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**D E C I S I O N**  
**of 30 March 2006**

**Case Number:** T 1108/03 - 3.3.02

**Application Number:** 93902156.4

**Publication Number:** 0620744

**IPC:** A61K 49/00

**Language of the proceedings:** EN

**Title of invention:**  
Improvements in or relating to contrast agents

**Patent Proprietor:**  
GE Healthcare AS

**Opponent:**  
Alliance Pharmaceutical Corporation

**Headword:**  
Contrast Agents/GE Healthcare

**Relevant legal provisions:**  
EPC Art. 84

**Keyword:**  
"Second auxiliary request - not admitted"  
"Main and first auxiliary request - clarity of claims  
(denied)"

**Decisions cited:**

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**Catchword:**

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Case Number: T 1108/03 - 3.3.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.02  
of 30 March 2006

**Appellant:**  
(Proprietor of the patent)

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**Decision under appeal:**

Decision of the Opposition Division of the  
European Patent Office posted 18 August 2003  
revoking European patent No. 0620744 pursuant  
to Article 102(1) EPC.

**Composition of the Board:**

**Chairman:** U. Oswald  
**Members:** H. Kellner  
J. Willems

## Summary of facts and submissions

- I. European patent No. 0 620 744 based on application No. 93 902 156.4 was granted with 13 claims.

Independent claims 1, 9 and 11 to 13 as granted read as follows:

"1. A contrast agent comprising microbubble-generating microparticles comprising a carbohydrate and admixed therewith within the microparticulate structure a surfactant, wherein the microbubbles generated by said microparticles comprise gas selected from sulphur hexafluoride and fluorinated hydrocarbons which are in gaseous form at 37°C.

9. A process for preparing a contrast agent as claimed in claim 1 which comprises (i) mixing solutions of the carbohydrate and surfactant and removing the solvent(s) therefrom and (ii) micronising the resulting mixture to yield the desired microparticles.

11. Use of a contrast agent as claimed in any of claims 1 to 8 in diagnostic imaging.

12. Use of a contrast agent as claimed in any of claims 1 to 8 in diagnostic ultrasonic imaging.

13. Use of a contrast agent as claimed in any of claims 1 to 8 in magnetic resonance imaging."

- II. Opposition was filed against the granted patent under Article 100(a) EPC for lack of novelty and inventive step, under Article 100(b) EPC for insufficiency of disclosure and under Article 100(c) EPC for the subject-matter of the patent extending the content of

the application as filed. Additionally, it was stated that the patentability was excluded on the grounds of Article 52(4) EPC.

- III. By its decision pronounced at oral proceedings on 29 July 2003 and posted on 18 August 2003, the opposition division revoked the patent under Article 102(1), (3) EPC. Neither the set of claims of the main request nor the set of claims of the auxiliary request filed during the oral proceedings met the requirements of Article 84 EPC since they contained the wording "fluorinated low molecular weight hydrocarbons".

During the oral proceedings, it was considered that the sets of claims of the main request and of the auxiliary request submitted in writing before the oral proceedings took place, violated the provisions of Article 123(2) EPC because the definition of the gas involved, characterised by the wording "which are in gaseous form at 37°C", was broader than the definition in the application as filed.

- IV. The appellant (patentee) lodged an appeal against said decision and on 29 December 2003 submitted two sets of claims together with the grounds of appeal:

Claim 1 of the main request reads as follows:

"1. A contrast agent comprising microbubble-generating carbohydrate microparticles having a surfactant admixed within the microparticulate structure, wherein the microbubbles generated by said microparticles comprise gas selected from sulphur hexafluoride and fluorinated hydrocarbons which are in gaseous form at 37°C, with

the proviso that the surfactant is not a saturated C<sub>10-20</sub> fatty acid when the microparticulate carbohydrate is galactose."

The wording of Claim 1 of the auxiliary request is (bold letters characterise the differences to claim 1 of the main request):

"1. A contrast agent comprising microbubble-generating carbohydrate microparticles having a surfactant admixed within the microparticulate structure, wherein the microbubbles generated by said microparticles comprise gas selected from sulphur hexafluoride and **a fluorinated low molecular weight hydrocarbon wherein said molecular weight is such that said fluorinated hydrocarbon comprised within said microbubbles is in gaseous form at 37°C**, with the proviso that the surfactant is not a saturated C<sub>10-20</sub> fatty acid when the microparticulate carbohydrate is galactose."

In each of the sets of claims, independent claims 9 and 11 to 13 have the same wording as in the patent as granted.

V. With a letter dated 20 February 2006 the opponent (respondent) withdrew its opposition.

Its arguments on file by virtue of having been submitted in writing may be summarised as follows:

The wording "in gaseous form when at 37°C" was unclear, because the definition in the claims of the present requests did not even make use of the generally acknowledged term "boiling point". Thus, it was left

open whether it was intended to limit the claims to compounds with a boiling point of 37°C and below. As an example, it stated that even water was "in gaseous form at 37°C" in the form of relative humidity.

On the other hand, the terms "in gaseous form when at 37°C" and "low molecular weight" could not be interchangeably used because the molecular weight of fluorinated hydrocarbons and their existence in gaseous form at 37°C were largely unrelated.

Thus, a claim containing only the 37°C restriction could arguably be read to include also fluorinated hydrocarbons that could not be regarded as "low molecular weight fluorinated hydrocarbons". Therefore this definition constituted a broadening within the meaning of Article 123(2) EPC.

With respect to the subject-matter of the auxiliary request, clarity was to be objected because of the wording "low molecular weight" contained in it.

Additionally, the subject-matter of claims 11 to 13 in both requests referred to diagnostic methods which were not patentable under Article 52(4) EPC.

VI. On 30 March 2006, oral proceedings took place before the board in the presence of representatives of the appellant.

At the beginning of these oral proceedings, the appellant sought to introduce a new set of claims as second auxiliary request. It was not admitted into the proceedings. Neither did the board admit a further set

of claims (so-called "last second auxiliary request") which was intended to be introduced after discussion of different objections to the patentability of the subject-matter claimed.

VII. The appellant mainly argued that the sets of claims of the main request and of the auxiliary request had been reworded in order to overcome the objections raised with regard to original disclosure and clarity in writing. The same was true for the set of claims it wanted to introduce at the beginning of the oral proceedings.

The further set of claims ("last second auxiliary request") it wanted to file during the proceedings was submitted in order to overcome the newly raised argument that the wording "the microbubbles generated by said microparticles comprise ..." could refer to subject-matter extending the content of the application as filed.

With respect to the definition given for the gas comprised in the microbubbles, it emphasised that it was clear to the skilled person that the term "which are in gaseous form at 37°C" meant that the amount of this gas existing within the microbubbles during diagnostic application was enough to provide for a substantial amelioration of the effect on which the applied diagnostic method was based.

VIII. The appellant (patentee) requested that the decision under appeal be set aside and that the case be remitted to the first instance for further prosecution on the basis of the sets of claims filed as main or,

alternatively, first auxiliary request (filed with the grounds of appeal of 29 December 2003) or, more alternatively, the set of claims filed as last second auxiliary request during the oral proceedings.

The respondent (opponent) had requested in writing that the appeal be dismissed.

### **Reasons for the decision**

1. The appeal is admissible.
  
2. The sets of claims of the two requests filed in writing on 29 December 2003 represent a response to the arguments set out in the first-instance decision. They can be regarded as an attempt to overcome the objections by narrowing the scope of the subject-matter of the patent in suit and they were therefore admitted into the proceedings.

The set of claims which the appellant sought to introduce at the beginning of the proceedings was late-filed. It could not represent an answer to newly-raised arguments and was not prima facie allowable because of various problems with regard to clarity and original disclosure.

The set of claims finally presented during the oral proceedings as last second auxiliary request was late-filed as well. The features were rearranged and gave the requested claim 1 a totally new structure resulting in a highly complex further assessment. Additionally, the connection between the gas contained in the

microbubbles and the word "comprising" was not clearly removed in the new wording. Therefore it did not represent a clear and progressive reaction to the previously discussed objection in this context. For these reasons it was not admitted into the proceedings either.

3. As regards the subject-matter of the patent in suit as now claimed in the amended form of the main request and of the auxiliary request submitted with the letter of 29 December 2003 (the only two requests admitted into the proceedings), the fluorinated hydrocarbons comprised within the microbubbles generated by the microparticles have to be "in gaseous form at 37°C". The value of 37°C according to this wording is not defined as a boiling point that could refer to normal pressure according to the common general knowledge of the skilled person reading the claim. Thus, the conditions under which the fluorinated hydrocarbons have to be in gaseous form - be it the influence of pressure as such or be it the influence of other parameters - are totally open. Other parameters are for instance characterised by the fact that bubbles are to be created in a stream of blood under additional pressure (blood pressure) or in any other fluid in a human or animal body or even a plant under normal pressure and by the fact that they are exposed to ultrasound or X-ray radiation or electromagnetic fields of MR (see page 6 of the original application, lines 24 to 29).

Therefore, the feature that the fluorinated hydrocarbons comprised within the microbubbles generated by the microparticles had to be "in gaseous

form at 37°C" does not clearly define the matter for which protection is sought. The requirements of Article 84 EPC are not fulfilled.

4. In these circumstances, the arguments of the appellant cannot succeed:

The appellant submitted *inter alia* that the definition of the fluorinated hydrocarbon to be used was clear because the skilled person could see that the response of a diagnostic method was ameliorated because of the presence of the contrast agent as soon as enough microbubbles containing the gas were in the bloodstream.

The claimed subject-matter, however, must be regarded as a contrast agent *per se* with no further restriction in claim 1 as to the kind of diagnostic method and category of patient or even object for which it was to be used. Therefore, there is no definition at all of the conditions under which the microbubbles have to develop, particularly not the pressure. But the skilled person knows that the indication of a temperature at which any substance was to change from the fluid form to the gaseous form is useless without defining the pressure under which this transition should occur.

5. Accordingly, claim 1 of the main request and claim 1 of the auxiliary request do not meet the requirements of Article 84 EPC.

**Order**

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

The appeal is dismissed.

The Registrar:

The Chairman:

A. Townend

U. Oswald