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D E C I S I O N
of 14 March 2001

Case Number: T 0629/98 - 3.3.4

Application Number: 91913465.0

Publication Number: 0533845

IPC: G01N 33/48

Language of the proceedings: EN

Title of invention:

USING 5,10,15,20-TETRAKIS(r-CARBOXYPHENYL)PORPHINE FOR
DETECTING AND TREATING LUNG CANCER

Applicant:

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, et al

Opponent:

-

Headword:

Lung Cancer/UNIVERSITY OF CALIFORNIA

Relevant legal provisions:

EPC Art. 52(4), 111(1)

Keyword:

"Patentable inventions (yes) - after amendment - second
medical use type of claim"
"Remittal (yes)"

Decisions cited:

T 0385/86, G 0005/86

Catchword:

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Boards of Appeal

Chambres de recours

Case Number: T 0629/98 - 3.3.4

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 14 March 2001

Appellant: THE REGENTS OF THE UNIVERSITY OF CALIFORNIA et al
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 28 January 1998
refusing European patent application
No. 91 913 465.0 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: U. M. Kinkeldey
Members: L. Galligani
V. Di Cerbo

Summary of Facts and Submissions

- I. The applicants lodged an appeal against the decision of the examining division issued on 28 January 1998 whereby the European patent application 91 913 465.0 (published as WO-A-91/19977) was rejected. Basis of the rejection were claims 1 to 11 filed on 15 November 1996. Claims 8 to 11 thereof were considered by the examining division to relate to a diagnostic method which was not susceptible of industrial application and, thus, non-patentable under Article 52(4) EPC. This was because, contrary to the case of decision T 385/86 (OJ EPO 1988, 308), the feature "*for locating sites of lung malignancies*" related to establishing a clinical picture in a patient. Moreover, it was held that, since the cited compounds had a site selective therapeutical treatment effect, the claims in question had the character of a medical treatment.
- II. With the statement of grounds of appeal, the appellants filed claims 1 to 13 of a new main request and of an auxiliary request. In both requests, claims 1 to 7 were identical to claims 1 to 7 of the request before the examining division, and claims 12 and 13 were in the form of a "second medical use" (cf G 5/83, OJ EPO 1985, 64). In claims 8 to 11 of the main request the feature "*for locating sites of lung malignancies*", which had been objected to by the examining division, was replaced by the feature "*for providing pictures usable in the localisation of sites of lung malignancies*". In the auxiliary request, the latter claims were in the form of a second medical use.
- III. The examining division did not rectify its decision

under Article 109(1) EPC, and remitted the appeal to the board of appeal, cf Article 109(2) EPC.

IV. In respect of claims 8 to 11 of the main request, the appellants submitted that the feature "*for locating sites of lung malignancies*" only indicated the field of use of the method, and that the features **i)** injecting the substance into the blood stream and **ii)** forming an image were technical features in the sense of decision T 385/86 (*supra*). As for the selective destruction effect of the quoted compounds on lung malignancies, they observed that the ^{64}Cu compound was merely a radiotracer which had no such an effect. As for the ^{67}Cu compound, they submitted that, when imaging was concerned, the radioactive dose was limited to what was required to obtain an image.

V. On 8 August 2000, the board issued a communication pursuant to Article 110 EPC with a provisional opinion on the case, expressing reservations on the patentability under Article 52(4) EPC of claims 8 to 11 of the main request in the light of the case law of the boards of appeal, and notwithstanding the submissions by the appellants.

VI. In reply thereto, on 16 October 2000, the appellants filed new claims 1 to 13 as a sole request. These claims were identical to the claims of the auxiliary request previously on file, cf Section II above. Of them, claims 8 to 13 read:

"8. Use of the ^{67}Cu complex of 5, 10, 15, 20-tetrakis(4-carboxyphenyl)porphinato in the preparation of a substance to be administered to a patient for the diagnosis of lung cancer, whereby an image is formed

from the emitted gamma radiation for locating sites of lung malignancies."

"9. Use of the ^{64}Cu complex of 5, 10, 15, 20-tetrakis(4-carboxyphenyl)porphinato in the preparation of a substance to be administered to a patient for the diagnosis of lung cancer, whereby positron emission tomography of the emitted positron radiation is performed for locating sites of lung malignancies."

"10. Use according to claim 8 or 9, wherein said substance is to be injected into the bloodstream of the patient"

"11. Use according to claim 8 or 9, wherein said substance is to be directed in aerosol form into the lungs of the patient"

"12. Use of the ^{67}Cu complex of 5, 10, 15, 20-tetrakis(4-carboxyphenyl)porphinato in the preparation of a substance to be injected into the bloodstream of a patient for the treatment of lung cancer, whereby said complex provides a source of α radiation for selective destruction of lung malignancies."

"13. Use of the ^{67}Cu complex of 5, 10, 15, 20-tetrakis(4-carboxyphenyl)porphinato in the preparation of a substance to be directed in aerosol form into the lungs of a patient for the treatment of lung cancer, whereby said complex provides a source of α radiation for selective destruction of lung malignancies."

VII. The appellants requested that the decision under appeal be set aside and a patent be granted on the basis of claims 1 to 13 as filed on 16 October 2000. They

requested oral proceedings in the event that the board of appeal should decide to maintain the refusal.

Reasons for the Decision

1. Claims 1 to 7, which are identical with claims 1 to 7 as filed except for the addition of the qualifier "in vitro" in respect of the method, are not under discussion here as they were not objected to by the examining division.

There are no formal objections under Article 123(2) EPC to claims 8 to 13 which are now formulated in terms of the use of the quoted compounds for the preparation of a substance for a diagnostic (claims 8 to 11) or therapeutic application (claims 12 and 13), as both said diagnostic and therapeutic applications are disclosed in the application as filed (cf eg claims 8 to 13 as filed).

2. Claims directed to the use of a substance or composition for the treatment of the human or animal body by therapy or to a diagnostic method practised on the human or animal body are not patentable under Article 52(4) EPC. However, according to the established case law of the boards of appeal, a patent may be granted with claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic or diagnostic application, even in a case in which the process of manufacture as such does not differ from known processes using the same ingredient, cf eg G 5/83, supra ("second medical use" claims).

3. Claims 8 to 13 now on file are formulated in terms of the use of either the ^{67}Cu complex of 5, 10, 15, 20-tetrakis(4-carboxyphenyl)porphinato (claims 8, 10-13) or the ^{64}Cu complex of 5, 10, 15, 20-tetrakis(4-carboxyphenyl)porphinato (claims 9-11) in the preparation of a substance to be administered to a patient for a diagnostic or a therapeutic application. In claims 8 to 11 the medical application is a diagnostic method which allows to determine the presence or absence of lung malignancies in a patient to whom the substance is administered (deductive medical decision phase; cf decision T 385/86, point 3.3 of the reasons), ie a method of diagnosis practiced on the human body which provides an immediate clinical picture. In claims 12 and 13 the medical application is a therapeutic method for selective destruction of lung malignancies in a patient to whom the substance is administered either by injection or by aerosol.
4. The formulation of the said claims is thus in line with the principles outlined in point 2 above, and no longer raises issues under Article 52(4) EPC.
5. However, the substantive question whether the claims relate to a new and inventive therapeutic or diagnostic application has yet to be examined, in particular having regard to the prior art related to the use of radiolabeled porphyrin compounds, eg in conjugation with antibodies, for tumour imaging and internal radiation therapy, cf eg document US-A-4 783 529 as well as the references cited on page 4 of the application as filed.
6. In order to ensure that the appellants have the opportunity of having the question of the substantive

patentability of the said claims decided by the examining division, and with the possibility of a further appeal remaining open, the board considers it appropriate to make use of the power granted to it under Article 111(1) EPC to remit the case to the examining division for further prosecution.

7. Oral proceedings were requested by the appellants only in the event that the board should decide to maintain the refusal (cf Section VII supra). Thus, the present decision, which is in favour of the appellants, can be taken without appointing oral proceedings.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the examining division for further prosecution on the basis of claims 1 to 13 as filed on 16 October 2000.

The Registrar:

The Chairperson:

U. Bultmann

U. Kinkeldey