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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MICHAEL MUNROW, JORDAN BAJOR, and MALCOLM G. MUNRO

Appeal 2017-002061
Application 13/589,975
Technology Center 3700

Before DONALD E. ADAMS, JEFFREY N. FREDMAN, and TIMOTHY G. MAJORS, *Administrative Patent Judges*.

MAJORS, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellants submit this appeal under 35 U.S.C. § 134(a) involving claims to a system for deploying a needle in tissue.[1] The Examiner rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] Appellants identify Gynesonics, Inc. as the real party in interest. App. Br. 3.

STATEMENT OF THE CASE

Appellants' "invention relates to methods and systems for controlling the deployment of needles using visual feedback from an ultrasonic or other image." Spec. ¶ 2.

Appellants' drawings are helpful in understanding the invention. Figure 4, which shows an exemplary needle treatment probe for treating uterine fibroids, is reproduced below.

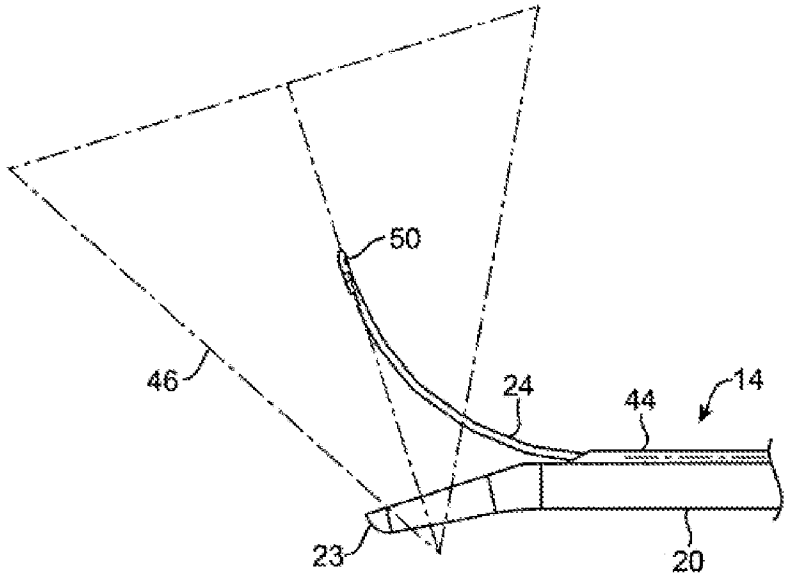

FIG. 4

Id. ¶ 22, Fig. 4. Figure 4 depicts the distal portion of probe (14) including, *inter alia*, a shaft (20) with an ultrasound imaging array (un-numbered in Fig. 4) near the shaft's distal end (23), which array provides a field of view (46) for display. *Id.* ¶ 29, Fig. 1 (showing probe (14) with imaging array (26) connected to system controller (12), including an ultrasound display (18)). Probe (14) also includes a needle guide (44) through which a treatment needle (24) (e.g., for tissue ablation) is deployed. *Id.* ¶¶ 30–31.

Figure 8B from the Specification is also reproduced below.

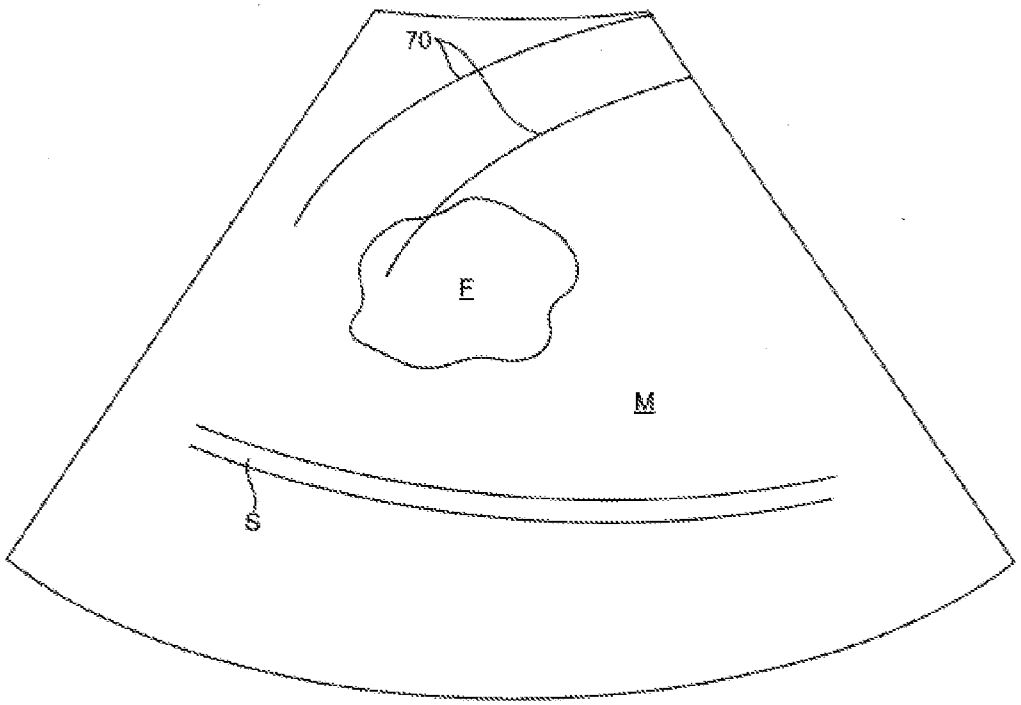

FIG. 8B

Id. Fig. 8B. Figure 8B shows an ultrasound display image for viewing by the physician when using the needle deployment probe to treat a uterine fibroid (F). *Id.* ¶ 26. The Specification explains that the probe is placed in the uterus, and the physician scans the myometrium (M) to locate fibroids (F) and other anatomical features like the treatment-sensitive serosa (S). *Id.* ¶ 32. To aid proper alignment of the needle with the targeted fibroid (F), projected needle information (e.g., a needle guide overlay (lines 70) showing the projected needle deployment path) is provided on the ultrasound display so the probe and needle path can be adjusted accordingly before needle deployment. *Id.* ¶¶ 14, 33–34, and Fig. 8C (realigning so projected needle path (lines 70) more accurately targets the fibroid).

Claims 24, 26–32, 38, and 40 are on appeal. Claim 24 is illustrative:

> 24. A system for deploying a needle in tissue, said system comprising:
>
> a probe having a shaft;
>
> a needle deployable outwardly from the shaft along a fixed path relative to the shaft;
>
> an imaging transducer on the shaft, wherein the fixed path of the needle lies within an image field produced by the imaging transducer; and
>
> a system controller including a screen for displaying the image produced by the transducer, wherein the system controller displays an overlay with projected needle treatment information on the screen, wherein the projected needle treatment information includes a projected needle path, wherein *a user can manipulate the probe to simultaneously align both the image field and the projected needle path with a target anatomy visible on the screen prior to deployment of the needle*, wherein *the location of the projected needle path in the image field remains fixed relative to the image field as the probe is manipulated.*

App. Br. 14 (Claims App.) (emphases added).

The claims stand rejected as follows:

I. Claims 24, 26, 27, 31, 32, and 38 under 35 U.S.C. § 103(a) over Grossman[2] and Burbank,[3] in view of Steins[4] and/or Wang[5] ("Rejection I").

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[2] Grossman, US 2006/0189972 A1, published Aug. 24, 2006.
[3] Burbank et al., US 6,254,601 B1, issued July 3, 2001.
[4] Steins et al., US 6,733,458 B1, issued May 11, 2004.
[5] Wang et al., US 6,695,786 B2, issued Feb. 24, 2004.

II. Claims 28–32 and 40 under 35 U.S.C. § 103(a) over Grossman and Burbank, in view of Steins and/or Wang, and in further view of Rittman[6] and Podhajsky[7] ("Rejection II").

III. Claims 30 and 31 under 35 U.S.C. § 103(a) over Grossman and Burbank, in view of Steins and/or Wang, and in further view of Rittman, Podhajsky, and Dobak[8] ("Rejection III").

For each rejection, the Examiner relies on the combination of Grossman and Burbank (along with the other references) as an "alternative" to Grossman (along with the other references) without Burbank's teachings. Ans. 3, 8, and 13. In this appeal, we consider the "alternatives" together.

The Examiner withdrew the rejection of the claims under 35 U.S.C. § 112, second paragraph. Final Act. (mailed Aug. 10, 2015) 2–3; Ans. 14.

REJECTION I

Issue

Has the Examiner established by a preponderance of the evidence that claims 24, 26, 27, 31, 32, and 38 would have been obvious over Grossman, Burbank, and Steins and/or Wang?

Findings of Fact (FF)

The Examiner's findings of fact and statement of the rejection are provided at pages 3–9 of the Final Rejection dated Aug. 10, 2015. *See also* Ans. 3–8, 14–19. The following findings are provided for emphasis.

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[6] Rittman, III et al., US 6,575,969 B1, issued June 10, 2003.
[7] Podhajsky, WO 2006/042117 A2, published Apr. 20, 2006.
[8] Dobak, III, US 2001/0035189 A1, published Nov. 1, 2001.

FF 1. Grossman teaches devices, systems, and methods for imaging and treating uterine fibroid tumors in real-time. Grossman, Abstract. More specifically, Grossman teaches:

> A sheath, catheter, or probe may be transcervically introduced into the uterus. A location of the fibroid tumor may be determined by using a visualization element within or on the sheath. Preferably, the physician will be able to image the tumors transendometrially from within the uterine cavity. This visualization element may comprise an ultrasonic element . . . that is capable of producing a visual image. Once having identified the location, a portion of the sheath is steered to position at least one treatment needle at the determined location. The needle is anchored within the uterine tissue and the fibroid is treated with the needle.

Id. ¶ 16.

FF 2. Figure 3C of Grossman is reproduced below.

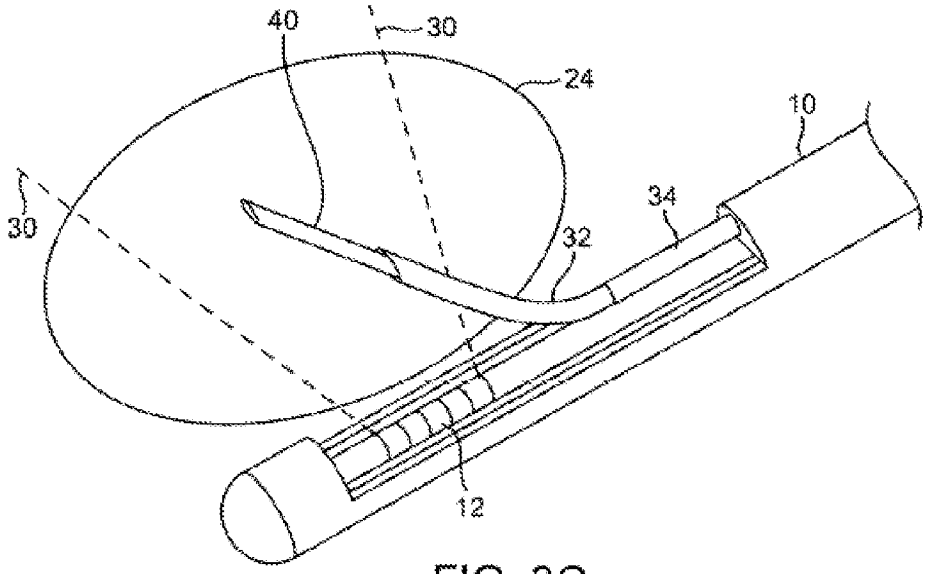

FIG. 3C

Id. at Fig. 3C. Figure 3C shows an embodiment of a device with telescoping ablation needles and an on-board ultrasound imaging array. *Id.* ¶ 26. As depicted, the device includes, *inter alia*, a steerable catheter (10), an

ultrasound catheter (12) providing ultrasound visualization (dashed lines 30) of a fibroid tumor (24), and a lumen (34) through which telescoping needles (32 and 40) are deployed. *Id.* ¶ 39. Grossman teaches "[r]adiofrequency ablative energy is delivered in a bipolar fashion between the two telescoping needles **40**, **32**" to ablate the fibroid tumor. *Id.*

FF 3. Grossman teaches an ultrasound recognition and radiofrequency treatment computer system that includes ultrasound mapping, ultrasound recognition of treatment area, and radiofrequency ablation treatment under ultrasound imaging. *Id.* ¶ 50, Fig. 13A–B (showing system (88) with a computer interface and display of the image field, and coupled to a probe device (90)).

FF 4. Burbank teaches devices for treating uterine disorders, including uterine fibroids. Burbank, Abstract. Burbank's Figure 8 is below.

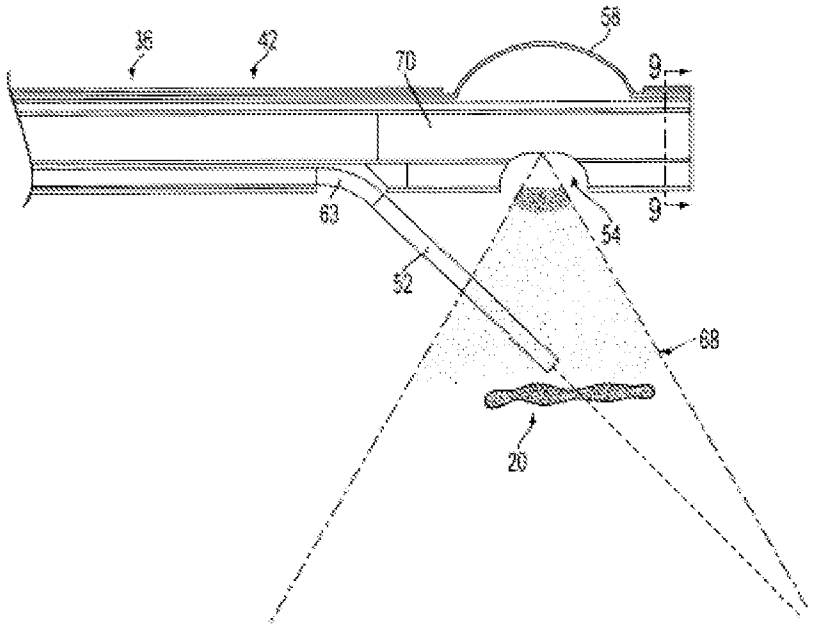

FIG. 8

Id. at Fig. 8. Figure 8 shows a distal end portion of an embodiment of Burbank's device. A shown, the device includes, among other features,

cannula (36), locating device (70) (e.g., ultrasonic imaging device) with an imaging window (54) generating an image plane (68). The device further includes a guide port (63) through which tissue penetrating member (52) is extendable. *Id.* at 9:20–56; *see also id.* at 8:14–28 and Figs. 6–7.

FF 5. Steins relates to ultrasound and needle-guidance systems. Steins, Abstract. As background, Steins teaches:

> Medical device guidance systems are used in medical applications for the purpose of guiding various types of invasive medical devices, such as aspiration and biopsy needles, endoscopes, etc., towards specific targets within a patient's body. These guidance systems simplify such procedures and make them safer and quicker to perform.

Id. at 1:7–12. As further background, Steins describes an example of guiding a biopsy needle based on an ultrasound image, wherein:

> From the relative position information [of the needle and ultrasound imaging plane], the projected or actual needle path is computed and is superimposed in real time on the displayed diagnostic image of the patient. This enables the physician to visualize the projected needle path and plan the biopsy procedure even before the needle is inserted into the body.

Id. at 1:24–30.

FF 6. Steins teaches "displaying a projected and actual trajectory of an invasive medical device relative to and within a portion of a subject for use in a diagnostic medical ultrasound system." *Id.* at 2:1–4, Figs. 2A–B (showing actual (206) and predicted trajectory (208) of needle (132) relative to target (210) in an image (118)). Steins teaches "the clinician can refer to graphical cues [lines, dots, dashes etc.] generated by the guidance system to the ultrasound image **118** to modify the invasive device's **132** trajectory **208** or reposition the ultrasound probe **104**." *Id.* at 12:30–33. Steins teaches

"the clinician is able to more clearly see the relationship between the predicted trajectory **208** as represented on the image **118** and the representation **210** of the target **204**." *Id.* at 12:38–41.

FF 7. Wang relates to an instrument guide "for mounting an invasive instrument such as a biopsy needle to an imaging probe, controlling its position, monitoring its position, and/or predictively displaying its position on a user display of the medical imaging system." Wang, Abstract.

FF 8. Wang's Figure 9B is reproduced below.

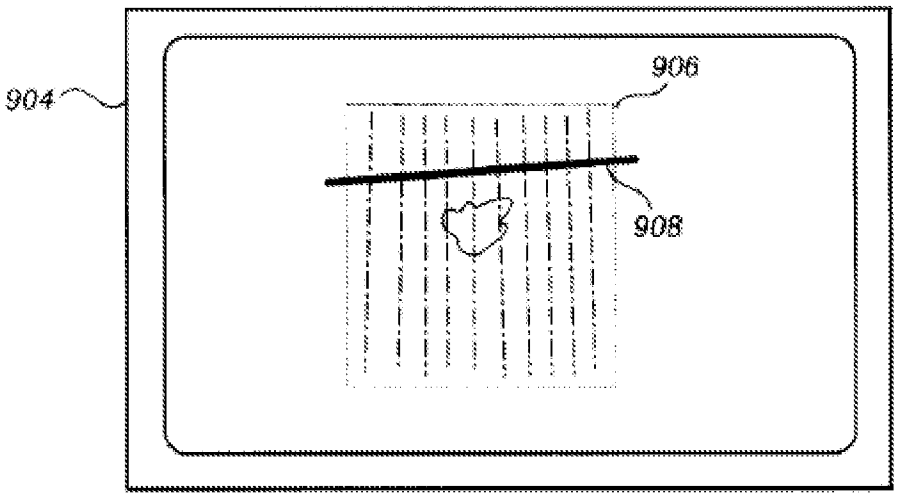

FIG. 9B

Id. at Fig. 9B. Figure 9B shows an ultrasound display (904) and a needle projection image (908) in ultrasound image area (906). *Id.*; *see also id.* Fig. 9A and 8:1–25; *see also id.* at 4:58–61 ("[E]ven if the biopsy needle is outside the field of view of the imaged plane being displayed, its projection will appear on the display. This can be of great assistance in guiding the biopsy needle to the desired target location.").

Analysis

Claim 24

We select claim 24, the only independent claim, as representative. 37 C.F.R. § 41.37(c)(1)(iv).

The Examiner finds that Grossman teaches the limitations of the system recited in claim 24, except that "Grossman does not appear to explicitly disclose displaying projected needle treatment information including a projected needle path as claimed." Ans. 4. According to the Examiner, however, both Steins and Wang disclose "displaying needle treatment information in the form of a projected needle path." *Id.*; *see also id.* at 15 ("Steins and Wang are relied upon to teach the fundamental concept of overlaying projected needle path information on an image."). The Examiner reasons it would have been obvious to include a "projected needle path" in Grossman's system to "help[] the clinician plan the deployment of the needle," to "ensure that the desired target can be reached," and to enhance "safety and outcome of the patient." *Id.* at 4, 5.

As to the "fixed" relationship between the projected needle path and image field required in claim 24, and its final two "wherein" clauses, the Examiner finds that Grossman and Burbank teach a fixed relationship between the location of the ultrasound imaging module and the end of the lumen through which the needle passes. *Id.* at 5–7 ("Burbank discloses a probe very similar to that of Grossman [and] includes a guide port which guides a tissue penetrating member along a fixed path in the imaging

plane.").[9] With this "fixed" structure and relationship, the Examiner reasons that simultaneous "movement of the probe also results in movement of the lumen through which the needle will pass," thus, providing the same relative change to both the image field and projected needle path, meeting the limitations of claim 24. *Id.* at 5–6.[10]

We agree with and adopt the Examiner's fact finding, reasoning, and conclusion of obviousness. Grossman and Burbank disclose known probe structures, having a distal end with an imaging transducer and outwardly deployable needle that, once deployed is visible in the image field. FF 1–4. Grossman discloses that the needle and imaging transducer may be fixed or, optionally, movable relative to each other. FF 1–3;[11] *see also* Ans. 15–16 ("independent movement . . . is not a requirement of the device, but simply a possible option."). Even if Grossman did not teach a fixed relationship between the probe/transducer and the needle lumen/needle (we are

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[9] Even if Grossman did not teach such a fixed relationship, the Examiner concludes it would have been obvious modify Grossman's device in view of Burbank to allow a constant view of the needle and avoid the need to align multiple structures in the viewing plane. Ans. 7.

[10] The Examiner alternatively reasons it would have been obvious "that the projected needle path should be updated such that it maintains a fixed relationship with the imaging field as the probe is moved." Ans. 6. According to the Examiner, given a fixed relationship between the probe and needle-deploying lumen, updating as proposed provides a more accurate prediction of where the needle would be deployed in the tissue when the probe is moved. *Id.*

[11] *See also*, *e.g.*, Grossman ¶¶ 17, 21 ("The sheath, visualization element, and/or treatment needle may be integrally formed or comprise[] separate, modular components. . . . Further, at least a portion of the sheath, visualization element, and/or treatment needle may be steerable, rotatable, deflectable, flexible, pre-shaped, or pre-formed . . . .").

persuaded it does), Burbank provides this teaching, and Appellants provide no persuasive argument or evidence to the contrary. The Examiner also finds that overlaying a projected needle path on an ultrasound image is a "fundamental concept," as evidenced by Steins and Wang, so it would have been obvious to include this feature in a device/system as taught in Grossman and Burbank. Ans. 15; Reply Br. 2 ("Applicant does not necessarily disagree that Steins and Wang include the 'fundamental concept of overlying projected needle path information on an image.'"). And we agree with the Examiner's finding. The reason to include a projected needle path in the image is so the clinician knows with reasonable precision, a priori, where the needle is going to go in the patient once deployed. It would have been obvious to incorporate such a feature in the Grossman/Burbank system for, at minimum, planning and safety — and Steins and Wang, regardless of their specific implementations of this fundamental concept, support the Examiner on this point. FF 5–8. Modifying the cited art as proposed by the Examiner, thus, results in a system with all the limitations of claim 24.

We address below Appellants' arguments.

Appellants argue the Examiner's combination of the prior art would not result in the system of claim 24. App. Br. 6–7. More specifically, Appellants contend the combination would not result in a system meeting claim 24's final two wherein clauses: "wherein a user can manipulate the probe to simultaneously align both the image field and the projected needle path . . ." and "wherein the location of the projected needle path in the image field remains fixed relative to the image field as the probe is manipulated." *Id.* at 7. According to Appellants, this is because Steins and Wang "are

directed to systems where the needle is not constrained to a fixed path relative to the imaging probe." *Id.*

Appellants' argument is unpersuasive because it fails to grapple adequately with the combination/modification of the prior art actually proposed by the Examiner. As noted above, the Examiner is relying on Grossman and Burbank as teaching a fixed relationship between the probe and needle lumen, and for Steins and Wang for the "fundamental concept" in this art of adding projected needle path information for safety, planning, etc. FF 5–8; Ans. 4–7, 15. The Examiner provided a persuasive rationale for why and how this feature would be included in a system as disclosed in Grossman and Burbank to meet the limitations of claim 24. *See, e.g.*, Ans. 4–7, 15–19.[12] Appellants provide no persuasive argument or evidence otherwise, and instead focus on disclosures in Steins and Wang where at least some independent movement between the needle and ultrasound probe is desired. But arguing the teachings of the references individually, as Appellants do here, does not rebut the Examiner's rejection relying on what the references teach or suggest in combination. *In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986).

For similar reasons, Appellants' argument that the Examiner has improperly relied on inherency are unpersuasive. App. Br. 7–8. The art, as

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[12] The Examiner explains that the skilled person need only modify the user interface (e.g., via software) of Grossman's system and that "[g]iven a known shape/size of the needle and knowing the location of the end of the needle lumen would allow one of ordinary skill in the art to easily create an overlay on an image of the projected needle path without requiring any additional tracking of the needle or altering the structure of the needle and probe of Grossman." Ans. 17–19.

combined and modified by the Examiner to add the needle path information, does indeed appear to provide the functionality recited in claim 24's final two wherein clauses. But even if it did not, the Examiner provided a reasoned explanation why it would have been obvious to include that functionality. *See, e.g.*, Ans. 5–6. Appellants' attorney argument does not overcome the Examiner's findings and explanation on this record.

Appellants also argue the Examiner fails to establish that the skilled person would have combined the cited art based on "clear differences" between the references. App. Br. 9. Appellants contend Steins and Wang use "mobile needles that are not fixed relative to the imaging probe," and thus rely on "an entirely different principle of operation from the Grossman device." *Id.*[13] Indeed, Appellants contend Wang desires "unfettered freedom of movement of the instrument within the imaged plane," which "teach[es] away" from use of needle guides like Grossman that restrict movement of the needle within the imaged plane. *Id.* (quoting portions of Wang at 2:36–47). Appellants contend "the proposed modification cannot change the principle of operation of the reference being modified." *Id.* at 9. According to Appellants, modifying Grossman as proposed "would necessitate at least some changes to the structure of the needle and imaging probe, such as to incorporate [tracking] sensors," or else the combination "would result in a non-functional device." *Id.* at 10.

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[13] Appellants contend "Burbank, like Grossman, describes constrained deployment of a needle form the imaging probe," and therefore Appellants arguments related to teaching away and changing the device's principle of operation similarly apply to Burbank. App. Br. 10

We remain unpersuaded. The Examiner is not proposing wholesale incorporation of the devices exemplified in Steins or Wang into the system of Grossman. *In re Keller*, 642 F.2d 413, 425 (CCPA 1981) (holding "[t]he test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference"). Quite the opposite, the Examiner is relying on the Steins and Wang as evidence that it was well known in the art to include projected needle path information as a desirable feature in devices using an ultrasound image and a treatment needle for ablating uterine fibroids. Ans. 4–5, 14–15; FF5–8. While true that Steins and Wang seemingly desire devices where the ultrasound probe and treatment needle are independently movable, Appellants point us to no persuasive evidence that criticizes, discredits, or discourages including a needle path feature in other systems, even if those systems operate on the principle of "fixing" the ultrasound probe and needle lumen/needle relative to each other. *In re Fulton*, 391 F.3d at 1201 ("The prior art's mere disclosure of more than one alternative does not constitute a teaching away from . . . alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed."). The Examiner is neither proposing to "unfix" the probe and needle lumen in Grossman or Burbank, nor to "fix" together the needle and probe of Steins or Wang. To the extent any change in the principle of operation of Grossman's system is being proposed, it is only by an improvement — the addition of an art-recognized feature (projected needle path information) in a predictable way would make that system better, more accurate, and safer.

As for Appellants' contention that Grossman's system would require at least some structural changes, including additional needle-tracking

sensors, this contention is unsupported with evidence. So too, Appellants provide no evidentiary support for the contention that, without such changes, the result is a "non-functional device." App. Br. 10. The Examiner, on the other hand, has provided a persuasive explanation of how the proposed modification would be done *without* the structural changes Appellants urge would have been necessary. Ans. 17–19. And, even assuming Grossman's device would need additional sensors, we are not persuaded those changes would have exceeded the abilities of the skilled artisan seeking to add a projected needle path feature.

Conclusion of Law

The preponderance of the evidence on this record supports the Examiner's conclusion that claim 24 would have been obvious over Grossman and Burbank, in further view of Steins and/or Wang. Claims 26, 27, 31, 32, and 38 have not been argued separately and fall with claim 24.

REJECTIONS II & III

We adopt the Examiner's fact finding, reasoning, and conclusion of obviousness in support of Rejections II and III. Ans. 8–14.

Appellants rely on their arguments related to Rejection I and claim 24, arguing only that the additional references (Rittman, Podhajsky, and Dobak) do not make up for the alleged deficiencies of Grossman, Burbank, Steins, and Wang. App. Br. 11–12. We are not persuaded this combination is deficient for reasons explained above (Section I). Accordingly, we affirm Rejections II and III.

SUMMARY

We affirm the rejections for obviousness on appeal.

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