The opinion in support of the decision being entered today was *not* written for publication and is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte AJAY KAPUR, JEFFREY WAYNE EBERHARD, BORIS YAMRON, KAI E. THOMENIUS, DONALD JOSEPH BUCKLEY, JR., ROGER NEAL JOHNSON, REINHOLD F. WIRTH, OLIVER ASTLEY, BEALE OPSAHL-ONG, SERGE LOUIS WILFRID MULLER, and STEVE CARR

Appeal 2007-1926
Application 10/062,334
Technology Center 3700

DECIDED: June 15, 2007

Before TONI R. SCHEINER, LORA M. GREEN, and RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal from the final rejection of claims 1-10 and 12-20. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF CASE

The claims are drawn to an apparatus and method for generating an image of an object. Three-dimensional information about the object is acquired from a movable radiation source and an ultrasound probe is combined to generate a three-dimensional image of the object.

Claims 1-10 and 12-20, all the pending claims, stand rejected over prior art (Br. 2). The Examiner relies on the following evidence of unpatentability:

Getzinger	U.S. Pat. 5,640,956	Jun. 24, 1997
Liou	U.S. Pat. 5,839,440	Nov. 24, 1998
Niklason	U.S. Pat. 5,872,828	Feb. 16, 1999
Nields	U.S. Pat. 6,459,925 B1	Oct. 1, 2002

Claims 1-10 and 12-20 stand rejected under 35 U.S.C. § 103 as obvious over Nields in view of Niklason, Getzinger, and Liou (Answer 2). Claim 10 was separately argued and stands or falls apart from claims 1-9 and 12-20 (Br. 11[1]). 37 C.F.R. § 41.37(c)(1)(vii). We select claim 1 as representative of claims 2-9 and 12-20. Claims 1 and 10 read as follows:

> 1. A method for generating an image of an object of interest, said method comprising:
>
> acquiring a first three-dimensional dataset of the object at a first position using a radiation source and a detector, the radiation source being movable with respect to the detector to a plurality of positions including the first position;

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[1] According to 37 C.F.R. § 41.37(c)(1)(vii), "[a]ny claim argued separately should be placed under a subheading identifying the claim by number." Claim 10 was not properly argued because the separate arguments for its patentability were not placed under a subheading which specifically identified it by claim number. Nonetheless, we have considered Appellants' separate arguments directed to claim 10.

acquiring a second three-dimensional dataset of the object at the first position using an ultrasound probe; and

combining the first three-dimensional dataset and the second three-dimensional dataset to generate a three-dimensional image of the object.

10. An apparatus comprising:

a tomosynthesis imaging system having a radiation source movable with respect to a detector, the tomosynthesis imaging system configured to acquire three-dimensional tomosynthesis dataset;

a compression paddle coupled to the tomosynthesis imaging system;

an ultrasound probe mover assembly mechanically aligned with said compression paddle and with respect to the movable radiation source of the tomosynthesis imaging system; and

an ultrasound probe coupled with said probe mover assembly such that said ultrasound probe emits an ultrasound output signal through said compression paddle and an object of interest, the ultrasound probe configured to acquire three-dimensional ultrasound dataset.

THE PRIOR ART

Nields teaches a system "for x-ray imaging and ultrasound imaging of a body region of interest in a spatially correlatable manner" (Nields, Abstract). Nields

> provides for the transmission of x-ray radiation through a selected body region-of-interest within a predetermined, three-dimensional frame of reference to obtain x-ray image data corresponding with one or more x-ray images. Additionally, an ultrasound signal is directed into a limited, selectively targeted portion of the x-rayed body region of interest to provide ultrasound image data corresponding with one or more

> ultrasound images of the targeted portion of the selected body region. The x-ray and ultrasound image data are acquired in spatial co-relation by utilizing x-ray imaging means and ultrasound imaging means each supportably positioned in known co-relation to the predetermined, three-dimensional frame of reference. This arrangement allows the x-ray and ultrasound image data to combinatively provide correlated, three-dimensional image data corresponding with the body region of interest. In turn, the spatially correlated information allows for an enhanced medical diagnosis of a given location of interest within the body region (e.g., potential lesion or suspicious mass in a breast application) and enhanced biopsy options in relation thereto.

(Nields, col. 3, ll. 9-33).

The x-ray source ("x-ray tube source") is mounted on a support arm ("22") and can be jointly and selectively pivoted relative to the x-ray detector ("x-ray receiver/imager") for imaging the tissue from different directions (Nields, col. 7, ll. 15-29 and 57-64).

Getzinger teaches "[a]pparatus and methods . . . for correlating radiologic and ultrasonic images of biological tissue" (Getzinger, Abstract) "to provide holographic views of a patient's breast tissue" (Getzinger, col. 2, ll. 41-44). Ultrasonic data "comprises a three-dimensional volume sampling of the tissue being examined" (Getzinger, col. 3, ll. 55-57). X-ray beam data is aligned with the three-dimensional ultrasonic data (Getzinger, col. 7, 1. 50 to col. 8, l. 22).

Niklason describes systems and methods for generating three-dimensional (tomosynthetic) images of tissue using a movable x-ray source (Niklason, Abstract; col. 2, ll. 50-58). The methods "are adaptable to current mammography systems with minor modifications" (Niklason, col. 8, ll. 37-

39). Niklason teaches that its methods "improve the specificity of mammography with improved lesion margin visibility and [ ] improve early breast cancer detection" (Niklason, col. 6, ll. 17-21).

Liou teaches that three-dimensional (3D) "image registration techniques are utilized in the fusion of 3D images obtained from various modalities such as CT, PET (Positron Emission Tomography), SPECT (Single Positron Emission Tomography), MRI (Magnetic Resonance Imaging) and ultrasound imaging techniques" (Liou, col. 2, ll. 51-56).

DISCUSSION

The issue in this appeal is whether the claimed method and apparatus would have been obvious to one of ordinary skill in the art at the time the invention was made in view of Nields combined with Niklason, Getzinger, and Liou.

The Examiner states that Nields teaches combining ultrasound data and x-ray data in a spatially co-related manner (Answer 2). The x-ray data is generated with a movable radiation source (Answer 3) as required by claim 1. The Examiner asserts that Nields does not teach obtaining three-dimensional tomosynthetic (x-ray) and three-dimensional ultrasound images (Answer 3). However, the Examiner argues three-dimensional images constructed from ultrasound data and x-ray data were known in the art as evidenced by Getzinger and Niklason, respectively (Answer 3). Furthermore, the Examiner finds that methods of combining three-dimensional images from various modalities, including CT (x-ray) and ultrasound were known in the art at taught in Liou (Answer 3). The Examiner reasons that it would have been obvious to a person of ordinary

skill in the art to have combined three-dimensional ultrasound and x-ray data to obtain "all possible information from all angles regarding the three-dimensional breast tissue while reducing the time it takes to acquire the 3D information by not having to take multiples images which are then combined to form the 3D data" (Answer 3).

Appellants contend that there is no motivation to have combined Nields with the secondary references because "Nields itself would provide a solution to the motivation suggested by the Examiner" (Br. 10). They argue that "Nields provides three-dimensional information from all angles regarding the breast tissue" (Br. 10). Consequently, they assert "[t]here is no need to directly acquire the three-dimensional x-ray or ultrasound dataset" (Br. 10).

In making an obviousness determination, it is necessary to consider the differences between the claimed invention and the prior art in the context of the level of the person of ordinary skill in the art. *Graham v. John Deere Co.*, 383 U.S. 1, 13-14, 148 USPQ 459, 465 (1966).

The Examiner provides evidence that combining three-dimensional information from different imaging modalities was known in the art prior to the application's filing date. Both Nields and Getzinger teach combining ultra-sound and x-ray image data in register to produce more comprehensive information about a biological tissue, such as breast tissue (Nields, col. 3, ll. 9-33; Getzinger, col. 3, ll. 41-44). Each patent describes a different approach to combining ultrasound and x-ray data to produce information about the tissue in three-dimensions. Liou explicitly teaches that "prior art 3D registration techniques" have been utilized to blend images obtained

from various modalities, including x-ray ("CT") and ultrasound (Liou, col. 2, ll. 51-56). In sum, the evidence of record establishes that a person of ordinary skill in the art was familiar with combining three-dimensional data from different imaging media and had the technical knowledge to do so. The skilled worker would also have had reason to combine such data for the purpose of "enhanced medical diagnosis" (Nields, col. 3, l. 31) associated with the higher informational content of a 3D multi-modality (i.e., x-ray and ultrasound) image.

However, neither Nields nor Getzinger teach a method of combining three-dimensional data acquired from an ultrasound probe and movable x-ray source "to generate a three-dimensional image of the object" as required by claim 1. But ultrasound three-dimensional images were known in the prior art (Getzinger, col. 9, ll. 51-53). Three-dimensional x-ray images using a movable x-ray source were also known prior to the application's filing date (Niklason, Abstract; col. 2, ll. 50-58). Putting different images together collected from different imaging modalities was also known (e.g., Nields and Getzinger), including to produce three-dimensional images (Liou, col. 2, ll. 51-56). In sum, the prior art suggests the claimed method of combining known imaging modalities – ultrasound and x-ray – by known methods to produce a composite three-dimensional image. A claim which unites elements with no change in their respective functions to yield a predictable result is not patentable in the absence of secondary considerations.

> For over a half century, the [Supreme] Court has held that a "patent for a combination which only unites old elements with no change in their respective functions ...obviously withdraws

> what is already known into the field of its monopoly and diminishes the resources available to skillful men." *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152 [87 USPQ 303] (1950). This is a principal reason for declining to allow patents for what is obvious. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.

KSR Int'l v. Teleflex Inc., 127 S. Ct. 1727, 82 USPQ2d 1385, 1395 (2007).

The Examiner provides a sound reason for combining ultrasound with x-ray data to produce a composite three-dimensional image: to provide more information about the tissue (Answer 3). As acknowledged in Nields, "spatially correlated information [from ultrasound and x-ray] allows for an enhanced medical diagnosis of a given location of interest within the body region" (Nields, col. 3, ll. 29-31). Dimensional information improves "lesion margin visibility" and "early breast cancer detection" (Niklason, col. 6, ll. 10-21). In sum, we agree with the Examiner's conclusion that the claimed invention would have been obvious to a person of skill in the art at the time the application was filed.

Appellants argue that there would have no motivation to have combined Nields with the secondary references because "Nields itself would provide a solution to the motivation suggested by the Examiner" (Br. 10). We do not find this argument persuasive. Appellants have focused on the Nields disclosure alone, rather than on what the prior art teaches as a whole. We find it compelling that, as pointed out by the Examiner, Liou teaches that "it is known to correlate 3D images from various modalities such as CT [x-ray] and ultrasound" (Answer 3). In other words, the concept of blending three-dimensional images from different technologies was known to the

skilled worker. The reason for correlating data from different technologies in single three-dimensional image is to improve diagnosis and visibility of the tissue of interest; this is logical because it combines information from different technologies, providing more information than either technology alone. It is a "self-evident proposition that mankind, in particular, inventors, strive to improve that which already exists." *Pro-Mold & Tool Co., Inc. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1629-30 (Fed. Cir. 1996). Thus, the skilled worker would have had reason to improve Nields for the expected advantage of enhancing diagnosis and image visibility. Appellants' argument that Nields, and also Niklason, "already provide a solution to the same problem" (Br. 12) ignores the fact the skilled worker normally is motivated to improve what is known in the art, especially when there are explicit suggestions to do so, such as Liou's statement about combining different modalities to produce composite three-dimensional images. Explicit teachings that would lead a person of ordinary skill in the art to a claim's subject matter are not required; "the inferences and creative steps a person of ordinary skill in the art would employ" are also to be taken into account. *KSR*, 82 USPQ2d at 1396.

For the reasons discussed above, we affirm the rejection of claim 1. Because they were not separately argued, claims 2-9 and 12-20 fall with claim 1.

Claim 10

Claim 10 is directed to an apparatus for imaging which comprises "a compression paddle coupled to the tomosynthesis imaging system" and an

"ultrasound probe assembly." The "ultrasound probe assembly" is "mechanically aligned with said compression paddle and with respect to the movable radiation source of the tomosynthesis imaging system." The claim also requires that the "ultrasound probe . . . emits an ultrasound signal through said compression paddle."

The claimed features are described by Nields. Fig. 3 shows the compression paddle 34 coupled to the tomosynthesis imaging system. The ultrasound assembly 100 (including the ultrasound probe), compression paddle 34, and x-ray receiver/imager are connected to the first support arm 20 (Nields, Fig. 3; col. 7, ll. 57-65; col. 8, ll. 20-23 and 58-50). The x-ray tube source 42 is mounted to the second support arm 22 (Nields, Fig. 3; col. 7, ll. 57-57-59). "First and second support arms 20 and 22 can be jointly pivoted relative to pedestal 16" (Nields, col. 7, ll. 15-29; Fig. 3). Thus, the ultrasound assembly (on first support arm 20) is "mechanically aligned" with the radiation source (on second support arm 22), as required by claim 10.

The ultrasound probe emits a signal through the compression paddle and object of interest, meeting the requirements of claim 10 (Nields, col. 8, ll. 50-56: "XYZ ultrasound positioning assembly 140 is employed to selectively position ultrasound imaging head 110 through the window 36 of compression paddle 34 to establish direct breast contact for targeted ultrasound imaging in determinable spatial relation to the predetermined XYZ frame of reference").

In sum, Nields shows that the ultrasound data and x-ray data are registered through the compression paddle, contrary to Appellants' assertion (Br. 11; Reply Br. 4). Accordingly, we affirm the rejection of claim 10.

In affirming the rejection of claim 10, we recognize that we have relied upon disclosure in Nields which was not described or cited in the Answer. Accordingly, to provide Appellants with the opportunity to respond, we designate the rejection of claim 10 as a new ground under 37 C.F.R. § 41.50(b).

TIME PERIOD

Regarding the affirmed rejection(s), 37 C.F.R. § 41.52(a)(1) provides "[a]ppellant may file a single request for rehearing within two months from the date of the original decision of the Board."

In addition to affirming the examiner's rejection(s) of one or more claims, this decision contains a new ground of rejection of claim 10 pursuant to 37 C.F.R. § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 C.F.R. § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 C.F.R. § 41.50(b) also provides that the appellant, *WITHIN TWO MONTHS FROM THE DATE OF THE DECISION*, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

> (1) *Reopen prosecution*. Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the

> examiner, in which event the proceeding will be remanded to the examiner. . . .
> (2) *Request rehearing*. Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

Should the appellant elect to prosecute further before the examiner pursuant to 37 C.F.R. § 41.50(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejection, the effective date of the affirmance is deferred until conclusion of the prosecution before the examiner unless, as a mere incident to the limited prosecution, the affirmed rejection is overcome.

If the appellant elects prosecution before the examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Board of Patent Appeals and Interferences for final action on the affirmed rejection, including any timely request for rehearing thereof.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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