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**Datasheet for the decision
of 25 January 2019**

Case Number: T 0516/14 - 3.2.02

Application Number: 00978341.6

Publication Number: 1231860

IPC: A61B6/00, A61B6/03, A61B6/06

Language of the proceedings: EN

Title of invention:
APPARATUS FOR CONE BEAM VOLUME COMPUTED TOMOGRAPHY MAMMOGRAPHY

Patent Proprietor:
THE UNIVERSITY OF ROCHESTER

Opponents:
MIR Medical Imaging Research Holding GmbH
Siemens Aktiengesellschaft

Headword:

Relevant legal provisions:
EPC Art. 54(1), 54(2), 56, 83, 123(2)
EPC R. 115(2), 142(1)(b)
RPBA Art. 12(2), 12(4), 13(1), 13(3), 15(3)

Keyword:

Summons to oral proceedings - continuation of proceedings
without duly summoned party
Insolvency of opponent - interruption of proceedings (no)
Amendments - extension beyond the content of the application
as filed (no)
Sufficiency of disclosure - (yes)
Novelty - (yes)
Late-filed objection - admitted (no)
Inventive step - (yes)

Decisions cited:

T 0629/05, T 1533/07, T 1841/11

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 0516/14 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 25 January 2019

Appellant: MIR Medical Imaging Research Holding GmbH
(Opponent 1) Tretenäcker 9
91096 Möhrendorf (DE)

acting through its insolvency administrator
Mr Harald Schwartz
Königstorgraben 3
90402 Nürnberg (DE)

Appellant: Siemens Aktiengesellschaft
(Opponent 2) Werner-von-Siemens-Straße 1
80333 München (DE)

Respondent: THE UNIVERSITY OF ROCHESTER
(Patent Proprietor) 518 Hylan Building
Rochester, NY 14627-0140 (US)

Representative: Kuhnen & Wacker
Patent- und Rechtsanwaltsbüro PartG mbB
Prinz-Ludwig-Straße 40A
85354 Freising (DE)

Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
17 January 2014 concerning the maintenance of
European Patent No. 1231860 in amended form**

Composition of the Board:

| | |
|-----------------|---------------|
| Chairman | E. Dufrasne |
| Members: | D. Ceccarelli |
| | M. Stern |

Summary of Facts and Submissions

- I. The opponents have appealed against the Opposition Division's decision, despatched on 17 January 2014, that account being taken of the amendments made by the proprietor according to the main request, European patent No. 1 231 860 and the invention to which it related met the requirements of the EPC.

- II. Opponent 1 filed notice of appeal and paid the appeal fee on 25 March 2014. The statement setting out the grounds of appeal was received on 23 May 2014.

Opponent 2 filed notice of appeal and paid the appeal fee on 19 February 2014. The statement setting out the grounds of appeal was received on 19 May 2014.

- III. The Board summoned the parties to oral proceedings to be held on 25 January 2019. In the communication accompanying the summons, dated 8 November 2018, the Board provided its preliminary opinion. In particular, the Board noted that objections made by general references to submissions made in the proceedings at first instance appeared to lack substantiation and might be disregarded by the Board. It also stressed that in the context of the problem and solution approach for the assessment of inventive step, it would first have to be established which documents may qualify as the closest prior art. The attention of the parties was drawn to the provisions of Article 114(2) EPC and Articles 12 and 13 RPBA, subject to which the admission of further submissions would have to be decided on.

- IV. By letter dated 14 January 2019, Mr Schwartz informed the Board that he had been ordered to be the insolvency

administrator of the appellant opponent 1 by order of the insolvency court of Fürth, Germany, on 14 July 2016 and that the appeal proceedings would be interrupted "conform § 240 S1 ZPO, german law".

- V. By communication dated 18 January 2019, the Board informed the parties that it did not intend to interrupt the appeal proceedings, drawing attention to Rule 142(1) EPC and decision T 1533/07 in which a request of interruption of the appeal proceedings by the insolvency administrator of the opponent was refused by the competent board. The issue of the interruption would be considered during the oral proceedings, which were maintained as scheduled.
- VI. By letter dated 22 January 2019, the Board and the other parties were informed that the insolvency administrator of the appellant opponent 1 would not take part in the oral proceedings.
- VII. Oral proceedings took place on 25 January 2019 in the absence of the appellant opponent 1.

The appellant opponent 1 ("opponent 1" in the following) had requested in writing that the decision under appeal be set aside and that the patent be revoked.

The appellant opponent 2 ("opponent 2" in the following) requested that the decision under appeal be set aside and that the patent be revoked.

The respondent patent proprietor ("the proprietor" in the following) requested that the decision under appeal be set aside and that the patent be maintained on the basis of one of the main request and auxiliary requests

1 to 3, 4a to 4c and 5, all filed with letter dated 20 December 2018.

VIII. The following documents are mentioned in the present decision:

- D1: US-A-3,973,126;
- D2: US-B-6,298,114;
- D3: WO-A-93/17620;
- D9: US-A-5,949,811;
- E2: JP-A-H07303633;
- E3: "Cone-beam computed tomography with a flat-panel imager: Initial performance characterization", DA Jaffray and JH Siewerdsen, Med. Phys. 27(6), pages 1311 to 1323, June 2000;
- E4: DE-A-2636761;
- E5: WO-A-99/01066;
- Z17: US-A-4,015,836.

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

"A device (200) for producing a three-dimensional tomographic mammography image of a breast (B) of a patient (P), the device (200) comprising:

a gantry frame (206);

at least one motor (212, 214), for moving the gantry frame (206) to form a data acquisition geometry;

a source (210) of radiation (C) attached to the gantry frame (206) to move with the gantry frame (206);

a flat panel detector (208) attached to the gantry frame (206) to move with the gantry frame (206), the flat panel detector (208) being disposed in a path of

the radiation (C); and

a support (202) comprising a breast holder (205) and a table (202) on which the patient (P) rests while projection images of the breast (B) are taken; the table (202) presents a through hole (204) so that the breast (B) to be scanned descends through the hole (204) in the table (202) into the breast holder (205) and the through hole (204) is disposed relative to the source (210) of radiation (C) and the flat panel detector (208) so that the breast (B) to be scanned only is disposed between the source (210) of radiation (C) and the flat panel detector (208);

wherein the at least one motor (212, 214) is adapted to move the gantry frame (206) so that the flat panel detector (208) takes the projection images of the breast (B) by rotating the gantry frame (206) supporting the source (210) and the flat panel detector (208) around an axis (A) passing through the breast (B) so that as the source (210) travels along an orbit (O), the breast (B) remains in the path of the radiation (C) emitted by the source (210);

the device (200) is **characterized in that:**

- a) the source (210) of radiation (C) is a source (210) of cone-beam radiation (C);
- b) the projection images of the breast (B) taken by the flat panel detector (208) are cone beam volume computed tomography breast projection images;
- c) there is provided a reconstruction and processing module (336) forming the three-dimensional tomographic mammography image of the breast (B) from the projection

images of the breast (B) taken by the flat panel detector (208) by performing a cone beam volume CT reconstruction on the image signal;

d) the breast holder (205) is configured to pull the breast out of the chest wall to assure proper imaging of the chest wall and to apply a light and reproducible compression to form the breast (B) into a cylindrical shape."

Claims 2 to 28 of the patent as granted are dependent claims.

X. The arguments of opponent 1, where relevant to the present decision, may be summarised as follows:

Interruption of appeal proceedings

With the opening of insolvency proceedings over the assets of opponent 1, the appeal proceedings had to be interrupted according to § 240 S1 ZPO, German law.

General objections

All objections and arguments presented in the opposition proceedings were referred to.

Added subject-matter

The feature of claim 1 of the main request "the breast holder (205) is configured to pull the breast out of the chest wall to assure proper imaging of the chest wall and to apply a light and reproducible compression to form the breast (B) into a cylindrical shape" belonged to a combination of interacting features that formed an entire scanner, and had been picked out of

context, which resulted in a non-allowable intermediate generalisation.

There was no basis in the original application for the feature of claim 1 of the main request "the table (202) presents a through hole (204) so that the breast (B) to be scanned descends through the hole (204) in the table (202) into the breast holder (205) and the through hole (204) is disposed relative to the source (210) of radiation (C) and the flat panel detector (208) so that the breast (B) to be scanned only is disposed between the source (210) or radiation (C) and the flat panel detector (208)". More specifically, while according to this claimed feature the breast was held in the path of the radiation due to its penetration through the hole, according to original claim 44, it was the breast holder that held the breast in position.

Insufficiency of disclosure

The disclosure of the patent did not enable the skilled person to provide a breast holder configured to pull the breast out of the chest wall as defined in claim 1 of the main request. The breast holder, by applying pressure on the breast as disclosed in the patent, would displace the breast towards the chest rather than pulling it out of the chest wall. Only gravity - not the breast holder - could be responsible for pulling the breast out during the patient's examination.

A breast holder configured to apply a light and reproducible compression to form the breast into a cylindrical shape was not sufficiently disclosed either. The two halves of the breast holder as disclosed in the patent would apply a larger compression towards the chest wall and would depend on

the breast shape and dimensions. Hence, it was hardly possible to obtain a reproducible compression. Figures 7E, 7F and 9C did not show any cylindrical compression either.

A flat panel detector according to claim 1 of the main request was not sufficiently disclosed as it was not clear and unambiguous which specific detector had to be implemented for the invention to be carried out as claimed.

Lack of novelty

D3, which disclosed a device comprising a mechanical arrangement that made it suitable for providing a three-dimensional mammography image of a breast, was novelty-destroying for the subject-matter of claim 1 of the main request.

Lack of inventive step

If not novelty-destroying, D3 at least rendered the subject-matter of claim 1 of the main request obvious.

The subject-matter of claim 1 was not inventive in view of D1 alone, or in combination with D3. More specifically, the only claimed features not explicitly disclosed in D1 were a source of cone-beam radiation and a flat panel detector. Such features were however obvious to the average skilled person. D1 disclosed that the breast was pulled out of the chest wall by gravity. In any case, a breast holder configured to pull the breast out of the chest wall was disclosed in D3 (figure 4).

The subject-matter of claim 1 of the main request was

not inventive starting from D9, which disclosed a device suitable for providing a three-dimensional tomographic image of a breast (figures 1 and 12A). It did not disclose the claimed features of the breast holder. However, the claimed subject-matter was obvious in view of a combination with D1 or D2.

More generally, the skilled person would have no difficulty in combining the teaching of documents concerning whole body CT scanners with devices for performing CT mammography since the technology behind the image provision was essentially the same.

XI. The arguments of opponent 2, where relevant to the present decision, may be summarised as follows:

Interruption of appeal proceedings

There were no reasons for interrupting the appeal proceedings. German law was not applicable in proceedings before the EPO. Rule 142(1)(b) EPC was not applicable to the present situation, since it concerned the interruption of proceedings in cases of insolvency of the patent proprietor. Moreover, reference was made to decision T 1533/07.

General objections

All objections and arguments presented in the opposition proceedings were referred to.

Added subject-matter

The feature of claim 1 of the main request "the breast holder (205) is configured to pull the breast out of the chest wall" was not disclosed in the application as

originally filed. The skilled person would recognise that the disclosed movement of the two halves of the breast holder could only result in the application of pressure to the breast without any pulling action out of the chest wall.

Insufficiency of disclosure

The disclosure of the patent did not enable to skilled person to provide a breast holder configured to pull the breast out of the chest wall as defined in claim 1 of the main request. The whole patent comprised only one passage, in paragraph [0041], mentioning that the breast was pulled out of the chest wall by the breast holder. However, it did not explain how, especially in view of the fact that different patients had breasts of different sizes and that no harm should be caused to the patient. The common general knowledge did not help the skilled person either. Rather, it was clear that only gravity - not the breast holder - could be responsible for pulling out the breast during the patient's examination.

A breast holder configured to apply a light and reproducible compression to form the breast into a cylindrical shape was not sufficiently disclosed. Such a shape might only be obtained with specific combinations of the breast size and the diameter of the cylinder built up by the two halves of the breast holder. Hence, the claimed cylindrical shape could not be obtained on a regular basis. Even the embodiment of figures 2A, 2F, 7D to 7g and 8B showed a breast which did not have the claimed cylindrical shape.

The feature that "the projection images of the breast taken by the flat panel detector are cone beam volume

computed tomography breast projection images" was not sufficiently disclosed either. The term "computed" could refer to "images" rather than "tomography". Moreover, the claimed reconstruction and processing module forming the three-dimensional tomographic image of the breast by performing the reconstruction of the image signal could not be carried out by the skilled person because no specific image signal was defined in the claim.

The feature that "the breast (B) to be scanned only is disposed between the source (210) of radiation (C) and the flat panel detector(208)" was also objected to. If the term "only" referred to "the breast" and not the action of scanning, i.e. if only the breast was scanned, then no imaging of the chest wall would take place, which was in contradiction with the further claim requirement that proper imaging of the chest wall had to be ensured.

Lack of novelty

The subject-matter of claim 1 of the main request was not novel over D1 or Z17. These documents, which were identical in their relevant parts, disclosed, in particular, a support table with a hole, a fluid-filled container to accommodate a breast, and a breast holder configured to pull the breast out of the chest wall as claimed. A patient lying on the support table with her breast extending through the hole would have the breast pulled out of the chest wall by gravity, at least when the breast was not in the container.

D3 was also novelty-destroying for the subject-matter of claim 1 of the main request. In particular, D3 disclosed a breast holder (figure 4) that applied

pressure to the breast in the same way as described in the patent in suit. D3 did not disclose that imaging of the breast was performed while the patient was standing. Hence, it could not be excluded that figure 5 disclosed a hole in a table through which the breast to be scanned descended.

Lack of inventive step

The subject-matter of claim 1 of the main request was not inventive when starting from D1, E3, E4, E5 or E2.

The objection starting from E2 had been raised in appeal for the first time during the oral proceedings because the representative had been given and studied the case only shortly before the oral proceedings. The objection had to be admitted because it was based on the same arguments as those already on file, albeit on the basis of a different choice of prior-art documents. Hence, it did not raise any new issues for the proprietor and the Board to deal with. Furthermore, E2 was *prima facie* relevant as it disclosed many of the features of claim 1 of the main request. Although it was in Japanese, a translation, D2, had been provided. The fact that the figures and their reference signs in these two documents were not the same was not relevant, since the figures were still similar.

E3 and E5 concerned whole body CT scanners. However, E3 disclosed examinations of the breast (figure 5) and tests with objects of cylindrical shape (table 1 and figure 2). E5 provided three-dimensional tomographic images and was suitable for scanning the breast, as shown in figure 9. Hence, both E3 and E5 could qualify as the closest prior art.

Starting from D1 or E4 as the closest prior art, it was argued that those documents disclosed a breast holder configured to pull the breast out of the chest wall as defined in claim 1 of the main request since at least for some time during the use of the mammography devices of both D1 and E4 (page 4, second paragraph) the breast was pulled out of the chest wall by gravity. According to the patent, the pulling out of the breast could not be important as a piston (218, figure 7D) for pushing the breast up was optionally employed.

- XII. The arguments of the proprietor, where relevant to the present decision, may be summarised as follows:

Interruption of appeal proceedings

The proceedings must not be interrupted. According to Rule 142(1) EPC, proceedings before the EPO were only interrupted in the event of legal incapacity of the applicant/proprietor or its legal representative, not of another person or party involved in the proceedings. § 240 ZPO had no effect with regard to proceedings before the EPO.

Added subject-matter

The subject-matter of claim 1 of the main request was based on the application as originally filed.

More particularly, the feature "the breast holder (205) is configured to pull the breast out of the chest wall to assure proper imaging of the chest wall and to apply a light and reproducible compression to form the breast (B) into a cylindrical shape" had a literal basis in the description as originally filed (page 14, lines 20 to 22 of WO-A-01/35829). No other features of the

scanner illustrated in figures 2A to 2F were necessary to solve the problem of the invention.

The feature "the table (202) presents a through hole (204) so that the breast (B) to be scanned descends through the hole (204) in the table (202) into the breast holder (205) and the through hole (204) is disposed relative to the source (210) of radiation (C) and the flat panel detector (208) so that the breast (B) to be scanned only is disposed between the source (210) or radiation (C) and the flat panel detector (208)" was also based on the original disclosure. In particular, it was disclosed on page 14, lines 4 to 16; page 18, line 13 to page 19, line 4; and page 19, lines 9 to 17, of WO-A-01/35829.

Insufficiency of disclosure

The skilled person, on the basis of the teaching of the patent and common general knowledge, had no difficulty in providing a breast holder configured to pull the breast out of the chest wall and apply a light and reproducible compression to form the breast into a cylindrical shape as defined in claim 1 of the main request. The patent taught that, with the patient lying on the support table, two halves of the breast holder were brought together to compress the breast into the desired cylindrical shape (paragraph [0051]). The process was illustrated in figure 7D. Taking into account that the breast was compressed while gravity was acting on it in a direction out of the chest wall, the result was that the action of the breast holder pulled the breast out of the chest wall, as disclosed in paragraph [0041]. The cylindrical shape into which the breast was formed was due to the corresponding shape of the breast holder (205a and 205b in figure

7D). A reproducible compression, important for images of the same patient, was obtainable by applying the same force with the breast holder for successive examinations.

A flat panel detector according to claim 1 of the main request was sufficiently disclosed in claims 20 and 21 as well as tables 1 and 2 and paragraphs [0054] to [0056] of the patent.

The feature that "the projection images of the breast taken by the flat panel detector are cone beam volume computed tomography breast projection images" and the reconstruction and processing module as defined in claim 1 of the main request were also sufficiently disclosed. As illustrated in figure 3 of the patent, flat panel detector 208 captured two-dimensional images and provided two-dimensional data to reconstruction and processing module 336, which used those data to compute cone-beam volume computed tomography mammography. Based on that disclosure, it was clear that the term "computed" had to refer to "tomography" and not to "images".

The wording in claim 1 of the main request that "the breast (B) to be scanned only is disposed between the source (210) of radiation (C) and the flat panel detector(208)" meant that the claim was restricted to a mammography CT system as only the breast was scanned. It did not encompass standard whole body CT systems, which delivered unnecessary radiation to body parts other than the breast.

Lack of novelty

The subject-matter of claim 1 of the main request was novel.

D1 and Z17 did not disclose a breast holder to pull the breast out from the chest wall. To the contrary, they disclosed a container for the breast filled with water or a similar medium. The medium pushed the breast towards the chest wall since the breast, with its high fat content, floated in the medium. The claim required that the breast holder - not only gravity - pulled the breast out of the chest wall.

D3 did not disclose a CT device or the production of CT images. Moreover, D3 did not disclose a table with a hole for the breast to descend through. As explained on page 7 of D3, figure 5 was a bottom view, which meant that the breast was not descending through the hole in table top 11 (figure 3).

Lack of inventive step

The objection of lack of inventive step starting from E2 must not be admitted. It had been raised very late in the appeal proceedings without any compelling reason. The proprietor was not prepared to address it. Moreover, E2 was in Japanese, and D2 did not represent a true translation since the figures in the documents were different. It was also not clear why E2 should be, *prima facie*, more relevant than the many documents already in the proceedings.

D9, E3 and E5 could not qualify as the closest prior art as they concerned whole body CT scanners incapable of imaging just the breasts well.

D1 and E4 did not disclose a breast holder to pull the breast out from the chest wall. Furthermore, they taught away from it as they proposed breast holders pushing the breast towards the chest wall. Piston 218 of the patent was not employed to push the breast towards the chest wall but to push up the nipple and obtain a better cylindrical shape.

D3 concerned stereotactic x-ray biopsy guidance by employing two standard two-dimensional mammograms taken from different angles. It did not concern a CT device and did not disclose CT images.

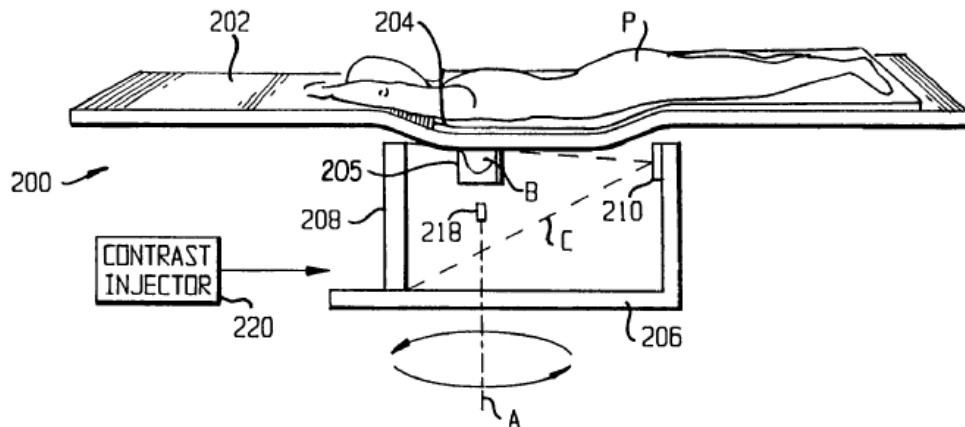
It followed that the skilled person, based on the cited prior art, would not arrive at the subject-matter of claim 1 of the main request in an obvious way.

Reasons for the Decision

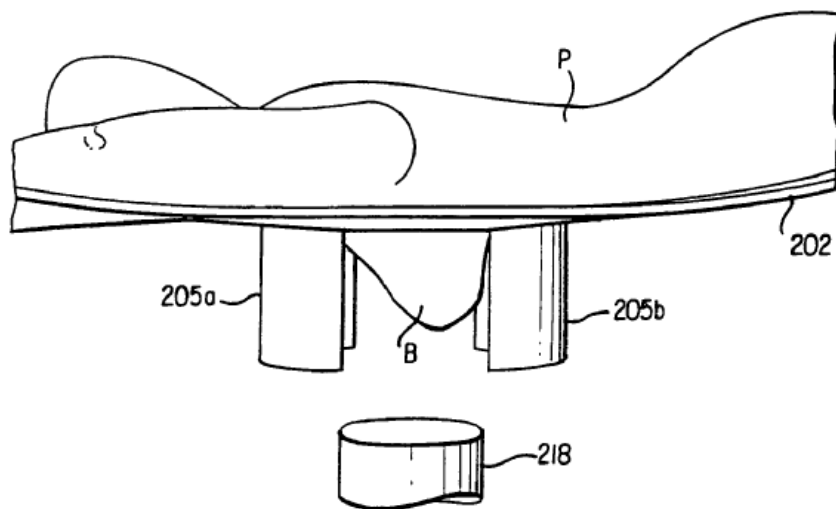
1. The appeals are admissible.
2. The invention

The invention relates to a device for producing a three-dimensional tomographic mammography image, with the general objective of making possible an early detection of breast cancer.

The device is generally depicted in figure 2A, reproduced below.



It comprises a gantry frame (206) movable by a motor and to which a source (210) of cone-beam radiation (C) and a flat panel detector (208) are attached, and a support comprising a table (202) on which a patient rests while projection images of a breast (B) are taken. The table has a through hole (204), through which the breast descends. The support further comprises a breast holder (205) configured to pull the breast out of the chest wall and form it into a cylindrical shape. According to an embodiment depicted in figure 7D reproduced below, the breast holder comprises two halves 205a and 205b which are pressed together to pull and form the breast as claimed. A piston (208) may be provided to push the nipple towards the chest wall (page 5, lines 23 and 24).



In use, the breast is positioned between the source of radiation and the flat panel detector while the motor rotates the gantry frame around an axis passing through the breast so that the breast remains in the path of the radiation emitted by the source and projection images are taken by the flat panel detector. A reconstruction and processing module forms a three-dimensional tomographic mammography image from the projection images.

According to the patent, the three-dimensional tomographic mammography image obtained with the claimed invention makes it possible to better detect breast cancer (paragraphs [0025] to [0032] in particular).

3. Although having been duly summoned by communication dated 8 November 2018, opponent 1 was not present at the oral proceedings as announced by letter dated 22 January 2019. In accordance with Rule 115(2) EPC and Article 15(3) RPBA, the proceedings were continued without opponent 1, who is treated as relying only on its written case.

4. Interruption of appeal proceedings

The insolvency administrator of opponent 1 submitted that with the opening of insolvency proceedings over the assets of opponent 1, the appeal proceedings had to be interrupted according to § 240 S1 ZPO, German law.

In proceedings before the EPO, the applicable law is basically codified in the EPC. Interruption of proceedings is the subject of Rule 142 EPC.

Rule 142(1)(b) EPC stipulates that proceedings before the EPO are to be interrupted "in the event of the applicant for or proprietor of a patent, as a result of some action taken against his property, being prevented by legal reasons from continuing the proceedings".

Neither this nor any other provision mentions an opponent in opposition proceedings. The application of Rule 142(1)(b) EPC to an opponent by analogy is not justified either. Generally, in opposition proceedings, the legal situation for an opponent is different from that of a patent proprietor. While for a patent proprietor the irremediable loss of its patent is at stake, the opponent, if unsuccessful, could still bring an action for revocation before national courts.

According to German law (Schulte, Patentgesetz mit EPÜ, 9. Auflage, Einleitung, 190) when insolvency proceedings are opened, the insolvency administrator is entrusted with the administration of the insolvency assets which may include an opposition, as in the present case. As a consequence, for this appeal, the insolvency administrator became a party to the proceedings, acting for opponent 1 *ex officio* as of 14 July 2016. This provided the administrator with

enough time to become acquainted with the case and prepare for the oral proceedings scheduled on 25 January 2019.

In conclusion, the Board sees no compelling reason for an interruption and, following also decision T 1533/07 (point 2 of the Reasons), decides to continue the appeal proceedings.

5. General objections

The opponents generally referred to all objections and arguments presented in the opposition proceedings.

In accordance with what was pointed out already in the communication accompanying the summons to oral proceedings, such objections lack substantiation. In particular, such general references do not deal clearly and concisely with the reasons in the impugned decision.

Hence, those objections do not meet the requirements of Article 12(2) RPBA and are disregarded under Article 12(4) RPBA.

6. Main request - Added subject-matter

6.1 The Opposition Division and the parties, when considering the requirements of Article 123(2) EPC concerning added subject-matter, partly referred to the content of the international application published under the PCT (WO-A-01/35829). The application as originally filed, however, was amended before publication by the filing of substitute sheets, which differ in substance from the original application documents. It is on the basis of the application as

originally filed, to which the Board refers in the following, that the requirements of Article 123(2) EPC have to be assessed.

6.2 The opponents raised a number of objections against claim 1 of the main request.

The Board sees a general basis for the subject-matter of that claim on claims 16 and 31 to 33, page 11, line 4, to page 12, line 21, and figures 2A to 2C of the application as filed.

Both opponents objected to the feature "the breast holder (205) is configured to pull the breast out of the chest wall to assure proper imaging of the chest wall and to apply a light and reproducible compression to form the breast (B) into a cylindrical shape".

This feature finds a literal basis on page 12, lines 19 to 21, of the application as originally filed. Thus, the argument of opponent 2 that the feature as such was not originally disclosed is without merit.

Opponent 1 argued that the feature belonged to a combination of interacting features that formed an entire scanner, and had been picked out of context, thereby constituting a non-allowable intermediate generalisation. The Board does not share this view as the claimed feature of the breast holder specifically relates to the forming of the breast, whereas the other features of the scanner mentioned by opponent 1, i.e. the material of the breast holder and the motors for driving the gantry frame and the flat panel detector, have different technical purposes. For this reason, these latter features are not inextricably linked, from a technical point of view, with the claimed feature of

the breast holder. It follows that the intermediate generalisation does not add any technical information that was not present in the application as originally filed.

As regards the objection of opponent 1 to the feature "the table (202) presents a through hole (204) so that the breast (B) to be scanned descends through the hole (204) in the table (202) into the breast holder (205) and the through hole (204) is disposed relative to the source (210) of radiation (C) and the flat panel detector (208) so that the breast (B) to be scanned only is disposed between the source (210) or radiation (C) and the flat panel detector (208)", the definition of the hole and its position with respect to the breast holder finds a basis in page 12, lines 4 to 6, of the application as originally filed. Furthermore, the Board does not see why claim 1 of the main request should require that the breast be held in position by the hole as argued by opponent 1. The claim merely specifies that the position of the hole is such that, in use, the breast descends into the breast holder. It is the latter that holds the breast in position, as its very name makes clear.

6.3 In summary, none of the objections as to added subject-matter raised by the opponents are convincing and Article 123(2) EPC is complied with.

7. Insufficiency of disclosure

7.1 The requirement of sufficiency of disclosure, prescribed in Article 83 EPC, is distinct from the requirements of clarity of the claims (Article 84 EPC). Sufficiency of disclosure has to be assessed taking into consideration the disclosure of the patent as a

whole as well as the common general knowledge of the person skilled in the art (e.g. T 629/05, point 4 of the Reasons). This implies that the patent does not have to describe in detail every structural feature to be employed for achieving a certain function as long as the skilled person can reasonably be expected to figure out suitable arrangements based on common general knowledge.

- 7.2 The opponents submitted that the disclosure of the patent did not enable to skilled person to provide a breast holder configured to pull the breast out of the chest wall as defined in claim 1 of the main request.

The patent explains that the breast holder, in use, applies a compression to the breast to form it into a cylindrical shape (page 5, lines 21 to 23). The breast holder may comprise two halves, to be brought together around the breast to compress the breast into the cylindrical shape (paragraph [0051]). Due to the shape of the breast, the two halves of the breast holder will contact the base of the breast close to the chest wall first. As the proprietor argued, it is plausible that, by applying compression, the breast will deform towards the other extremity, out of the chest wall, where there is space left by the two halves. In any case, because of the compression acting on the periphery of the breast, the skilled person, wanting to make sure that the breast is pulled out from the chest wall by the breast holder as claimed, would simply have to provide some outward displacement of the breast holder, which, by friction, would pull the breast with it. Thus, the patent sufficiently discloses a breast holder configured to pull the breast out of the chest wall within the meaning of claim 1. An interpretation according to which the pulling out would only be the

result of gravity is ruled out by the wording of the claim, which requires the breast holder to pull the breast out of the chest wall.

- 7.3 The opponents further objected that a breast holder configured to apply a light and reproducible compression to form the breast into a cylindrical shape was not sufficiently disclosed either.

While the Board agrees with the opponents that the compression between two halves of the breast holder is higher towards the chest wall and depends on the breast shape and dimensions, it is also true that the skilled person can set up the size of the two halves of the breast holder and the level of compression for the particular patient under examination and that, once the set-up has taken place, the compression would be reproducible for the specific patient. What is meant by the cylindrical shape and how it can be obtained is clear from paragraphs [0041], [0050] and [0051]: it is the shape that the breast will assume when squeezed between the two halves of the breast holder, possibly after the additional application of an axial load by a piston acting on the breast nipple (page 5, lines 23 and 24). Whether some figures of the patent, possibly because of their schematic nature, do not show a breast in the claimed cylindrical shape is of no relevance as long as that shape is sufficiently disclosed in the remainder of the patent.

- 7.4 Opponent 1 raised a further general insufficiency objection to the claimed flat panel detector. The Board shares the proprietor's view that the details of suitable flat panel detectors disclosed in paragraphs [0054] to [0056] - especially page 7, lines 24, 25 and 47 to 49 - together with table 2 provide sufficient

disclosure of flat panel detectors within the meaning of the claim.

- 7.5 Opponent 2 argued that the feature that "the projection images of the breast taken by the flat panel detector are cone beam volume computed tomography breast projection images" and the claimed reconstruction and processing module were not sufficiently disclosed.

The expression "computed tomography" is well known in the art. Moreover, an interpretation according to which the flat panel detector should take "computed images" does not make technical sense as a detector takes images as such. How they are computed belongs to the data processing that takes place afterwards. The claim defines that the images taken by the flat panel detector will be processed to obtain a cone-beam volume computed tomography of the breast as explained, in particular, in paragraph [0025] of the patent. In this context, the expression "image signal" has to be interpreted as the signal comprising the image information taken by the flat panel detector.

- 7.6 A further objection as to lack of sufficiency raised by opponent 2 was directed at the expression that "the breast (B) to be scanned only is disposed between the source (210) of radiation (C) and the flat panel detector(208)".

The Board agrees with the interpretation provided by the proprietor that the term "only" must refer to the breast. In other words, the claim, read in context, requires that only the patient's breast - no other part of the body - is put between the source of radiation and the flat panel detector. An interpretation according to which the term "only" refers to the action

of scanning is technically meaningless in the context of the patent, which clearly teaches that the breast undergoes several other manipulations during the examination (for example, the forming into a cylindrical shape and, optionally, the injection of a contrast medium).

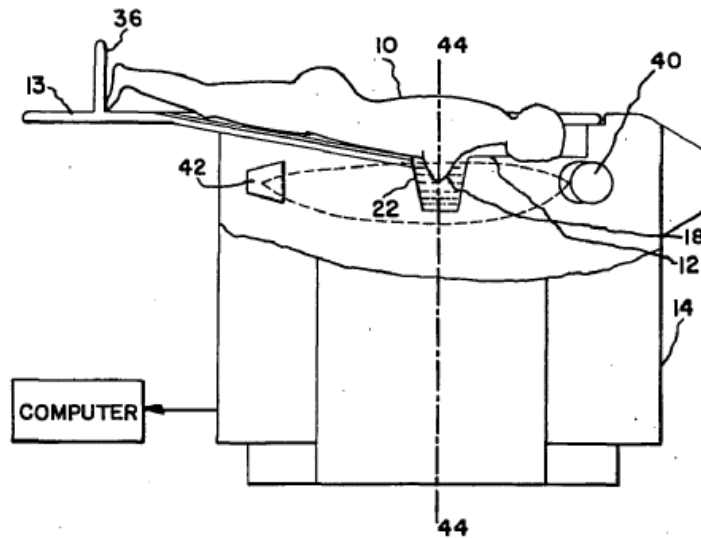
The alleged contradiction to which opponent 2 pointed, i.e. that it would not be possible to obtain imaging of the chest wall as required by the claim, does not exist. Within the meaning of the claim, the chest wall, being adjacent to the breast, is imaged together with the breast.

7.7 In summary, the invention as defined in claim 1 of the main request is sufficiently disclosed. Hence, Article 83 EPC is complied with.

8. Lack of novelty

The opponents argued that the subject-matter of claim 1 of the main request was not novel over each of D1, D3 and Z17.

8.1 Z17 is a US patent derived from a division of D1. To a large extent, these documents provide the same technical disclosure. They concern a mammography machine for examination of a breast positioned in a water-filled container (figure 5, reproduced below).



The inventions of D1 and Z17 stem from the observation that in conical structures of soft tissue such as a breast, a practical tomographic system is incapable of resolving tumours in the region of a tissue-air interface. Surrounding the breast with a medium, such as water, that has an x-ray absorption coefficient close to that of the soft tissue should improve that resolution (column 3, lines 4 to 17, of D1 and column 3, lines 8 to 21, of Z17).

Both D1 and Z17 disclose a device for producing tomographic mammography images of a breast, with a support including a table (12) on which a patient (10) rests, the table having a hole (18) and a breast holder (in the form of fluid-filled container 22), and means for rotating a source of radiation (40) and a detector array (42) about an axis (44) passing through the breast so that multiple images from different observation angles are acquired and the image information is transmitted to a computer for the reconstruction of tissue images (column 4, line 59, to column 5, line 1, of D1 and column 4, line 63, to column 5, line 5, of Z17).

Neither D1 nor Z17 disclose a breast holder configured to pull the breast out of the chest wall and apply compression to form the breast into a cylindrical shape. As the proprietor submitted, due to its high fat content, a breast would float in the medium (water or similar - column 3, lines 12 to 17 and 62 to 67, of D1, and column 3, lines 16 to 21, and column 3, line 66, to column 4, line 3, of Z17). Moreover, in column 3, lines 7 to 12, of D1 and column 3, lines 11 to 16, of Z17, it is even taught that the problem of the inventions of D1 and Z17, solved by the provision of water or a similar medium in a breast holder, would be unimportant in the case of substantially cylindrical structures. This points to the fact that the breast shape in the breast holder of D1 and Z17 is not cylindrical.

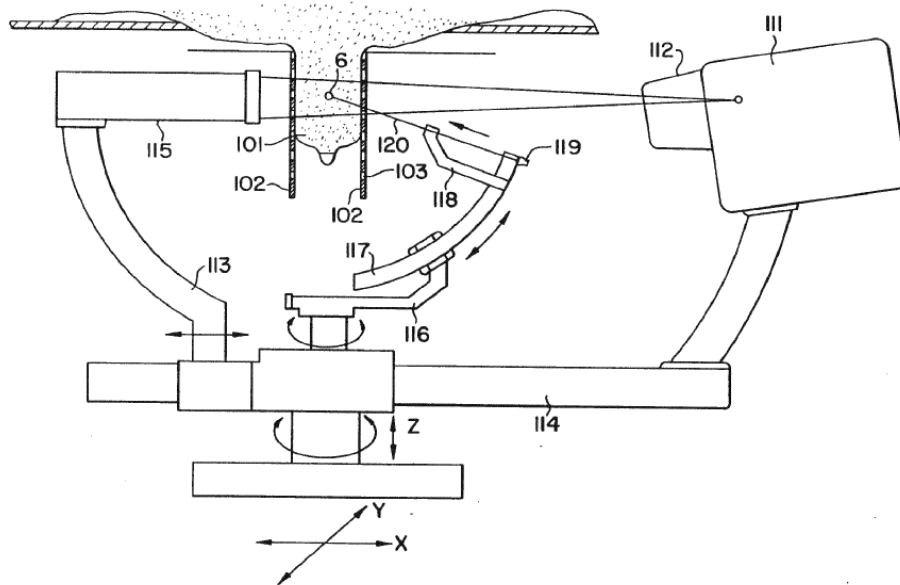
The argument of opponent 2, that a patient lying on the support table with her breast extending through the hole would have the breast pulled out of the chest wall by gravity at least when the breast was not in the container is not convincing since, according to claim 1 of the main request, the breast holder - not just gravity - has to be configured to pull the breast out of the chest wall.

It follows that the subject-matter of claim 1 is novel over each of D1 and Z17.

- 8.2 D3 concerns a device for aiming a puncturing device at an area of interest within a breast of a patient in order to sample, excise or treat suspicious breast lesions (page 1, lines 4 to 12).

With reference to figure 5 reproduced below, it discloses a device with an imaging system (supported by

elongated arm 114) and a movable puncture element (supported by arms 116 and 117) which share a common isocentre. The imaging system comprises means for rotating a source of radiation and a detector array about an axis (Z) passing through the breast so that multiple x-ray images from different observation angles may be obtained.



The images obtained are used to position the area of interest such that it overlies the isocentre. According to D3, this is done by ensuring that the area of interest overlies the isocentre in at least two views (page 5, lines 4 to 7, page 9, lines 14 to 17, and page 11, lines 6 to 8). The device further includes a support including a table on which a patient rests, the table being provided with a hole and a breast holder for applying compression to the breast (page 10, lines 1 to 7).

D3 does not disclose any reconstruction and processing module for forming a three-dimensional tomographic

image of the breast from the projection images acquired by the detector array. On the contrary, on page 7, lines 22 to 26, it is stated that the device of D3 takes advantage of the isocentric geometry for correctly aiming the puncturing device at an area of interest "without the need for realignment, re-imaging of the patient or repeated calculations". The argument of opponent 1 that the mechanical arrangement of the device of D3 would make it possible to form the three-dimensional image is beside the point, since there is no direct and unambiguous teaching that the device as such comprises a reconstruction and processing module suitable for the formation of such an image.

It follows that the subject-matter of claim 1 is also novel over D3.

8.3 As a consequence, claim 1 of the main request is novel (Article 54(1) and (2) EPC).

9. Lack of inventive step

9.1 Opponent 2 raised an objection of lack of inventive step of the subject-matter of claim 1 of the main request starting from E2 for the first time in appeal during the oral proceedings.

Such an objection constitutes an amendment to the appellant's case filed after the statement of grounds of appeal and after oral proceedings had been arranged. Under Article 13(1) RPBA the admission of such an amendment into the appeal proceedings is at the Board's discretion, which is to be exercised in view of, *inter alia*, the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy. Under Article 13(3) RPBA,

such an amendment should not be admitted if it raises issues which the Board and the other parties cannot reasonably be expected to deal with without adjournment of the oral proceedings. A further relevant criterion, according to the established jurisprudence of the boards of appeal, may be the *prima facie* relevance of the amendment.

The objection of lack of inventive step starting from E2 was raised at the latest possible moment in the appeal proceedings without objective reasons. The argument of opponent 2 that the representative had been given and studied the case only shortly before the oral proceedings is without merit as it is a consequence of a free choice of opponent 2.

The new objection clearly raises new complex technical issues as it starts from a document which had not been considered before in the appeal proceedings. Moreover, the document is in a non-official language, and no official translation of it has been provided. D2, which does not belong to the state of the art because of its late filing date, cannot constitute a true translation as it comprises different figures and reference signs. Hence, not even the *prima facie* relevance of E2 could be established.

For these reasons, under Article 13(1) and (3) RPBA, the Board does not admit the objection starting from E2 into the proceedings.

9.2 According to the established jurisprudence of the boards of appeal, inventive step can be assessed following the problem and solution approach.

Accordingly, it has to be established which document or

documents may qualify as the closest prior art. Such documents, which should constitute a promising starting point towards the invention, should be in a technical field and address a technical problem similar to that of the invention as defined in claim 1 of the main request (e.g. T 1841/11, points 2.1 to 2.7 of the Reasons).

In the appeal proceedings, there are objections raised by the opponents starting from D1, D3, D9, E3, E4 and E5.

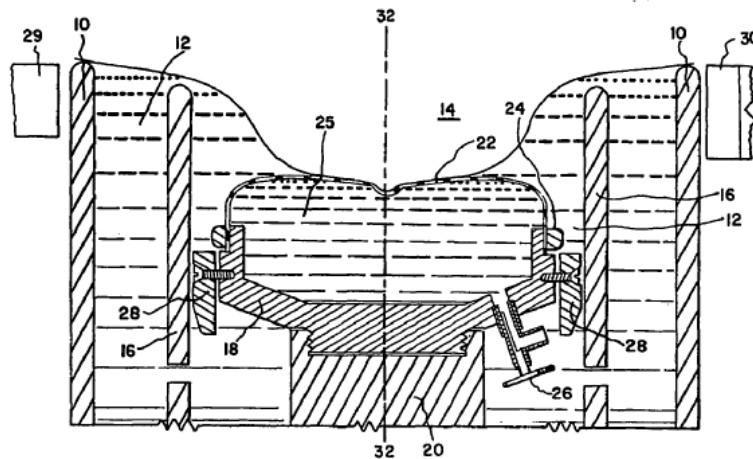
D9 concerns a general-purpose X-ray apparatus. It is mainly directed to setting up proper X-ray conditions as regards the x-ray dose for achieving a certain image level for a particular application (column 5, lines 24 to 63). It is not specifically concerned with mammography and the forming and imaging of the breast only, by providing an x-ray source and a detector rotatable around an axis passing through the breast as defined in claim 1 of the main request. It is only with hindsight that the skilled person would figure out and try to solve problems specific to mammography starting from such a general-purpose document.

Similar considerations apply to E3 and E5, which are concerned with general-purpose cone beam CT systems, albeit providing three-dimensional volumetric images (abstract of E3 and page 1, first four lines of the section entitled "BACKGROUND OF THE INVENTION" in E5). The general reference to a breast in figure 5 of E3, pointed out by opponent 2, does not make the device in E3 a mammography device.

For these reasons, D9, E3 and E5 do not qualify as the closest prior art. Starting from those documents, the

skilled person would not arrive at the subject-matter of claim 1 of the main request in an obvious way. Whether the skilled person, starting from a mammography device and faced with a specific problem in that field would possibly consult whole body CT scanners, as argued by opponent 1, is another question which may depend on the specific problem. There is no need for the Board to answer this question in the present case.

9.3 E4 relates to mammography. Figure 1 of this document is reproduced below.



More specifically, E4 is concerned with the positioning and forming of a hanging breast (14) during X-ray image acquisition with a source (29) and a detector (30) to be rotated around an axis (32) passing through the breast. To improve image acquisition, it proposes to hold the breast in a container (10) filled with an X-ray transmitting medium (12), which can be water (page 5, first half of the third paragraph). An expandable support (18 and 22), which can be filled with the X-ray transmitting medium, is used to form the breast into a cylindrical shape by pressing it towards the chest wall (page 5, last paragraph).

E4 does not disclose a breast holder configured to pull the breast out of the chest wall.

As already explained with relation to D1 and Z17, the argument of opponent 2 that the breast would be pulled out of the chest wall by gravity, at least when the breast was not in the container, is not convincing. According to claim 1 of the main request, the breast holder - not just gravity - has to be configured to pull the breast out of the chest wall.

- 9.4 Starting from either D1 or E4 as the closest prior art, the technical effect of the distinguishing feature of the breast holder configured to pull the breast out of the chest is to have the breast spaced from the chest wall during imaging. According to the patent, that ensures proper imaging of the chest wall and solves the technical problem of better detecting breast cancer. As far as D1 is concerned, the distinguishing feature of the breast holder configured to apply compression to form the breast into a cylindrical shape permits improving the imaging of the breast and addresses the same technical problem.

D1 teaches away from providing a breast holder configured to apply compression to form the breast into a cylindrical shape. More particularly, it stresses the importance of having water or a similar medium in the breast holder to improve imaging of conical structures in contrast to cylindrical structures (column 3, lines 4 to 17). The skilled person would have no reason to provide a breast holder for forming the breast into a cylindrical shape as required by the claim based on that teaching.

E4 teaches away from providing a breast holder configured to pull the breast out of the chest wall. More particularly, it stresses the importance of compressing the breast towards the chest wall by providing an expandable support (page 5, last paragraph). The skilled person would have no reason to provide a breast holder for doing the opposite, i.e. pulling the breast out of the chest wall, as required by the claim.

The argument of opponent 2 that according to the patent the pulling out of the breast could not be important as a piston for pushing the breast up was optionally employed is without merit. As the proprietor argued, when used, the piston of the patent is not employed to push the breast towards the chest wall but only to push up the nipple (page 5, lines 23 to 27).

It follows that, irrespective of whether the distinguishing features as such may be disclosed in other documents cited in the appeal proceedings, the skilled person would not arrive at the subject-matter of claim 1 of the main request in an obvious way when starting from D1 or E4.

- 9.5 Starting from D3 as the closest prior art, a distinguishing feature of the subject-matter of claim 1 of the main request is the claimed reconstruction and processing module for forming a three-dimensional tomographic image of the breast from the projection images acquired by the detector array. The technical effect of the possibility of providing a three-dimensional image, easier to visually analyse than a two-dimensional image, addresses yet the same problem of better detecting breast cancer.

D3 teaches away from that distinguishing feature as it stresses the advantage of having a device for aiming a puncturing device at an area of interest within a breast of a patient "without the need for realignment, re-imaging of the patient or repeated calculations".

Hence, irrespective of whether that distinguishing feature as such may be disclosed in other documents cited in the appeal proceedings, the skilled person would not arrive at the subject-matter of claim 1 of the main request in an obvious way when starting from D3.

9.6 In summary, none of the objections of lack of inventive step in the appeal proceedings is successful. It follows that the subject-matter of claim 1 of the main request is inventive (Article 56 EPC).

10. As a consequence, the patent can be maintained on the basis of the main request. There is therefore no need for the Board to consider the lower-ranking requests of the proprietor.

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, with the order to maintain the patent on the basis of:
 - claim 1 of the main request filed with letter dated 20 December 2018 and claims 2 to 28 of the patent as granted;
 - description and figures of the patent as granted.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated