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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/112,664	10/18/2013	Sitharthan Kamalakaran	2011P00455WOUS	2263

24737 7590 02/20/2018

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EXAMINER
LUONG, PETER

ART UNIT	PAPER NUMBER
3777	

NOTIFICATION DATE	DELIVERY MODE
02/20/2018	ELECTRONIC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte SITHARTHAN KAMALAKARAN and BALASUNDAR RAJU

Appeal 2017-000530
Application 14/112,664
Technology Center 3700

Before DEBORAH KATZ, TAWEN CHANG, 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 a device and system for providing device visibility in medical images, and claims to related methods. The Examiner rejected the claims as anticipated and obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM-IN-PART and enter a New Ground of Rejection.

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[1] Appellants identify the Real Party in Interest as KONINKLIJKE PHILIPS N.V. App. Br. 4.

STATEMENT OF THE CASE

Appellants' invention "relates to medical image visibility and more particularly to systems and methods for increasing device visibility in medical images." Spec. 1:4–5.

The Specification explains that "[v]isualization of a catheter or needle is important in many medical intervention procedures," but that current techniques for visualization have drawbacks (e.g., use of toxic dyes, and lack of clear contrast and accuracy). *Id.* at 1:6–14. The invention seeks to overcome these drawbacks with "a medical device having nanoparticles incorporated therein, the nanoparticles being configured to be responsive to at least one excitation signal." *Id.* at 1:21–23. Upon excitation by the signal, nanoparticles on the device generate response emissions, which are captured by a sensor and, using the response emissions, a rendering of the device in a medical image is created. *Id.* at 1:23–2:1.

An embodiment of Appellants' invention is shown below.

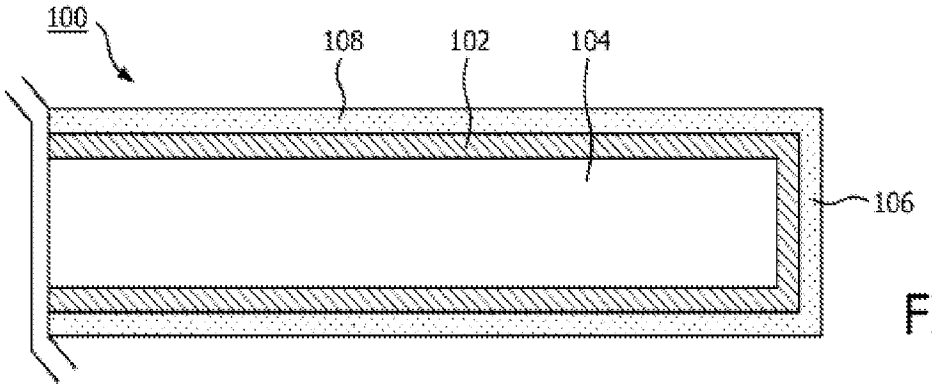

FIG. 1

Spec., Fig. 1. Figure 1 shows a cross-sectional view of a portion of medical device (100), such as a catheter, needle, probe, or balloon. *Id.*; *see also id.* at 5:13–17. As depicted, device (100) includes a surface (102) that may form a

cavity (104). *Id.* at 5:17–18. A material layer/volume (106) is formed on the device surface (102), and layer (106) includes a composition — nanomaterials in or on the layer — to aid in visualization of the device in medical images. *Id.* at 5:18–22.

Claims 1, 4–7, 10, 15, 16, 19, 22, 23, 26, 29, 30, and 32 are on appeal. Claims 1 and 26 are illustrative and reproduced below:

> 1. A medical device configured for internal use within a subject, comprising:
>
> a structure having a length dimension and a surface;
>
> a volume associated with the surface and extending along at least a portion of the length dimension; and
>
> nanomaterials incorporated in the volume and configured to be responsive to at least one excitation signal such that the excitation signal generates a response from the nanomaterials to enable location of the structure within an interior of the subject.
>
> 26. A method for generating an image of a medical device configured for internal use within a subject, comprising:
>
> exciting nanomaterials included in a medical device using a first electromagnetic frequency of excitation for the nanomaterials to obtain a first imageable response, the first imageable response being detectable over surrounding materials;
>
> exciting the nanomaterials included in the medical device using a second electromagnetic frequency of excitation for the nanomaterials to obtain a second imageable response which includes a realizable difference from the first imageable response, the second imageable response being detectable over the surrounding materials;
>
> subtracting the first imageable response from the second imageable response to provide an image of the medical device relative to a subject.

App. Br. 22, 26 (Claims App.).

The claims stand rejected by the Examiner as follows:

I. Claims 1, 4–7, 10, 15, 16, 19, 22, and 23 under 35 U.S.C. § 102(b) as anticipated by Lewkowicz,[2] as further evidenced by Bromberg[3] ("Rejection I").

II. Claims 26 and 32 under 35 U.S.C. § 103(a) as obvious over Toms[4] and Alfano[5] ("Rejection II").

III. Claims 29 and 30 under 35 U.S.C. § 103(a) as obvious over Toms, Alfano, and Lewkowicz ("Rejection III).

I

Issue

Has the Examiner established by a preponderance of the evidence that Lewkowicz, as evidenced by Bromberg, describes the subject matter of claims 1, 4–7, 10, 15, 16, 19, 22, and 23?

Findings of Fact (FF)

The Examiner's findings of fact and explanation of the rejection are provided at page 2 of the Final Rejection (Aug. 13, 2015) ("Final Act."). *See also* Adv. Act. (Oct. 29, 2015) 2; Ans. 2–3, 4–6. The following findings are provided for emphasis and convenient reference.

FF 1. Lewkowicz discloses an in vivo examining and testing device for observing lumens in a patient's body. Lewkowicz ¶ 9.

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[2] Lewkowicz et al., US 2003/0040685 A1, published Feb. 27, 2003.
[3] Bromberg et al., US 2006/0040388 A1, published Feb. 23, 2006.
[4] Toms et al., US 2006/0173362 A1, published Aug. 3, 2006.
[5] Alfano et al., US 6,280,386 B1, issued Aug. 28, 2001.

FF. 2. An embodiment of Lewkowicz's device is shown below.

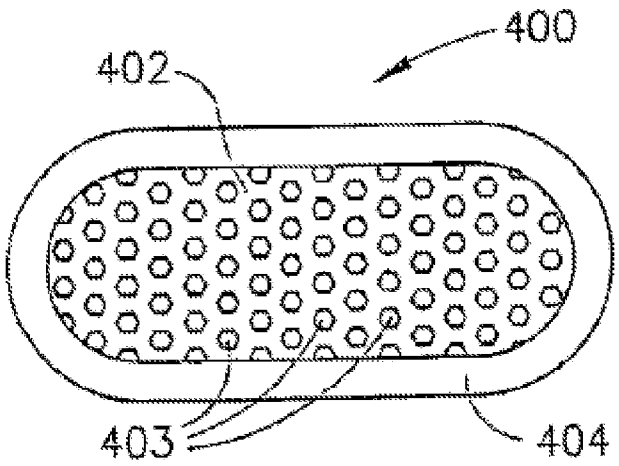

FIG.3C

Id. Fig. 3C. Figure 3C shows testing device (400), having an outer coating (404) and an internal filling (402). *Id.* ¶ 76. The internal filling (402) comprises a marker (403), such as a radio opaque material "or other detectable material [e.g., dyes, radioactive markers, etc.] . . . [that] can be viewed by x-ray or other detection methods." *Id.* Lewkowicz discloses that, in embodiments, "the marker is magnetite (Fe_3O_4), for example, powdered magnetite in poly(methyl methacrylate)." *Id.*

FF 3. Lewkowicz discloses "device **400** is inserted into a patient's **300** GI tract and can be monitored by a suitable detector **301**, for example, an x-ray machine, a gamma camera or a magnetometer." *Id.* ¶ 77; *see also id.* Figs. 3C and 3D. Lewkowicz discloses "detector **301** is typically moved along the patient's **300** body and utilizing a plurality of detectors or receivers . . . and a processing unit **302**, can detect and calculate, by known methods, the location of the marker **403**." *Id.* ¶ 77; *see id.* ¶ 14.

FF 4. Lewkowicz discloses:

> The internal filling, which in one embodiment can be one or more layers or a suspension or liquid or gas, typically constitutes small particles or molecules and can produce pressure within the device by, for example, serving as an ion source or sink. The filling may also contain adhesives and fillers to, for example, further provide mechanical stability to the device.

Id. ¶ 51.

FF 5. Bromberg relates to magnetic nanoparticles, and compositions containing such particles, and discloses:

> The coatings on the surface of *nanostructured powders* are of great interest, because the coatings alter the charge, functionality, and reactivity of the surface, and enhance the stability and dispersibility of the nanoparticles in water-prepared monolayer and bilayer surfactant coatings on *magnetite (Fe_3O_4) nanoparticles* using the self-assembly method.

Bromberg ¶ 5 (emphases added).

Analysis

Claim 1

The Examiner finds that Lewkowicz describes the subject matter in claim 1. According to the Examiner:

> Lewkowicz et al. discloses a medical device (400; Fig. 3C) comprising a structure having a length dimension and a surface (404; Fig. 3C); a volume associated with the surface and extending along at least a portion of the length dimension (Fig. 3C); and nanomaterials incorporated in the volume and configured to be responsive to at least one excitation signal such that the excitation signal generates a response from the nanomaterials to enable location of the structure within a subject (403; Fig. 3C).

Final Act. 2. The Examiner finds "magnetite powder (Fe3O4) [a detectable marker (403) in Lewkowicz] . . . is a nano-particle as evidenced by Bromberg." Adv. Act. 2. The Examiner finds that "applicant has failed to provide a special definition or meaning to nanomaterials,"[6] and the Examiner states that "nano-particles are interpreted to be nanomaterials" as claimed. *Id.* Thus, the Examiner finds Lewkowicz anticipates claim 1.

Appellants argue "Lewkowicz fails to teach or suggest at least that the magnetite is a nanomaterial as recited in the medical device of claim 1." App. Br. 11. According to Appellants, "[a] 'nanomaterial' is a well known term in the art that has a special meaning. Nanomaterials are known to include nanotubes, nanorods, nanospheres, nanocages or quantum dots (*See*, *e.g.*, Original Specification, p. 6, lines 2–4)." *Id.* As to Bromberg, Appellants contend "Bromberg does not evidence that the magnetite taught by Lewkowicz must be a nanomaterial." *Id.* at 12. Appellants also allege that Lewkowicz uses the term "nano-particles" in relation to a different embodiment and that, because this other embodiment discloses the potential addition of markers (e.g., barium), "this embodiment teaches away from the nanomaterials of the device of claim 1." *Id.*

The preponderance of the evidence supports the Examiner's finding that Lewkowicz anticipates claim 1. Appellants' Specification uses the terms "nanomaterial" and "nanoparticle" interchangeably,[7] and we are

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[6] Appellants agree no express definition is provided: "Applicants and the Examiner agree that no special definition or meaning was given to the term 'nanomaterials' by Applicants in the Original Specification." Reply Br. 6.
[7] *See*, *e.g.*, Spec. 5:25, 6:22–23 ("metallic nanoparticles"), 8:22–23 ("gold nanorods (i.e., cylindrical gold nanoparticles)").

persuaded on this record that the skilled person would interpret powdered magnetite (Fe_3O_4), as taught in Lewkowicz, as a nanoparticle. FF 2, 5. The Examiner has made a prima facie showing on this point, citing Bromberg in support, and Appellants adduce no persuasive evidence showing that powdered magnetite is not a nanoparticle. Appellants contend a "nanomaterial . . . has a specific meaning," yet Appellants do not state, or provide evidence showing, what that "specific meaning" is. Appellants cite a portion of the Specification but this disclosure simply lists potential nanomaterials (carbon nanotubes, quantum dots, etc.). Spec. 6:2–4. This list is not limiting. Indeed, other portions of the Specification confirm that nanotubes, nanorods, etc. are just examples of nanomaterials. Spec. 3:17–18 ("nanomaterials that may be employed include, e.g., carbon nanotubes, nanorods or nanospheres.").[8]

The fact that Lewkowicz describes a use of "nano-particles" elsewhere related to a different embodiment than the one shown in Figure 3C is also not dispositive. Lewkowicz ¶ 86. Those "nano-particles" are described as having specific characteristics for a specific purpose — a solid

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[8] Even if Appellants were correct, and a nanomaterial was limited to, for instance, nanotubes or quantum dots, we observe that Toms clearly teaches the use of quantum dots/nanoparticles as imaging agents, and discloses that such optical nanoparticles can be coated on indwelling medical devices. Toms ¶¶ 80–81. Indeed, Toms teaches quantum dots have several advantages over conventional optical labels (e.g., dyes), including low toxicity, high fluorescing efficiency, and resistance to photo-bleaching. *See, e.g., id.* ¶¶ 3–4, 51. The Examiner, however, relies on Toms only for purposes of the obviousness rejection of claims 26, 29, 30, and 32, and also does not identify these particular teachings in the reference. So, we do not rely on Toms or these teachings here.

hydrophobic inner core and a cationic exterior to help facilitate disintegration of a plug. *Id.* Those particular particles are not used as the "markers" (like magnetite) in this other embodiment. But Lewkowicz does not disclose that magnetite powder is not a nanoparticle, and Appellants cite no disclosure that nanoparticles/nanomaterials cannot or should not be used as imaging agents. As to this latter point, in any event, an alleged "teaching away" is not germane to a rejection for anticipation. *In re Malagari*, 499 F.2d 1297, 1302 (CCPA 1974) (emphasis added) ("If the rejection under § 102 is proper, . . . appellant cannot overcome it by showing . . . teaching away in the art, which [is] relevant only to an obviousness rejection.").

For these reasons, we affirm the Examiner's rejection of claim 1 as anticipated by Lewkowicz, as evidenced by Bromberg. Claims 4, 7, 10, and 19 were not separately argued and, therefore, fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

Claims 5, 15, and 22

Claim 5 depends from claim 1, and adds "wherein the volume includes a tube forming an annular cavity relative to the surface, the annular cavity including the *nanomaterials in suspension*." App. Br. 22 (emphasis added). Appellants dispute whether this limitation is taught in Lewkowicz. *Id.* at 13–14. Claims 15 and 22 depend from independent claims 10 and 19 respectively, and have similar limitations to the one disputed in claim 5.

The Examiner cites to Figure 3C and structure 402 in Lewkowicz as disclosing "nanomaterials in suspension." (Final Act. 2). Appellants argue in response that, although

> Figs. 2A and 2B have an internal filling which may be in a suspension . . . [,] Lewkowicz fails to disclose or suggest that

> the cited embodiments recited in Figs. 3C and 3D . . . having a magnetized magnetite may be placed in a suspension within the cavity of the device.

App. Br. 13.

On this record, the Examiner has not shown that Lewkowicz anticipates the invention in claim 5 (or claims 15 and 22). The Examiner has not persuasively established the magnetite marker in Figure 3C is in suspension. The Examiner invokes Lewkowicz's teaching in paragraph 51 (*see* Ans. 5; FF 4), which expressly discloses an internal filling can be a suspension or liquid or gas, but that teaching relates to another embodiment — the testing device shown in Figures 2A and 2B. Lewkowicz ¶ 51. Picking and choosing from distinct embodiments in the art, while permissible in an obviousness inquiry, is generally inappropriate to show anticipation. *In re Arkley*, 455 F.2d 586, 587 (CCPA 1972) (explaining that anticipation requires the art "clearly and unequivocally disclose the claimed [invention] or direct those skilled in the art to the [invention] without *any* need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference."). For this reason, we reverse the Examiner's rejection of claims 5, 15, and 22 as anticipated by Lewkowicz.

Notwithstanding the above, we conclude that claim 5 (and claims 15 and 22) would have been obvious over Lewkowicz. Picking and choosing is permissible when obviousness is the issue. And here, the skilled person need only choose to combine features of two embodiments of a single reference — the use of a magnetite marker (as in Fig. 3C) with the internal filling that is a suspension (as described in relation to Figs. 2A and 2B).

Lewkowicz ¶¶ 51, 76. The reason for doing so comes expressly from Lewkowicz, which teaches (in relation to the Fig. 3C embodiment) that "internal filling **402** can be fabricated as described above." *Id.* ¶ 76. Reasonably understood, this disclosure points to the preceding embodiments (i.e., Figs. 2A and 2B), which as noted teach the internal filling may be formed as a suspension, liquid, or gas. *Id.* ¶ 51. At most, this is just a substitution of known alternative formulations for the internal filling and is within the capabilities of the skilled artisan. We, therefore, enter new grounds of rejection of claims 5, 15, and 22 under 35 U.S.C. § 103(a) over Lewkowicz. 37 C.F.R. § 41.50(b).

Claims 6, 16, and 23

Claim 6 depends from claims 1 and 5, and adds "an *agitation mechanism* in communication with the suspension to prevent the nanomaterials from settling." App. Br. 23 (emphasis added). Appellants dispute whether this limitation is taught in Lewkowicz. *Id.* at 14–15. Claims 16 and 23 depend from independent claims 10 and 19 respectively, and have similar limitations to the one disputed in claim 6.

The Examiner contends the disputed limitation is taught at paragraph 51 of Lewkowicz. Final Act. 2; Ans. 6. More specifically, according to the Examiner, "Lewkowicz discloses the internal filling is a suspension or liquid comprising small particles or molecules and can produce pressure within the device and further contain fillers to provide mechanical stability." Ans. 6. The Examiner also asserts that "[i]f the prior art structure is capable of performing the intended use, then it meets the claim." *Id.*

We are not persuaded the Examiner met the burden to show that claims 6, 16, and 23 are anticipated by Lewkowicz. Here too, the Examiner is improperly picking and choosing between embodiments for a rejection under § 102. Moreover, the Examiner fails to explain how the cited language in paragraph 51 of Lewkowicz satisfies the claimed "agitation mechanism." This is a structural element, not just an "intended use" as the Examiner asserts. *Id.* And the Examiner does not clearly identify a structure in the cited portions of Lewkowicz that is even capable of agitating (i.e., pumping, mixing, or vibrating) the nanomaterials to keep them from settling. *See, e.g.*, Spec. 10:19–20. For these reasons, we reverse the rejection of claims 6, 16, and 23.

Conclusion

The preponderance of the evidence supports the Examiner's finding that claims 1, 4, 7, 10, and 19 are anticipated by Lewkowicz.

The preponderance of the evidence does not support the Examiner's finding that Lewkowicz anticipates claims 5, 15, and 22, or claims 6, 16, and 23. Those rejections are reversed but, for reasons explained, we enter a new ground of rejection for claims 5, 15, and 22 under § 103.

II & III

The Examiner rejected claims 26 and 32 as obvious over Toms and Alfano (Rejection II), and rejected claims 29 and 30 over Toms, Alfano, and Lewkowicz (Rejection III). Final Act. 3–4.

The Examiner, citing only paragraph 78, finds Toms discloses the method of claim 26 except for "subtracting the first imageable response from

the second imageable response to provide an image of the medical device relative to the subject." *Id.* at 3–4; *see* Toms ¶ 78. The Examiner turns to Alfano as teaching the "subtracting" step. *Id.* at 4. The Examiner relies on Lewkowicz as teaching certain elements in dependent claims 29 and 30. *Id.*

There is one issue here that is dispositive on Rejections II and III: whether the portion of Toms cited by the Examiner teaches "exciting nanomaterials included in a medical device" as recited in claim 26, from which each of claims 29, 30, and 32 depend. App. Br. 18. Appellants argue the Examiner misinterprets claim 26 (and Toms) by contending the nanomaterials and the medical device are one and the same. According to Appellants, "[u]nder the Examiner's interpretation, the nanomaterials would be the recited medical device." *Id.* The Examiner does not dispute this characterization. Indeed, the Examiner's Answer offers no response to Appellants' arguments on the obviousness rejections. And, in the Advisory Action, the Examiner states "applicant has failed to provide a special definition or meaning for the term medical device," so "the nanomaterials can be interpreted to the medical device." Adv. Act. 2.

Appellants have the better position on this record. The relevant phrase in claim 26 is "exciting nanomaterials included in a medical device." App. Br. 26. This indicates the nanomaterials and the medical device (whatever it may be) are not the same thing. The Examiner's reading renders claim language superfluous, and results in the illogical conclusion that nanomaterials are included in themselves. *Stumbo v. Eastman Outdoors, Inc.*, 508 F.3d 1358, 1362 (Fed. Cir. 2007) (rejecting construction that makes claim terms superfluous). Even the broadest reasonable

interpretation does not justify such a result. The Examiner has not shown that the cited teachings in Alfano or Lewkowicz make up for this deficiency.

SUMMARY

We affirm the rejection of claims 1, 4, 7, 10, and 19 as anticipated by Lewkowicz.

We reverse the rejection of claims 5, 15, and 22 as anticipated by Lewkowicz, but enter a new ground of rejection of claims 5, 15, and 22 as obvious over Lewkowicz.

We reverse the rejection of claims 6, 16, and 23 as anticipated by Lewkowicz.

We reverse the rejection of claims 26 and 32 as obvious over Toms and Alfano, and also reverse the rejection of claims 29 and 30 as obvious over Toms, Alfano, and Lewkowicz.

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b). Section 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review." Section 41.50(b) also provides:

> When the Board enters such a non-final decision, the appellant, within two months from the date of the decision, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:
>
> (1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new Evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the prosecution will be remanded to the examiner. The new ground of rejection is

> binding upon the examiner unless an amendment or new Evidence not previously of Record is made which, in the opinion of the examiner, overcomes the new ground of rejection designated in the decision. Should the examiner reject the claims, appellant may again appeal to the Board pursuant to this subpart.
>
> (2) *Request rehearing*. Request that the proceeding be reheard under §41.52 by the Board upon the same Record. The request for rehearing must address any new ground of rejection and state with particularity the points believed to have been misapprehended or overlooked in entering the new ground of rejection and also state all other grounds upon which rehearing is sought.

Further guidance on responding to a new ground of rejection can be found in the MANUAL OF PATENT EXAMINING PROCEDURE § 1214.01 (9th Ed., Rev. 07.2015, Nov. 2015).

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).

AFFIRMED-IN-PART; 37 C.F.R. § 41.50(b)