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**Datasheet for the decision
of 13 November 2017**

Case Number: T 0699/12 - 3.4.01

Application Number: 03723593.4

Publication Number: 1501604

IPC: A61N5/10

Language of the proceedings: EN

Title of invention:

METHOD FOR PERFORMING IN VIVO DOSIMETRY

Patent Proprietor:

Nilsson, Görgen

Opponent:

IBA DOSIMETRY GmbH

Headword:

Relevant legal provisions:

EPC Art. 53(c)

Keyword:

Exceptions to patentability - method for treatment by therapy
(no)

Remittal to the department of first instance - (yes)

Decisions cited:

G 0001/04, G 0001/07, T 0836/08, T 0923/08, G 0003/14,
T 0245/87

Catchword:



Beschwerdekammern
Boards of Appeal
Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 0699/12 - 3.4.01

D E C I S I O N
of Technical Board of Appeal 3.4.01
of 13 November 2017

Appellant: Nilsson, Görgen
(Patent Proprietor) Gryningsvägen 47
743 32 Storvreta (SE)

Representative: Awapatent AB
P.O. Box 665
831 27 Östersund (SE)

Respondent: IBA DOSIMETRY GmbH
(Opponent) Bahnhofstrasse 5
90592 Schwarzenbruck (DE)

Representative: De Groote, Christophe
Abyoo sprl
Centre Monnet
Avenue Jean Monnet, 1
1348 Louvain-la-Neuve (BE)

Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 27 January 2012
revoking European patent No. 1501604 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman G. Assi
Members: T. Zinke
J. Geschwind

Summary of Facts and Submissions

- I. An opposition was filed against European patent No. 1 501 604 as a whole.
- II. The opposition was based on the ground for opposition of Art. 100(a) EPC for lack of novelty, lack of inventive step and exclusion from patentability (Art. 53(c) EPC), of Art. 100(b) EPC and of Art. 100(c) EPC.
- III. The opposition division revoked the patent, because it held that claim 1 as granted (patentee's main request) was not allowable under Art. 53(c) EPC. Patentee's auxiliary requests 1 to 5 were not admitted into the opposition proceedings, because they involved amendments not occasioned by a ground of opposition contrary to the requirement of R. 80 EPC. It was further held that patentee's auxiliary requests 6 to 7 did not comply with Art. 123(3) EPC.
- IV. The appellant (patentee) filed an appeal against the opposition division's decision.

With the notice of appeal, the appellant requested that the decision be set aside and the patent be maintained as granted.

With the statement setting out the grounds of appeal, the appellant further requested, as a first auxiliary request, that the case be remitted to the opposition division and, as a second auxiliary request, that the patent be granted based on an amended claim set as filed together with the statement of grounds.

- V. With letter of 15 October 2012 the respondent (opponent) requested, as a main request, that the decision be maintained and the appeal be dismissed. As a first auxiliary request, the respondent requested to remit the case to the opposition division, if the Board of Appeal did not confirm the revocation of the patent on the grounds of Art. 53(c) EPC.
- VI. Both parties requested, as a respective further auxiliary request, oral proceedings.
- VII. Summons to attend oral proceedings were issued on 12 July 2017.
- VIII. With letter of 7 September 2017, the respondent withdrew its request for oral proceedings and informed the Board that it would not attend the oral proceedings.
- IX. On 17 October 2017, the Board issued a communication pursuant to Art. 15(1) RPBA, expressing its provisional opinion with regard to the parties' submissions and requests then on file.
- X. With letter of 8 November 2017, the appellant requested, as a main request, that the decision be set aside and the patent be maintained as granted. As a new first auxiliary request, it was requested to grant a patent based on the amended claim set as filed with the statement setting out the grounds of appeal for the then second auxiliary request. Moreover, the appellant filed an amended claim set according to a new second auxiliary request.

XI. Oral proceedings before the Board took place on 13 November 2017 in the presence of the appellant and the appellant's representative only.

During oral proceedings the appellant filed an amended claim set according to a new first auxiliary request. The former first and second auxiliary requests were maintained as new second and third auxiliary requests.

Hence, the final requests of the appellant were that the decision under appeal be set aside and the patent be maintained as granted (main request) or that a patent be granted based on claim sets as submitted for a first, second or third auxiliary request.

The final requests of the respondent were the requests as submitted with letter of 15 October 2012.

XII. Claim 1 of the patent as granted according to the patentee's main request reads:

"1. Method for enabling quantification of dose delivery in radiotherapy treatment, characterized in that it comprises the steps of:

- irradiation of a phantom following a treatment plan of a patient,*
- measurement of the irradiation in said phantom,*
- collecting information regarding the irradiation by information means arranged between the phantom and the radiation source, wherein said measurements are divided in time-intervals,*

and

- analysing the measurements for obtaining information regarding the relationship between the measurements in the phantom and measurements in the information means*

*between the phantom and the treatment source at each time-interval,
- using said relationship information during verification of the treatment of the patient."*

Claims 2 to 14 are dependent claims, whereas claims 15 and 16 claim computer program products.

XIII. The claims of the patentee's auxiliary requests are not relevant for this decision.

Reasons for the Decision

1. Applicable law

This decision is issued after the entry into force of the EPC 2000 on 13 December 2017 whereas the application was filed before this date. Reference is thus made to the relevant transitional provisions for the amended and new provisions of the EPC, from which it can be derived which Articles and Rules of the EPC 1973 are still applicable to the present application and which Articles and Rules of the EPC 2000 are to apply. When Articles or Rules of the former version of the EPC are cited, their citations are followed by the indication "1973" (cf. EPC, Citation practice).

2. The appeal is admissible.

3. Appellant's main request

3.1 Interpretation of claim 1

3.1.1 A main issue at dispute concerns the interpretation of the last feature of claim 1, i.e. *"using said*

relationship information during verification of the treatment of the patient".

- 3.1.2 According to the Merriam-Webster online dictionary 2017 *"to verify" means "to establish the truth, accuracy or reality of"*. Taking further into account the introduction of claim 1, i.e. *"method for enabling quantification of dose delivery in radiotherapy treatment"*, the last feature of claim 1 should be interpreted as meaning that *"the verification of the treatment of the patient"* relates to the mentioned *"quantification of dose delivery in the radiotherapy treatment of the patient"*.
- 3.1.3 It should be noted, however, that neither the actual irradiation of the patient nor any adaptation of a possible further irradiation based on the quantified dose delivery is part of the method of claim 1.
- 3.1.4 In the decision under appeal (cf. Reasons, section 2.) the opposition division interpreted the claim differently, i.e. *"When attempting to interpret said claim in the light of the description, the skilled person finds numerous passages in said description such as paragraphs 9, 13-14 and 17 of the patent specification as well as page 11, lines 6-26 of the A-publication, which reveal that said dose delivery quantification actually pertains to in vivo dose verification, wherein irradiation of the patient is implicitly required in order to verify the dose during the treatment.*
Therefore, claim 1 involves not only the pre-treatment steps of calibrating using a phantom and the post-treatment step of using said relationship information, but also the intermediate treatment step of irradiating the patient for therapeutic purposes. Therefore, a

therapeutic step is implicitly involved in the claimed subject-matter, which suffices to render the method of claim 1 a method for treatment of the human body by therapy excluded from patent protection under Art. 53(c) EPC."

- 3.1.5 According to the jurisprudence of the boards (cf. Case Law of the Boards of Appeal, 8th edition, 2016, section I.B.4.3.4 b, "*Surgical step part of claimed method*"), there is no uniform approach how to interpret method claims, in which no particular therapeutic/surgical step is claimed, although it derives from the context that such a therapeutic/surgical step would be present in relation to the claimed method.

In particular, in T 0836/08 the board found that "*the fact that the method was performed after, or even during, a surgical intervention on the body did not mean that the claimed position-tracking method as such was a method of treatment by surgery.*" (cf. Case Law book, page 55).

On the other hand, although further decision T 0923/08 was concerned with circumstances similar to those in cited T 0836/08, the board came to a very different result, i.e. "*where a method for determining measurements of the human or animal body necessarily entailed a surgical step consisting of fixing to the human or animal body a measuring device indispensable for performance of the method, that step had to be deemed an essential feature of the method which was covered by such method, even if none of the claimed method features expressly related to this step. Such a method was excluded from patentability under Art. 53(c) EPC*" (cf. Case Law book, page 55).

3.1.6 Decision G 01/07 (OJ EPO 2011, 134) also dealt with the question, whether it is acceptable that a surgical step might be left out from the claim in order to avoid the exclusion of Art. 53(c) EPC (cf. Reasons, section 4.3). In particular, *"Under Article 84 EPC, whether or not a step being or encompassing a surgical step excluded from patentability can be omitted either by using positive wording for such omission like "pre-delivered" or by simply leaving it out from the claim depends on whether the claimed invention is fully and completely defined by the features of the claim without that step. That requires an assessment of the individual case under consideration."* (cf. Reasons, section 4.3.1).

However, since the present main request concerns the maintenance of patent as granted, objections under Art. 84 EPC are not to be examined according to decision G 03/14 (OJ EPO 2015, A102).

3.1.7 It should, moreover, be noted that decision G 01/07 avoided to state that a surgical step that is not mentioned in a claim could nevertheless be read into the claim.

3.1.8 In the present case, the claimed method implies an irradiation of the patient, because otherwise a quantification of the dose delivery in the radiotherapy treatment of the patient (i.e. *"the verification of the treatment"*) would not be possible. However, according to Art. 84 EPC 1973, the claims define the matter for which protection is sought. Moreover, according to Art. 69 EPC 1973, they determine the extent of protection conferred by a European patent. Hence, when carefully considering the wording of the claims, there is no basis for identifying a step like an *"intermediate*

treatment of irradiating the patient for therapeutic purposes" that is de facto not claimed.

- 3.1.9 Hence, claim 1 should not be interpreted to include a step of irradiating the patient.
- 3.2 Art. 53(c) EPC
- 3.2.1 According to Art. 53(c) EPC European patents shall not be granted in respect of methods for treatment of the human or animal body by surgery or therapy.
- 3.2.2 Decision G 01/04 (OJ EPO 2006, 334) clarified that a method claim falls under the prohibition of patenting methods for treatment by therapy or surgery under Art. 53(c) EPC if it comprises or encompasses at least one feature defining a physical activity of action that constitutes a method step for treatment of a human or animal body by surgery or therapy (cf. Reasons, point 6.2.1). This was confirmed in G 01/07 (cf. Reasons, point 3.2.5).
- 3.2.3 According to the patent specification the *"invention is thereby a method to calibrate the detectors to be used In Vivo (during treatment) in a time-efficient and accurate way to achieve high quality, reliable dose measurements during treatment"* (cf. B1-specification, paragraph [0009]).
- 3.2.4 Art. 53(c) EPC, however, does not exclude methods from patent protection that are used during a therapeutic or surgical treatment of a human or animal body, but methods that are therapeutic or surgical treatments of a human or animal body.

3.2.5 In this regard, the Enlarged Board of Appeal in G 01/07 addressed methods only concerning the operation of a device (possibly during a therapeutic or surgical treatment) and stated the following:

"Methods which are merely directed to the operating of a device without themselves providing any functional interaction with the effects produced by the device on the body are teachings in which the performance of a physical activity or action that constitutes a method step for treatment of a human or animal body by surgery or therapy is not required in order for the teaching of the claimed invention to be complete. Hence, even if in such a case the use of the device itself requires the application of a surgical step to the body or is for therapeutic treatment the same does not apply to the claimed method for operating the device. It appears therefore to be correct to say that such inventions are not methods for treatment of the human or animal body within the meaning of Article 53(c) EPC and that the distinction made in the jurisprudence of the technical boards properly delimits patentable methods of a merely technical nature from such inventions as fall within the exclusion under Article 53(c) EPC. Whether or not a claimed invention only concerns the operation of a device without any functional link to the effects of the device on the body, is not an issue of law but requires an evaluation of the overall technical circumstances of the case and is therefore a matter to be determined by the first instance and the technical boards of appeal in the individual cases under consideration."

3.2.6 In the decision under appeal, the opposition division discussed decision T 0245/87 (OJ EPO 1989, 171), which is one of the decisions mentioned in G 01/07 dealing

with a method claim that claims the operation of a device, and held:

"The patentee argued that claim 1 allegedly pertains to verification of the operational status of a radiotherapy device in a manner similar to that in the decision T245/87 in order to prove the absence of a functional link between the method and the therapeutic effect on the patient and thus the non-medical character of the method. However, the opposition division cannot accept said arguments for the following reasons: a) claim 1 makes no reference to a radiotherapy device, but to radiotherapy treatment, b) the medical purpose of claim 1 is to verify the actual treatment of the patient by quantifying the dose received by him, which is different from verifying the output dose delivered by a radiotherapy device and c) the aforementioned paragraph 17 of the description discloses a clear functional link between the method and the adaptation of the treatment."

This argumentation, however, is not convincing for the following reasons.

- (a) Claim 1 indeed includes some references to devices as e.g. *"information means arranged between the phantom and the radiation source"*, but it is evident from the patent specification that the claimed method is for calibrating detectors intended for use in an apparatus for radiotherapy during treatment of a patient to verify the accuracy of the delivered dose to the patient (cf. e.g. paragraph [0001] of the B1-specification). This means that the claimed method is only a calibration method for the *"information means"* combined with a verification method of the

radiation source, even without any explicit reference to the radiotherapy device in claim 1.

- (b) It is correct that the intention of the claimed method is to verify the actual dose that the patient should receive. However, from the features of claim 1 it is clear that actually there is no measurement inside the patient (which is not possible). Rather, the "*verification*" is an estimation of the received dose by using actual measurements of the calibrated information means. Hence, what is measured is the output dose of the radiation source and it is checked, whether the radiation source worked as expected.

- (c) The reference to the "*functional link*" in paragraph [0017] of the B1-specification is not convincing, because - as already discussed above - this adaptation of the further treatments based on the verification is not claimed in claim 1. Hence, the medical practitioner is not hindered in his decision how to possibly adapt the next phases of the treatment.

3.2.7 As stated above, the wording of claim 1 of the patent as granted does not include any step that could be considered as a being of surgical or therapeutic nature, since no actual irradiating step is claimed. The "*verification*" (i.e. "*quantification of the dose delivery*", cf. above) of the treatment has no therapeutic or surgical effects as such.

3.2.8 The method as claimed in claim 1 only determines (verifies) the radiation dose during a treatment, but does not have any influence on it. Hence, it only

determines whether the treatment (radiation) source worked as expected.

3.2.9 In conclusion, the claimed method only concerns the technical operation of a device (the radiation/treatment source and the information means/detectors) without any functional link to the effects of the device on the body. In the claimed method there is no step that would influence the treatment of the patient. Rather, it only monitors the actual treatment. The medical practitioner is free to choose the next steps of treatment of a patient and is not hindered in performing his therapeutic tasks.

3.2.10 For this reason, the exclusion under Art. 53(c) EPC does not apply to claim 1.

4. Art. 111(1) EPC 1973

In accordance with the respondent's first auxiliary request and considering that the appellant did not raise any objections during oral proceedings, the case is remitted to the opposition division for further prosecution.

5. Art. 113 EPC

In the Board's communication under Art. 15(1) RPBA the parties were informed about the issues to be discussed during oral proceedings, including claim interpretation and the issues at dispute under Art. 53(c) EPC. However, the respondent did not submit any arguments and was not represented at the oral proceedings.

During oral proceedings before the Board, due to its absence, the respondent gave up the possibility to make

submissions in this regard. In accordance with the provisions of Art. 15(3) RPBA, the respondent was then treated as relying only on its written case.

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 for further prosecution.

The Registrar:

The Chairman:



R. Schumacher

G. Assi

Decision electronically authenticated