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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte STEFANO DE BENI and MARCO MACCIO’

Appeal 2019-000703
Application 12/508,266¹
Technology Center 3700

Before MICHAEL W. KIM, PHILIP J. HOFFMANN, and
CYNTHIA L. MURPHY, *Administrative Patent Judges*.

HOFFMANN, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellants appeal from the Examiner’s rejection of claims 1, 4–12, 14, 17–24, 27–29, 31, and 32. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

According to Appellants, “[t]he invention relates to a device and a method for guiding surgical tools by ultrasonic imaging.” Spec. 1, ll. 11–12.

¹ “The real party in interest is Esaote, S.P.A.” Appeal Br. 3.

Claims 1, 12, and 27 are the independent claims under appeal. Below, we reproduce claim 1 as illustrative of the appealed claims.

1. A device for guiding surgical tools by real-time ultrasonic imaging, which device comprising:

a) an ultrasound system for acquiring in real-time a sequential plurality of 3D ultrasonic images of a target area;

b) a system for determining in real-time and tracking of the position and orientation of a surgical tool and for defining in real-time the direction of a characteristic axis of the tool corresponding to the detected position and orientation of the tool;

c) a unit for determining in real-time the position of a working end of the tool along said direction of said characteristic axis;

d) a system for determining the relative position in space of each 3D ultrasonic image and the direction of the characteristic axis of the tool corresponding to each 3D ultrasonic image; and

e) a unit for generating, for one or more of the 3D ultrasonic images acquired sequentially, a real-time 2D image defined by a 2D image plane that intersects a corresponding 3D ultrasonic image, which 2D image plane is perpendicular to the direction of the characteristic axis of the tool determined in real-time and is spaced a predetermined distance forward of the working end of the tool with reference to the orientation and position of the tool upon acquisition of the corresponding 3D ultrasonic image, said 2D image being generated using the corresponding 3D ultrasonic image;

f) a monitor and a unit for displaying said real-time 2D image on said monitor, said real-time 2D image being from the point of view of the tool;

wherein the intersection of the characteristic axis of the tool and the 2D image plane is indicated in said 2D image; and

wherein the position of the target to be treated by said tool is also indicated in said 2D image.

REJECTIONS AND PRIOR ART

The Examiner rejects the claims as follows:

- I. Claims 1, 4–12, 14, 17–24, 27–29, 31, and 32 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written-description requirement;
- II. Claims 1, 4–12, 14, 17–24, 27–29, 31, and 32 under 35 U.S.C. § 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter that Appellants regard as the invention;
- III. Claims 1, 4, 7–10, 12, 14, 19–23, 27–29, 31, and 32 under 35 U.S.C. § 103(a) as unpatentable over Downey et al. (US 2009/0093715 A1, pub. Apr. 9, 2009) (“Downey”), Yanof et al. (US 6,505,065 B1, iss. Jan 7, 2003) (“Yanof”), and Wang et al. (US 2002/0156376 A1, pub. Oct. 24, 2002) (“Wang”);
and
- IV. Claims 5, 6, 11, 17, 18, and 24 under 35 U.S.C. § 103(a) as unpatentable over Downey, Yanof, Wang, and Ben-Haim et al. (US 2001/0044578 A1, pub. Nov. 22, 2001) (“Ben-Haim”).

ANALYSIS

Rejection I

As stated above, the Examiner rejects certain claims as failing to comply with the written-description requirement of § 112, first paragraph. For the following reasons, we do not sustain the rejection.

Specifically, the Examiner rejects independent claims 1, 12, and 27 because claim 1’s recitation of

which 2D image plane is perpendicular to the direction of the characteristic axis of the tool determined in real-time and is spaced a predetermined distance forward of the working end of the tool with reference to the orientation and position of the tool upon acquisition of the corresponding 3D ultrasonic image, said 2D image being generated using the corresponding 3D ultrasonic image

(Appeal Br., Claims App. (Claim 1)) as well as similar recitations in claims 12 and 27 are “not mentioned in the [S]pecification and[, thus, are] considered new matter.” Final Action 5. We agree with Appellants, however, that the claims’ recitations are mentioned numerous times throughout the Specification, such that at least page 9, lines 14–32, and page 18, lines 23–30 of the Specification provides written-description support for the claims recitation. Appeal Br. 8. Although the Examiner further explains that these portions of Appellants’ Specification do not provide support for the above claim recitations because “[t]he portion of the [S]pecification cited by [A]ppellant[s] refers to a ‘cutting’ plane, and it is unclear how this relates to the claimed ‘image’ plane” (Answer 2), Appellants’ Specification clearly describes that “the cutting plane [is the plane] along which the 2D image is generated” (Spec. 9, ll. 18–19)—thus, it is clear that the cutting plane is an image plane.

The Examiner also states that claims 1, 12, and 27 lack support in the written description because “it is unclear what direction is ‘forward’ of the working end of the tool. It is unclear what distance a ‘predetermined distance forward’ would encompass.” Final Action 5. This does not present a proper basis for a written-description rejection. Regardless, at least page 18, lines 23–30 of Appellants’ Specification mentions the claim recitations, thereby providing written-description support. Appeal Br. 13–

14. Specifically, this portion of the Specification describes guiding a surgical tool's movement forward along the tool's axis from one location in a patient to another location in the patient which is spaced apart from the previous location.

The Examiner also states that claims 1, 12, and 27 lack written-description support because “[n]o algorithm is provided to acquire this particular image plane.” Final Action 5. It appears that the Examiner is stating that for the recited function of “generating, for one or more of the 3D ultrasonic images acquired sequentially, a real-time 2D image defined by a 2D image plane that intersects a corresponding 3D ultrasonic image,” the Specification does not provide sufficient detail on how that function is achieved to constitute possession of the invention. *See* Examining Computer-Implemented Functional Claim Limitations for Compliance With 35 U.S.C. 112, 84 Fed. Reg. 57, 61–62 (Jan. 7, 2019) (citing *Vasudevan Software, Inc. v. MicroStrategy, Inc.*, 782 F.3d 671 (Fed. Cir. 2015); *LizardTech Inc. v. Earth Resource Mapping Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005); MPEP 2161.01). As the Examiner recognizes (*see, e.g.*, Answer 5, citing paragraph 95 of Appellants’ published application), however, we agree with Appellants that “[t]he [Specification] acknowledges that the general concept of generating a 2D image from a 3D image is known ([*See*] [p]age 17, lines 24–27 of the [Specification] as filed)” (Reply Br. 4). As evidence that the general concept is known, the Specification refers to EP 1 167 996. We agree with Appellants that when all this is considered as a whole, it constitutes adequate evidence that Appellants had sufficient possession of the recited function, even without further implementation details in the Specification itself.

Finally, the Examiner rejects independent claim 1 as failing to comply with the written-description requirement because claim 1's recitation of "said real-time 2D image being from the point of view of the tool' is not described in the [S]pecification in such a way as to reasonably convey to one skilled in the relevant art that [Appellants], at the time the application was filed, had possession of the claimed invention." Final Action 5. We disagree, however, and agree with Appellants that their Specification sufficiently describes this recitation. Appeal Br. 10. For example, Appellants' Specification explains that

[p]articularly, referring to the needle, a cutting plane may be defined, which is oriented perpendicular to the characteristic functional axis of the tool 2 and is at a predetermined distance from the internal or front end tip, with reference to the direction of insertion of the needle. In this case, the image generated along said cutting plane and reconstructed from the volumetric image data, i.e. the voxels that fall within such cutting plane will be as viewed by an observer situated at the tip of the needle and looking towards the longitudinal axis of the needle in the direction of insertion of the latter.

Spec. 18, ll. 23–30.

Rejection II

As stated above, the Examiner rejects certain claims as indefinite under § 112, second paragraph. For the following reasons, we do not sustain the rejection.

Specifically, the Examiner rejects independent claims 1, 12, and 27 because claim 1's recitation of

which 2D image plane is perpendicular to the direction of the characteristic axis of the tool determined in real-time and is spaced a predetermined distance forward of the working end of

the tool with reference to the orientation and position of the tool upon acquisition of the corresponding 3D ultrasonic image, said 2D image being generated using the corresponding 3D ultrasonic image

(Appeal Br., Claims App. (Claim 1)), and similar recitations in claims 12 and 27, are “not mentioned in the [S]pecification, and it is also unclear what image plane is attempted to be defined by this terminology, and it is unclear what direction is ‘forward’ of the working end of the tool.” Final Action 7. Consistent with the above discussion regarding *Rejection I*, we agree with Appellants, however, that at least page 18, lines 23–30 of their Specification mentions the claim recitation. Appeal Br. 13–14. Specifically, as discussed above, the cited portion of the Specification describes guiding a surgical tool’s movement forward along the tool’s axis from one location in a patient to another location in the patient which is spaced apart from the previous location, and defining an imaging plane perpendicular to the tool’s forward movement which is offset from the tool’s tip. Accordingly, based on the express language of the claims and the description in Appellants’ Specification, we disagree with the Examiner, and agree with Appellants that one of ordinary skill would understand what is meant by the claim recitation (*id.*).

Finally, the Examiner indicates that in “claim 1 the limitation ‘said real-time 2D image being from the point of view of the tool’ renders the claim indefinite, [because] it is unclear what is meant by an image being ‘from the point of view of the tool.’” Final Action 7. Consistent with the above discussion regarding *Rejections I* and *II*, we agree with Appellants that this claim recitation clearly describes a view that would be seen if an

observer were looking from the tip of the tool in a direction along the tool's axis. Appeal Br. 14, citing Spec. 18, ll. 23–30.

Rejection III

As set forth above, independent claim 1 recites, in relevant part, *a unit for generating, for one or more of the 3D ultrasonic images acquired sequentially, a real-time 2D image defined by a 2D image plane that intersects a corresponding 3D ultrasonic image, which 2D image plane is perpendicular to the direction of the characteristic axis of the tool determined in real-time and is spaced a predetermined distance forward of the working end of the tool with reference to the orientation and position of the tool upon acquisition of the corresponding 3D ultrasonic image, said 2D image being generated using the corresponding 3D ultrasonic image.*

Appeal Br., Claims App. (emphases added). The Examiner appears to rely on Downey's paragraphs 87, 97, 99, and 101 to disclose this recitation.

Final Action 9. We agree with Appellants, however, that the Examiner errs in this reliance, and, therefore, we do not sustain the rejection. *See* Appeal Br. 15–17.

More specifically, the Examiner does not support adequately that Downey's system includes (using the claim's nomenclature) a unit that generates a real-time 2D image defined by a 2D image plane that intersects a corresponding 3D ultrasonic image, which 2D image plane is perpendicular to the direction of the characteristic axis of the tool determined in real-time and *is spaced a predetermined distance forward of the working end of the tool*, as claim 1 recites. Rather, Downey's paragraph 99 discloses (using the claim's nomenclature) generating a real-time 2D image defined by a 2D image plane that intersects a corresponding 3D ultrasonic image, which 2D

image plane is perpendicular to the direction of the characteristic axis of the tool determined in real-time, but does *not* disclose that the 2D image plane is spaced a predetermined distance forward of the working end of the tool. *See* Downey ¶ 99 (“The display provides three orthogonal planes intersecting on the planned needle trajectory. One plane is orthogonal to the needle in an approximate transverse orientation As the transducer is moved, the display is updated in real-time showing the appropriate new planned trajectory.”).

Further, as Appellants point out, Downey’s paragraph 103 indicates that, in fact, this plane intersects the needle tip—i.e., the plane is not spaced a predetermined distance forward of the working end of the tool. *See* Appeal Br. 16; *see* Downey ¶ 103 (“The needle segmentation module . . . is used to segment the needle and its tip in real-time or near real-time and display the result. Using the segmented location of the needle tip, the approximate transverse plane that passes through the needle is displayed.”).

Notwithstanding the above, it is not clear whether the Examiner proposes to modify Downey to generate a real-time 2D image defined by a 2D image plane that is spaced a predetermined distance forward of the working end of the tool. For example, while discussing the generation of a 2D image from a 3D image, in the Response to Arguments section of the Final Office Action, the Examiner states that

it should be noted that a variety of different ways of displaying image data is known in the art, and it would be an obvious design choice to display the data in any known format which the user finds most convenient. The [E]xaminer further notes that the generation of a 2D image from a 3D image by determining the plane is known in the art, as described in [Appellants’ Specification on page 17].

Final Action 13. This statement also appears verbatim in the Answer's Response to Argument section. *See* Answer 4–5. However, the statement that there are “different ways of displaying data” does not support adequately that it would have been obvious to modify Downey to generate a real-time 2D image defined by a 2D image plane that is spaced a predetermined distance forward of the working end of the tool, at least because such a modification would result in displaying *different* data (i.e., data that corresponds to a location spaced a predetermined forward of the working end of the tool) while not displaying the data that Downey does display (i.e., data that corresponds to the location of the working end of the tool, as explained in Downey's paragraphs 99 and 103), and does not explain why one would have desired this change. Further, although we agree with the Examiner that Appellants' Specification acknowledges that generally “generation of a 2D image from a 3D image by determining the plane is known in the art,” this does not establish that it is known to generate a real-time 2D image defined by a 2D image plane at the exact point claimed, i.e., that *is spaced a predetermined distance forward of the working end of the tool*.

Thus, based on the foregoing, we do not sustain the Examiner's obviousness rejection of independent claim 1. We also do not sustain the obviousness rejection of independent claims 12 and 27, each of which includes a recitation similar to that discussed above with respect to, and which the Examiner rejects with, independent claim 1. Further, we do not sustain the obviousness rejection of claims 4, 7–10, 14, 19–23, 28, 29, 31, and 32 that depend from independent claims 1, 12, and 27.

Rejection IV

Claims 5, 6, 11, 17, 18, and 24 depend from independent claims 1 and 12, and as set forth above, we do not sustain the independent claims' rejection. The Examiner does not rely on Ben-Haim to disclose anything that would remedy the deficiency in the independent claims' rejection. Thus, we do not sustain the Examiner's obviousness rejection of dependent claims 5, 6, 11, 17, 18, and 24.

DECISION

We REVERSE the Examiner's written-description, enablement, and obviousness rejections of claims 1, 4–12, 14, 17–24, 27–29, 31, and 32.

REVERSED