BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

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

Datasheet for the decision of 2 August 2012

Case Number: T 1888/09 - 3.3.02

Application Number: 04808887.6

Publication Number: 1694365

IPC: A61K 49/00

Language of the proceedings: EN

Title of invention:
Optical imaging contrast agents

Applicant:
GE HEALTHCARE AS

Headword:
Optical imaging contrast agents/GE HEALTHCARE AS

Relevant legal provisions:
EPC Art. 82
EPC R. 44

Keyword:
"Unity of invention - (no): common concept not novel"

Decisions cited:
W 0011/89

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1888/09 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 2 August 2012

Appellant: (Applicant)
GE HEALTHCARE AS
Nycoveien 2
NO-0485 Oslo (NO)

Representative:
Flechsler, Insa
GE Healthcare Limited
Amersham Place
Little Chalfont
Bucks. HP7 9NA (GB)

Decision under appeal:
Decision of the Examining Division of the European Patent Office posted 1 April 2009 refusing European application No. 04808887.6 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: U. Oswald
Members: A. Lindner
R. Cramer

Summary of Facts and Submissions

I. European patent application No. 04 808 887.6 was refused by a decision of the examining division pronounced on 19 March 2009 and dispatched on 1 April 2009 on the basis of Article 97(2) EPC on the grounds that the subject-matter claimed in the main and sole request lacked inventive step and unity of invention.

Regarding inventive step, the examining division came to the conclusion that the claimed subject-matter was rendered obvious by combining the teaching of document (2), which was defined as closest prior art, with the teaching of any one of documents (9) to (11).

Concerning unity of invention, the examining division argued that the common concept of using a contrast agent having a molecular weight below 14,000 Daltons, comprising an optical imaging moiety and having affinity for an abnormally expressed biological target associated with oseophagal cancer was not novel in the light of document (2). As a consequence, the claimed subject-matter lacked unity of invention.

II. The documents cited during the opposition and appeal proceedings included the following:

(2) WO 00/61194

(9) Database MEDLINE [Online] US National Library of Medicine(NLM), Bethesda, MD, US; May 1995 (1995-05), Fléjou J.F., et al: "Overexpression of protein p53 and Barrett esophagus. A frequent and early event in the course of carcinogenesis"

(10) Database MEDLINE [Online] US National Library of Medicine(NLM), Bethesda, MD, US; June 1996 (1996-6), Castella E., et al: "Expression of CD44H and CD44v3 in normal oesophagus, Barrett mucosa and oesophageal carcinoma."

(11) Database MEDLINE [Online] US National Library of Medicine(NLM), Bethesda, MD, US; 1999, Seery J.P., et al.: "Abnormal expression of the E-cadherinca-tenin complex in dysplastic Barretts oesophagus."

III. The applicant (appellant) lodged an appeal against this decision.

IV. With the letter dated 26 June 2012, the appellant informed the board that it would not be represented at the oral proceedings scheduled for 2 August 2012.

V. Oral proceedings were held on 2 August 2012, in the absence of the duly summoned appellant, in accordance with Rule 115 EPC and Article 15(3) RPBA.

VI. The independent claims of the main and sole request read as follows:

"1. A method of optical imaging of oesophageal cancer and Barrett's oesophagus of an animate subject involving administering an optical imaging contrast agent to the subject and generating an optical image of at least a part of said subject to which said contrast agent has distributed; wherein said contrast agent has a molecular weight below 14,000 Daltons and an affinity for an abnormally expressed biological target associated with oesophageal cancer or Barrett's oesophagus, said biological target being selected from:

E-cadherin, CD44, P62/c-myc (HGF receptor), p53 and EGFR/erB-2.

7. Use of the contrast agent as defined in any one of claims 1 to 4 in the manufacture of a diagnostic agent for use in a method of diagnosis of oesophageal cancer and Barrett's oesophagus involving administration of said diagnostic agent to an animate subject and generation of an image of at least part of said subject.

8. The contrast agent as defined in any one of claims 1 to 4 for use in a method of diagnosis of oesophageal cancer and Barrett's oesophagus."

VII. Regarding unity of invention, the appellant essentially argued as follows:

The skilled person, reading document (2) as a whole, would infer that the agents described therein are useful for cancer imaging at any location of the mammalian body where somatostatin receptors, VIP-receptors or neurotensin receptors are abnormally expressed. Document (2) was, however, silent on whether those receptors are definitely involved in either Barrett's oesophagus or oesophageal cancer. Example 41, which was the only *in vivo* supporting evidence supplied by document (2), referred to whole body imaging in implanted tumours in the flanks of mice. Document (2) merely taught that "hollow organs", of which the oesophagus was but one example, had advantages with respect to tissue penetration of the optical signal, and hence when detecting dyes of a particular wavelength range. As a consequence, the present claims

comprised a unifying feature ("…contrast agent of molecular weight below 14,000 Daltons and having affinity for an abnormally expressed biological target associated with oesophageal cancer or Barrett's oesophagus…") which was novel and inventive over the teaching of document (2). As a consequence, the requirements of Article 82 EPC were met.

VIII. The appellant requested that the decision under appeal be set aside and the case be remitted back to the first instance for further prosecution.

Reasons for the decision

1. The appeal is admissible.

2. Unity of invention

2.1 When deciding on unity of invention, it is mandatory under Article 82 EPC to determine whether or not the inventions or groups of inventions as claimed form a single general inventive concept. According to Rule 44 EPC, the requirement of unity of invention under Article 82 EPC shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features, i.e. features which define a contribution which each of the claimed inventions considered as a whole makes over the prior art.

According to the established jurisprudence of the boards of appeal (see e.g. W 11/89, point 4.1 of the Reasons for the Decision, OJ EPO 1993, 225), the

assessment of unity of invention requires as a precondition an analysis of the technical problem or problems underlying the respective group(s) of invention(s) based on the disclosure of the application as originally filed. As a next step, it has to be determined whether or not the solution to this problem makes a contribution over the prior art.

2.2 In the present case, the problem underlying the present invention may be defined as the provision of contrast agents for optical imaging of oesophageal cancer or Barrett's oesophagus in patients (see page 1, lines 4-5 of the original application). This problem was solved by the subject-matter according to present claim 8 comprising five groups of contrast agents, characterised by their affinity to either E-cadherin, CD44, P62/c-myc, p53 or EGFR/erB-2. These five groups of contrasts are *a priori* linked by (a) a molecular weight of < 14,000 Daltons and (b) by the common effect of having affinity for an abnormally expressed biological target associated with oesophageal cancer or Barrett's oesophagus. It is therefore possible to formulate a common concept, which can be defined as follows: provision of a contrast agent for optically imaging of oesophageal cancer or Barrett's oesophagus, wherein said contrast agent has a molecular weight below 14,000 Daltons and an affinity for an abnormally expressed biological target associated with oesophageal cancer or Barrett’s oesophagus. In the absence of any prior art, the thus defined common concept also constitutes ***a priori*** a single general inventive concept as required by Article 82 EPC.

2.3 The objection of the examining division was, however, directed to lack of unity *a posteriori*, taking into account the teaching of document (2).

Document (2) discloses optical imaging agents comprising a fluorescent dye conjugated to a short-chain peptide having affinity to somatostatin receptors, VIP receptors or neurotensin receptors, all of which are abnormally expressed in tumoral cells. Said compounds are particularly suitable for the diagnosis or hollow organs including the oesophagus (see page 3, lines 1-28). Compared to antibodies the short-chain peptides carrying the fluorescent dye are characterised by advantageous properties such as reduced blood half-live and less allergenic side effects (page 14, lines 18-24).

It follows therefrom that the common concept defined in paragraph 2.2 above is not novel in the light of document (2). In this context, it is noted that document (2) does not explicitly mention contrast agents with a molecular mass of below 14,000 Daltons. However, a molecular mass of below 14,000 Daltons is implicitly disclosed therein, as the fluorescent dye is covalently bonded to short-chain peptides (see page 3, lines 10-12), so that the molecular mass of the resulting product is automatically below 14,000 Daltons. In view of the fact that the above-mentioned common concept is not novel and that it is not possible to formulate an alternative common concept for the invention claimed in claim 8, there is lack of unity of invention.

Alternatively, making reference to Rule 44 EPC, it can be reasoned that in the light of the teaching of document (2), claim 8 does not contain any special technical features, either of the same or the corresponding type, which could make a contribution over the prior art.

The requirements of Article 82 EPC are therefore not met.

2.4 The above reasoning applies *mutatis mutandis* to the further independent claims, which concern a method claim (claim 1) and a Swiss-type claim (claim 7) involving the same contrast agents.

2.5 Further arguments of the appellant

Regarding the argument that there was no teaching in document (2) that the somatostatin receptors, VIP receptors or neurotensin receptors were involved in oesophageal cancer, reference is again made to page 3, lines 1-28, according to which these receptors are overexpressed in tumour cells and tumour tissue which can be used for diagnosing hollow organs such as the oesophagus. This means that diagnosis of tumours which are located in the oesophagus constitutes a preferred embodiment of the more general teaching, according to which the receptors mentioned above are used for diagnosing tumours in hollow organs. The fact that document (2) does not contain a specific example describing the diagnosis of the oesophagus is of no consequence, as the description (see page 4, line 19 - page 24, line 15) contains numerous fluorescent dyes and short-chain peptides which according to the

teaching on page 3, lines 1-28, are suitable for diagnosing hollow organs including the oesophagus. As a consequence, this argument cannot succeed.

2.6 In view of this finding, the evaluation of inventive step is not necessary.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman

N. Maslin U. Oswald