, pages 521 to 528

D8: DE-A-26 08 771

D34: "Patentee's experiments" filed with letter of 23 April 2009

V. The decision of the opposition division, as far as relevant to the present decision, can be summarised as follows:

a) The method of granted claim 1 was novel over the disclosure of document D1 in view of at least three technical features, namely the cross-sectional dimension of the passages for the mixture to be foamed, the use of a blood dispersible gas and the half-life of the obtained microfoam. The same arguments were valid for the device of claim 20. That device was novel over the disclosure of D8 at least for the size range of the cross-sectional dimension

b) The method of granted claim 1 was inventive over D1, taken as the closest state of the art, as there was no indication in D1 or D8 to prompt the skilled person to further amend the method resulting from the combination of the teaching of the two documents by making at least three further

selections, namely replacing air by a physiologically acceptable blood dispersible gas, passing the mixture through passages having at least one cross-sectional dimension of from 0.1 to 30µm and providing a microfoam having a half-life of at least 2 minutes, which were necessary to arrive at the claimed method. The additional experimental data provided by the opponent were considered as not reproducing the contested method, while the experiments submitted by the patent proprietor showed that even in extreme conditions and in the limits of the ranges the problem of producing a stable uniform injectable microfoam had been solved.

c) The presence of an inventive step was acknowledged also for the devices of claim 20 and 36.

- VI. The opponent (appellant) lodged an appeal against that decision. In the statement of grounds of appeal the appellant gave reasons why the novelty and the inventive step analysis of claim 1 with respect to document D1 in the decision under appeal did not hold.
- VII. With the reply to that statement the patent proprietor (respondent) countered the argument of the appellant.
- VIII. In a communication sent in preparation to oral proceedings the Board observed that lack of novelty was objected by the appellant only with regard to claim 1 with respect to document D1 (paragraph 1) and that also with regard to inventive step, the appellant had provided arguments in the statement of grounds of appeal only with regard to the method of claim 1 and with reference to document D1 (paragraph 2).

- IX. With letter of 13 January 2014 the appellant informed the Board that no one on its side would attend the oral proceedings. No other submissions were made.
- X. Oral proceedings were held on 13 February 2014 in the announced absence of the appellant.
- XI. The arguments of the appellant, as far as relevant to the present decision, can be summarised as follows:

*Novelty*

- a) None of the three features identified in the decision under appeal as distinguishing for the subject-matter of claim 1 over the disclosure of D1 could be acknowledged as such. The half-life of the microfoam was not a process feature, but a product feature which could not confer novelty to the claimed process. Air was a "blood dispersible gas" in the sense of the opposed patent as nowhere in claim 1 the use of nitrogen containing gases such as air was excluded from the scope of protection and air was at least in part soluble in blood. As to the dimension of the multiple openings, the claim did not define a closed range, but a range open in the upper limit, as confirmed by the German text of the claim; the range was therefore not distinguishing with respect to D1. On that basis the disclosure of document D1 was novelty destroying for the subject-matter of granted claim 1.

*Inventive step*

- b) Also the arguments on inventive step in the appealed decision were erroneous. It was not

correct that it was necessary to add three selections to the teaching of D1 and D8, namely the replacement of air with a physiologically acceptable blood dispersible gas, the choice of the dimension of the openings and the further choice of a micro-foam with a specific half-life, to come to the method of claim 1. Indeed air was already a blood dispersible gas according to claim 1 and the choice of the dimension of the openings was an arbitrary one, as it was clear that the smaller they were, the smaller the dimension of the foam bubbles would be. A product feature, such as the half-life of the microfoam, could not confer inventiveness to an obvious method of production of the microfoam. In addition the analysis of the experiments in D34 in the decision was superficial and did not acknowledge that the available tests were not sufficient to show that the problem was solved over the whole breadth of the claim, all the more because many tests did not result in the production of a satisfactory microfoam. On that basis the method of claim 1 did not involve an inventive step.

XII. The arguments of the respondent, as far as relevant to the present decision, can be summarised as follows:

*Novelty*

- a) The three features identified in the decision under appeal as distinguishing for the subject-matter of claim 1 over the disclosure of D1 did indeed constitute differences which justified novelty. The half-life of the microfoam was a property of the product obtained by the claimed method and as such was also a distinguishing

feature of the method itself. Air could not be considered as a "physiologically acceptable blood dispersible gas capable of being substantially completely dissolved in or absorbed by blood" due to the high quantity of nitrogen (80%), of which blood was normally already saturated; while a certain quantity of nitrogen could be present in such a gas as confirmed by claim 2 and the teaching in the patent description (in particular paragraph [0040]), it could not be present in the high percentages typical of air. The range for at least one cross-sectional dimension of the openings was a closed one with a lower and an upper limit and indicated a further feature for which no disclosure was available in D1; in this respect the wording of the German version of the claim was irrelevant.

*Inventive step*

- b) The identified distinguishing features with respect to D1 were critical in reliably obtaining a stable microfoam to be used for schlerotherapy. D1 provided no information at all on the dimension of the openings and on the properties (density, half-life) of the obtained foam and could not hint to the adoption of the missing features. The choice of the gas and of the dimension of the openings together with the control of the gas/liquid ratio permitted to obtain the desired properties of the microfoam as shown by the many examples in D34, which provided sufficient evidence for the whole scope of the claim. On that basis the method of claim 1 involved the required inventive step.



XIII. The appellant requested in writing that the decision under appeal be set aside and the European patent be revoked.

XIV. The respondent requested that the appeal be dismissed.

## **Reasons for the Decision**

### *Novelty*

1. Novelty of the method of claim 1 with respect to the disclosure of D1 was acknowledged in the decision under appeal with respect to three features, namely the cross-sectional dimension of the passages for the mixture to be foamed, the use of a blood dispersible gas and the half-life of the obtained microfoam.

1.1 Document D1 discusses a method for producing a microfoam for use in sclerotherapy in a single paragraph (page 526, fourth paragraph), which discloses a syringe with a perforated plunger which is moved reciprocally back and forth to mix air and a sclerosant liquid (Phlebocid) until a fine bubble foam is produced (first four sentences of the paragraph). The chosen sclerosant liquid gave with respect to similar composition the stiffest foam with the most uniform distribution of the air bubbles (last sentence of the paragraph).

1.2 In D1 no information is present on the dimension of the perforations in the plunger. The specification in granted claim 1 that the "passages have at least one cross-sectional dimension of from 0.1 to 30µm" constitutes therefore a first difference of the claimed method with respect to the one disclosed in D1. In this respect the feature under analysis has a crystal clear

meaning and indicates that out of the cross-sectional dimensions of the passages at least one is in the closed range 0.1 to 30µm. A different understanding of the claim, such as the one proposed by the appellant, according to which the claim would indicate only a lower limit for the range of dimensions, does not correspond to the wording of the claim as granted. The German wording of the claim (which in any case has exactly the same meaning) is in this respect not relevant, as according to Article 70(1) EPC the text of a European patent in the language of the proceedings (in the present case English) shall be the authentic text in any proceedings before the European Patent Office and in any Contracting State.

- 1.3 D1 does not give any indication of the half-life of the produced micro-foam. This feature which is defined in granted claim 1 as a quality of the product obtained by the claimed method is as such a feature of the method itself and constitutes a second difference with respect to the disclosure of D1. While steps of a method of production defined in a product-by-process claim may be disregarded, as long as they do not necessarily imply a difference in the product as such, a method of production of a product characterised both by method steps and by features of the obtained product, such as the one of granted claim 1, is distinguished from a previously disclosed method both if some steps are missing in the method of the prior art and if the features of the product are different or unknown, unless it is convincingly shown that the product features are necessarily obtained by performing the method of the prior art (and therefore are implicitly disclosed). In the present case, no evidence is present that the feature related to the half-life of the foam is implicitly obtained by performing the method of D1

(which would in any case be difficult to show, as very little detail is given in D1 of the method of production).

1.4 As to the feature of claim 1 that the gas to be mixed is a "physiologically acceptable blood dispersible gas capable of being substantially completely dissolved in or absorbed by blood", the question arises whether air falls under this definition. While there is no doubt that the oxygen and the carbon dioxide present in air fall under the definition (they are indeed the preferred constituents of the gas, see e.g. granted claim 9), nitrogen, which is a physiologically acceptable gas (see paragraph [0012] in the patent), is less soluble than oxygen and carbon dioxide (half as soluble as oxygen, fifty times less soluble than carbon dioxide, see Table 1 in the patent) and is present in normal air at 80% by volume. However, no definite condition is given by the claim on the solubility of the components of the gas or on the quantity of gas and of blood for which substantially complete dissolution or absorption should take place, which could exclude the presence of nitrogen at a high volume percentage, such as in air. This is confirmed in the patent itself by the wording of dependent claim 2, which in a preferred embodiment allows the presence of almost 50% nitrogen by volume, and of paragraph [0040], which mentions the possible presence of a proportion of nitrogen as in air. Under such circumstances it cannot be acknowledged that the definition of the gas in granted claim 1 excludes the use of air.

1.5 On that basis novelty of claim 1 with respect to the disclosure of D1 is acknowledged in view of the dimension of the openings and of the half-life of the microfoam.

*Inventive step*

2. As far as inventive step is concerned, the appellant has not accomplished a full analysis according to the problem-solution approach, but has contested the decision on inventiveness of claim 1 with respect to document D1 on the basis of two main arguments. Firstly, the replacement of air with a physiologically acceptable blood dispersible gas, the choice of the dimension of the openings and the further choice of a micro-foam with a specific half-life were not three selections which had to be added to the teaching of the prior art, as air was already a blood dispersible gas according to granted claim 1, the choice of the dimension of the openings was an arbitrary one and a product feature, such as the half-life of the microfoam, could not confer inventiveness to an obvious method of production of the microfoam. Secondly, the available tests were not sufficient to show that the problem was solved over the whole breadth of the claim, all the more because many of the tests performed by the respondent did not result in the production of a satisfactory microfoam.

2.1 With regard to the second argument, it is crucial that the properties of the product which determine whether a satisfactory foam is produced appear in the wording of granted claim 1, which includes a limitation on the density of the microfoam ("between 0.07g/ml to 0.19g/ml") and on its half-life ("at least 2 minutes") together with the indication that the product is a microfoam. In that respect the tests which refer to conditions according to which a non-satisfactory product is obtained do not fall under the claim. Under such circumstances it cannot be said that the

unsuccessful tests show methods falling under the claim and producing unsatisfactory results, so that the problem cannot be considered to be solved over the whole breadth, as the claim covers only those situations in which a satisfactory product is obtained. The argument of the appellant is therefore not relevant for inventive step and could be pertinent, if at all, for sufficiency of disclosure, whereby, however, lack of sufficiency has never been raised by the appellant as a ground of opposition.

2.2 As to the first argument, while the Board agrees with the appellant that air is not excluded as a blood dispersible gas from the wording of claim 1 (see point 1.4, above), the argument that the half-life of the microfoam cannot confer inventiveness to the method and that the choice of the dimension of the opening is an arbitrary one cannot be followed by the Board. The half-life of the microfoam is a parameter clearly related to its stability, which is the desired aim of the claimed method. Which value is obtained in D1 is not known (see point 1.3, above). The fact that a satisfactorily stable foam is not always obtained is shown by the examples of D34, where satisfactorily results are obtained only under specific conditions (as accepted and even stressed by the appellant in its second argument which therefore appears to be somewhat contradictory with the first one). Moreover, nowhere in D1 or in the cited prior art the information can be found that by means of the choice of the dimension of the openings and by controlling to ratio of gas to liquid as according to granted claim 1 the desired stability of the microfoam (in terms of a half-life of at least two minutes) can be obtained. It follows therefore that the specification of a critical property for foam stability is a crucial one for the

establishment of inventiveness and the choice of the dimension of the openings cannot be considered an arbitrary one.

- 2.3 The Board finds therefore both arguments on inventive step of the appellant, apart from being partially contradictory between themselves, as not convincing. On that basis, there are no reason to put into doubt the decision under appeal with regard to inventive step of the method of claim 1 and that decision therefore holds as it stands.

### *Conclusions*

3. The Board has found that none of the reasons for setting aside the decision impugned which have been indicated by the appellant in the statement setting out the grounds of appeal, which contains the only submissions of the appellant in appeal proceedings, stays against the patent as granted. No reasons for setting aside the decision have been indicated by the appellant with regard to independent claims 20 and 36, which claims therefore do not need to be analysed by the Board. On that basis, the appeal is to be dismissed.

**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:



L. Fernández Gómez

D. Boulois

Decision electronically authenticated