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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JAVAD RAHIMIAN and MOHAMMAD SHENASA

Appeal 2017-005598
Application 13/399,704
Technology Center 3700

Before JEFFREY N. FREDMAN, JOHN E. SCHNEIDER, and TIMOTHY G. MAJORS, *Administrative Patent Judges*.

MAJORS, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellants[1] submit this appeal under 35 U.S.C. § 134 involving claims to methods and systems for navigating within body structures to cardiac ablation targets without the use of ionizing radiation or iodinated agents. The Examiner rejected the claims for lack of patent-eligible subject matter, for lack of written description, and for obviousness. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

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[1] Appellants identify the Real Party in Interest as VOXEL RAD, LTD. App. Br. 3.

STATEMENT OF THE CASE

The Specification discloses that "[t]ranscatheter procedures are rapidly replacing surgical procedures, such as coronary interventions . . . and catheter ablation of complex arrhythmias for arrhythmia surgery." Spec. ¶ 2. However, "[t]ypically transcatheter approaches are done under fluoroscopy which uses ionizing radiation," exposure to which is of concern for patients and medical personnel. *Id.* According to the Specification, "[a]ngiography comprises obtaining x-ray fluoroscopic imaging that involves guiding a catheter through femoral or carotid arteries . . . with x-ray fluoroscopic image guidance, and frequent injection of iodinated contrast agent to visualize internal anatomy of the vasculature . . . and plan an appropriate treatment." *Id.* ¶¶ 3–4 ("X-ray angiography is considered the industry's typical imaging standard for the evaluation of cardiovascular anatomy within the body.").[2]

Further to the transcatheter treatment of arrhythmias, the Specification explains that "AF [i.e., atrial fibrillation] ablation using RF typically requires multiple site burns and is typically a lengthy procedure with high radiation exposure." Spec. ¶ 11. "Successful AF ablation can depend on completely ablating target tissue without any gaps," where such "gaps are usually the cause of reconnection and recurrence of AF." *Id.* According to the Specification, "[t]raditional ablation catheters and electrodes do not identify

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[2] The Specification discloses that other methods "such as magnetic resonance angiography (MRA)" may be "used to delineate the cardio-vascular system." Yet, the Specification explains, "[w]hile MRA has the advantage of using non-ionizing radio frequency (RF) energy, it does not provide by itself real-time guidance within the vasculature." Spec. ¶ 5.

the characteristics of the arrhythmogenic substrate via direct visualization and monitoring while ablating, nor do they ablate uniformly without possible gaps." *Id.* ¶ 13.

Appellants' invention "relates to a system for navigating within body structures utilizing non ionizing and non iodinated agents." Spec. ¶ 21. According to the Specification, a "main advantage" with embodiments of the invention "is that it can be completely ionizing radiation free." *Id.* Moreover, in embodiments, a steerable catheter with a camera (e.g., CCD or CMOS) for direct imaging is included with the disclosed angiovision system and methods, and an ablation catheter may also be "integrated with the angiovision catheter to uniformly or non-uniformly generate heat or cryoablation of the arrhythmogenic substrate." *Id.* ¶¶ 18–19. "The uniform ablation reduces gaps in the ablation which are often the cause of reconnection and recurrence of AF and other cardiac arrhythmias." *Id.* ¶ 19.

Claims 1–4, 6–8, 10, 11, 23, 25, and 27–38 are on appeal. Claim 1 is illustrative and is reproduced below:

> 1. An ionizing radiation-free method to navigate within body structures to cardiac tissue ablation targets, the method comprising:
>
> capturing and loading a digital image identifying a vascular system of a patient into a memory storage device, the digital image acquired without using ionizing radiation and iodinated agents, the digital image comprising a magnetic resonance angiogram (MRA) including images of the vascular system and at least one infrared (IR) marker placed external to the patient prior to acquiring the digital image, the digital image further including images of the at least one IR marker taken by two IR cameras, each IR camera capturing the image of the at least one IR marker from a different position with respect to the patient;

> generating stereotactic coordinates in a stereotactic coordinate system based at least in part on the digital image, locations of the at least one IR marker detected by the MRA and the two IR cameras, and an entry point of a first catheter, the locations of the at least one IR marker providing registration information for the stereotactic coordinate system, the first catheter including a first camera operationally coupled to a first fiber optic bundle and at least one electromagnetic sensor associated with an electromagnetic coordinate system;
>
> generating from the digital image a 3D rendering of the patient's vascular system in stereotactic space, the 3D rendering including an indication of the entry point and a cardiac ablation target using the stereotactic coordinate system;
>
> generating a roadmap from the entry point to the cardiac ablation target on the 3D rendering;
>
> co-registering the electromagnetic and the stereotactic coordinate systems in order to fuse positional information of the at least one electromagnetic sensor with the 3D rendering;
>
> obtaining a position associated with the first catheter from an in-room global positioning system (GPS) configured to track the at least one electromagnetic sensor;
>
> fusing the position associated with the first catheter on the 3D rendering, the position comprising the longitudinal, lateral, anterior-posterior, pitch, roll, and yaw location of the first catheter;
>
> displaying the 3D rendering including indications for the position of the first catheter, the cardiac ablation target, the entry point, and the roadmap, the 3D rendering used to navigate the first catheter to the cardiac ablation target, the first camera providing an angioscopic view of the cardiac ablation target.

App. Br. (Claims App'x A, i–ii).

Claims 23 and 27, the other independent claims on appeal, are similar to claim 1. Claim 23 is a method and also recites, *inter alia*, "deploying a second catheter through the first catheter at the cardiac ablation target." Claims App'x iii–iv. Claim 23 further recites that this second catheter includes certain features, such as "including a multi-strut ablation electrode

having an ellipsoid shape after deployment," and that it is configured to deliver RF energy to each strut and simultaneously ablate tissues in multiple linear positions. *Id.* Claim 27 is an ionizing radiation-free system for angionavigation and includes, among several limitations, first and second preoperative imaging systems. *Id.* at iv–v. The first system includes at least two infrared cameras that capture an image of external stereotactic fiduciary markers, and the second system captures a digital image of the patient's vasculature and the external stereotactic fiduciary markers using non-ionizing radiation and non-iodinated agents (e.g., MRA). Claim 27 also recites, *inter alia*, computer image and tracking systems, and first and second catheters that include (respectively) a camera and an ablation electrode configured to ablate in multiple linear positions.

The claims stand rejected as follows:

I. Claims 1–4, 6–8, 10, 11, 23, 25, and 27–38 under 35 U.S.C. § 101 for lack of patent-eligible subject matter. Ans. 2–4. ("Rejection I").

II. Claims 27–35 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. *Id.* at 4–5. ("Rejection II").

III. Claims 1, 7, 8, 10, and 11 under 35 U.S.C. § 103(a) as unpatentable over Greenan,[3] Tremblay,[4] and Hunter.[5] *Id.* at 5–9. ("Rejection III").

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[3] Greenan et al., US 2008/0171934 A1, published July 17, 2008.
[4] Tremblay et al., US 2005/0054910 A1, published Mar. 10, 2005.
[5] Hunter et al., US 2004/0097806 A1, published May 20, 2004.

IV. The Examiner also rejects other claims that depend from independent claim 1 over the Greenan, Tremblay, and Hunter combination, in further combination with one or more additional references: Werneth[6] (claim 2); Rothe[7] (claim 3); Ben-Haim[8] (claim 4); Anderson[9] (claim 6); Werneth and Rothe (claim 25). *Id.* at 9–13. ("Rejection IV").

V. Claim 23 under 35 U.S.C. § 103(a) as unpatentable over Greenan, Tremblay, Hunter, and Rothe. *Id.* at 13–16. ("Rejection V").

VI. The Examiner also rejects claims 37 and 38, which depend from independent claim 23, over the Greenan, Tremblay, Hunter, and Rothe combination, in further combination with Maschke[10] and Werneth. *Id.* at 22–24. ("Rejection VI").

VII. Claims 27–31, 34, and 35 under 35 U.S.C. § 103(a) as unpatentable over Maschke, Tremblay, Greenan, and Rothe. *Id.* at 16–21. ("Rejection VII").

VIII. The Examiner also rejects claims 32 and 33, which depend from independent claim 27, over the Maschke, Tremblay, Greenan, Rothe combination, in further combination with Anderson (claim 32) or Hunter (claim 33). *Id.* at 21–22. ("Rejection VIII").

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[6] Werneth et al., US 2007/0083193 A1, published Apr. 12, 2007.
[7] Rothe et al., US 2010/0094081 A1, published Apr. 15, 2010.
[8] Ben-Haim, US 6,083,170, issued July 4, 2000.
[9] Anderson, US 2009/0088756 A1, published Apr. 2, 2009.
[10] Maschke, US 2008/0043901 A1, published Feb. 21, 2008.

I. SUBJECT MATTER ELIGIBILITY

1. Supreme Court Eligibility Framework

An invention is patent-eligible if it claims a "new and useful process, machine, manufacture, or composition of matter." 35 U.S.C. § 101. Nevertheless, the Supreme Court has interpreted § 101 to include certain implicit exceptions: "[l]aws of nature, natural phenomena, and abstract ideas" are not patentable. *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014).[11]

The Supreme Court has further established a two-step framework, described in *Mayo* and *Alice* for assessing whether a claim falls within one of those excepted, patent-ineligible, categories. *Id.* at 217–218 (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 75–77 (2012)). Under that framework, the Supreme Court explains, first "we determine whether the claims at issue are directed to one of those patent-ineligible concepts." *Id.* "If so, we then ask, '[w]hat else is there in the claims before us?'" *Id.* (quoting *Mayo*, 566 U.S. at 78). In answering this second question, the Court explains,

> we consider the elements of each claim both individually and as an ordered combination to determine whether the additional elements transform the nature of the claim into a patent-eligible application. . . . We have described step two of this analysis as a search for an inventive concept—*i.e.*, an element or combination of elements that is sufficient to ensure that the patent in practice

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[11] For instance, concepts determined to be abstract ideas, and thus patent ineligible, include certain methods of organizing human activity, such as fundamental economic practices (*Alice*, 573 U.S. at 219–20; *Bilski v. Kappos*, 561 U.S. 593, 611 (2010)); mathematical formulas (*Parker v. Flook*, 437 U.S. 584, 594–95 (1978)); and mental processes (*Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)).

> amounts to significantly more than a patent upon the [ineligible concept] itself.

Id. (internal citations and quotation marks omitted) (alteration in original).

2. Subject Matter Eligibility Guidance

The Patent Office recently published revised guidance on the application of § 101 in proceedings taking place before the Office. 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50 (Jan. 7, 2019) (hereafter "Revised Guidance"). Under that guidance, we look to whether the claim recites:

> (1) Step 2A – Prong One: any judicial exceptions, including certain groupings of abstract ideas (i.e., mathematical concepts, certain methods of organizing human activity, such as a fundamental economic practice, or mental processes); and
>
> (2) Step 2A – Prong Two: additional elements that integrate the judicial exception into a practical application (*see* MPEP[12] § 2106.05(a)–(c), (e)–(h)).[13]

Only if a claim (1) recites a judicial exception and (2) does not integrate that exception into a practical application, do we then look to whether the claim:

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[12] All Manual of Patent Examining Procedure (MPEP) citations herein are to MPEP Rev. 08.2017, January 2018.

[13] We acknowledge that some of the considerations at Step 2A, Prong Two, properly may be evaluated under Step 2 of *Alice* (Step 2B of the Office guidance). For purposes of maintaining consistent treatment within the Office, we evaluate them under Step 1 of *Alice* (Step 2A of the Office guidance). *See* 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. at 55 n. 25, 27–32. "As before, Step 1 of the USPTO's eligibility analysis entails considering whether the claimed subject matter falls within the four statutory categories [e.g., process, machine, etc.]" and the Revised Guidance "does not change Step 1 . . . analysis." *Id.* at 53–54.

(3) adds a specific limitation beyond the judicial exception that is not "well-understood, routine, conventional" in the field (*see* MPEP § 2106.05(d)); or

(4) simply appends well-understood, routine, conventional activities previously known to the industry, specified at a high level of generality, to the judicial exception.

See Revised Guidance 56 ("Step 2B: If the Claim Is Directed to a Judicial Exception, Evaluate Whether the Claim Provides an Inventive Concept").

3. Examiner's §101 Rejection

According to the Examiner, the pending claims are "directed to a method of navigating a catheter by generating a roadmap using stereotactic markers and images that were not acquired using contrast agent." Ans. 2; *see also* Final Act. 2–4. Moreover, the Examiner asserts, "the claimed invention relies upon obtaining and comparing intangible data, which is considered an abstract idea . . . as it involves mathematically relating data or is an idea of itself." Ans. 2. As for the "additional steps," the Examiner asserts that those steps are simply "insignificant post-solution activity," "data-gathering," or "routine and conventional data processing steps" applying an abstract idea in a computer environment. *Id.* at 2–3. The claims, the Examiner finds, fail to improve the functioning of a computer itself or improve any other technology. *Id.* at 3 ("While . . . the claims result in an image-guided treatment technique, this is not considered a meaningful limitation beyond generally linking the use of an abstract idea to a particular technological environment."). Moreover, the Examiner finds, "the claimed invention . . . fails to recite any specific machine for performing the apparent computational steps." *Id.* at 3.

Appellants argue the claims are not directed to an abstract idea. App. Br. 18–19. To the contrary, Appellants argue, the "claimed inventions provide a specific approach to solving the problem of how to navigate a catheter to perform functions, such as ablation without gaps to avoid reconnection and reoccurrence of atrial fibrillation, without exposing the patient and staff to ionizing radiation." *Id.* at 18. According to Appellants, the Examiner's assertion "that the claims are directed to the abstract idea of 'obtaining and comparing intangible data'" is "undoubtedly an oversimplification." *Id.* at 18–19 (quoting Final Act. 2). Appellants highlight that the claims include, among other limitations, "navigating a catheter through a patient using a 3D rendering in stereotactic space that is generated by fusing a MRA image and two IR images taken by IR cameras," "fusing positional information in electromagnetic coordinates from a sensor on the catheter with the stereotactic coordinates in the 3D rendering . . . using a GPS system," and also "using the 3D rendering and an angioscopic image from a camera on the catheter to provide 3D stereoscopic vision in stereoscopic space of an ablation site." *Id.* at 19. For at least these reasons, Appellants contend, "[t]he present claims could not be viewed as a generic description of obtaining and comparing intangible data, and thus are not 'directed to' that purported concept." *Id.*

4. Analysis

Appellants' arguments are persuasive, and we disagree with the Examiner's conclusion that the claims are patent-ineligible under § 101. We explain further below.

Alice/Mayo Step 1; Revised Guidance Step 2A

From the standpoint of *Alice/Mayo* Step 1 (and Revised Guidance Step 2A), we do not agree with the Examiner's determination[14] that the claims are directed to an abstract idea. As a threshold matter, we note that the Examiner first states that the claims "*are directed to* a method of navigating a catheter by generating a roadmap using stereotactic markers and images that were not acquired using contrast agent." Ans. 2 (emphasis added). We do not agree that the claims, so characterized by the Examiner, are necessarily an abstract idea. The Examiner does not demonstrate how this distillation of the claimed subject matter falls within any of the well-recognized categories of abstract ideas (i.e., mathematical concepts or formulas, methods of organizing human activity, such as those involving economic principles or commercial interactions, or mental processes performed in the human mind). *See* Revised Guidance 52 (Step 2A).

The Examiner continues, however, and asserts that the claimed invention "relies upon obtaining and comparing intangible data, which is considered an abstract idea." Ans. 2. That a claim may "rely upon" ineligible subject matter is not enough to show that a claim is *directed to* ineligible subject matter. Were it so, most every invention might be found unpatentable under § 101. Indeed, the Supreme Court has long recognized that all inventions, at some level, embody or apply laws of nature, natural phenomena, and abstract ideas and, thus, we must "tread carefully in construing this exclusionary principle lest it swallow all of patent law."

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[14] We recognize that the Revised Patent Subject Matter Eligibility Guidance was not available to the Examiner when formulating this rejection.

Alice, 573 U.S. at 217; *Thales Visionix Inc. v. United States*, 850 F.3d 1343, 1349 (Fed. Cir. 2017) (holding "it is not enough to merely identify a patent-ineligible concept underlying the claim; we must determine whether the patent-ineligible concept is what the claim is 'directed to.'").

Insofar as the Examiner's position is that the claims are directed to the abstract idea of "obtaining and comparing intangible data," as Appellants contend, that is an oversimplification of the claims. App. Br. 19. On that point, we must neither overgeneralize the claims nor overemphasize limitations that might recite an abstract idea dissected from the whole.[15] *Thales*, 850 F.3d at 1347 ("[We] ensure at step one that we articulate what the claims are directed to with enough specificity to ensure the step one inquiry is meaningful").

When the claims as a whole are considered, even if some aspects of the invention may rely on comparing data or on mathematical concepts, those aspects have been sufficiently integrated into a practical application. Claim 1, for example, requires and recites specific physical structures, hardware, data, and computing operations that provide a technologically advantageous, radiation-free method for navigating a catheter to an ablation target within a patient's vasculature. These features include, *inter alia*: a digital image acquired of an infrared (IR) marker placed external to a patient, without using ionizing radiation (i.e., comprising a magnetic resonance angiogram) and with the use two IR cameras placed at different positions relative to the patient; a catheter including an electromagnetic

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[15] The Examiner does not identify on this record the particular language in the claims that allegedly recites an abstract idea. *See* Revised Guidance (Step 2A, Prong 1).

sensor as well as a camera; generating a 3D rendering of a patient's vascular system using a stereotactic coordinate system and co-registering an electromagnetic coordinate system (associated with the sensor on the catheter) with the 3D rendering; and tracking the catheter's electromagnetic sensor from an in-room GPS. Like the system in *Thales*, comprising an arrangement of inertial sensors and object-tracking calculations based on certain reference frames, the claims here are sufficiently specific and concrete, providing a practical and real-world technological solution, that we conclude satisfies the requirements of § 101. *Thales*, 850 F.3d at 1348–49.

Having reached the decision above, we need not analyze the claims under Step 2B of the Revised Guidance or Step 2 of *Alice*. *See* Revised Guidance 51; *Thales*, 850 F.3d at 1349 ("Because we find the claims are not directed to an abstract idea, we need not proceed to step two").

II. WRITTEN DESCRIPTION

The Examiner has rejected independent claim 27 (and its dependent claims) for non-compliance with the written description requirement of 35 U.S.C. § 112, first paragraph. Ans. 4–5. Claim 27 recites, *inter alia*, "a second preoperative imaging system to capture a digital image of a vascular system of the patient and the external stereotactic fiduciary markers using [] non ionizing radiation and non iodinated agents." Claims App'x v. Yet, according to the Examiner, "the specification does not disclose a second imaging system." Ans. 5.

We disagree. As Appellants point out, the Specification describes a first imaging system comprising at least two IR cameras, and further describes "[a] second preoperative imaging system [that] captures a digital image of the patient's vasculature and the [IR] markers using non ionizing

radiation . . . , such as the MR system disclosed at least at ¶¶ 37 and 77 of the specification." App. Br. 21; *see* Spec. ¶ 37 ("A planning MR angiography scan is acquired prior to angionavigation with stereotactic fiduciary markers to produce digitally reconstructed 3D rendering of vascular system.").

The Examiner responds that "these paragraphs disclose an image that has been acquired ahead of time." Ans. 26. But the Examiner fails to explain why the timing of the image acquisition is germane to claim 27, which does not exclude a system that acquires an MRA before the 3D renderings are generated and the catheter is tracked to its ablation target. Indeed, the claim itself recites that the "second" system is a "*preoperative* imaging system." Claims App'x v. (emphasis added). Based on the disclosures cited to us by Appellants, we are persuaded the skilled artisan would understand that the inventors were in possession of a method employing, for example, a preoperative system for acquiring MRA images—sufficiently describing the "second preoperative imaging system" with the features recited in claim 27.

III. OBVIOUSNESS

Rejections III–IV

The Examiner rejected independent claim 1, and various claims that depend from claim 1 as obvious over the combination of Greenan, Tremblay, and Hunter (Rejection III). Ans. 5–9. Certain other claims that depend from claim 1 are rejected over the Greenan, Tremblay, Hunter combination, adding further references to address limitations added to those dependent claims (Rejection IV). Ans. 9–12. For purposes of addressing Rejections III and IV, we focus principally on claim 1 and the Examiner's

findings and reasoning as to the combination of Greenan, Tremblay, and Hunter.

The Examiner finds that Greenan discloses an ionizing radiation-free method for navigating within body structures. Ans. 5. According to the Examiner, Greenan's method includes capturing a digital image of a patient's vasculature, the image comprising MRA "and at least one electromagnetic marker placed external to the patient prior to acquiring the digital image." *Id.* (citing Greenan ¶¶ 16, 17, 55–59, 64, and 68). Further, the Examiner finds, Greenan discloses generating stereotactic coordinates and 3D renderings of the patient's vascular system. Ans. 6. The Examiner also finds that Greenan discloses a catheter that includes a camera and at least one sensing coil, along with the step of obtaining the position of the catheter from a GPS system. *Id.* (citing, e.g., Greenan ¶¶ 23–24, 28, 58, and 63).

The Examiner finds that Greenan does not disclose infrared (IR) markers, fiber optic bundles, cardiac ablation targets, and 3D renderings of roadmaps. Ans. 7. The Examiner, thus, turns to Tremblay and Hunter. According to the Examiner, Tremblay discloses digital images of IR markers taken by two IR cameras, fiber optic bundles for operating such cameras, and a camera providing a view of an ablation target. *Id.* (citing Tremblay ¶¶ 63, 70–71, 78, 88, and Fig. 1A (items 11a and 11b)). Because Tremblay does not disclose 3D renderings of roadmaps, the Examiner cites Hunter. *Id.* at 7–8 (discussing Hunter's teaching of generating a roadmap for a catheter to an ablation target on a 3D rendering).

The Examiner concludes it would have been obvious to combine Greenan, Tremblay, and Hunter to arrive at the method recited in claim 1.

According to the Examiner, the ordinarily skilled person would "add an IR marker, as disclosed by Tremblay, for the purpose of tracking a device that is being imaged by an infrared camera" (citing ¶ 88) and "couple a camera to a fiber optic bundle . . . for the purpose of operating the infrared cameras." Ans. 8. The Examiner concludes it would have been obvious to obtain views of an ablation target, as disclosed in Tremblay, to treat a region of interest. *Id.* And, the Examiner reasons, the person of ordinary skill would have generated "a 3D rendered cardiac ablation roadmap, as disclosed by Hunter, for the purpose of navigating through a portion of the anatomy." *Id.*

We are unpersuaded on the record before us, that the Examiner has met the burden to show that claim 1 would have been obvious over the cited disclosures in Greenan, Tremblay, and Hunter. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992) (The Examiner "bears the initial burden . . . of presenting a *prima facie* case of unpatentability.").

As an initial matter, the Examiner did not show or sufficiently explain how the alleged tracking system in Greenan discloses the in-room global positioning system configured to track the electromagnetic sensor (in the catheter) as recited in claim 1. We are not persuaded, at present, that tracking a catheter in an electromagnetic field would necessarily satisfy the claimed in-room GPS system. *See* Greenan ¶¶ 23–24.

Second, the Examiner states that Greenan's digital images include images of "at least one electromagnetic marker placed external to the patient prior to acquiring the digital image." Ans. 5 (citing Greenan ¶¶ 16, 17, 68). However, as Appellants note, the Examiner's finding does not appear to be accurate. The cited paragraphs disclose electromagnetic markers positioned

inside the patient—not images of *IR markers placed external to the patient* as claimed. App. Br. 12–13.

Third, with respect to Tremblay, Appellants contend that "Tremblay uses two IR cameras placed within line of sight to track [0078] two precision-machined plastic tools [0088]." App. Br. 12. Hence, Appellants contend:

> Tremblay's use of two IR cameras does not involve placing at least one IR marker external to the patient prior to acquiring the digital image, where the digital image includes the MRA image and the images of the at least one IR marker taken by the two IR cameras, each image of the at least one IR marker taken from a different position with respect to the patient.

App. Br. 12. The Examiner summarily responds, and "disagrees and submit[s] that this limitation is disclosed in paragraph [0088]." Ans. 25 (citing Tremblay ¶¶ 35, 88). But the Examiner's findings and response are inadequate to explain clearly and sufficiently how those cited teachings in Tremblay disclose the specific arrangement of IR cameras and external IR markers (and images captured of such markers) that would satisfy the elements of claim 1.[16]

Finally, in the Examiner's rationale for combining the references, the Examiner states that it would be obvious to couple a camera to a fiber optic bundle "for the purpose of operating the infrared cameras." Ans. 8. But the "fiber optic bundle" in claim 1 is associated with the camera included on the catheter, not the two differently-placed IR cameras configured to obtain images of the one or more IR markers external to the patient. The Examiner

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[16] We decline to decide, in the first instance on appeal, whether other (un-cited) disclosures in Tremblay would be sufficient to meet the claim limitations related to IR cameras and external IR markers.

appears to be mixing the required elements of the camera systems that are claimed, adding to the lack of clarity to the rejection.

For the above reasons, we determine that the preponderance of the evidence cited by the Examiner does not support the Examiner's conclusion that claim 1 would have been obvious over the Greenan, Tremblay, and Hunter combination. The rejection of the claims that depend from claim 1 (remainder of Rejection III and Rejection IV), fall for the same reasons as the Examiner has not shown that the cited teachings in the other references make up for the deficiencies of the Greenan, Tremblay, and Hunter combination on this record.

Rejections V–VI

Rejections V and VI relate to independent claim 23 and its dependent claims (claims 37 and 38). Those rejections (as with Rejections III–IV, related to claim 1) rely on substantially the same teachings in Greenan, Tremblay, and Hunter. *See, e.g.*, Ans. 13–15. Rothe is relied upon by the Examiner solely for purposes of disclosing the features of the second, ablation catheter recited in claim 23. *Id.* at 15. Because claim 23 includes substantially the same limitations from claim 1, for which we concluded that the Examiner had not made a sufficient showing that those limitations were disclosed in the cited teachings of Greenan, Tremblay, and Hunter, we also reverse Rejections V and VI.

Rejections VII–VIII

For Rejection VII, the Examiner rejects independent claim 27 over the combination of Maschke, Tremblay, Greenan, and Rothe. Other claims depending from claim 27 are rejected over that same combination, or that combination along with additional references (Rejection VIII) to address

elements added to certain dependent claims (e.g., Anderson is relied on for claim 32, and zeroing an electromagnetic coordinate system). Ans. 21.

According to the Examiner, Maschke discloses an ionizing radiation-free system for angionavigation and ablation of cardiac tissue. Ans. 16. Appellants, however, argue that the Examiner is incorrect because "Maschke suggests a hybrid imaging system that uses radiographic and nuclear medical examinations, with a gamma radiation source arranged in the body." App. Br. 16 (citing Maschke ¶ 17 ("To this end, a diagnosis device is proposed for combined and/or combinable radiographic and nuclear medical examinations with an x-ray source, with an examination room for accommodating a patient, with a gamma radiation source arranged in the body . . . .")). The Examiner provides no response to Appellants' argument on this point and, thus, we agree with Appellants here.

Although the Examiner cites Greenan as teaching obtaining images with non-ionizing radiation, the Examiner does not provide a persuasive rationale for how and why Maschke's system would be modified in light of Greenan. Ans. 18. Instead, the Examiner simply states that it would have been obvious to use Greenan's method "to obtain images using non-ionizing radiation . . . for the purpose of generating an electromagnetic field around markers which will be used for tracking." *Id.* at 19. That reasoning is insufficient, particularly in view of Maschke's teaching that, for instance, by using its system and method, "high costs of MRI as well as the effects of strong magnetic fields on other components can be avoided." Maschke ¶ 63 ("Also, MRI may not provide functional image data . . . .").

For the reasons above, we reverse the Examiner's rejection of claim 27 (as well as dependent claims 28–31, 34, and 35) over Maschke,

Tremblay, Greenan, and Rothe. We similarly reverse Rejection VIII, related to claims 32 and 33, which depend from claim 27, because Rejection VIII relies on the same Maschke, Tremblay, Greenan, and Rothe combination, and the Examiner has not shown that the additional references (Anderson and Hunter) make up for the noted deficiencies on this record.

SUMMARY

We reverse the rejections for ineligible subject matter, lack of written description, and obviousness that are on appeal.

REVERSED