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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JEREMY B. COX, JIAYE Z. JHO, and ROBERT N. GOLDEN

Appeal 2019-001612
Application 14/141,046
Technology Center 3700

Before JENNIFER D. BAHR, MICHAEL J. FITZPATRICK, and
LEE L. STEPINA, *Administrative Patent Judges*.

BAHR, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant¹ appeals from the Examiner's decision to reject claims 1–19. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

¹ We use the word “Appellant” to refer to “applicant” as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as C. R. Bard, Inc. Appeal Br. 3.

CLAIMED SUBJECT MATTER

Appellant's invention is "directed to a guidance system for assisting with the insertion of a needle or other medical component into the body of a patient" using "ultrasound imaging or other suitable imaging technology." Spec. ¶ 5. Claim 1, reproduced below, is illustrative of the claimed subject matter.

1. A guidance system, comprising:
 - an ultrasound imaging probe for ultrasonically imaging an image area including an internal body portion target;
 - a medical device separate from the imaging probe configured for insertion into the internal body portion target, the medical device having a magnetic field associated therewith;
 - one or more sensors associated with the probe designed that can be used to sense the magnetic field;
 - a processor designed to use data relating to the magnetic field sensed by the one or more sensors to determine a position and/or orientation of the medical device; and
 - a display designed to show an image of the internal body portion target taken by the ultrasound imaging probe and a depiction representative of the medical device positioned and oriented with respect to the image based on the position and the orientation determined by the processor, such that an approach to the internal body portion target is depicted when the medical device is outside of the image area.

EVIDENCE

The prior art relied upon by the Examiner is:

Name	Reference	Date
Haynor	US 5,879,297	Mar. 9, 1999
Gronningsaeter	US 6,019,724	Feb. 1, 2000
Steins	US 6,733,458 B1	May 11, 2004

REJECTIONS²

Claims 1–10 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Steins, Haynor, and Gronningsaeter.

Claims 11–19 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Steins, Haynor, and Gronningsaeter.³

OPINION

Claims 1–4 and 7–10

The Examiner found that Steins discloses a guidance system comprising an ultrasound imaging probe for imaging an image area including an internal body portion target, a medical device separate from the imaging probe configured for insertion into the target, magnetic location sensors for the ultrasound probe and the medical device, a processor designed to determine a position and/or orientation of the medical device using data from the magnetic location sensors, and “a display designed to show an image of the internal body portion target taken by the ultrasound imaging probe and a depiction of the medical device positioned and oriented

² The Examiner has withdrawn the provisional obviousness-type double patenting rejection of claims 1–19 in view of the filing of a Terminal Disclaimer. Ans. 16; *see* Final Act. 15–16.

³ Although the Examiner omitted Gronningsaeter from the statement of the rejection on page 9 of the Final Action, the Examiner discussed and relied on Gronningsaeter in the detailed explanation of the rejection on pages 11–12 of the Final Action. Further, Appellant understood that the Examiner applied Gronningsaeter in the rejection. *See* Appeal Br. 14. The Examiner clarifies that the statement of this rejection should have included Steins, Haynor, and Gronningsaeter, and corrects this error in restating this rejection in the Answer. *See* Ans. 3, 11.

with respect to the image.” Final Act. 4–5 (citing Steins, Fig. 1; 5:24–29; 9:47–55; 10:1–26). The Examiner found that Steins “is silent” with respect to “the medical device having a magnetic field associated therewith.” *Id.* at 5.

The Examiner found that Haynor “teaches a medical device having a magnetic field associated therewith (col. 4, lines 27-35) to sense a magnet’s static magnetic field strength and locate a medical device (col. 4, lines 35-46).” Final Act. 5. The Examiner found that the display of Steins is capable of the functionality recited in claim 1 and, further, that

Gronningsaeter . . . teaches a depiction representative of the medical device positioned and oriented with respect to the image based on the position and the orientation determined by the processor, such that an approach to the internal body portion target is depicted when the medical device is outside of the image area (col. 8, lines 19-36; FIGS. 10A-11D) for calculating a position of a tool tip and a direction of the tool for a surgeon to plan a least damaging route by aiming the tool and by observing a set of images that is displayed (col. 7, lines 63-67).

Id. at 5–6; *see* Gronningsaeter, Fig. 10B. The Examiner determined that it would have been obvious to modify Steins’s magnetic location sensor to determine the relative position and orientation of the medical device in view of the medical device magnetic sensing of Haynor and to provide a depiction representative of the medical device positioned and oriented with respect to the image as determined by the processor, such that an approach to the internal body portion target is depicted when the medical device is outside of the image area, as taught by Gronningsaeter. Final Act. 6. According to the Examiner, “[d]oing so would have allowed for calculating a position of a tool tip and a direction of the tool for a surgeon to plan a least damaging

route by aiming the tool and by observing a set of images that is displayed as recognized by Gronningsaeter” *Id.*; see Gronningsaeter 7:63–67.

Appellant argues that Steins already provides means for determining position and orientation of the medical device and the ultrasound imaging probe, and, “[t]hus, there is no problem for someone viewing Steins to attempt to solve.” Appeal Br. 11. Further, Appellant notes that the Steins patent application was filed more than two years after Haynor issued, but Steins does not even mention Haynor’s technology, much less incorporate it as a potential embodiment. *Id.* Appellant argues, “That Steins ignores Haynor further leads to the conclusion that there is, in fact, no valid reason for making the proposed modification of Steins and Haynor.” *Id.* at 12.

Appellant’s argument that Steins does not mention Haynor is unavailing. To the extent that Appellant insists on an express teaching, suggestion, or motivation in the references to make the proposed modification, such arguments have been foreclosed by the Supreme Court. See *KSR Int’l Co v. Teleflex Inc.*, 550 U.S. 398, 419 (2007) (the Supreme Court stating that a rigid insistence on teaching, suggestion, or motivation is incompatible with its precedent concerning obviousness). “The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents.” *Id.* Instead, the relevant inquiry is whether the Examiner has set forth “some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), *cited with approval in KSR*, 550 U.S. at 418.

As the Examiner explains, “Steins and Haynor are directed to a same problem of determining location and orientation of a medical device in a human body, and while Steins teaches broader use of the magnetic sensors, Haynor teaches a specific configuration that is under the broader teaching of Steins.” Ans. 18. Thus, the modification of Steins (i.e., to incorporate the particular magnetic location and orientation sensing system of Haynor) is nothing more than the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the improvement. *See KSR*, 550 U.S. at 417. In this case, therefore, the Examiner has articulated reasoning with some rational underpinning to support the determination that the proposed modification would have been obvious.

Appellant also contends that Gronningsaeter does not teach depicting the approach to the target *when the medical device is outside of the image area*. Appeal Br. 12–13. In particular, Appellant asserts that, although Gronningsaeter teaches superimposing the location and trajectory of the medical device when the medical device is in the image area, Gronningsaeter cannot provide that information when the medical device is outside of the image area. *Id.* at 13. Appellant points to Gronningsaeter’s Figure 10C, and the associated description, to support the assertion that Gronningsaeter does not teach depicting the approach to the target when the medical device is outside of the image area. *Id.* (citing Gronningsaeter 8:27–37).

Gronningsaeter’s Figure 10C depicts a situation in which the tool (i.e., the medical device) “is not inside the *plane* defined by the 2D ultrasonic image,” and, thus, “the tool or tool trajectory will intercept the 2D image in a

single point (10.8).” Gronningsaeter 8:27–30 (boldface omitted, emphasis added). However, Appellant’s argument is unsound because it ignores Gronningsaeter’s Figure 10B, which shows a display depicting a tool (10.6) outside of the image (10.2) area and the tool trajectory (10.7) superimposed on the image.⁴ *See* Gronningsaeter 8:19–27; *compare id.*, Fig. 2B, *with id.* Fig. 2A (showing a depiction of a tool (10.5) located within the image (10.1) area).

For the above reasons, Appellant does not apprise us of error in the rejection of claim 1 as unpatentable over Steins, Haynor, and Gronningsaeter.⁵ Accordingly, we sustain the rejection of claim 1, as well as claims 2–4 and 7–10, for which Appellant does not present any separate arguments and which, thus, fall with claim 1. *See* Appeal Br. 9–11; 37 C.F.R. § 41.37(c)(1)(iv) (permitting the Board to select a single claim to decide the appeal as to a single ground of rejection of a group of claims argued together).

Claims 5 and 6

Appellant contends that “the Examiner did not actually provide a substantive rejection of claim 5 anywhere in the [Final] Action.” Appeal

⁴ Appellant’s assertion to the contrary (Reply Br. 9) is unconvincing.

⁵ Appellant presents new arguments in the Reply Brief directed to purported incompatibilities between Haynor and Steins. *See* Reply Br. 6–9. These arguments are untimely, and Appellant does not present any evidence or explanation to show good cause why it should be considered by the Board at this time. *See* 37 C.F.R. § 41.41(b)(2) (“Any argument raised in the reply brief which was not raised in the appeal brief, or is not responsive to an argument raised in the examiner’s answer . . . will not be considered by the Board for purposes of the present appeal, unless good cause is shown.”). Accordingly, we do not consider these arguments.

Br. 13. However, as the Examiner explains, the Final Action contained a typographical error, in that, page 7 of the Final Action “states:

‘12. Regarding **claim 6** and **claim 7,**’ and should read ‘12. Regarding **claim 5** and **claim 6,**.’” Ans. 2; *see id.* at 8–9 (restating the rejection with the correction).

In addressing the “medical device is magnetized” limitation of claim 5, the Examiner finds that Haynor “teaches a medical device magnetized with a permanent magnet, and the magnetized medical device providing the magnetic field,” and determines it would have been obvious to modify the magnetic location sensor of Steins “in view of the medical device with permanent magnet of Haynor.” Ans. 9 (citing Haynor 4:27–46). Appellant acknowledges that Haynor describes a “static magnetic field strength of a magnet in a tube,” but contends that this does not constitute “disclosure of a magnetized medical device.” Reply Br. 10 (asserting that “magnetized” means “to induce magnetic properties in”). Appellant argues that Haynor’s plastic feeding tube cannot be magnetized because it is made of plastic, which “is not a ferromagnetic metal,” and that “none of the cited art teaches a magnetized medical device, nor a magnetized needle or cannula.” *Id.* at 10–11.

Appellant’s Specification describes an embodiment in which “the stylet itself can be magnetized or composed of magnetic materials,” as well as an embodiment in which magnetic elements are disposed along the stylet length. *See Spec.* ¶ 166. Further, Appellant’s Specification describes a needle embodiment in which a donut-shaped magnet can be positioned in one of several positions along the cannula of the needle, as well as an embodiment in which “the needle itself can be magnetized.” *Id.* ¶ 168.

Appellant appears to be arguing that providing a magnetic element (i.e., a permanent magnet) in a medical device, as taught in Haynor, would not satisfy the claim limitation “wherein the medical device is magnetized.” However, Appellant fails to persuade us that the “magnetized” language in claim 5 in fact distinguishes over such a structure. We understand the Examiner’s position to be that a medical device comprising magnetic material is “magnetized,” and Appellant does not provide any cogent explanation as to why this position is unreasonable. *See* Ans. 9 (finding that Haynor “teaches a medical device magnetized with a permanent magnet, and the magnetized medical device providing the magnetic field”). The fact that the medical device might also comprise other material that is not magnetic does not negate the fact that the medical device is magnetized by virtue of comprising magnetic material.

For the above reasons, Appellant fails to apprise us of error in the rejection of claim 5 as unpatentable over Steins, Haynor, and Gronningsaeter. Accordingly, we sustain the rejection of claim 5, as well as claim 6, which depends from claim 5 and for which Appellant does not present any separate arguments and which, thus, falls with claim 5. *See* Appeal Br. 9–11; 37 C.F.R. § 41.37(c)(1)(iv).

Claims 11 and 13–19

In rejecting claim 11, the Examiner’s findings and reasoning are substantially similar to those set forth in rejecting claim 1, and Appellant relies on the same arguments asserted for claim 1 in contesting the rejection of claim 11. *See* Final Act. 9–12; Ans. 11–13; Appeal Br. 14–15. These arguments fail to apprise us of error in the rejection of claim 1 and, likewise, fail to apprise us of error in the rejection of claim 11.

Appellant also acknowledges that the Examiner applied Gronningsaeter in the rejection despite omitting Gronningsaeter in the statement of the rejection on page 9 of the Final Action. Appeal Br. 14. Appellant then submits that this omission “does not appear to be merely a typographical error, as otherwise claims 1–[19] would have been included under the same section of the [Final] Action.” *Id.* We do not agree with Appellant on this point. First, the Examiner’s discussion of Gronningsaeter in the detailed explanation of the rejection on pages 11–12 of the Final Action makes it clear that the Examiner’s rejection relies on Gronningsaeter. Further, it is not uncommon for examiners to address each independent claim in a separate rejection, even if the references, findings, and reasoning are the same in the rejections. Appellant was on notice, and clearly appreciated, that the Examiner applied Gronningsaeter in the rejection of claims 11–19. *See* Appeal Br. 14 (stating, “the Examiner then applies an additional reference (Gronningsaeter)”). Further, the Examiner confirms and corrects the typographical error in the Answer. *See* Ans. 3, 11.

For the above reasons, Appellant does not apprise us of error in the rejection of claim 11. Accordingly, we sustain the rejection of claim 11, as well as claims 13–19, for which Appellant does not present any separate arguments and which, thus, fall with claim 11, as unpatentable over Steins, Haynor, and Gronningsaeter. *See* Appeal Br. 14–15; 37 C.F.R. § 41.37(c)(1)(iv)

Claim 12

Appellant’s Appeal Brief groups all of claims 11–19 together and, notably, does not include a separate argument for claim 12. *See* Appeal Br. 14–15. Appellant presents an argument in the Reply Brief separately

contesting the rejection of claim 12. *See* Reply Br. 11. This argument is untimely, and Appellant does not present any evidence or explanation to show good cause why it should be considered by the Board at this time. *See* 37 C.F.R. § 41.41(b)(2).⁶ Thus, pursuant to 37 C.F.R. § 41.37(c)(1)(iv), claim 12 falls with claim 11, and, accordingly, we sustain the rejection of claim 12 as unpatentable over Steins, Haynor, and Gronningsaeter.

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1-10	103(a)	Steins, Haynor, Gronningsaeter	1-10	
11-19	103(a)	Steins, Haynor, Gronningsaeter	11-19	
Overall Outcome			1-19	

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED

⁶ Appellant's argument incorporates the argument asserted against the rejection of claim 5, which, for the reasons discussed above, fails to apprise us of error in the rejection of claim 5 and, likewise, would fail to apprise of error in the rejection of claim 12. *See* Reply Br. 11.