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Datasheet for the decision of 8 December 2017

Case Number: T 0640/12 - 3.4.01

Application Number: 07425094.5

Publication Number: 1962100

IPC: G01R33/383

Language of the proceedings: EN

Title of invention:
Magnetic structure for MRI machines and MRI machine particularly for orthopedic or rheumatologic applications

Applicant:
Esaote S.p.A.

Headword:

Relevant legal provisions:
EPC 1973 Art. 84, 56

Keyword:
Inventive step - (no)
Auxiliary request - clarity (no)

Decisions cited:

Catchword:

Europäisches Patentamt
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Beschwerdekammern

Boards of Appeal

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Case Number: T 0640/12 - 3.4.01

D E C I S I O N
of Technical Board of Appeal 3.4.01
of 8 December 2017

Appellant: (Applicant)	Esaote S.p.A. via Enrico Melen, 77 16152 Genova (IT)
Representative:	Karaghiosoff, Giorgio Alessandro c/o Praxi Intellectual Property S.p.A. - Savona Via F. Baracca 1R, 4° piano "Il Gabbiano" 17100 Savona (IT)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 1 December 2011 refusing European patent application No. 07425094.5**

Composition of the Board:

Chairman	P. Fontenay
Members:	F. Neumann
	D. Rogers

Summary of Facts and Submissions

I. The Examining Division refused European patent application No. 07 425 094.5. Objections of lack of clarity and lack of inventive step were raised against the claims of both requests on file at that time.

Reference was made to the following prior art document:
D6: WO 2005/109026.

II. The Appellant (Applicant) filed an appeal against the decision.

With the statement setting out the grounds of appeal, the Appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the claims of either a main request or an auxiliary request, both filed with the statement of grounds.

In addition thereto, oral proceedings were requested.

III. The Board issued a summons to oral proceedings and a communication. The Board set out some provisional and non-binding remarks mainly concerning clarity and inventive step of the claims of both requests on file at that time.

IV. In response to the Board's communication, with letter of 24 November 2017, the Appellant filed a set of claims forming the basis of a new main request. Auxiliary Request 1, filed with the statement setting out the grounds of appeal, was neither withdrawn nor replaced.

V. Oral proceedings took place in the absence of the Appellant.

VI. The final requests of the Appellant, are as follows:

As a main request, that the decision under appeal be set aside and that a patent be granted on the basis of claims 1-17 of the "*Principal Request New Claims*" filed with letter of 24 November 2017.

Alternatively, that the decision under appeal be set aside and that a patent be granted on the basis of claims 1-17 filed as Auxiliary Request 1 with the statement setting out the grounds of appeal of 23 March 2012.

VII. Claim 1 of the main request reads as follows:

"*Magnetic structure for MRI machines, which magnetic structure comprises*
a yoke (4) having a geometry having an U or C-shaped section or an annular section a length along an axis perpendicular to the plane along said section and an inner and an outer side;
means (5) generating the magnetic field are secured to the inner side of the yoke (4) the said means being of permanent magnetic type and consisting of two opposing magnetic field generating elements each of the said opposing magnetic field generating elements has a layer of permanently magnetized material and a pole piece (6,7) disposed thereon, on the side of the said layers of permanently magnetized material facing each other; the said opposing magnetic field generating elements being secured to the inner side of the yoke (4) spaced

apart one from the other for generating a magnetic field (Bo) between said poles;
the said means (5) generating the magnetic field and/or at least a part of the said yoke delimit a cavity (CV) for housing a part of a patient body, which cavity can be accessed by at least two openings on two opposing sides of the yoke (4) perpendicular to the said axis,
each pole is formed by two layers one of which is a solid material layer (6) having a thickness from 50% to 75% of the total thickness of the pole and a contact surface to a second layer, the said second layer being a laminated layer (7) having a thickness comprised from 50 to 25% of the total thickness of the pole, the first and the second layer being ferromagnetic and the side of the second layer (7) opposite to the first layer (6) forming the side the pole facing the opposite pole, the maximum permeability of the laminated layer being comprised from 5000 to 7000, preferably 6000;
the sides facing each other of the said opposite poles (6, 7) have a surface comprised from 350 to 2500 preferably from 400 to 2000 cm^2;
on the said sides of the poles facing each other the said poles have a central portion with a plane surface, the plane surfaces of the said central portions of the opposing poles being parallel one with respect to the other and the free distance between the said poles (6, 7) at the said central portion is lower than 30 cm and particularly in the range from 10 to 20 cm;
the layers of permanently magnetized material of each magnetic field generation element being composed of neodymium, wherein the neodymium remanence has a value of 1.1 Tesla or more, particularly from 1.1 to 1.4, preferably from 1.2 to 1.3 Tesla and said layers have a global thickness comprised from 2 to 6 cm with a surface of the side which is in contact with a side of

the pole (6, 7) being equal to the surface of the said side of the pole (6,7) or slightly greater than it;
the extension of the imaging volume (VI), in the direction of the said axis perpendicular to the plane of the section of the yoke (4), is smaller than the extension of the yoke (4) said extension of the imaging volume (VI) corresponding to a length from 10% to 40% particularly from 15% to 35% and preferably from 20% to 30% of the total length of the extension of the yoke along the said axis;
the magnetic structure has an overall volume size from about 0,03 m^3 to about 0.18 m^3, length, height and depth comprised in the range from 30cm x 32cm x 38 cm to 46cm x 55cm x 68cm and a weight from 150 kg to 1200 kg."

Claim 1 of Auxiliary Request 1 reads as follows:

"*Magnetic structure for MRI machines, which magnetic structure comprises*
a yoke (4) having a geometry having an U or C-shaped section or a quadrilateral section,
the said yoke (4) being formed respectively by three or four walls (104,204, 304) a first and a second of which walls (104, 204) are opposed one with respect to the other and are connected together along one peripheral edge by a third wall or along two opposite peripheral edges by a third and by a fourth wall;
said first and second opposed walls being held at a predetermined distance one from the other by the said third wall or by the said third and fourth walls;
means (5) generating a magnetic field are provided being of permanent magnetic type and consisting of two opposing magnetic field generating elements each one containing a layer of permanently magnetized material and a pole (6,7) superposed to the said magnetized

material layer on the respectively facing sides of the said layers of permamnently [sic] magnetized material; the said opposing magnetic field generating elements being borne spaced apart one from the other by the two walls (104,204) of the yoke (4) for generating a magnetic field (Bo) between said poles
which poles (6,7) and which means (5) generating the magnetic field and/or at least a part of which yoke delimit a cavity (CV) for housing at least a part of a patient body, which cavity can be accessed by at least two openings on two opposing sides of the yoke(4) perpendicular to the three or four walls, while inside the volume of said cavity (CV) in a partial volume, so called imaging volume (VI) the said imaging volume (VI) having the form of a sphere having a diameter from 5 to 14 cm, preferably about from 6 to 9 cm, particularly for the hand or an ellipsoid having a major diameter comprised from 10 to 20 cm and a minor diameter comprised from 5 to 12 cm;
the homogeneity of said magnetic field in the said imaging volume is provided with a peak to peak variation from 30 to 50 ppm (parts per million);
the said poles (6, 7) being made of a ferromagnetic material having a maximum permeability of 6000;
each pole is formed by two layers one of which is a solid material layer (6) having a thickness from 50% to 75% of the total thickness of the pole and a contact surface to a second layer which second layer is a laminated layer (7) having a thickness comprised from 50 to 25% of the total thickness of the pole, the first and the second layer having a surface identical to the surface of the pole on the side of the pole facing the opposite pole, the maximum permeability of the laminated layer being comprised from 5000 to 7000, preferably 6000;

the sides facing each other of the said opposite poles (6, 7) have a surface comprised from 350 to 2500 preferably from 400 to 2000 cm^2;
on the sides facing each other of the said opposite poles, the said poles have a central portion with a plane surface, the plane surfaces of the said central portions of the opposing poles being paralle [sic] one with respect to the other and the free distance between the said poles (6, 7) at the said central portion is lower than 30 cm and particularly in the range from 10 to 20 cm;
the layers of permanently magnetized material of each magnetic field generation element being possibly composed of neodymium, wherein the neodymium remanence has a value of 1.1 Tesla or more, particularly from 1.1 to 1.4, preferably from 1.2 to 1.3 Tesla and said layers have a global thickness comprised from 2 to 6 cm with a surface of the side which is in contact with a side of the pole (6, 7) being equal to the surface of the said side of the pole (6,7) or slightly greater than it;
the extension of the imaging volume (VI), in the direction of an axis passing through the two openings on two opposing sides of the yoke (4) which are perpendicular to the three or four walls, is smaller than the axial extension of the yoke (4) said extension corresponding to a length from 10% to 40% particularly from 15% to 35% and preferably from 20% to 30% of the total length of the yoke along the same direction;
the magnetic structure has an overall volume size from about 0,03 m^3 to about 0.18 m^3, dimensions comprised from 30cm x 32cm x 38 cm and 46cm x 55cm x 68cm and a weight from 150 kg to 1200 kg."

Claims 2 to 17 of both requests are dependent claims.

VIII. The arguments of the appellant, insofar as they are pertinent to the present decision, are set out below in the reasons for the decision.

Reasons for the Decision

1. The appeal is admissible.

2. Main request

2.1 Admissibility

2.1.1 The claims of the main request were filed in response to the Board's communication.

2.1.2 In view of the fact that the amendments represented an attempt to overcome at least some of the objections raised in the Board's communication, the main request was admitted into the proceedings.

2.2 Art. 56 EPC 1973

2.2.1 It has not been contested that D6 represents the closest prior art.

D6 discloses a magnetic structure for a dedicated MRI apparatus. The MRI apparatus has a U-shaped structure with two parallel opposed pole pieces disposed a predetermined distance from each other by a U-shaped magnetic yoke. The pole pieces and the yoke delimit a cavity for receiving at least a portion of the trunk of a human body. An imaging volume exists within this cavity which has magnetic field values which enable MRI images of sufficient quality of a patient's spine to be obtained.

The magnetic field generating elements are made up of a three-layer structure comprising a permanently magnetised neodymium layer and a pole piece comprised of a solid material layer with a maximum permeability of about 6000 and a laminated layer with a maximum permeability of between 5000 and 7000 (page 5, lines 19-33). The thicknesses of the layers and the construction parameters of the magnet structure are designed to provide the necessary magnetic field strength and homogeneity for imaging a spine region.

The magnetic structure of claim 1 is composed of the same elements as the magnetic structure of D6. It is only the dimensions of the various elements and their relationship to each other which distinguishes the claimed subject-matter from the magnetic structure of D6.

Specifically, the subject matter of claim 1 differs from the magnetic structure of D6 in that:

(i) the laminated layer has a thickness between 50 and 25% of the total thickness of the pole;
(ii) the surface area of the poles is between 350 and 2500 cm^2;
(iii) the distance between the plane surfaces of the poles is lower than 30 cm;
(iv) the layers have a global thickness between 2 to 6 cm;
(v) the volume of the magnetic structure is between about 0,03 m^3 and 0,18 m^3; and
(vi) the weight of the magnetic structure is between 150 kg and 1200 kg.

No other differences have been identified by the Appellant either in the statement of grounds or in the submissions of 24 November 2017.

2.2.2 The stated aim of the invention is to define "*a magnetic structure for MRI machines that is specifically adapted to acquire diagnostic MRI images of anatomical regions of the hand and/or foot and/or possibly the knee or the elbow*".

It is noted that the aim of the invention in D6 was to provide a magnet structure of reduced size for MRI imaging of the spine region (page 4, lines 28-33). Thus, the underlying motivation of D6 and that of the present invention is the same, i.e. the provision of a magnetic structure of reduced size for dedicated MRI imaging of specific body parts.

2.2.3 Part of the solution of this problem is to define the dimensional constraints to be placed on the magnetic structure. Defining the intended use of the magnetic structure automatically implies certain restrictions on the design thereof.

It is also necessary to define the properties of the magnetic field which optimise the size and shape of the imaging volume for the required body part. Clearly, the properties of the magnetic field must also be such as to guarantee a sufficient signal-to-noise ratio and image resolution.

These considerations are not new and have all been laid out on pages 2 to 4 of D6.

2.2.4 The definition of the dimensions which are required in order to make the magnetic structure suitable to

accommodate "*anatomical regions of the hand and/or foot and/or possibly the knee or the elbow*" concerns the design specification of the structure. Specifically, the distance between the poles (distinguishing feature (iii)) is directly related to the maximum size of the body part to be inserted therebetween. The definition of such a design specification cannot be considered to involve any inventive activity.

Moreover, the volume and weight of the magnetic structure (distinguishing features (v) and (vi)) are merely a consequence of building the structure in accordance with the required dimensional specifications. The definition of the volume and weight cannot be considered to involve any inventive activity.

2.2.5 The only distinguishing features which could possibly contribute to an inventive step are those features relating to the construction of the magnetic field generating elements, namely features (i), (ii) and (iv).

2.2.6 From D6 it is known that the strength and homogeneity of the static magnetic field is determined by the construction of the magnetic field generating elements. Moreover, it is known that the sizes of the patient-receiving cavity and the imaging volume have an influence on the characteristics of the magnetic field to be generated between the two poles. Furthermore, the strength of the static magnetic field affects both the resolution of the acquired images and the signal-to-noise ratio.

Admittedly, this interdependency of the various parameters makes the determination of the dimensions of the components of the magnetic field generating

elements somewhat complex. However, this complexity is mitigated by the fact that it is known from D6 which characteristics the magnetic field has to display for imaging a body part. In particular, D6 uses a static magnetic field strength of 0.2 T to 0.3 T and a homogeneity with a peak-to-peak variation of 50 ppm in the desired imaging volume (page 5, lines 13-18).

So not only is the required size of the cavity known, but also the required magnetic field values are known.

The Board agrees with the view of the Examining Division that it lies within the normal activities of the skilled person to optimise physical dimensions in such a way as to reach the desired effect. In the present case, given the required physical dimensions of the cavity and the imaging volume, this means establishing the dimensions of the three layers making up the magnetic generating elements (i.e. the surface area, the axial extent and the thickness thereof) in order to provide the magnetic field homogeneity and strength which D6 has shown to be appropriate for imaging body parts. In the same manner that these dimensions were established for spinal imaging in D6, this involves routine - albeit somewhat complex - calculations and does not involve any inventive activity.

2.2.7 The Appellant argued that the structure of D6 could not be simply downsized in a linear fashion: a single scaling factor would not apply to all of the parameters involved in the downsizing. Changing one parameter would affect the other parameters differently, the relationship between the various parameters being undefined and unpredictable. In view of the unpredictable influence that the parameters have on

each other, the determination of the various parameters was more than simply an obvious optimisation process.

2.2.8 As pointed out in the contested decision, the dimensions of the layers making up the magnetic field generating elements depend on, e.g., the material of the layers, the size and shape of the yoke and the presence of shimming means. The skilled person would therefore realise that the calculations involve more than a simple linear downscaling.

Nevertheless, the structural arrangement of the magnetic generating elements is the same as that used in D6. Only the dimensions of the various components have been modified to adapt to the newly-defined use of the magnetic structure. As indicated above, the optimisation of the physical dimensions of the magnetic field generating elements does not go beyond what would fall within the normal design activities of the skilled person.

No inventive step can be recognised in what is ultimately a routine optimisation procedure.

2.2.9 Since claim 1 does not involve an inventive step, the main request is not allowable.

3. Auxiliary Request 1

3.1 Art. 84 EPC 1973

3.1.1 Claim 1 is not clear, concise or supported by the description in the following respects.

3.1.2 A number of features are drafted as a result to be achieved rather than defining the concrete structural

features which are necessary to achieve the desired result. This results in a lack of clarity.

For example, claim 1 states that the homogeneity of the magnetic field has a peak-to peak variation from 30-50 ppm. Claim 1 also sets out that the imaging volume has the form of a sphere having a certain diameter or an ellipsoid having certain dimensions. Moreover, claim 1 defines the linear extent of the imaging volume. If these results are all the inevitable consequence of the specific arrangement, dimensions and materials defined in claim 1, then their inclusion in claim 1 is superfluous, thus leading to a lack of conciseness. If not, then they lead to a lack of clarity since it is not apparent how these results may be achieved. Indeed, it would appear that the inclusion of these features represents an attempt to distinguish the claimed subject-matter from the prior art by reference to a number of desiderata. This is particularly apparent with respect to the claimed shape of the imaging volume which may be either a sphere or an ellipsoid. It is not clear how one or the other of these geometries may be achieved.

3.1.3 It is not clear what is meant by "*dimensions comprised from 30cm x 32cm x 38cm and 46cm x 55 cm x 68cm*" in claim 1. It is not clear whether this is an either/or choice or whether it defines a range of acceptable dimensions. In the latter case, it is not clear whether each of the length, breadth and height dimensions may be varied independently of each other or if some relationship between the various dimensions has to be maintained.

3.1.4 Claim 1 sets out that the cavity is for housing "*at least a part of a patient body*". This would imply that

the cavity may also house an entire patient body. In view of the fact that the aim of the invention is to provide a magnetic structure for smaller MRI machines specifically adapted for hand, foot, knee or elbow imaging (page 8, lines 10-25), the use of "*at least*" is not supported by the description.

3.1.5 Claim 1 is unclear with respect to the permeability of the poles. The maximum permeability of the ferromagnetic material from which the poles are made is defined as being 6000 (page 2, lines 13-15 of claim 1). Since the laminated layer is also ferromagnetic (see page 32, line 20), the statement later in the claim that the laminated layer can have a permeability up to 7000 is contradictory.

3.1.6 These points were raised in the Board's communication of 25 August 2017 with respect to claim 1 of the main request pending at that time. It was noted that the wording of claim 1 of Auxiliary Request 1 was only slightly different to the wording of claim 1 of the main request and that the amendments did not affect the substance of the claim.

Although the amendments now made to claim 1 of the current main request overcome the above objections, claim 1 of Auxiliary Request 1 has been left unamended. Consequently, the above objections still apply.

No counter-arguments were provided by the Appellant in defence of Auxiliary Request 1.

3.1.7 Since claim 1 is still unclear in the above respects, Auxiliary Request 1 is not allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

R. Schumacher P. Fontenay

Decision electronically authenticated