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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* SHUKI VITEK, BENNY ASSIF, and ADI GREENBERG

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Appeal 2017-000744  
Application 13/222,086<sup>1</sup>  
Technology Center 3700

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Before JEFFREY N. FREDMAN, RYAN H. FLAX, and  
KRISTI L. R. SAWERT, *Administrative Patent Judges*.

SAWERT, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) from the rejection of claims 1–3 and 5–22. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

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<sup>1</sup> Appellants identify Insightec Ltd. as the real party in interest.  
Appeal Br. 2.

STATEMENT OF THE CASE

Claims 1–3 and 5–22 are on appeal and stand rejected as follows:

- A. Claims 1–3 and 5–22 under 35 U.S.C. § 101 as directed to non-statutory subject matter;
- B. Claims 1–3 and 5–22 under 35 U.S.C. § 112, first paragraph, for lacking enablement;
- C. Claims 1–3 and 5–22 under 35 U.S.C. § 112, first paragraph, for lacking written description;
- D. Claims 1–3 and 5–22 under 35 U.S.C. § 112, second paragraph, for indefiniteness;
- E. Claims 1, 5, 9, 14–16, 18 and 20 under 35 U.S.C. § 102(b) for anticipation by Gray<sup>2</sup>;
- F. Claims 2, 13, and 17 under 35 U.S.C. § 103 for obviousness over Gray in view of Stevenson<sup>3</sup>;
- G. Claims 3 and 6–8 under 35 U.S.C. § 103 for obviousness over Gray in view of Cory<sup>4</sup>;
- H. Claims 10, 11, and 19 under 35 U.S.C. § 103 for obviousness over Gray in view of Vitek<sup>5</sup>;
- I. Claim 12 under 35 U.S.C. § 103 for obviousness over Gray

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<sup>2</sup> Robert W. Gray et al., U.S. Patent Publ. No. 2004/0263172 A1 (Dec. 30, 2004) (“Gray”).

<sup>3</sup> Robert A. Stevenson, U.S. Patent Publ. No. 2009/0163980 A1 (Jun. 25, 2009) (“Stevenson”).

<sup>4</sup> David G. Cory and Werner E. Maas, U.S. Patent No. 5,532,594 (Jul. 2, 1996) (“Cory”).

<sup>5</sup> Shuki Vitek et al., U.S. Patent No. 6,735,461 B2 (May 11, 2004) (“Vitek”).

- in view of Vitek, and further in view of Ben-Shmuel<sup>6</sup>;
- J. Claim 21 under 35 U.S.C. § 103 for obviousness over Gray in view of Yamanaka<sup>7</sup>; and
- K. Claim 22 under 35 U.S.C. § 103 for obviousness over Gray in view of Yamanaka and further in view of Vitek.

Non-Final Act. 2–18.

Claim 1 is representative of the subject matter on appeal. *See* 37 C.F.R. § 41.37(c)(1)(iv). Claim 1 recites:

1. A method of performing treatment of an anatomic region in conjunction with magnetic resonance (MR) imaging of the region, the treatment comprising at least one radio-frequency-sensitive (RF-sensitive) operation, the method comprising the steps of:

during an MR imaging operation, temporarily suppressing gradient field activity; and

by a controller in response to a signal indicative of gradient-field-activity suppression, initiating the RF-sensitive operation.

Appeal Br. 18.

## DISCUSSION

### Background

The claimed invention generally relates to “medical diagnosis and treatment methods guided by magnetic resonance imaging (MRI).” Spec.

¶ 1. The Specification states that “[m]agnetic resonance imaging may be

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<sup>6</sup> Eran Ben-Shmuel, U.S. Patent Publ. No. 2009/0236333 A1 (Sept. 24, 2009) (“Ben-Shmuel”).

<sup>7</sup> Masaaki Yamanaka, U.S. Patent No. 7,259,560 B2 (Aug. 21, 2007) (“Yamanaka”).

used in conjunction with ultrasound focusing in a variety of medical applications.” Spec. ¶ 2. For example, the Specification explains that, “[t]o visualize the target tissue and guide the ultrasound focus during therapy, magnetic resonance imaging may be used.” *Id.* ¶ 3.

The Specification states, however, that “[t]he simultaneous operation of ultrasound and MRI apparatus can lead to undesired interferences.” *Id.* ¶ 5. For example, “focused ultrasound procedures often involve RF-sensitive operations (such as the ultrasound detection that may accompany treatment with focused ultrasound) that are easily disturbed by RF excitation signals and/or time-varying field gradient generated by the MRI system.” *Id.* The Specification provides that “[p]rior-art approaches to avoiding such interference include shielding as well as signal filtering and/or processing,” but states that these prior-art solutions are “difficult to implement,” and add cost and complexity to the ultrasound system. *Id.*

The Specification explains that applicants’ solution to minimize or avoid interferences between MRI and ultrasound is to operate the MRI machine in accordance with predetermined pulse sequences, to provide a signal from the MRI machine “signaling the onset of gradient idle times, i.e., time intervals in which magnetic field gradients, or time variations thereof, are completely or partially suppressed,” and to perform the RF-sensitive operations of the ultrasound in accordance with the signaled suppression of MRI gradients. *Id.* ¶¶ 5, 29.

### Analysis

On appeal, the Board “reviews the obviousness rejection for error based upon the issues identified by appellant, and in light of the arguments and evidence produced thereon.” *Ex parte Frye*, 94 USPQ2d 1072, 1075

(BPAI 2010) (precedential). Upon review of the record, we affirm the rejection of claims 1–3 and 5–22 under 35 U.S.C. § 112, second paragraph, as indefinite for failure of the Specification to identify the required corresponding structure for the “controller” and “module” means-plus-function claim terms. But we reverse the remainder of the Examiner’s rejections.

*A. Non-Statutory Subject Matter*

The Examiner rejected claims 1–3 and 5–22 under 35 U.S.C. § 101 as directed to non-statutory subject matter. Under § 101, “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof” may be eligible for a patent. But, “[l]aws of nature, natural phenomena, and abstract ideas are not patentable.” *Mayo Collaborative Services v. Prometheus Labs., Inc.*, 566 U.S. 66, 701 (2012) (citation omitted). “Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry.” *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 591 (2013).

The Supreme Court has articulated a two-step test for patent eligibility under § 101 that “distinguish[es] patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts.” *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2355 (2014) (citing *Mayo*, 566 U.S. at 76–78) (“the *Alice/Mayo* test”). “First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts. If so, we then ask, what else is there in the claims before us?” *Id.* (citation and quotations omitted). Second, we “search for an inventive concept—i.e., an element or combination of elements that is sufficient to ensure that the patent in practice amounts to

significantly more than a patent upon the ineligible concept itself.” *Id.* (quotations and alterations omitted).

As to step one of the *Alice/Mayo* test, the Examiner asserts that the claims “are directed to the general concept of avoiding signal interference, particularly in a dual modality system where simultaneous operations would obviously cause interferences.” Ans. 3. And as to step two, the Examiner adds that any additional steps in the pending claims are “insignificant post solution activity” or “conventional techniques” for the field in question. *Id.* at 3–4.

Having reviewed the evidence, we disagree with the Examiner that the appealed claims are unpatentable under § 101. Because “there is no . . . single, succinct, usable definition or test” for identifying an “abstract idea” in accordance with the *Alice/Mayo* test, “the decisional mechanism courts now apply is to examine earlier cases in which a similar or parallel descriptive nature can be seen.” *Amdocs (Israel) Ltd. v. Openet Telecom, Inc.*, 841 F.3d 1288, 1294 (Fed. Cir. 2016). Here, we find the Federal Circuit’s analysis in *Thales Visionix Inc. v. United States*, 850 F.3d 1343 (Fed. Cir. 2017), to be particularly useful in analyzing the present facts.

In *Thales*, the Federal Circuit held that claims directed to a system and method using inertial sensors to reduce error in measuring position and orientation were not directed to an abstract idea merely because some utilization of mathematical equations was involved. *Id.* at 1348–49. “At step one, ‘it is not enough to merely identify a patent-ineligible concept underlying the claim; we must determine whether that patent-ineligible concept is what the claim is ‘directed to’” and “[t]hat a mathematical equation is required to complete the claimed method and system does not

doom the claims to abstraction.” *Id.* at 1349 (quoting *Rapid Litig. Management Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1050 (Fed. Cir. 2016)).

Similarly here, the pending claims are not directed to a mere abstract idea simply because mathematics is involved in practicing the invention. The claims are directed to using and operating an MRI device with another medical device in a way that improves (or allows) the combined performance of each; i.e., the two devices do not interfere with one another. Spec. ¶¶ 5–14. This is similar to the invention claimed in *Thales*, which used conventional sensors in a non-conventional manner, in that conventional devices are used and, specifically, controlled in new ways, by taking the potentially-interfering functioning of each other into account, that improves the results achieved. The fact that mathematics is involved does not doom the appealed claims to abstraction any more than it did the claims in *Thales*.

Furthermore, although the pending claims recite only generic components such as an MRI, a controller, or ultrasound, the inventive concept is the particular arrangement of these known devices and components to allow for a novel solution to the problem of interference produced by an MRI. Specifically, claim 1 recites performing an RF-sensitive operation during the time that the MRI field is suppressed. *See* Appeal Br. 18. Thus, we determine that Appellants do not claim all methods or devices for preventing signal noise produced by the operation of an MRI from affecting RF-sensitive operations. Instead, the rejected claims recite a particular arrangement or, more precisely, a particular sequence of signal processing and operation of conventional devices as an alternative to prior

art methods of shielding the RF-sensitive equipment or using signal processing to extract undesired portions of the received signals.

For these reasons, we conclude that Federal Circuit precedent supports the conclusion that the claims on appeal are not directed to patent-ineligible subject matter. We therefore reverse the rejection of claims 1–3 and 5–22 under 35 U.S.C. § 101 as directed to non-statutory subject matter.

*B. Enablement*

The Examiner rejected claims 1–3 and 5–22 under 35 U.S.C. § 112, first paragraph, for lack of enablement. Non-Final Act. 6–7. The first paragraph of § 112 requires that the specification enable a person of ordinary skill in the art “to make and use the invention.” The enablement requirement is met when the skilled artisan, having read the specification, could practice the claimed invention without “undue experimentation.” *In re Wands*, 858 F.2d 731, 736–37 (Fed. Cir. 1988). “Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations,” including: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737 (“the *Wands* factors”).

The Examiner asserts that the “specification, while being enabling for RF-sensitive ultrasound operations that are particularly sensitive to RF disturbances from the MRI apparatus 300 include ultrasound imaging (in parallel with MRI) and measurements of the cavitation spectrum or of acoustic reflections, does not reasonably provide enablement for other RF-

sensitive operations.” Non-Final Act. 6–7. The Examiner states that “[i]t would require undue experimentation to determine the RF-sensitive operations that can work in synchronization with the particularly disclosed MR pulse sequence.” *Id.* at 7.

We agree with Appellants that the Examiner has not sufficiently supported this rejection by a preponderance of the evidence. *See* Reply Br. 7–8. Here, Appellants argue that one of ordinary skill in the art would understand how to identify other RF-sensitive operations not specifically disclosed in view of the Specification. Appeal Br. 9–10 (citing Specification ¶¶ 27–32). But Examiner provides insufficient evidentiary support or solid scientific rationale for the rejection. Moreover, we note that the Specification states that signals with low power levels are especially susceptible to signal noise generated by interference from the MRI. Spec. ¶ 30. Thus, without sufficient reasoning or evidence to the contrary, we agree with Appellants that an ordinarily skilled artisan would understand the types of signals in the art that are susceptible to significant losses of accuracy or precision due to radio frequency interference generated by outside sources like an MRI. For these reasons, we reverse the rejection of claims 1–3 and 5–22 under 35 U.S.C. § 112, first paragraph, for an alleged lack of enablement.

### *C. Written Description*

The Examiner rejects claims 1–3 and 5–22 under 35 U.S.C. § 112, first paragraph, for lack of written description. Non-Final Act. 7–9. The first paragraph of § 112 requires that the specification contain a written description of the claimed invention. “[T]he hallmark of written description is disclosure.” *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351

(Fed. Cir. 2010) (en banc). The written description requirement is met when the specification “conveys to those skilled in the art that the inventor had possession of” and “actually invented” the claimed subject matter. *Id.*

The Examiner asserts that the claim elements “controller . . . initiating,” “controller for synchronizing,” “module for receiving information,” “module for initiating,” “treatment controller,” “MRI controller,” “treatment apparatus,” and “treatment system” are means-plus-function limitations that invoke 35 U.S.C. 112, sixth paragraph. Non-Final Act. 7. “However,” the Examiner continues, “the written description fails to disclose the corresponding structure, material, or acts for the claimed function.” *Id.*

Because the lack of corresponding structure for a means-plus-function claim term is the basis for a rejection for indefiniteness, rather than written description, these assertions are addressed with respect to the indefiniteness rejection, below. *See, e.g., In re Dossel*, 115 F.3d 942, 946 (Fed. Cir. 1997) (“Failure to describe adequately the necessary structure, material, or acts in the written description means that the drafter has failed to comply with the mandate of § 112 ¶ 2 . . . the mandate that all claims must particularly point out and distinctly claim the subject matter which the applicant regards as his invention.”).

Thus, we reverse the rejection of claims 1–3 and 5–22 under 35 U.S.C. § 112, first paragraph, for lack of written description.

#### *D. Indefiniteness*

The Examiner rejects claims 1–3 and 5–22 under 35 U.S.C. § 112, second paragraph, for indefiniteness. Non-Final Act. 7–8.

##### *(1) Means-plus-function terms*

As noted above, the Examiner asserts that the claim elements “controller . . . initiating,” “controller for synchronizing,” “module for receiving information,” “module for initiating,” “treatment controller,” “MRI controller,” “treatment apparatus,” and “treatment system” are means-plus-function limitations that invoke 35 U.S.C. § 112, sixth paragraph, but that the written description fails to disclose the corresponding structure, material, or acts for those claimed functions. *Id.* at 8.

Appellants do not appear to contest that the claim terms identified by the Examiner are means-plus-function terms. Appeal Br. 10–11, 13–14. Instead, Appellants argue that the ordinarily skilled artisan would understand that (1) the “module” terms are computer software; (2) a “treatment apparatus” is associated with an “ultrasound transducer”; (3) a “treatment system” is associated with an ultrasound imaging probe or phased-array ultrasound transducer system; and (4) the “controller” claim terms correspond to a processor. *Id.*

As an initial matter, the Examiner’s Non-Final Action identifies the structures for “treatment apparatus” (2) and “treatment system” (3), which comports with the structures that Appellants identify above. *See* Non-Final Act. 6 (finding “the treatment apparatus to be an ultrasound transducer,” and “the treatment system to be an ultrasound system”). Thus, the rejection of the claim limitations “treatment apparatus” and “treatment system” appears not well-founded, and the Examiner provides no additional argument or response as to any of these terms in the Answer. We therefore reverse the rejection as applied to these claim terms.

We now turn to the question of indefiniteness of the “module” (1) and “controller” (4) claim terms. Non-Final Act. 8. In response to the

Examiner's rejection, Appellants assert that the recited "controller," "treatment controller," and "MRI controller" correspond to a processor, such as that described in paragraph 34 of the Specification. Appeal Br. 11.

Appellants further allege that the ordinarily skilled artisan would understand that "a 'module' is a part of a computer or computer program" and therefore corresponds to "structures implemented in, for example, a computer." *Id.*

"In cases involving a computer-implemented invention in which the inventor has invoked means-plus-function claiming, [the Federal Circuit] has consistently required that the structure disclosed in the specification be more than simply a general purpose computer or microprocessor." *EON Corp. IP Holdings LLC v. AT & T Mobility LLC*, 785 F.3d 616, 621 (Fed. Cir. 2015) (quotation omitted). Thus, an algorithm is required to provide sufficient structure unless the function can be performed by any general purpose computer with no special programming. *Id.*

Here, the Specification discloses no such algorithm for the "controller" or "module" terms. Applicants point to paragraphs 32 and 33 of the Specification as "illustrat[ing] the operation sequence" required, Appeal Br. 11, but the high level description in those paragraphs cannot fairly be described as disclosing an "algorithm." Instead, the Specification merely states that "functionality for synchronizing an MRI apparatus and a focused ultrasound system as described above, whether integrated with the MRI and/or ultrasound controller or provided by a separate controller, may be structured in one or more *modules implemented in hardware, software, or a combination of both.*" Spec. ¶ 34 (emphasis added).

For these reasons, we affirm the Examiner's rejection of claims 1–3 and 5–22 because the various "controller" and "module" means-plus-

function claim terms lack corresponding structure in the Specification, and therefore are indefinite under 35 U.S.C. § 112, second paragraph.

(2) “temporarily”

The Examiner also rejected claims 1–3 and 5–13 for the recitation of the term “temporarily.” The Examiner asserts that the term is indefinite because “the specification does not provide a standard for ascertaining the requisite degree.” Non-Final Act. 8. Appellants respond that terms of degree are not necessarily indefinite, and that the ordinarily skilled artisan would understand the meaning of “temporarily” in the context of the claims, and in view of Figure 4 and the accompanying description in the Specification. Appeal Br. 12–13.

“Claim language employing terms of degree has long been found definite where it provided enough certainty to one of skill in the art when read in the context of the invention.” *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370 (Fed. Cir. 2014). On review of the record, we determine that the preponderance of the evidence supports Appellants’ position. Specifically, the Specification states that the MRI is operated according to various pulse sequences. Spec. ¶ 29. Thus, at one end of the spectrum, “temporarily” cannot mean that the MRI operation is suspended indefinitely, as it must continue operation in accordance with the pulse sequence timing. At the other end of the spectrum, “temporarily” must mean sufficient time to allow the required “suppressing gradient field activity,” as recited in claim 1, to take place. The Specification provides a specific example of a 1 ms suppression time within a pulse period of 20-30 ms, along with additional relevant information about typical frequencies of operation for an MRI. *See* Spec. ¶¶ 28, 31.

Thus, we determine that, because the Specification provides sufficient information for one of ordinary skill in the art to understand the meaning of “temporarily” in the context of the claims, that term is not indefinite here.

*E. Anticipation/Obviousness*

The Examiner rejects claims 1, 5, 9, 14–16, 18, and 20 under 35 U.S.C. § 102(b) as anticipated by Gray. Non-Final Act. 9–12. The Examiner also makes several obviousness rejections under 35 U.S.C. § 103: claims 2, 13, and 17 over Gray in view of Stevenson, claims 3 and 6–8 over Gray in view of Cory, claims 10, 11, and 19 over Gray in view of Vitek, claim 12 over Gray in view of Vitek, and further in view of Ben-Shmuel, claim 21 over Gray in view of Yamanaka, and claim 22 over Gray in view of Yamanaka and further in view of Vitek. *Id.* at 12–18.

A claim is anticipated, and therefore unpatentable under 35 U.S.C. § 102, if all of its limitations are disclosed either explicitly or inherently in a single prior art reference. *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). A claimed invention is unpatentable if the differences between it and the prior art are “such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.” 35 U.S.C. § 103(a) (pre-AIA). To assess whether the subject matter would have been obvious, the Board follows guidance in *Graham v. John Deere Co.*, 383 U.S. 1 (1966) and *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). The obviousness “analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR*, 550 U.S. at 418.

The Examiner’s rejections rely on Gray for teaching the initiation of the RF-sensitive operation in response to a signal indicative of gradient-field suppression. Non-Final Act. 10 (citing Gray ¶¶ 94–95). Appellants argue that Gray fails to “disclose, teach, or suggest initializing or causing performance of RF-sensitive operations in response to a signal or other information.” Appeal Br. 15 (emphases omitted). Instead, Appellants assert, Gray merely discloses a pacemaker that sends a signal to an MRI that a pace correction pulse is about to occur and the MRI operation is suspended in response to that signal from the pacemaker. *Id.* Put differently, Gray’s MRI system operates in response to a signal from the pacemaker, instead of initializing RF-sensitive operations carried out in response to suppression of the MRI gradient. *Id.* at 15–16.

In the Answer, the Examiner appears to concede that the claimed signal and response are not explicitly disclosed by Gray, but argues that such a disclosure is implicit. *See* Ans.18 (“The examiner submits that while it is not explicitly stated that the pacemaker has received a message to proceed, that the entire point of including the sensor/transceiver is to send messages back and forth between the pacemaker and MRI system; therefore it is implicit that a message to proceed would have been received by the pacemaker.”). We agree with Appellants, however, that the Examiner has failed to sufficiently show or explain why the missing descriptive matter is necessarily present in Gray. *See MEHL/Biophile Int’l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999) (“Inherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient.” (quotation omitted)). For example, as Appellants reasonably explain, “[m]erely

allowing the pacemaker and the MRI system to transmit signals therebetween does not mean that the RF-sensitive operation will necessarily be initialized or caused to perform in response to the transmitted signal.”

Reply Br. 11 (emphases omitted).

Thus, because the Examiner has failed to identify a disclosure of the “signal” in independent claims 1, 15, and 21, the “information” in claim 14, or the “signaling” in claim 20, we reverse the anticipation and obviousness rejections of claims 1–3 and 5–22.

#### SUMMARY

We affirm the rejection of claims 1–3 and 5–22 as indefinite for failure of the Specification to identify the required corresponding structure for the “controller” and “module” means-plus-function claim terms. We reverse the remainder of the Examiner’s rejections.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv). *See* 37 C.F.R. § 41.50(f).

AFFIRMED