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Datasheet for the decision of 21 November 2024

Case Number: T 1011/22 - 3.2.02

Application Number: 14855181.5

Publication Number: 3060132

IPC: A61B10/02, A61B6/00, A61B6/02, A61B6/04

Language of the proceedings: EN

Title of invention:
SYSTEM AND METHOD FOR NAVIGATING X-RAY GUIDED BREAST BIOPSY

Patent Proprietor:
Hologic, Inc.

Opponent:

Headword:

Relevant legal provisions:
EPC Art. 54
RPBA 2020 Art. 11

Keyword:
Novelty - main request (yes)
Remittal - (yes)

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Decisions cited:

Catchword:

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Case Number: T 1011/22 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 21 November 2024

Appellant: (Patent Proprietor)	Hologic, Inc. 250 Campus Drive Marlborough, MA 01752 (US)
Representative:	Hoyng Rokh Monegier B.V. Rembrandt Tower, 30th Floor Amstelplein 1 1096 HA Amsterdam (NL)
Respondent: (Opponent)	
Representative:	De Ros, Alberto BIRD & BIRD SOCIETA TRA AVVOCATI S.R.L. Via Porlezza, 12 20123 Milano (IT)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 23 February 2022 revoking European patent No. 3060132 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	S. Böttcher
	N. Obrovski

Summary of Facts and Submissions

I. The patent proprietor filed an appeal against the decision of the Opposition Division to revoke the patent. The Opposition Division held that the subject-matter of claim 1 of the patent as granted lacked novelty in view of D2 = WO 2012/122399 A1.

II. The appellant (patent proprietor) requests that the decision be set aside and that the case be remitted to the Opposition Division for further assessment based on the main request (patent as granted). Auxiliary, it requests that the patent be maintained on the basis of the main request or on the basis of any of auxiliary requests A to H filed with the statement of grounds of appeal (SGA).

III. The opponent withdrew the opposition on 11 November 2022 without submitting a reply to the SGA.

IV. Claim 1 of the main request (patent as granted) reads as follows:

"A method (160) of obtaining a target location for performing a biopsy on a breast of a patient, the method comprising:
compressing the breast of the patient with a paddle of an imaging system;
performing an initial imaging procedure on the breast of the patient, wherein the initial imaging procedure comprises imaging the breast with an x-ray source at a first energy to obtain a first image and a second energy to obtain a second image;
generating a composite image from the first image and the second image;

displaying the composite image;
targeting a region of interest on the composite image to obtain the target location for performing the biopsy on the breast of the patient."

Claim 11 of the main request (patent as granted) reads as follows:

"A method of identifying a region of interest for performing a biopsy on a breast of a patient, the method comprising:
compressing the breast of the patient with a paddle of an imaging system;
delivering a plurality of x-ray energies to the breast from an x-ray source, so as to obtain a plurality of images;
identifying at least one difference between the plurality of images, wherein the difference corresponds to the region of interest;
displaying at least one image of the breast;
identifying the region of interest on the displayed image for performing the biopsy on the breast of the patient."

Claim 12 of the main request (patent as granted) reads as follows:

"A system (1) for obtaining a target location for performing a biopsy on a breast of a patient, the system comprising:
an imaging system;
a paddle for compressing the breast of the patient;
the imaging system arranged to performing an initial imaging procedure on the breast of the patient, wherein the initial imaging procedure comprises imaging the breast with an x-ray source at a first energy to obtain

a first image and a second energy to obtain a second image;
the imaging system arranged generate a composite image from the first image and the second image;
a display (5,122) for displaying the composite image;
a biopsy assembly arranged to target a region of interest on the composite image to obtain the target location for performing the biopsy on the breast of the patient."

V. Documents referred to by the appellant.

D2 WO 2012/122399
E1 D. Kopans, "Breast imaging", 3rd edition, published 2 November 2006;
E2 Mark B. Williams, et al., "Optimization of exposure parameters in full field digital mammography", published 20 May 2008
E3 Idris A Elbakri et al., "Automatic exposure control for a slot scanning full field digital mammography system", published September 2005 in Med. Phys., 32(9), pages 2763 to 2770 (abstract only)
E4 Steve Si Jia Feng et al., "Clinical Digital Breast Tomosynthesis System: Dosimetric Characterization" Radiology, 2012, Apr., 263(1): 35-42

VI. The appellant's arguments may be summarised as follows.

Main request - novelty in view of D2

The imaging procedure mentioned in paragraph [0062] of D2 could not be considered an initial imaging procedure in the sense of claim 1 since an initial imaging procedure either was an imaging procedure for acquiring "scout images" as mentioned in paragraph [0099] or at

least required a further imaging step which had to be considered as implicitly included in claim 1.

In D2, it was the 3D slice image TrSE on which a region of interest was targeted to obtain the target location for performing the biopsy on the breast of the patient, and not the dual-energy 2D mammogram image MpCDE. The MpCDE only revealed positions of possible vascular abnormalities in two dimensions.

Hence, D2 did not disclose to target a ROI on the weighted combination dual-energy 2D mammogram image mentioned in paragraph [0062].

The same arguments held for claim 12.

With respect to claim 11, the region of interest identified on the MpCDE was not identified for performing the biopsy on the breast of the patient, since in paragraph [0062] the TrSE revealed 3D positions of the abnormalities.

Hence, the subject-matter of claims 1, 11 and 12 was novel over D2.

Reasons for the Decision

1. Subject-matter of the patent

The patent relates to imaging methods of a breast of a patient to obtain a target location for performing a biopsy and to an imaging system for obtaining such a target location. The purpose is to provide an image guided biopsy approach that targets and presents a region of interest reliably, accurately and consistently (paragraph [0006]). A "region of

interest" (ROI) can be a mass or calcification or a specific area within the breast that may contain such a mass or calcification (paragraph [0002]).

In the method according to claim 1 of the patent as granted (main request) the breast of the patient is compressed with a paddle of an imaging system and an initial imaging procedure is performed. This initial imaging procedure comprises obtaining two X-ray images, one at a first energy and one at a second energy. From the two images a composite image is generated and displayed. Then, a region of interest is targeted on the composite image for performing the biopsy.

In the method according to claim 11 of the main request the breast is also compressed with a paddle of an imaging system. Then, a plurality of X-ray images are obtained and at least one difference corresponding to a ROI is identified between the images. The method further comprises displaying at least one image of the breast and identifying the ROI on this image for performing the biopsy.

Claim 12 relates to an apparatus for performing the method according to claim 1.

2. Main request - novelty in view of D2

2.1 D2 relates to systems and methods that facilitate screening and diagnosis of breast abnormalities (paragraph [0013]). D2 mentions in paragraph [0045] that the systems may integrate a biopsy capability with lesion localization software.

2.2 In the Opposition Division's view, the term "initial" in claim 1 did not have any intrinsic meaning apart

from that something else, which was however not specified, had to happen thereafter. The Board agrees with this finding.

Although "scout images", i.e. images to confirm that the target is in the imaging window, may be obtained as initial images in an imaging procedure, it cannot be concluded that an initial imaging procedure is inherently a procedure where scout images are taken. From paragraphs [0081] and [0082] and Figure 19 of the patent it can rather be derived that the initial imaging procedure (column 30, lines 25 to 26) is meant to be followed by a further imaging procedure after the biopsy (column 31, lines 4 to 7). However, this further imaging procedure is not mentioned in the claim, and the subject-matter of the claim cannot be regarded as being limited to methods that include this (or any other) further imaging procedure. Hence, the imaging procedure described in paragraph [0062] of D2 can be regarded as an initial imaging procedure.

2.3 The Opposition Division further considered that the step of targeting a region of interest (ROI) was implicitly disclosed either in paragraph [0063], referring to identification of an abnormality in the composite image, or in paragraph [0045], mentioning a lesion localization software.

In paragraph [0062] it is mentioned that a 2D low-energy mammogram and a 2D high-energy mammogram can be computer-processed to form a weighted combination dual energy 2D mammogram image (MpCDE). This MpCDE image is displayed which can help to reveal positions of possible vascular abnormalities in two dimensions. Paragraph [0063] mentions "identification of an abnormality in the MpCDE image". However, a two-

dimensional image cannot be used to determine the 3D position of the abnormality, which would be necessary to obtain the target location for a biopsy. Furthermore, "targeting" requires more than just revealing or identifying an abnormality.

Paragraph [0045] refers to "lesion localization software" which can use "any image", including a 2D image obtained during a dual energy image acquisition process. However, this paragraph does not disclose directly and unambiguously that the targeting is performed (solely) on a composite image obtained from imaging with two energies such as the MpCDE image described in paragraph [0062].

Consequently, since a direct and unambiguous disclosure is required to establish a lack of novelty, the subject-matter of claim 1 is novel since D2 does not disclose the method step "targeting a region of interest on the composite image to obtain the target location for performing the biopsy on the breast of the patient".

2.4 The same arguments hold for claim 12. Hence, the subject-matter of claim 12 is novel since D2 does not disclose a biopsy assembly "arranged to target a region of interest on the composite image to obtain the target location for performing the biopsy on the breast of the patient".

2.5 Claim 11 does not require targeting of a ROI, but requires identification of at least one difference between two images. The displayed image of the breast is not necessarily one of the X-ray images obtained in the method.

The Opposition Division held that paragraph [0057] and claim 6 of D2 implicitly disclosed "the identification of the difference between the images and the ROI upon display of the dual energy subtraction image".

Paragraph [0057] of D2 discloses that several images may be displayed simultaneously, including a subtraction of the low energy image from the high energy image. This subtracted image shows at least one difference between the two images which can represent a ROI. However, this paragraph does not directly and unambiguously disclose that this ROI is identified on a (different) image of the breast. In fact, the actual step of identification is not mentioned at all in paragraph [0057], but rather that the display configuration "enhances the ability to visualise and characterise lesions".

Claim 6, which apparently corresponds to the description in paragraphs [0062] and [0063], discloses to form a weighted combination 2D image from a low energy X-ray image and a high-energy X-ray image, and to display this 2D image and at least one 3D slice image of the breast. It is further mentioned that an abnormality identified the displayed combination 2D image can also be identified and visualised in the 3D image. However, claim 6 does not refer to any differences between the X-ray images or to the weighted combination dual-energy image being obtained by subtracting one image from the other. Subtraction of the images is only mentioned in paragraph [0065] as an example of a weighted combination.

Hence, both paragraph [0057] and claim 6 disclose some sort of identification of the lesion such that it can be seen in the image. However, they don't disclose

directly and unambiguously (as it would be required for a lack of novelty) that the lesion is identified on the displayed image, i.e. that the lesion is indicated on the image.

Hence, the subject-matter of claim 11 is also novel over D2.

3. Remittal to the opposition division

3.1 The sole reason in the appealed decision for rejecting the main request is a lack of novelty over D2. It follows from the reasoning above that this finding of lack of novelty must be set aside.

3.2 Since the opposition was withdrawn, the question arises as to whether the opposition proceedings should be continued pursuant to Rule 84(2) EPC for assessment of the grounds of opposition under Article 100(a) EPC (inventive step), 100(b) and 100(c) EPC, which have not been considered so far by the Opposition Division.

3.3 The primary object of the appeal proceedings is to review the decision under appeal in a judicial manner (see Article 12(2) RPBA 2020). In the present case, no decision exists for these outstanding issues. The Board considers that these circumstances constitute special reasons in the sense of Article 11 RPBA 2020 for remitting the case to the Opposition Division, in accordance with the appellant's main request. Upon remittal, the Opposition Division will have to exercise its discretion as to whether the opposition proceedings should be continued pursuant to Rule 84(2) EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division for further prosecution.

The Registrar: The Chairman:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated