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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/126,188	04/27/2011	Sandeep Dalal	2008P01186WOUS	1539

24737 7590 02/12/2018
PHILIPS INTELLECTUAL PROPERTY & STANDARDS
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ART UNIT	PAPER NUMBER
3777	

NOTIFICATION DATE	DELIVERY MODE
02/12/2018	ELECTRONIC

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte SANDEEP DALAL,
BALASUNDARA RAJU, and AJAY ANAND

Appeal 2017-001680
Application 13/126,188
Technology Center 3700

Before JEFFREY N. FREDMAN, ELIZABETH A. LAVIER, and TIMOTHY G. MAJORS, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal[1] under 35 U.S.C. § 134 involving claims to an ultrasound therapy method. The Examiner rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

Statement of the Case

Background

"Ultrasound therapy for tissue ablation includes insonifying a tissue of interest with high intensity ultrasound that is absorbed and converted into heat, raising the temperature of the tissues. As the temperature rises above

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[1] Appellants identify the real party in interest as KONINKLIJKE PHILIPS N.V. (*see* App. Br. 3).

55°C, coagulative necrosis of the tissues occurs resulting in immediate cell death" (Spec. ¶ 2). "The ultrasound lesion sizes depend not only on the ultrasound beam characteristics, but also on the sonication time" (*id.* ¶ 3).

"In order to optimally treat tumors that are larger than the size of a single ultrasound lesion, the ultrasound beam needs to be repositioned in different parts of the tumor" (*id.* ¶ 4). "In practice, doctors treat an additional small margin encompassing the tumor to also treat microscopic cancerous tissue that may not be visible in the diagnostic imaging scans of the tumor. The tumor and margin is also knows as the Planned Target Volume (PTV)" (*id.* ¶ 4). "If the PTV is larger than one ablation, which is frequently the case, a sequence of multiple overlapping ablations, called a 'composite ablation', has to be created" (*id.* ¶ 4).

The Claims

Claims 1, 4, 5, 7–9, 11, 13–15, and 17–20 are on appeal. Claim 1 is representative and reads as follows:

1. An ultrasound therapy method comprising acts of:

obtaining a first image of a region of interest;

graphically delineating a planned target volume (PTV) using the first image;

selecting ablation shapes of ultrasound beams from a library to completely cover the PTV, the library comprises the ablation shapes pre-computed by a thermal acoustic modeling tool and obtained through experiments;

until the PTV is fully ablated repeating

performing an ultrasound ablation on the PTV using an ultrasound transducer that applies energy based on the selected ablation shapes;

> obtaining a latest image of the region of interest after performing the ultrasound ablation;
>
> determining remaining areas of the PTV that have not been ablated by comparing ablation lesions from the latest imaging and estimated ablation lesions from the library; and
>
> selecting and modifying, based on a feedback, one or more ablation shapes of ultrasound beams from the library to completely cover the determined remaining areas while avoiding covering ablated portions of the PTV based on the latest image.

The issues

A. The Examiner rejected claims 1, 4, 9, 11, 15, and 17 under 35 U.S.C. § 103(a) as obvious over Shahidi,[2] Diederich,[3] Dodd III,[4] and Freundlich[5] (Final Act. 6–12).

B. The Examiner rejected claims 5, 7, 8, 13, 14, and 18–20 under 35 U.S.C. § 103(a) as obvious over Shahidi, Diederich, Dodd III, Freundlich, and Nields[6] (Final Act. 12–15).

A. 35 U.S.C. § 103(a) over Shahidi, Diederich, Dodd III, and Freundlich

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that Shahidi, Diederich, Dodd III, and Freundlich render the rejected claims obvious?

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[2] Shahidi, US 2009/0221999 A1, published Sept. 3, 2009.
[3] Diederich et al., US 2007/0255267 A1, published Nov. 1, 2007.
[4] Dodd III, et al., US 2007/0055225 A1, published Mar. 8, 2007.
[5] Freundlich et al., US 6,618,620 B1, issued Sept. 9, 2003.
[6] Nields et al., US 2008/0033420 A1, published Feb. 7, 2008.

Findings of Fact

1. Shahidi teaches "achieving a curative outcome in unresectable cases by use of minimally invasive in situ ablation techniques including . . . high-frequency focused ultrasound" (Shahidi ¶ 6). Shahidi teaches the invention "is not limited to IFM probe design, but may easily be applied to the design of other probe types, such as . . . ultrasound ('US') probes" (Shahidi ¶ 32).

2. Shahidi teaches "images of the patient are used to construct a mapping of the anatomical structures of the site where the thermal therapy is intended" (Shahidi ¶ 34).

3. Shahidi teaches "this mapping is morphed to the specific volumetric and spatial relationships among the anatomical structures appearing in the image. From this process a patient-specific site model is produced for near-real-time monitoring of the thermal ablation or ablation planning" (Shahidi ¶ 34).

4. Figure 1 of Shahidi, graphically delineating a target volume, is reproduced below:

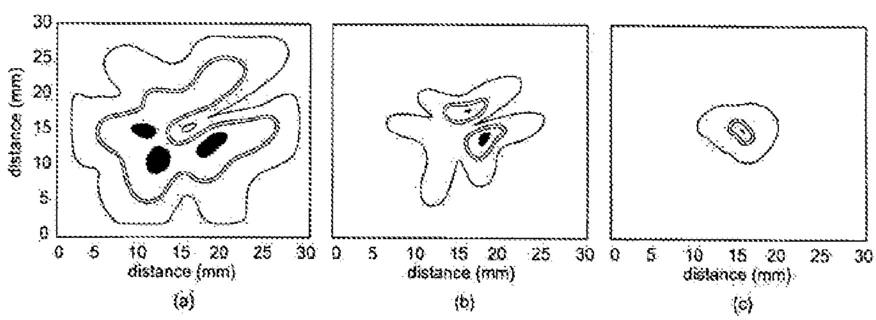

FIG. 1

Figure 1 illustrates "power patterns in a homogeneous media . . . from a microwave energy source" (Shahidi ¶ 40).

5. Shahidi teaches: "In order to create an arbitrary shape suited for targeted thermal therapy, the integrated EM/thermal model is needed to determine the exact antenna geometries and excitation characteristics (frequency, amplitude, phasing) that can produce a desired shape for a hot spot" (Shahidi ¶ 66).

6. Shahidi teaches "a set of antenna and frequency configurations may be found that create predefined ablation volume elements. This information can be stored in a library" (Shahidi ¶ 97). Shahidi further teaches a "thermal therapy tool provided on computer-readable media includes a library of generalized site models" (Shahidi ¶ 19).

7. Shahidi teaches:

> Shape modeling algorithms may be used to process volumetric information obtained from an image-guidance part of the planning tool, e.g., as discussed earlier in connection with images **51***b*, which can proceed with breaking a pathology into multiple sub-segments of known geometries that would match a library of preset antenna signal configurations designed to encompass each sub-segment.

(Shahidi ¶ 97).

8. Shahidi teaches: "For large tumors, multiple ablation applications may be necessary to encompass the entire volume, with probe placements for these multiple ablations currently based on the operator's estimates" (Shahidi ¶ 78).

9. Shahidi teaches computations "may factor in safety margins (to account for such things as image quality relied on to perform an anatomic atlas mapping, discussed below, variations of tissue type, the presence of

nearby vascular bodies microcirculation, etc.) in order to protect adjacent tissue" (Shahidi ¶ 88).

10. Shahidi teaches an "integral part of the system is the heat feed-back and monitoring mechanism. This mechanism allows the caregiver to adjust the shape, amount and depth of the energy being implemented. These parameters may be adjusted dynamically based on the displayed ultrasound guidance image and heat-monitoring feedback received during the procedure" (Shahidi ¶ 110).

11. Diederich teaches the "ultrasound system and methods of the present invention allow directional control and deep penetration of energy patterns for directed thermal arterial occlusion/coagulation" (Diederich ¶ 19).

12. Diederich teaches the "quality and pattern of the ultrasound energy output may be assessed with acoustic beam distributions . . . These results may also be correlated to shapes of thermal coagulation produced during heating trials" (Diederich ¶ 115).

13. Diederich teaches: "Biothermal acoustic models were developed by our group to study ultrasound applicators for hyperthermia and thermal therapy . . . In order to improve accuracy, the model incorporates dynamic tissue changes in response to accumulation of thermal dose" (Diederich ¶ 116).

14. Diederich teaches the "dynamic approach has been used to model transurethral **67** and interstitial ultrasound applicators and shown to be in excellent agreement with experiment" (Diederich ¶ 116).

15. Figure 12 of Diederich is reproduced below:

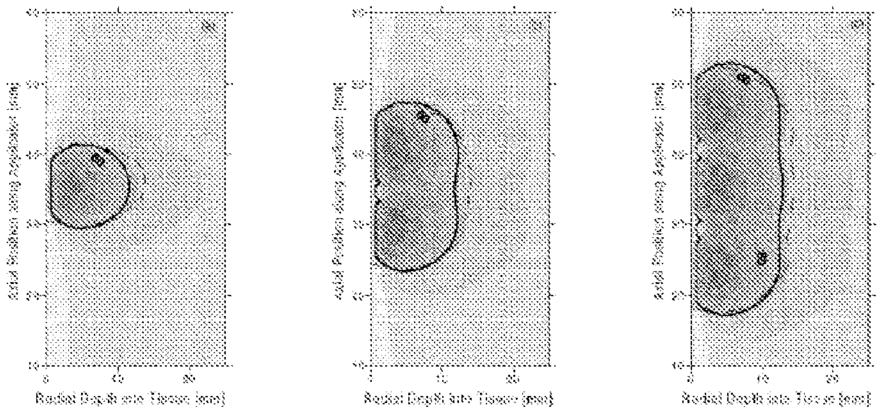

FIG. 12A FIG. 12B FIG. 12C

> FIG. **12** illustrates maximum temperature contours and lesion shapes for r-z simulations of an interstitial ultrasound applicator heating in vivo thigh muscle for 3 min with (a) one, (b) two, (c) three active transducers. The solid black contour lines represent simulated lesion shapes, and the dashed contour lines represent experimental in vivo measurements of lesions.

(Diederich ¶ 118).

16. Dodd III teaches ablation controllers "may take various forms . . . The controller may also be manipulated dynamically during an ablation procedure to change shape and size of an ablation under process. For example, via a concurrent imaging process, it may be determined that ablation should expand in a particular direction" (Dodd III ¶ 20).

17. Dodd III teaches

> the ablation procedure may be performed while also performing an imaging procedure . . . . Based on at least some of this information it may be determined whether a change in the size or shape of the ablation is desired (diamond **150**). For example, based on imaging feedback it may be determined that the targeted tissue has not been fully ablated and ablation should continue in a particular direction or a size of the ablation should

> be increased . . . . it may be determined whether ablation is complete. If so, method **100** ends. If instead it is determined that ablation is not completed, control passes back.

(Dodd III ¶¶ 24–26).

18. Dodd III teaches "by tailoring the shape and size of an ablation zone, tumors or other tissue may be treated with greater accuracy and precision. Likewise, the sparing of surrounding non-targeted tissue and organs can be improved" (Dodd III ¶ 31).

19. Freundlich teaches the "purpose of the treatment plan is to ensure complete ablation of target mass **104** by planning a series of sonications that will apply a series of thermal doses at various points within target mass **104**, resulting in a composite thermal dose sufficient to ablate the entire mass" (Freundlich 7:59–63).

20. Freundlich teaches an imager "provides real-time temperature sensitive magnetic resonance images of target mass **104** after some or all of the sonications. The planner **108** uses the images from the feedback imager **502** to construct an actual thermal dose distribution **600** comparing the actual composite thermal dose to the predicted composite thermal dose" (Freundlich 10:34–40).

21. Freundlich teaches

> Planner **108** uses thermal dose distribution **600** to automatically adjust the treatment plan, in real-time, after each sonication or uses the thermal dose distribution **600** in some of the points to adjust for the neighboring points. Planner **108** can adjust the treatment plan by adding treatment sites, removing treatment sites, or continuing to the next treatment site. Additionally, the thermal dose properties of some or all remaining treatment sites may automatically be adjusted by planner **108** based on real-time feedback from feedback imager **502**.

(Freundlich 10:49–58).

22. Freundlich teaches

> Multiple shapes of the focal spot can be created by controlling the relative phases and amplitudes of the em[]itted energy from the array, including steering and scanning of the beam, enabling electronic control of the focused beam to cover and treat multiple of spots in the defined zone of a defined tumor inside the body.

(Freundlich 2:8–13)

Principles of Law

"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 Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

Analysis

We adopt the Examiner's findings of fact and reasoning regarding the scope and content of the prior art (Final Act. 6–12; FF 1–22) and agree that the claims are obvious over Shahidi, Diederich, Dodd III, and Freundlich. We address Appellants' arguments below.

Claims 1 and 4

Appellants contend

> Shahidi fails to teach or suggest that ablation shapes from a library are specifically selected to completely cover a PTV. Instead, in Shahidi, the pathology is broken into multiple sub-segments in order to match sub-segments of the pathology to a predetermined ablation shape from the library. Shahidi does not specifically teach that the sub-segments cumulatively cover the entire pathology.

(App. Br. 12). Appellants contend "Shahidi does not teach selecting ablation shapes of ultrasound beams from a library to completely cover a

PTV. In fact, Shahidi is completely silent with respect to these features" (*id.* at 13).

We find this argument unpersuasive because Shahidi teaches: "For large tumors, multiple ablation applications may be necessary to encompass the entire volume, with probe placements for these multiple ablations currently based on the operator's estimates" (FF 8). This teaching to use multiple applications to treat an entire tumor volume reasonably suggests selecting ablation placements and shapes that completely cover the planned treatment volume, particularly when combined with Shahidi's teaching of "breaking a pathology into multiple sub-segments of known geometries that would match a library of preset antenna signal configurations designed to encompass each sub-segment" (FF 7).

Moreover, the Examiner's obviousness determination is not based on Shahidi alone, but includes Dodd III's teach of dynamic manipulation "during an ablation procedure to change shape and size of an ablation under process" (FF 16) because "based on imaging feedback it may be determined that the targeted tissue has not been fully ablated and ablation should continue in a particular direction or a size of the ablation should be increased" (FF 17). Freundlich also suggests the "purpose of the treatment plan is to ensure complete ablation of target mass **104** by planning a series of sonications that will apply a series of thermal doses at various points within target mass **104**, resulting in a composite thermal dose sufficient to ablate the entire mass" (FF 19).

Thus, Shahidi in combination with Dodd III and Freundlich reasonably suggests the use of multiple ablation shapes to fully ablate the planned treatment volume and ablate the entire mass (FF 7, 8, 16, 17, 19). "Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references." *In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986).

Appellants contend

> Diederich fails to teach or suggest at least performing acoustic modeling in order to pre-compute ablation shapes. Therefore, a person with ordinary skill in the art would have no teaching or suggestion when viewing the teachings of Diederich to utilize thermal acoustic modeling to pre-compute ablation shapes in the Shahidi system.

(App. Br. 13–14).

We find this argument unpersuasive because Diederich teaches the "quality and pattern of the ultrasound energy output may . . . be correlated to shapes of thermal coagulation produced during heating trials" (FF 12) and therefore "[b]iothermal acoustic models were developed by our group to study ultrasound applicators for hyperthermia and thermal therapy" (FF 13). Diederich is reasonably understood as teaching that biothermal acoustic models were developed to improve the quality, pattern, and shape of ultrasonic ablation, consistent with the Examiner's finding it obvious for Shahidi to "incorporate [Diederich's] 'acoustic thermal models' into [Shahidi's] 'thermal modeling tool' [in order to] improve accuracy in the modeling for ultrasound ablation" (Ans. 15).

Appellants contend "Dodd, III is completely silent with respect to at least the step of 'determining remaining areas of the PTV that have not been ablated by comparing ablation lesions from the latest imaging and estimated ablation lesions from the library' as recited in the method of claim 1"

(App.Br. 15). Appellants contend "[t]here is no teaching or suggestion in Dodd, III of determining remaining areas of the PTV that have not been ablated specifically by comparing ablation lesions from a latest imaging with estimated ablation lesions from a library" (*Id.*). Appellants also contend "the disclosure of Dodd, III is completely silent with respect to selecting ablation shapes of ultrasound beams from a library to completely cover determined remaining areas to be ablated" (*Id.* at 16).

We find these arguments unpersuasive because the "test [for obviousness] is what the combined teachings of the references as a whole would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425 (CCPA 1981). The test is not whether a single reference such as Dodd III teaches every element of the claim.

Dodd III teaches that "based on imaging feedback it may be determined that the targeted tissue has not been fully ablated and ablation should continue in a particular direction or a size of the ablation should be increased" (FF 17). Dodd III's teaching, in combination with Shahidi's teaching to employ "a library of preset antenna signal configurations designed to encompass each sub-segment" to ablate an entire tumor (FF 7), renders obvious the step of "comparing ablation lesions from the latest imaging and estimated ablasion lesions from the library" in order to utilize configurations that will complete the ablation process (FF 8, 17, 19) but "factor in safety margins . . . in order to protect adjacent tissue" as suggested by Shahidi (FF 9). Dodd III also teaches "by tailoring the shape and size of an ablation zone, tumors or other tissue may be treated with greater accuracy and precision. Likewise, the sparing of surrounding non-targeted tissue and organs can be improved" (FF 18).

Appellants contend "Freundlich solely discloses that the planner compares a <u>predicted composite thermal dose</u> and an actual thermal dose. The disclosure of Freundlich is completely silent with respect to performing a comparison which includes <u>estimated ablation lesions</u> from a library" (App. Br. 17). Appellants contend the "cited portions of Freundlich are completely silent with respect to selecting and modifying ablation shapes in order to cover a determined remaining area" (*Id.*)

We find these arguments unpersuasive because, as already noted, they fail to address the teachings of Shahidi, Diederich, Dodd III, and Freundlich in combination. *Merck*, 800 F.2d at 1097; *Keller*, 642 F.2d at 425. As particularly addressing the limitation "determining remaining areas of the PTV that have not been ablated by comparing ablation lesions from the latest imaging and estimated ablation lesions from the library" in claim 1, Freundlich teaches real time feedback that "uses the images from the feedback imager **502** to construct an actual thermal dose distribution **600** comparing the actual composite thermal dose to the predicted composite thermal dose" (FF 20). Freundlich explains that the planner can adjust the treamtent plan based on the thermal dose properties at treatment sites based on real time feedback (FF 21). Freundlich's teachings to compare actual and predicted (i.e. estimated) ablation lesion volumes, when combined with Shahidi's teaching of ablation lesion volume libraries for particular configurations of the ablation device (FF 6–7), renders obvious the comparison of imaging and estimated lesions to identify which configuration of the ablation device stored in the library should be used "to adjust the shape, amount and depth of the energy being implemented" as suggested by Shahidi (FF 10).

Claims 9, 11, 15, and 17

Appellants recite the limitations of claims 9 and 11 and contend:

> For the reasons stated with respect to the method of independent claim 1 and dependent claim 4, the disclosures of Shahidi, Diederich, Dodd, III and Freundlich, taken both singly and in combination, do not teach or suggest the non-transitory computer-readable storage medium of independent claim 9 or dependent claim 11.

(App. Br. 18). Appellants make similar statements regarding claims 15 and 17 (*see* App. Br. 19–20).

We find these arguments unpersuasive for the reasons already given above. We note that Shahidi teaches the use of computer readable media (FF 6), and Appellants do not specifically identify any other alleged error in the Examiner's rejection. "A statement which merely points out what a claim recites will not be considered an argument for separate patentability of the claim." 37 C.F.R. § 41.37(c)(iv). *See In re Lovin*, 652 F.3d 1349, 1357 (Fed. Cir. 2011) (the Board reasonably interpreted 37 C.F.R. § 41.37(c) as requiring "more substantive arguments in an appeal brief than a mere recitation of the claim elements and a naked assertion that the corresponding elements were not found in the prior art").

Conclusion of Law

The evidence of record supports the Examiner's conclusion that Shahidi, Diederich, Dodd III, and Freundlich render the rejected claims obvious.

B. 35 U.S.C. § 103(a) rejection over Shahidi, Diederich, Dodd III, Freundlich, and Nields

This rejections relies upon the underlying obviousness rejection over Shahidi, Diederich, Dodd III, and Freundlich. The Examiner provides sound, fact-based reasoning for combining Nields with Shahidi, Diederich, Dodd III, and Freundlich (Final Act. 12–15). Having affirmed the rejection of claim 1 over Shahidi, Diederich, Dodd III, and Freundlich for the reasons given above, we find the further combination with Nields renders the rejected claims obvious for the reasons given by the Examiner.

SUMMARY

In summary, we affirm the rejection of claims 1, 4, 9, 11, 15, and 17 under 35 U.S.C. § 103(a) as obvious over Shahidi, Diederich, Dodd III, and Freundlich.

We affirm the rejection of claims 5, 7, 8, 13, 14, and 18–20 under 35 U.S.C. § 103(a) as obvious over Shahidi, Diederich, Dodd III, Freundlich, and Nields.

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