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D E C I S I O N
of 28 April 1997

Case Number: T 0697/94 - 3.4.1

Application Number: 87201308.1

Publication Number: 0254351

IPC: A61N 5/10

Language of the proceedings: EN

Title of invention:

A trolley for treating a part of the body with radioactive material

Patentee:

VAN 'T HOOFT, ERIC

Opponent:

Isotopen-Technik Dr. Sauerwein GmbH

Headword:

-

Relevant legal provisions:

EPC Art. 56, 84, 123(2)

Keyword:

"Disclosure, clarity and inventive step (yes)"

"Time factor of 11 years between prior art and priority date a further indication of inventiveness"

Decisions cited:

-

Catchword:

-



Case Number: T 0697/94 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 28 April 1997

Appellant:
(Opponent)

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Respondent:
(Proprietor of the patent)

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Decision under appeal:

Interlocutory decision of the Opposition Division
of the European Patent Office dated 20 May 1994
concerning maintenance of European patent
No. 0 254 351 in amended form.

Composition of the Board:

Chairman: G. D. Paterson
Members: H. J. Reich
U. G. O. Himmler

Summary of Facts and Submissions

- I. The respondent is owner of European patent No. 0 254 351.
- II. This patent was opposed by the appellant on the grounds of lack of novelty and lack of inventive step according to Article 100(a) EPC, and on the ground mentioned in Article 100(c) EPC, reference being made with regard to Article 100(a) EPC *inter alia* to the prior art which can be derived from documents:

D1: US-A-3 861 380;

D2:(a) Prospectus "Gamma Radiographs; Sources Equipment Services" of the company "Automation Industries, Inc." 1972, pages 2 and 8;

(b) Drawings "Multitron 0-051" of "The Budd Company";

(c) Sworn statement of George W. Johnson, dated 31 December 1991;

(d) Sworn Statement of the company "Capital X-Ray Services, Inc." dated 31 December 1991; and

D3: CH-A-479 311.

- III. By an interlocutory decision within the meaning of Article 106(3)EPC the Opposition Division decided that the patent could be maintained in amended form on the basis of the following documents:

Claims: 1 to 5 received 5 November 1993 with letter of 5 November 1993;

Description: according to EP-B1-0 254 351, column 1 to column 4, line 41, wherein column 1, lines 19 to 54 are replaced by pages 1 to 3 received 5 November 1993 with letter dated 5 November 1993;

Drawings: Figures 1 to 4 according to EP-B1-0 254 351.

Amended Claim 1 on which the decision was based, reads as follows:

"1. An apparatus for delivering a radioactive source to at least one hollow, rigid or flexible needle or applicator implanted in a part of the body of a patient such as a lung, oesophagus, brain, prostate etc., the needle or applicator being introduced in the treatment area, the apparatus comprising a shielding block (3) for containment of the radioactive material adapted for coaction with a transport thread (9) and transport means (6) for transporting the radioactive material or a dummy via a connecting tube (13) from said shielding block to said needle or applicator, the transport means (6) being arranged before the shielding block as seen in the direction of displacement of the radioactive material, and the connecting tube having a detection point serving as a point of reference for the transport means, characterised in that a first connecting tube (13) for transporting the radioactive material by a first transport means (6) and a second connecting tube (13) for transporting the dummy by a second transport means (6) are joined between the shielding block (3) and the needle or applicator, said shielding block having at least one curved channel and said detection

point (14) being provided between the joining of the tubes and the needle or applicator for serving as a point of reference for the first and the second transport means (6)."

Claims 2 to 5 are dependent on Claim 1.

- IV. The Opposition Division took the view that Claim 1 is novel and implies an inventive step, since no document cited in the procedure, - in particular neither document D1 nor document D2 (multitron) - teaches or suggests a Y-joint exterior to a shielding block or to provide a single detection point behind the joining of the tubes. This very arrangement provides for an advantageous and safe operation of the claimed apparatus. It allows to first insert a dummy into the needle and to determine from a check of its position whether the passage through the tube is free or whether a kink occurs. Thereby, the arrival of the radioactive source in its destination in the needle can be guaranteed. In an oral proceedings before the Opposition Division all parties agreed that amended Claim 1 meets the requirements of Article 123(2) EPC.
- V. The appellant lodged an appeal against the interlocutory decision.
- VI. On the request of both parties oral proceedings before the Board were held on 28 April 1997. During the oral proceedings the appellant (opponent) requested that the decision under appeal be set aside and that the European patent No. 0 254 351 be revoked. The respondent (patentee) requested that the appeal be dismissed and that the patent be maintained in amended form, as allowed by the Opposition Division (see paragraph III above).

VII. In support of his request, the appellant essentially submitted that Claim 1 should not be allowable for the following reasons:

- (a) Claim 1 does not satisfy Article 123(2) EPC. The amendment of the location of the joint of the first and second connecting tubes from the wording of original Claim 6 reading "the transport channels for the transport threads with radioactive material, and the dummy, respectively, are joined **ahead** of a detection point" into that of present Claim 1 reading: "... are joined **between** the shielding block (3) and the needle or applicator ..." includes a location of the joint within the shielding block, which location is contrary to the position of the joint outside the shielding block as disclosed in the embodiment of Figure 3. The further amendment of the above text of original Claim 6 into "said detection point being provided **between** the joining of the tubes and the needle or applicator" includes as well a position of the detecting means inside a shielding block into the subject-matter of Claim 1, which position is not disclosed.

- (b) The wording of the first part of Claim 1 "a transport means (6) for transporting the radioactive material **or** a dummy" is inconsistent with the wording in its characterising part, reading, "... transporting the radioactive material by a first transport means ... and ... transporting the dummy by a second transport means ...". Hence, Claim 1 is not clear in the sense of Article 84 EPC.

- (c) Document D1 discloses some essential features of Claim 1, including control means 15' (see D1, column 3, lines 57 to 63) which implicitly comprise a detection point serving as a point of reference for the transport means. Document D2 teaches to add to the one transport means of the apparatus disclosed in document D1 a second transport means. Recognising the disadvantage of one only transport means in document D1 is not the result of a hindsight analysis in view of the subject-matter of the present invention, but a fact which is easily available from the practical use of the apparatus according to document D1. The apparatus disclosed in document D2 has one drive for a first radioactive source and another drive for a second radioactive source, each drive being provided with a dial at the crank. It is obvious for a skilled person, that one of said two drives may be used for transporting the dummy disclosed in document D1. Hence, from the obvious combination of the subject-matter disclosed in documents D1 and D2, only one step is necessary in order to arrive at the subject-matter of Claim 1, i.e. to select the position of the point of detection. Such a selection would not be inventive.
- (d) Claim 1 does not comprise subject-matter which solves the problem of decreasing the danger of broken transport threads for radioactive material, avoiding thereby that radioactive sources remain in the patient's body and cannot easily be removed.

VIII. The above submissions were contested by the respondent, who argued essentially as follows:

- (a) The claimed position of the joint between shielding block and needle or applicator and that of the detection point between joint and needle or applicator are clearly disclosed in original Claim 6.
- (b) The wording of the first part of Claim 1 reads on the nearest prior art according to document D1 and on the claimed invention without contradicting the specification in the characterising part.
- (c) The appellant's statement of the features distinguishing the apparatus according to Claim 1 from that of document D1 is based on hindsight, since none of the cited documents deals with the problem of increasing the safety of an apparatus for delivering a radioactive source to a needle implanted in the body of a patient. The skilled person is faced with the problems of the apparatus disclosed in document D1, i.e. avoiding errors and uncertainties in determining the position of the radioactive source in a patient's body caused by the indispensable decoupling of the implanted part (12) of the connection tube from the transport means when interchanging dummy and source at the top end of the actuating cable (10). For solving this problem, the skilled person would not consider the teaching of document D2. The Multitron according to document D2 belongs to a different technical field. It concerns weld seam testing, wherein a radioactive source is moved along a weld to be checked. Irregularities in the radiation intensity measured after having passed through the weld, are indicative of structural defects of the weld. The position of such defects

can be read from a dial provided at a manually actuated crank of the transport means. Each transport means for one of the various sources is provided with an own, individual dial. Document D2 gives no hint how to increase the security of a patient. It only suggests to reduce the number of outlets in the shielding block for avoiding leakage. Neither document D2 nor document D1 discloses a detection point serving as a point of reference for the various possible positions of the source or dummy. In the apparatus of document D1 control means, 15' comprises three coloured lamps as visual signals for a storage, transfer or irradiation position of the radioactive source.

The invention as claimed in Claim 1 provides in the joint part of the connecting tubes one detection point which serves as a point of reference for the transport means of the dummy and that of the source. The advantages of such arrangement are in detail described in the patent specification of the present invention column 2, line 40 to column 3, line 55. The invention allows to make an automatic test run of the dummy through the applicator, to check all connections and to report the position of any kinks or unsuitable curvatures which could result in the active source jamming during treatment. Thereby, the danger of broken cables, i.e. of a radioactive source which cannot easily be removed from a patient's body, is decreased. None of the cited documents hints at any improvement of a patient's safety.

Moreover, the "Multitron" according to document D2 was prior art at the publication date of document D1 in 1975. The time of eleven years until the priority date of the present invention in 1986 is indicative of an inventive step underlying the subject-matter of Claim 1.

IX. At the conclusion of the oral proceedings, the decision was announced that the appeal is dismissed.

Reasons for the Decision

1. Article 123(2) EPC

1.1 The preposition "between" expresses a local relation of a point (or object) to two other points (or objects) in opposite direction from it and defines its position **in** the space which separates the two points; see for instance "The Oxford English Dictionary", vol. I. Oxford, the Clarendon Press 1970, page 835, left column, paragraph A.I. Hence, the claimed wording "**between** shielding block and needle or applicator" defines the shielding block and needle or applicator as limits of the space wherein the joint may be positioned. In the same way, the claimed wording "**between** the joining of the tubes and the needle or applicator" means that joint and needle or applicator form borderlines of the space wherein the detection point may be located. The example in the Oxford Dictionary "Any station on the Inner Circle Railway between Tower Street and The Temple" is normally understood to exclude Tower street and The Temple from being "any station". In the analogous sense, shielding block and needle are not part of the space wherein the joint may be placed, and joint and needle no place for providing the detection means.

1.2 The wording in original Claim 6: "the transport channels ... are joined **ahead** of a detection point" only fixes one end of the space, i.e. the detection point as one limit of the joint and the joint as one limit for the detection point, the respective other end being open. Hence, the amendments introduced into Claim 1 transform the respective open end of the space available for positioning joint or detection point into a precisely defined end. They narrow the subject-matter of Claim 1 to two closed regions within which joint and detection point may be located respectively.

1.3 Contrary to the appellant's opinion in paragraph V-(a) above, the use of the preposition "between" in Claim 1 excludes a joint and a detection point located in the interior of the shielding block, from the subject-matter of Claim 1. It conforms the content of Claim 1 to the embodiment disclosed in Figure 3 and thereby avoids any objection under Article 123(2) EPC.

2. *Article 84 EPC*

The use of the indefinite article "a" before "transport means" in the pre-characterising part of Claim 1 has normally to be interpreted in that **one or more** transport means for source or dummy, are comprised in the apparatus claimed. Such a wording is consistent with the fact that the apparatus disclosed in document D1, comprises one transport means for transporting interchangeably source or dummy, and that the invention comprises a first transport means for source and second transport means for a dummy as defined in the characterising part of Claim 1. Therefore, the wording of Claim 1 forming the basis of the appellant's argument in paragraph V-(b) above, is regarded to satisfy Article 84 EPC.

3. *Inventive step*

3.1 The appellant concedes implicitly that Claim 1 is novel, in particular over document D1; see paragraph V-(c). Thus, the only further substantive issue raised in this appeal is that of inventive step.

3.2 As not contested by the appellant, document D1 discloses only features of Claim 1 defined by the wording of its pre-characterising part; see D1 in particular Figures 2 and 3 with the corresponding description, implanted applicator 12 (column 4, lines 14 to 17); shielding block 16 in Figure 3, transport thread 10 in Figure 2; transport means 15 in Figure 3, radioactive material 8 in Figure 2, dummy (column 4, lines 19 to 21), connecting tube 3 in Figure 3, detection point 23, 12' (column 3, lines 32 to 36).

3.3 Starting from the closest prior art disclosed in document D1 the objective problem underlying the present invention as claimed in Claim 1 is to bring a radioactive preparation accurately into the target area after a test run with a dummy in order to check whether the implanted guide tube for the transport thread of the radioactive source has been transported into the target area without kinks or unsuitable curvatures; see the patent under appeal, column 4, lines 39, 40, 5 to 9 and column 2, lines 43 to 47.

3.4 The above problem is solved by the technical means defined in the characterising part of the Claim 1. The claimed solution provides a first transport system for the source and a second transport system for the dummy. Two separate connection tubes for guiding source or dummy respectively are joined into a one guiding tube

comprising the implantable tube parts leading to the needle or applicator. Between joint and needle or applicator a detection point serves as common reference point for the separate transport means of source and dummy.

3.5 In the closest prior art according to document D1 one and the same transport means brings dummy and source to the target area. After the test run, the guiding system has to be opened for replacing the dummy by the source. The subsequent mechanical coupling of the internal and external parts of the guiding system causes a local uncertainty between one and the same reading of a transport control means and the corresponding actual position of dummy and source within the patient; see also paragraph VI-(c) above. The invention avoids such coupling errors by providing a closed guiding system in Y-form, wherein along the identical part of the way of dummy and radioactive material a common reference point for the movement of source and dummy coordinates their separate drives.

3.6 In order to arrive from the apparatus disclosed in document D1 at the subject-matter of Claim 1 a skilled person has:

- (a) to provide a second connecting tube and a second transport means for the dummy and to reshape the open I-form of the guiding system into a closed Y so that the dummy stays permanently within the closed guiding system; and

(b) to provide within the identical way part of dummy and radioactive material a detection point which serves as common reference point for the actions of the two separate transport means for dummy and source (in the disclosed embodiment a zero point for counts of step motor pulses corresponding to local decrements of the transfer).

3.7 When improving the accuracy of positioning dummies and radioactive material within a patient's body, in the Board's view, a skilled person would not consider the technical field of testing of materials, since a guiding system for a radioactive source within living tissue and that along the surface of materials give rise to different technical problems. Hence, the Board finds that the teaching of document D2 does not concern a neighbouring technical field, the prior art of which has to be considered when examining for inventive step. In particular, in the use of the Multitron according to document D2 there is no necessity to test the movability of the source along the weld by a dummy before checking the structure of the weld by the radiation of the source.

3.8 Contrary to the appellant's submission in paragraph V-(c), a skilled person cannot reasonably be expected to recognise in the second drive for a further radioactive source stored in the shielding block of document D2, a technical means contributing to avoid coupling errors in the open guiding system of document D1. The filed evidence concerning the technical features of the Multitron is totally silent about how the sources are mechanically guided outside the shielding block along the welds to be tested. Hence, document D2 only teaches to shape the channels for storing a plurality of sources within a shielding block in Y-form in order to reduce leakage from the shielding block. In the Board's view, Y-formed

shielding block channels for radioactive sources do not suggest to a skilled person to form a Y-formed closed guiding system which is partly implantable into a patient's body and permanently comprises a dummy.

- 3.9 The detection means 15' of document D1 and the dials at the cranks of the multitron (see D2(a), page 2, right column, paragraph 5) both show where the source is, i.e. they are optical position indicators. The reference point as claimed in Claim 1 has a different function. It normalises the reading of a position indicator. The Board does not agree with the appellant that a position indicator normally also detects the presence of the moved object in a reference point. Even if document D2 would explicitly state that the dial indicators are provided with a reference point detector, step (b) set out in paragraph 3.6 (b) above, would not be obvious for the following reasons:

Document D2(c) **inter alia** reads: "A separate driving cable **and** control unit can be connected to each source tube to drive the source assemblies, via the "Y" connection, to the exposing position". This means that each manually operated crank of the two known drive cables has its own dial indicator. Hence, the position indication of the first transport means works independent from that of the second transport means. Therefore, document D2 is regarded to give no hint to interrelate the position indications of two separate transport means or even to provide a common reference point for different drives.

- 3.10 In the Board's view, it is significant in the present case that the prior art disclosed by D1 and D2 had been made available to the public in combination since 1975, that is, 11 years before the priority date of the patent in suit. Having regard to the obvious

disadvantages associated with the apparatus of D1 (see paragraph VI-(c) above) and the clear advantages associated with the apparatus claimed in claim 1 as set out in paragraph III above, in the Board's judgment the time factor of 11 years is an additional indication confirming the inventiveness of the claimed subject-matter.

- 3.11 For the above reasons, the Board finds that the subject-matter of Claim 1 involves an inventive step within the meaning of Article 56 EPC.
4. Hence, it follows that amended Claim 1 is allowable. Dependent Claims 2 to 5 concern particular embodiments of the apparatus according to Claim 1 and are, therefore, likewise allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

M. Beer

G. D. Paterson