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DECISION of 14. October 2004

T 0650/01 - 3.4.1 Case Number:

Application Number: 94116843.7

Publication Number: 0655220

IPC: G01R 33/42

Language of the proceedings: EN

Title of invention:

Magnetic resonance imaging system

Patentee:

MEDRAD INC.

Opponent:

Liebel Flarsheim Co.

Headword:

Relevant legal provisions:

EPC Art. 100(a), 52(1), 56, 123(2)

Keyword:

"Main request, EPC Art. 100(a), opposition grounds - lack of patentability"

"Auxiliary requests, EPC Art. 123(2), Amendments - added subject-matter (yes)"

Decisions cited:

T 0092/93, T 1126/97, T 0081/03, G 0010/91

Catchword:



Europäisches Patentamt

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Beschwerdekammern

Boards of Appeal

Chambres de recours

Case Number: T 0650/01 - 3.4.1

DECISION

of the Technical Board of Appeal 3.4.1 of 14. October 2004

Respondent: Liebel Flarsheim Co. (Opponent) 2111 E. Galbraith Road

Cincinnati, Ohio 45237 (US)

Representative: Findlay, Alice Rosemary

Lloyd Wise

Commonwealth House 1-19 New Oxford Street London WC1A 1LW (GB)

Appellant:

(Proprietor of the patent) Kappa Manor II

271 Kappa Drive

Pittsburgh

MEDRAD INC.

Pennsylvania 15238-2870 (US)

Representative: Dörries, Hans Ulrich, Dr.

Dörries Frank-Molnia Pohlman

Postfach 22 16 61 D-80506 München (DE)

Decision under appeal: Interlocutory decision of the Opposition

Division of the European Patent Office posted 8 February 2001 concerning maintenance of European patent No. 0655220 in amended form.

Composition of the Board:

Chairman: G. Davies Members: G. Assi

H. K. Wolfrum

- 1 - T 0650/01

Summary of Facts and Submissions

- I. The appellant (patent proprietor) lodged an appeal, received on 6 April 2001, against the interlocutory decision of the opposition division, dispatched on 8 February 2001, concerning the maintenance of European patent No. 0 655 220 (application number 94 116 843.7) in amended form. The appeal fee was paid on 6 April 2001. The statement setting out the grounds of appeal was received on 8 June 2001.
- II. The opposition had been filed against the patent as a whole and was based on the ground pursuant to Article 100(a) EPC that the subject-matter of the patent was not patentable within the terms of Articles 52(1) and 56 EPC.

In the decision under appeal, the opposition division held that the ground for opposition did not prejudice the maintenance of the patent in amended form, having regard *inter alia* to the following documents:

- (D1) Investigative Radiology, Vol. 26, No. 8, August 1991, Sanjay Saini et al., "In Vitro Evaluation of a Mechanical Injector for Infusion of Magnetic Resonance Contrast Media, pages 748-751,
- (D2) US-A-4 885 538.
- III. Oral proceedings were held on 14 October 2004.
- IV. With the grounds of appeal, the appellant requested that the impugned decision be set aside and that the patent be maintained as granted (main request). With a

letter dated 13 September 2004, received on the same day, the appellant submitted auxiliary requests I, II, III and IV. With a letter dated 13 October 2004, received on the same day, the appellant submitted new auxiliary requests I, II, III and IV intended to replace the previous ones. At the oral proceedings, the appellant stated that, in case the auxiliary requests filed on 13 October 2004 were not admitted, the patent should be maintained on the basis of the previous auxiliary requests I, III and IV filed on 13 September 2004 and an amended auxiliary request II submitted during the oral proceedings.

The respondent requested that the appeal be dismissed.

- V. The appellant's <u>main request</u> includes claims 1-7 of the patent as granted, the wording of claim 1 being as follows:
 - "1. A magnetic resonance imaging system comprising:
 - a) a room shielded from electromagnetic interference;
 - b) a system controller located externally of the shielded room
 - c) a patient injection apparatus including injection apparatus control means located within the shielded room; and
 - d) a fiber optic communications link between the system controller and the injection apparatus control means."

The appellant's <u>auxiliary request I filed on</u>

13 September 2004 includes claim 1 with the following wording and claims 2-7 of the patent as granted:

T 0650/01

- "1. A magnetic resonance imaging system comprising:
- a) a room shielded from electromagnetic interference;
- b) a system controller located externally of the shielded room; and
- c) a patient injection apparatus including injection apparatus control means located within the shielded room;

characterized in that

d) a fiber optic communications link extends from the system controller to the injection apparatus control means."

The appellant's <u>amended auxiliary request II filed</u> <u>during the oral proceedings</u> includes claim 1 with the following wording and claims 2-6 of the patent as granted:

- "1. A magnetic resonance imaging system comprising:
- a) a room shielded from electromagnetic interference;
- b) a system controller located externally of the shielded room; and
- c) a patient injection apparatus including injection apparatus control means and an injection head unit located within the shielded room;

characterized in that

- d) a fiber optic communications link between the system controller and the injection apparatus control means;
- e) the injection apparatus control means is separated from the injection head unit, and
- f) the injection head unit includes two syringe and piston units which are connected to electric motors in the injection apparatus control means by non-rigid drive connections."

The appellant's <u>auxiliary request III filed on</u>

13 September 2004 includes claim 1 with the following wording and claims 2-7 of the patent as granted:

- "1. A magnetic resonance imaging system comprising:
- a) a room shielded from electromagnetic interference;
- b) a system controller located externally of the shielded room; and
- c) a patient injection apparatus including injection apparatus control means and an injection head unit located within the shielded room;

characterized in that

- d) a fiber optic communications link extends from the system controller to the injection apparatus control means, and
- e) the injection apparatus control means is separated from the injection head unit."

The appellant's <u>auxiliary request IV filed on</u>

13 September 2004 includes claim 1 with the following wording and claims 2-6 of the patent as granted:

- "1. A magnetic resonance imaging system comprising:
- a) a room shielded from electromagnetic interference;
- b) a system controller located externally of the shielded room; and
- c) a patient injection apparatus including injection apparatus control means and an injection head unit located within the shielded room;

characterized in that

d) a fiber optic communications link extends from the system controller to the injection apparatus control means; - 5 - T 0650/01

- e) the injection apparatus control means is separated from the injection head unit, and
- f) the injection head unit includes two syringe and piston units which are connected to electric motors in the injection apparatus control means by non-rigid drive connections."

The appellant's <u>auxiliary requests I, II, III and IV</u> <u>filed on 13 October 2004</u> differ from the auxiliary requests I, II, III and IV of 13 September 2004 in that claim 1 defines the patient injection apparatus as being "portable".

Reasons for the Decision

- 1. The appeal is admissible.
- 2. Admissibility of the appellant's auxiliary requests I, II, III and IV filed on 13 October 2004
- On 13 October 2004, on the eve of the oral proceedings, the appellant filed via telefax four new auxiliary requests intended to replace the auxiliary requests filed on 13 September 2004. The appellant submitted that, while preparing oral proceedings, it had identified an additional feature distinguishing the subject-matter of the patent in suit over the prior art. Claim 1 according to the new auxiliary requests was thus amended by including the feature that the patient injection apparatus is "portable".
- 2.2 At the oral proceedings, the respondent objected to the admission into the procedure of the new auxiliary

requests for various reasons. In particular, the requests were belated; the new feature was not previously the subject-matter of any of the claims of the patent but had been derived from the description; it was likely that the requirements of Article 123(2) EPC were not met; the issue of inventive step had to be considered from a new perspective; and, moreover, the amendment could be pursued within the frame of a pending divisional application. In summary, the respondent submitted that the admission of the new requests would be contrary to a fair and proper procedure and, moreover, to the established case law of the boards of appeal as represented by T 0092/93 (not published).

According to the appellant, the respondent's objections were not justified because the addition of a single word could not change the situation drastically, the original disclosure supported the amendment, and the amended claim 1 was prima facie allowable having regard to the cited prior art. Moreover, it was not uncommon that the boards of appeal admitted new requests filed during oral proceedings.

2.3 Any late amendment to a party's case may be admitted at the Board's discretion. The discretion is exercised in view of *inter alia* the complexity of the new subjectmatter, the current state of the proceedings and the need for procedural economy (Article 10b RPBA).

On this basis, the case law of the boards of appeal (T 0092/93, not published; T 1126/97, not published; T 0081/03, not published) has defined some conditions, which, in the absence of exceptional circumstances,

- 7 - T 0650/01

should be fulfilled before admitting amendments to claims filed at a late stage in the appeal procedure. The conditions may be summarized as follows:

- (i) There should be some justification for the late filing.
- (ii) The subject-matter of the new claims should not diverge considerably from the claims already filed; in particular, they should not contain subjectmatter which has not previously been claimed.
- (iii) The new claims should be clearly allowable in the sense that they do not introduce new objections under the EPC and overcome all outstanding objections.
- Having regard to the present case, the first condition

 (i) is not fulfilled. Indeed, the appellant could not provide a convincing justification for the late filing. It is no justification that, on the eve of the oral proceedings, the appellant identified an additional feature distinguishing the subject-matter of the patent in suit over the prior art. Rather, all requests for amendments should have been filed within the time limit set by the Board with the summons.

With regard to the second condition (ii), the amendment consists in the fact that the claimed patient injection apparatus is "portable". The introduction of a single word should not represent a complex issue from a technical point of view. From a procedural point of view, however, the respondent correctly stated that the feature was not the subject-matter of any of the claims

of the patent as granted but had been derived from the description. Thus, this feature had not been searched and the respondent, at the opposition stage, could not be expected to submit evidence for subject-matter which was not claimed. Neither could evidence be provided in the appeal proceedings because of the late filing of the amendment. Finally, the subject of the proceedings would be so changed by the new requests that remittal of the case to the first instance for further prosecution could not be excluded.

The third condition (iii) is not fulfilled either. From a substantive point of view, the respondent raised an objection under Article 123(2) EPC. This issue indubitably arises because paragraphs [0005] and [0008] and Figure 2 of the patent, cited by the appellant in support of the amendment, concern the portability of the MRI system and of the injection head unit rather than of the injection apparatus. Furthermore, the respondent addressed the issue of inventive step raising questions concerning the definition of the problem to be solved, the technical relationship between the portability of the patient injection apparatus and the fiber optic communications link, and the meaning of the new feature with respect to the prior art documents on file. These concerns are justified.

2.5 In conclusion, the conditions, on the basis of which a Board may exercise its discretion to admit late-filed requests, are not fulfilled. Hence, the appellant's auxiliary requests I, II, III and IV filed on 13 October 2004 were not admitted into the procedure.

3. Admissibility of the appellant's amended auxiliary request II submitted at the oral proceedings

The appellant's amended auxiliary request II submitted at the oral proceedings was not admitted since it was not clearly allowable (condition (iii)).

- 4. Appellant's main request
- The MRI system according to claim 1 of the main request comprises a fiber optic communications link "between" the system controller and the injection apparatus control means (feature d)). The meaning of the term "between" was controversial. Whereas the appellant interpreted the claim as meaning that the entire link between the system controller and the injection apparatus control means was realized by fiber optic cables, the respondent submitted that the claim only required the provision of a fiber optic communications link as part of the connection.

From a linguistic and technical point of view, both interpretations are feasible. Therefore, the respondent's interpretation may constitute a valid basis for assessing the issue of inventive step.

Moreover, the Board notes that the appellant's interpretation is not consistent with the disclosure in the description and drawings, which underlines the importance of providing a fiber optic or wireless communications link only for the part traversing the isolation room barrier. For this reason, the respondent's interpretation better reflects the whole disclosure of the patent in suit.

- 4.2 The respondent submitted that document D1 or, alternatively, D2 might be regarded as representing the closest prior art. Depending on the choice of the document, the subject-matter of claim 1 would lack inventive step, having regard to the combination of documents D1 and D2 or, alternatively, to the combination of documents D2 and D1. In this respect, the appellant took the view that the respondent's reliance on document D1 or, alternatively, D2 was an indication of hindsight.
- 4.3 The closest state of the art for assessing inventive step should be represented by a document, which, with regard to the claimed invention and from the point of view of a skilled person on the priority date applicable, pertains to the same or a closely related technical field, discloses subject-matter conceived for the same purpose, has the most technical features in common, ie requires the minimum of structural modifications, and relates to the same or a similar technical problem (Case Law of the Boards of Appeal of the European Patent Office, Fourth Edition, December 2001, paragraph I.D.3.1 on page 102).
- Occument D2 relates to a magnetic resonance imaging (MRI) system comprising a serial communications link connecting a digital computer with peripheral devices controlling various functions of the MRI system (column 1, "Field of the invention"). The document acknowledges that electronic noise is a very serious problem in MRI installations (column 1, lines 64 and 65). Thus, various precautions are typically taken to prevent noise sources from degrading the MRI process. For example, the patient, the coils and the RF

generating and detecting circuitry are all located in a shielded room, which isolates the signal detecting circuitry from external noise sources and also prevents RF energy from radiating outside of the room. Moreover, the data acquisition and control computers are generally located outside of the shielded room to prevent the noise they generate from interfering with signal detection (column 2, lines 12-25). In the light of this technical background, document D2 discloses a MRI data communications network which produces no electronic noise whatsoever during the time a MRI image is being acquired. In addition, it is capable of connecting many different types of peripheral devices to the same computer and provides sufficient versatility to permit different communications associated with the different types of peripheral devices (column 3, lines 41-54). According to Figure 1, a serial data communications system 50 includes a host computer 52, a DMA board 54, a serial bus controller 100, a distribution box 300 and a serial data bus 350. The serial data bus includes one or more serial bus nodes 400 connected by signal links 360 (column 6, lines 39-46). In a preferred embodiment, the use of bidirectional fiber optic cables between the serial bus controller 100 and the first node 400a located in the MRI shielded room ensures that no electrically conductive links exist between any system component outside of the MRI shielded room and any system component, in particular the peripheral devices, within the MRI shielded room (column 13, lines 4-9).

In summary, document D2 discloses a MRI system comprising features a), b) and d) of claim 1.

Therefore, document D2 relates to the technical field of the present invention, ie MRI systems. As for the present invention (paragraphs [0001], [0006] and [0007]) of the patent in suit), D2 discloses subject-matter conceived for the purpose of generating diagnostic images, and deals, in particular, with the technical problem of preventing peripheral devices within the MRI shielded room from generating electronic noise during the image acquisition time. Moreover, the known MRI system discloses three out of the four technical features recited by claim 1. For these reasons, the reliance on document D2 is not arbitrary and does not result from hindsight.

- 4.5 The subject-matter of claim 1 differs from the MRI system according to document D2 only in that it comprises a patient injection apparatus including injection apparatus control means located within the shielded room (feature c)). The claimed subject-matter solves the technical problem (paragraph [0006] of the patent in suit), which consists in providing an improved MRI contrast media delivery system having decreased interference with the magnetic field used to obtain the MR image.
- The use of contrast media in MRI systems is well-known in the state of the art. Document D1 concerns the evaluation of the performance of a commercially produced mechanical injector used for contrast media infusion in angiography and computed tomography, the injector being modified and installed in a clinical MRI system. The injector comprises a main unit incorporating the controlling electronics, a drive unit including a motor, and an injector head, these three

elements being located within a shielded room of the MRI system. Moreover, it comprises a control panel mounted adjacent the MRI operating console outside of the shielded room. The control panel and the main unit are connected with an interface cable (page 748, paragraph "Injector Hardware"). The document concludes that the installation of such an injector properly adapted to the specific environment of a MRI system produces no observable negative effect on MR images (page 751, penultimate sentence).

In summary, document D1 discloses a MRI system comprising features a), b) and c) of claim 1 as well as a communications link consisting of an interface cable.

For apparent reasons, the skilled person is aware of the fact that the general teaching of document D2 consists in that the connection between any peripheral device suitable for use within the shielded room of a MRI system and any system component outside of the shielded room is advantageously provided by a fiber optic communications link preventing noise from interfering with signal detection. Moreover, since, according to document D1, a patient injection apparatus is indeed suitable for use within the MRI shielded room, the skilled person comes to the obvious conclusion that the teaching of D2 is still valid if one of the peripheral devices is a contrast media injection apparatus.

The appellant objected to the combination of documents D2 and D1. In its view, document D2 was silent about the use of a contrast media injection apparatus in a MRI system. This view, however, ignores the fact that

the general teaching of D2 is not concerned with any particular peripheral device but rather leaves to the skilled person the choice of these devices. As regards this choice, the same skilled person knows from document D1 that an injector can be used, provided that measures are taken to avoid electromagnetic noise. These measures, in particular, consist in tailoring the injector head for a magnetic environment and in reshimming the magnets after installation of the injector.

The appellant also took the view that the combination of documents D2 and D1 would not directly lead to the claimed MRI system. According to D1, the injector's control panel was described as being distinguished from the MRI operating console. Thus, when combining the documents, the injector could not constitute a peripheral device of the MRI system of D2. The combination would rather lead to a MRI system comprising a system controller and, in parallel thereto, an injection system controlled by a panel separate from the MRI controller. This argument is not convincing because claim 1 does not define whether the system controller consists of a single unit. Moreover, the fact that document D1 concerns the evaluation of an injector which was originally designed for angiography and computer tomography and then modified for use in a MRI system should not be overlooked. This explains why, in D1, the injector's control panel is mounted adjacent to the MRI operating console outside of the shielded room. It would, however, be obvious, once evidence is provided for the feasibility of non-manual contrast media injection in MRI applications, to integrate the

injector's control panel into the MRI operating console at least for a fixed installation.

- 4.7 In conclusion, the ground for opposition pursuant to Article 100(a) EPC together with Articles 52(1) and 56 EPC prejudices the maintenance of the patent unamended. The main request is thus not allowable.
- 5. Appellant's auxiliary requests I, III and IV filed on 13 September 2004
- 5.1 In an attempt to better distinguish the invention as claimed from the disclosure of document D2, the MRI system of claim 1 according to the appellant's auxiliary requests I, III and IV filed on 13 September 2004 includes inter alia the amendment that the fiber optic communications link "extends from" the system controller "to" the injection apparatus control means.

The respondent objected to this amendment under Article 123(2) EPC. The appellant, however, submitted that this objection constituted a fresh ground for opposition which should not be considered. This view cannot be accepted because the objection concerns an amendment. It is stated in decision G 0010/91 (EPO OJ 1993, 420; No. 19) that "in case of amendments of the claims or other parts of a patent in the course of opposition or appeal proceedings, such amendments are to be fully examined as to their compatibility with the requirements of the EPC, (e.g. with regard to the provisions of Article 123(2) and (3) EPC)."

5.2 According to the application as filed, the MRI system, in general, includes a controller located externally of

a shielded imaging room, within which a contrast media injection head and a separate injection control unit are positioned. The system controller communicates with the injection control unit via external and internal transceivers which form a communications link for traversing the electromagnetic isolation barrier of the shielded room (column 3, lines 19-26, of the published application). In particular, according to a preferred embodiment, the MRI system comprises a wireless communications link, which extends through a window in the wall of the shielded room barrier and consists of electromagnetic transceivers operating in the infrared or the visual range. Alternatively, a fiber optic communications link is envisaged (column 3, lines 27-42). The preferred embodiment is shown on Figure 1. Externally of a shielded room 17, a communication line 20 connects a system controller 12 with an external transceiver 22 placed at a viewing window 24. A further transceiver 26 is positioned internally of the shielded room 17 at the viewing window 24 opposite the external transceiver 22. An internal communications link 28 connects the internal transceiver 26 with a contrast media injection control unit 30 (column 4, lines 33-55).

5.3 It results from this explicit disclosure that the wireless communications link according to the preferred embodiment only extends from the external transceiver 22 to the internal transceiver 26. As regards the fiber optic communications link, it is not at all described in the application as filed apart from being mentioned as an alternative embodiment. However, a skilled person would understand that the features relating to the wireless communications link also apply mutatis

mutandis to the fiber optic communications link, so that a fiber optic communications link extending from an external electrical to optical (E/O) converter to an internal optical to electrical (O/E) converter can be considered as forming part of the implicit disclosure. In distinction to this teaching derivable from the application as filed, a fiber optic communications link extending from the system controller to the injection apparatus control means represents subject-matter extending beyond the content of the application as filed for various reasons. First, this feature implies hardware which is not disclosed, in particular the integration of the E/O converter into the system controller and of the O/E converter into the injection apparatus control means. Moreover, the original disclosure implies that both the external communications line 20 and the internal communications link 28, as shown on Figure 1, are, in fact, electrical cables. Thus, there is no indication that the whole communications link could be optical. Finally, it would be inconsistent to interpret, on the one hand, in view of the preferred embodiment of Figure 1, the MRI system according to the original claim 5 as comprising a wireless communications link only extending between the external and internal transceivers and, on the other hand, the MRI system according to the original claim 4 as comprising a fiber optic communications link literally extending from the system controller to the infusion apparatus control means.

The appellant submitted that different interpretations were possible, all being derivable for a skilled person from the content of the application as filed. This is not convincing. It is not denied that the appellant's

interpretation of the original disclosure is technically feasible. However, the teaching of the application as filed simply consists in providing a MRI system with a communications link for traversing the electromagnetic barrier of the shielded room, which link does not rely on a connection made by electrical cables. The teaching does not concern whether the communications links provided inside or outside of the shielded room should also not consist of electrical cables. Furthermore, the teaching neither concerns the effect achieved nor the problem solved by such a measure. Albeit, in principle, the link could be realized in different ways, for example by fiber optic cables entirely or in part extending from the system controller to the injection apparatus control means, the particular choice underlying the appellant's amendment under consideration is not originally disclosed.

In conclusion, the requirements of Article 123(2) EPC are not met because the patent, in particular claim 1 according to the appellant's auxiliary requests I, III and IV filed on 13 September 2004, has been amended in such a way that it contains subject-matter which extends beyond the content of the application as filed. These auxiliary requests are thus not allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

R. Schumacher

G. Davies