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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte RAOUL FLORENT, WILLEM FREDERIK DEN HARTOG, and VINCENT MAURICE ANDRE AUVRAY

Appeal 2017-002513
Application 13/637,373[1]
Technology Center 1600

Before RICHARD M. LEBOVITZ, FRANCISCO C. PRATS, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge.*

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134(a) involves claims to devices and methods for identifying the anatomical location of an inserted medical device. The Examiner rejected the claims as being directed to subject matter ineligible for patenting, as failing to comply with the written description requirement, as being indefinite, and for obviousness.

We have jurisdiction under 35 U.S.C. § 6(b)(1).

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[1] Appellants state that the "real party in interest is the assignee of the present application, Koninklijke Philips Electronics N. V." Appeal Br. 3.

We affirm the Examiner's subject matter ineligibility and indefiniteness rejections.

We affirm the Examiner's written description rejection as to one of the claims rejected on that ground, but reverse as to the other claim subject to the rejection.

We reverse the Examiner's obviousness rejections.

STATEMENT OF THE CASE

The Specification discloses that the radiation dosage used for visualizing the heart during angioplasty procedures can be optimized automatically. Spec. 1–2. The Specification discloses, however, that automatic optimization of the imaging radiation requires an initial manual input as to whether the right or left coronary tree is being treated. *Id.* at 2. The Specification discloses that if the right or left coronary tree treatment is inputted incorrectly, the radiation dosage cannot be optimized automatically. *Id.*

Appellants' invention is directed to determining whether an interventional device, such as an inserted catheter, is in a particular part of a patient's anatomy, such as the right or left coronary tree. *Id.* Appellants' invention involves using a characteristic feature of the device's appearance, such as the device's shape, to determine the part of the anatomy in which the device is deployed. *Id.* at 2–3.

For example, an angioplasty catheter deployed in the aorta has two distinct characteristic shapes, depending on whether the catheter is guided into the left or right coronary ostium. *Id.* at 6–7. The Specification explains further:

> The shape of the aorta 20 and coronary ostia locations 20a, 20b are such that a tool such as the injection catheter tip 21 that enters one of the ostia 20a, 20b does not bend at all in the same way, depending in which ostium 20a, 20b it is entered. It is therefore possible, by examining the device shape DS of this intervention device 21, as seen in a projective image (in this case either from an angiogram or a fluoroscopy sequence), to determine which side of the coronary tree currently is imaged or treated.

Id. at 7; *see also* Figs. 2, 3 (showing different shapes of catheter 21 when guided into left coronary ostium 20a and right coronary ostium 20b).

The Specification explains that, to determine which coronary tree contains the device, the acquired image data regarding the shape of the deployed device is compared to image data from a database. *Id.* at 7 ("It is therefore possible to determine whether the intervention device 21 is located in a portion 20a, 20b of the vessel structure 20 by correlating the extracted device shape being the characterizing feature DS extracted by the feature extraction unit 11 with the provided classifier data CD."); *see also id.* at 6 ("The classifier data CD can e.g. be provided by a database storing classifier data CD being characteristic for the appearance of intervention device 21 when located in certain anatomy parts 20a, 20b.").

Claims 1 and 7 are illustrative and read as follows:

> 1. A device configured for automatically identifying an anatomical part of an anatomy structure comprising two or more anatomical parts, in which anatomy structure an intervention device resides, comprising:
>
> an imaging system via which said device is configured for using radiation to interrogate said anatomy structure, said device being further configured for, based on a result of the interrogating, deriving image content data;

an imaging-feature extraction unit; and

an imaging-based anatomy classification unit;

said imaging-feature extraction unit being configured for extracting at least one characterizing feature of the appearance of the intervention device using the derived image content data;

said classification unit being configured for:

a) correlating the at least one characterizing feature with provided classifier data that is linked correspondingly to particular anatomical categories into which said parts would be placeable in classifying said parts; and

b) with the links already having been created, determining, based on said links, in which part, from among said two or more anatomical parts, the interventional device is located.

7. A method for automatically identifying a part of an anatomy structure comprising two or more parts, in which anatomy structure an intervention device resides, comprising the steps of:

(a) extracting a characterizing feature of the appearance of the intervention device using provided image content data;

(b) correlating the extracted characterizing feature with provided classifier data;

(c) determining in which part of the two or more parts of the anatomy structure the intervention device is located; and

(d) providing the classifier data using provided three dimensional data of a model of the intervention device being located in a part of the two or more parts of the anatomy structure and using provided system geometry data of an imaging system.

Appeal Br. 43, 45–46.

The following rejections are before us for review:

(1) Claims 1–5, 7–12, and 14–28, as being directed to a patent-ineligible judicial exception (i.e., a law of nature, a natural phenomenon, or an abstract idea) (Ans. 2–4);

(2) Claims 3 and 27, under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement (Ans. 4–5);

(3) Claims 1–5, 19, 20–24, and 27, under 35 U.S.C. § 112, second paragraph, as being indefinite (Ans. 5–6);

(4) Claims 1, 4, 5, 7, 10, 11, 14–17, 20, 23, and 25–28, under 35 U.S.C. § 103(a) as being unpatentable over Simon[2] and Markowitz[3] (Ans. 7–10);

(5) Claims 2, 3, 8, 9, 12, and 24, under 35 U.S.C. § 103(a) as being unpatentable over Simon, Markowitz, and Brummer[4] (Ans. 10–14);

(6) Claim 18, under 35 U.S.C. § 103(a) as being unpatentable over Simon, Markowitz, and Solem[5] (Ans. 14);

(7) Claim 21, under 35 U.S.C. § 103(a) as being unpatentable over Simon, Markowitz, Brummer, and Solem (Ans. 14–15); and

(8) Claim 18, under 35 U.S.C. § 103(a) as being unpatentable over Simon, Markowitz, and Wittenbrink[6] (Ans. 15).

STANDARD OF REVIEW

> [T]he examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability. . . .
>
> After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the

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[2] US 8,608,481 B2 (issued Dec. 17, 2013).
[3] US 2009/0264752 A1 (published Oct. 22, 2009).
[4] US 6,898,302 B1 (issued May 24, 2005).
[5] US 2006/0039600 A1 (published Feb. 23, 2006).
[6] US 2004/0179010 A1 (published Sept. 16, 2004).

> record, by a preponderance of evidence with due consideration to persuasiveness of argument.

In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

PATENT ELIGIBILITY

The Examiner's Prima Facie Case

In rejecting claims 1–5, 7–12, and 14–28, as being directed to patent-ineligible subject matter, the Examiner finds that the claimed invention "relies upon collecting and comparing known information, obtaining and comparing intangible data, comparing new and stored information and using rules to identify options, using categories to organize store and transmit information, data recognition and storage, organizing information through mathematical correlations . . . ." Ans. 2. The Examiner finds that those activities are "abstract ideas, or a concept similar to those found by the courts to be abstract, as it involves mathematically relating data or an idea of itself (prong 1 of the two-part test)." *Id.*

As to "prong 2 of the two-part test," the Examiner finds that the recited steps and elements are directed to "insignificant post-solution activity and/or data gathering (e,g.–acquiring an image); and/or applying the abstract idea in a computer environment according to well-known, routine, and conventional techniques (e.g. – determining image features and using a classification technique to compare the image features to those in a database)." *Id.* at 3.

The Examiner reasons, therefore, that "these additional claim element(s) do not provide meaningful limitation(s) to transform the abstract idea into a patent eligible application of the abstract idea such that the claim(s) amounts to significantly more than the abstract idea itself." *Id.*

Analysis

Appellants do not persuade us that a preponderance of the evidence fails to support the Examiner's conclusion that the rejected claims recite subject matter ineligible for patenting.

35 U.S.C. § 101 states that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

The Supreme Court has "long held that this provision contains an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable." *Alice v. CLS*, 134 S. Ct. 2347, 2354 (2014).

Our reviewing court has summarized the Supreme Court's two-part test for distinguishing between (a) claims to patent-ineligible exceptions, and (b) claims to patent-eligible applications of those exceptions, as follows:

> Step one asks whether the claim is "directed to one of [the] patent-ineligible concepts." [*Alice*, 134 S. Ct. at 2354]. If the answer is no, the inquiry is over: the claim falls within the ambit of § 101. If the answer is yes, the inquiry moves to step two, which asks whether, considered both individually and as an ordered combination, "the additional elements 'transform the nature of the claim' into a patent-eligible application." *Id.* (quoting *Mayo* [*Collaborative Services v. Prometheus Labs, Inc.*, 132 S. Ct. 1289, 1297 (2012)]).
>
> Step two is described "as a search for an 'inventive concept.'" *Id.* (quoting *Mayo*, 132 S. Ct. at 1294). At step two, more is required than "well-understood, routine, conventional activity already engaged in by the scientific community," which fails to transform the claim into "significantly more than a patent upon the" ineligible concept itself. *Mayo*, 132 S. Ct. at 1298, 1294.

Rapid Litigation Mgmt. Ltd. v. CellzDirect, Inc., 827 F.3d 1042, 1047 (Fed. Cir. 2016) (paragraphing added).

As to step one of the *Alice* test, our reviewing court has explained that, when determining whether a claim is directed to an abstract idea, "both this court and the Supreme Court have found it sufficient to compare claims at issue to those claims already found to be directed to an abstract idea in previous cases." *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1334 (Fed. Cir. 2016).

In the present case, Appellants' claimed invention is similar in certain respects to the invention held by the court to be a patent-ineligible abstract idea in *Electric Power Group, LLC v. Alstom S.A.*, 830 F.3d 1350 (Fed. Cir. 2016). Like the process in the claim at issue in *Electric Power*, *see id.* at 1351–52, the inventive components of the device of Appellants' claim 1—the imaging-feature extraction unit and imaging-based classification unit—receive and analyze data (image data specifically), and inform a user of the determined result of that data analysis (the anatomical part in which the interventional device is located). Appeal Br. 43. As noted in the summary of Appellants' Specification presented above, the correlating step performed by claim 1's device simply involves comparing certain extracted (i.e., selected) image data to image data from a database to determine the anatomical location of the inserted device. Spec. 6–7.

In holding that the claims at issue in *Electric Power Group* were directed to a patent-ineligible concept, the court explained that "merely presenting the results of abstract processes of collecting and analyzing information, without more (such as identifying a particular tool for presentation), is abstract as an ancillary part of such collection and analysis."

830 F.3d at 1354. Indeed, the court's statement of its ultimate conclusion as to step one of the *Alice* analysis is applicable here:

> [T]he claims are clearly focused on the combination of those abstract-idea processes. The advance they purport to make is a process of gathering and analyzing information of a specified content, then displaying the results, and not any particular assertedly inventive technology for performing those functions. They are therefore directed to an abstract idea.

Id.; *see also In re BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litigation,* 774 F.3d 755, 761–63 (Fed. Cir. 2014) (holding step of comparing two DNA sequences to be abstract idea).

We acknowledge that, in addition to the functionally claimed components that perform the abstract data manipulation, the device of Appellants' claim 1 includes an imaging system that obtains the image data that is subsequently manipulated and compared to the database. Appeal Br. 43.

As our reviewing court has explained, however, "not every claim that recites concrete, tangible components escapes the reach of the abstract-idea inquiry." *In re TLI Communications LLC Patent Litigation*, 823 F.3d 607, 611 (Fed. Cir. 2016). In particular, in *TLI Communications*, the court noted that claims that reciting general-purpose computer components, a "scanner," an "interface," "network," and a "database" were nevertheless "directed to" an abstract idea. *Id.* (citing *Alice,* 134 S.Ct. at 2360; *Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat'l Assn,* 776 F.3d 1343, 1347 (Fed. Cir. 2014); *Mortg. Grader, Inc. v. First Choice Loan Serv. Inc.,* 811 F.3d 1314, 1324–25 (Fed. Cir. 2016)).

Thus, because claim 1 is directed to a device in which functionally claimed inventive elements merely collect and analyze information, we

agree with the Examiner that, under step one of the *Alice* test, claim 1 is directed to an abstract idea.

Step two of the *Alice* inquiry requires us to determine whether, aside from the judicial exception, claim 1 includes something more than "'well-understood, routine, conventional activity already engaged in by the scientific community,' which . . . transform[s] the claim into 'significantly more than a patent upon the' ineligible concept itself." *Rapid Litigation Mgmt. v. CellzDirect*, 827 F.3d at 1047 (quoting *Mayo*, 132 S.Ct. at 1298, 1294. As to step two of the *Alice* test, we again agree with the Examiner.

Aside from the functionally recited components which perform the abstract data manipulation —the imaging-feature extraction unit and imaging-based classification unit—an imaging system is the only other component in the device of Appellants' claim 1. Appeal Br. 43. As evidenced by Appellants' Specification (Spec. 1), as well as Simon (*see, e.g.*, Simon Fig. 2C) and Markowitz (*see, e.g.*, Markowitz ¶ 6), imaging systems using techniques such as fluoroscopy were routinely used when determining the location of a medical device inserted into a patient.

Thus, we agree with the Examiner that under step two of *Alice*, claim 1 does not contain anything beyond the abstract idea that transforms the claimed subject matter into significantly more than a claim to the abstract idea itself. Accordingly, we also agree with the Examiner that, under the two-step test of *Alice*, claim 1 is directed to subject matter ineligible for patenting.

We acknowledge Appellants' contention that the claimed combination of elements "provide[s] a technical improvement over the prior art of

record." Appeal Br. 38. Appellants, however, do not identify any specific evidence of record, comparative or otherwise, that supports that assertion.

We acknowledge also Appellants' contention that, on this record, the device of claim 1 is novel and unobvious. Appeal Br. 37.

As our reviewing court has explained, however, although Appellants may have "made a '[g]roundbreaking, innovative, or even brilliant discovery,' . . . that is not enough" to establish patent eligibility. *In re BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litigation,* 774 F.3d at 759 (citing *Association for Molecular Pathology v. Myriad*, 133 S.Ct. 2107, 2117 (2013)). Thus, that the combination of components recited in claim 1 might be novel and unobvious does not demonstrate that claim 1 recites subject matter eligible for patenting.

In sum, for the reasons discussed, we find that the preponderance of the evidence supports the Examiner's conclusion that claim 1 recites subject matter ineligible for patenting. We, therefore, affirm the Examiner's rejection of claim 1 on that ground.

In arguing that the remaining claims subject to this ground of rejection are directed to patent-eligible subject matter, Appellants rely on their arguments in relation to the Examiner's obviousness rejections. *See* Appeal Br. 39–41. As discussed above, however, that Appellants' claims might be directed to novel and unobvious combinations of steps or components does not demonstrate that those claims recite subject matter eligible for patenting. *See In re BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litigation,* 774 F.3d at 759. Accordingly, we also affirm the Examiner's rejection of claims 2–5, 7–12, and 14–28 as being directed to patent-ineligible subject matter.

WRITTEN DESCRIPTION

The Examiner's Prima Facie Case

In rejecting claims 3 and 27 as failing to comply with the written description requirement, the Examiner found that "[r]egarding claim 3, the disclosure does not define the term projection characteristic, therefore it has been interpreted as an image characteristic. Regarding claim 27, the disclosure does not define the term alternative, rendering the claim unclear." Ans. 5.

Analysis

"In the context of the written description requirement, an adequate prima facie case must . . . sufficiently explain to the applicant what, in the examiner's view, is missing from the written description." *Hyatt v. Dudas*, 492 F.3d 1365, 1370 (Fed. Cir. 2007).

The test for determining whether a specification is sufficient to support a particular claim "is whether the disclosure of the application relied upon 'reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.'" *Ralston Purina Co. v. Far-Mar-Co, Inc.,* 772 F.2d 1570, 1575 (Fed. Cir. 1985) (quoting *In re Kaslow,* 707 F.2d 1366, 1375 (Fed. Cir. 1983)).

Thus, "[i]t is not necessary that the application describe the claim limitations exactly, but only so clearly that persons of ordinary skill in the art will recognize from the disclosure that appellants invented processes including those limitations." *In re Wertheim*, 541 F.2d 257, 262 (CCPA 1976) (citation omitted).

As to claim 3, Appellants do not persuade us that a preponderance of the evidence fails to support the Examiner's determination that the term

"projection characteristics" (Appeal Br. 44 (claim 3)), lacks descriptive support in the Specification. Appellants contend that an ordinary artisan would have understood the meaning of "projection characteristics" based on disclosures in the Specification. Appeal Br. 26–27 (citing Spec. 6:12–19; *id.* at 8:16–19, 28–31; *id.* at 10:9–12, 22–24; *id.* at 11:3–5).

We acknowledge that, of the identified portions of the Specification, the term "projection characteristics" appears at pages 10 and 11. Those pages of the Specification, however, do not include a specific definition for "projection characteristics." *See* Spec. 10–11. Nor do Appellants explain specifically *why* the cited portions of the Specification demonstrate that an ordinary artisan would understand the meaning of the term. Nor do Appellants identify any definition of the term elsewhere in the record.

Thus, because the Specification does not explain the meaning of the term "projection characteristics" with sufficient clarity such that ordinarily skilled artisans would have recognized Appellants as having invented a process including those elements, Appellants do not persuade us that the Examiner erred in finding that the term "projection characteristics" in claim 3 lacks descriptive support in the Specification. We, therefore, affirm the Examiner's rejection of claim 3 under 35 U.S.C. § 112, first paragraph.

As to claim 27, however, we find that the preponderance of the evidence does not support the Examiner's determination that the term "alternative" in claim 27 lacks descriptive support.

Claim 27 recites "[t]he device of claim l, said determining entailing selecting from among alternatives, said alternatives respectively representing ones [sic] of said parts." Appeal Br. 49.

Claim 1 recites, as to the step further defined in claim 27, "determining, based on said links [of data corresponding to anatomical categories], in which part, from among said two or more anatomical parts, the interventional device is located." *Id.* at 43.

Thus, viewing claim 27 in light of the claim from which it depends, claim 1, the term "alternatives" means the plurality of anatomical parts from which one part may be selected. As the meaning of the term is, therefore, not unclear, and is supported in the Specification (*see, e.g.*, Spec. 8–9 (explaining that selection may be made from a plurality of anatomical portions of the heart)), we reverse the Examiner's rejection of claim 27 under 35 U.S.C. § 112, first paragraph.

INDEFINITENESS

The Examiner's Prima Facie Case

In rejecting claims 1–5, 19, 20–24, and 27 for indefiniteness, the Examiner determines that the terms "feature extraction unit," "classification unit," "classifier-data generation unit," and "estimation unit" are directed to "generic placeholder[s] coupled with functional language." Ans. 6.

The Examiner determines that those terms are indefinite under 35 U.S.C. § 112, second and sixth paragraphs, because they "are not associated with specific structures in the disclosure." *Id.*

Analysis

Terms recited using means plus function language are indefinite when the Specification does not provide specific structures or algorithms for performing the functions associated with the claimed means. *Ex parte Rodriguez*, 92 USPQ 2d 1395, 1400–1403 (BPAI) (precedential). Claim terms that do not use means plus function language, such as those identified

by the Examiner in this case, are also subject to the means plus function requirements when they use nonce words as generic placeholders to identify elements otherwise described solely by functional language. *Id.* at 1403–1406; *see also* MPEP § 2181.I.A. (describing "unit for" as nonce term potentially invoking means plus function requirements).

In the present case, Appellants do not contend that the Examiner erred in determining that the terms at issue, all recited in terms of a "unit" (Ans. 5–6), invoke the means plus function requirements. Rather, Appellants contend that the Examiner failed to acknowledge the claims' full recitations regarding the terms at issue. Appeal Br. 27; Reply Br. 15. Moreover, Appellants contend, the terms at issue find adequate structural or algorithmic support in the Specification. Appeal Br. 27–35; Reply Br. 15–18.

We find that the preponderance of the evidence supports the Examiner's position.

We acknowledge that the full terms determined by the Examiner to be indefinite are "imaging-feature extraction unit" (Appeal Br. 43–44 (claims 1 and 2)), "imaging-based anatomy classification unit" (*id.*), "medical-image-based classifier-data generation unit" (*id.* at 44 (claim 2)), and "estimation unit" (*id.* at 44 (claim 3)). Having carefully reviewed each of the portions of the Specification cited by Appellants, however, we are not persuaded that the Specification provides sufficiently specific structures or algorithms for performing the functions associated with the claimed units.

The portions of the Specification cited in relation to the imaging-feature extraction unit (Appeal Br. 28; Reply Br. 16) do not describe a specific device or algorithm that performs the image feature extracting function. Rather, the cited portions of the Specification state only that the

extraction is performed "using usual segmentation or image analysis tools." *See, e.g.*, Spec. 6, 9, 10. Appellants do not identify any specific disclosure in the Specification, or elsewhere in the record, explaining what specific algorithms or devices correspond to the "usual segmentation or image analysis tools." Accordingly, we agree with the Examiner that claims 1 and 2 are indefinite in their recitation of an "imaging-feature extraction unit."

Similarly, the portions of the Specification cited by Appellants in relation to the imaging-based anatomy classification unit (Appeal Br. 28; Reply Br. 16–17) do not describe a specific device or algorithm that perform the imaging-based anatomy classification function. For example, at page 2, the portion of the Specification cited by Appellants discloses the following:

> The anatomy part classification unit correlates the at least one characterizing feature DS with provided classifier data CD which are characteristic for a projection feature of the intervention device viewed under certain geometry of an imaging system. After correlating, the anatomy part classification unit determines in which part of the anatomy structure comprising several parts the intervention device is located.

Spec. 2.

As is evident, the cited portion of the Specification simply restates the function performed by the unit, without disclosing either an algorithm explaining specifically *how* that function is performed, or disclosing a specific device that performs that function.

Similarly, the portions of the Specification cited by Appellants (*see* Appeal Br. 29–30; Reply Br. 17–18) in relation to the medical-image-based classifier-data generation unit merely restate the function performed by the unit, without disclosing either an algorithm explaining specifically how that function is performed, or disclosing a specific device that performs that

function. For example, the cited portion of the Specification discloses the following at pages 2–3:

> According to another aspect of the invention the device further comprises a characterisation unit. The characterisation unit uses provided three dimensional data 3DD of a model of the intervention device which is located in a part of the several parts of the anatomy structure and uses provided system geometry data SGD of an imaging system to provide the classifier data CD.

Spec. 2–3.

Similarly, the portions of the Specification cited by Appellants (*see* Appeal Br. 34; Reply Br. 18–19) in relation to the estimation unit merely restate the function performed by the unit, without disclosing either an algorithm explaining specifically how that function is performed, or disclosing a specific device that performs that function. For example, the cited portion of the Specification discloses the following at page 3:

> According to yet another aspect of the invention the device further comprises an estimation unit. The estimation unit uses provided system geometry data SGD and provided three dimensional data 3DD of a model of the intervention device being located in a part of the several part of the anatomy structure to estimate a projection characteristics PS of the intervention device being located in a part of the several part of the anatomy structure.

Spec. 3.

In sum, for the reasons discussed, Appellants do not persuade us that the Examiner erred in determining that the claimed "imaging-feature extraction unit" (Appeal Br. 43–44 (claims 1 and 2)), "imaging-based anatomy classification unit" (*id.*), "medical-image-based classifier-data generation unit" (*id.* at 44 (claim 2)), and "estimation unit" (*id.* at 44 (claim 3)), render the claims containing those terms, and their dependent claims,

indefinite. We, therefore, affirm the Examiner's rejection of claims 1–5, 19, 20–24, and 27 under 35 U.S.C. § 112, second and sixth paragraphs.

OBVIOUSNESS

The Examiner's Prima Facie Case

In rejecting claims 1, 4, 5, 7, 10, 11, 14–17, 20, 23, and 25–28 over Simon and Markowitz, the Examiner cites Simon as describing devices and processes that differ from the rejected claims in that "Simon does not explicitly disclose details regarding an imaging system." Ans. 8

The Examiner cites Markowitz as disclosing an imaging system having the features required by the rejected claims, and reasons that "[i]t would have been obvious to one of ordinary skill in the art, having the teachings of Simon and Markowitz before him at the time the invention was made to add an imaging system, as disclosed by Markowitz, for the purpose of tracking a device [Markowitz, paragraph [00081]." *Id.*

Analysis

In *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), although the Supreme Court emphasized "an expansive and flexible approach" to the obviousness question, *id.* at 415, the Court also reaffirmed the importance of determining "whether there was an apparent reason to combine the known elements *in the fashion claimed* by the patent at issue." *Id.* at 418 (emphasis added).

Ultimately, therefore, "[i]n determining whether obviousness is established by combining the teachings of the prior art, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re GPAC Inc.*, 57 F.3d 1573, 1581 (Fed. Cir. 1995) (internal quotations omitted).

In this instance, Appellants persuade us that the preponderance of the evidence does not support the Examiner's conclusion of obviousness. In particular, Appellants persuade us (*see, e.g.*, Appeal Br. 8–12) that the combined teachings of Simon and Markowitz do not suggest using "at least one characterizing feature *of the appearance of the intervention device*" (*id.* at 43 (claim 1, emphasis added)) as a basis for the correlating (comparison) function that determines the location of the inserted device.

Claim 1 recites a device that includes an imaging-feature extraction unit that extracts at least one characterizing feature of the appearance of the intervention device from image data obtained by an imaging system. *Id.* As noted above, one characterizing feature of the appearance of the intervention device is the shape the device assumes when deployed in a particular portion of the patient's anatomy, such as the right or left coronary ostium. *See* Spec. 2–3, 6–7.

The device of claim 1 also contains an imaging-based anatomy classification unit that correlates, i.e. compares, the image data regarding the characterizing feature of the appearance of the intervention device to classifier data, e.g., from a database, thereby allowing determination of the location of the device. Appeal Br. 43; *see also* Spec. 6 (classifier data may be from a database).

Appellants' remaining independent claims similarly require the use of the appearance of the inserted device as an indication of the anatomical location of the device. *See* Appeal Br. 45–46 (claim 7 reciting "extracting a characterizing feature of the appearance of the intervention device using provided image content data [and] correlating the extracted characterizing feature with provided classifier data"); *id.* at 47–48 (claim 14 reciting

computer readable medium having executable instructions for "extracting a characterizing feature of the appearance of the intervention device using the derived image content data [and] correlating the extracted characterizing feature with provided classifier data").

In contrast to Appellants' claimed use of a feature of the appearance of the inserted device as an indication of the anatomical location of an inserted device, Simon discloses using measured physical properties or physiological conditions to determine the device's location. Simon, abstract ("A method to determine the location of an instrument within a patient can be based upon the measuring of a characteristic within the patient and matching the currently measured characteristic with a previously measured characteristic.").

In the portion of the reference cited by the Examiner as teaching or suggesting Appellants' claimed location-determining feature (*see* Ans. 17), Simon explains that, by measuring multiple physical properties or physiological conditions at a particular anatomical location, a "fingerprint" of the particular location can be created:

> An example of a blend of multiple features in the fingerprint may include a measured position (but may also include a pulsative pressure, velocity, etc.) during a physiological cycle, such as a cardiac cycle. The measured position can be blended with the cardiac cycle to generate a blended curve indicating the change in position over the time of the cardiac cycle. Also, the curve could be based on an average of several cardiac cycles and several subjects, as discussed herein. The blended curve could then be matched to a patient or procedure curve.

Id. 5:65–6:7.

Simon explains that, when a surgical device is subsequently deployed, the sensed physical properties or physiological conditions at a particular anatomical location, can be compared to the fingerprint to determine the device's location. *Id.* at 7:42–45 ("During a second procedure, such as the positioning of a second stent or a[n] angioplasty, the patient specific fingerprint can be used . . . to identify the location of a catheter during the second procedure.").

Thus, Simon's device is similar to the device of Appellants' claim 1 in that Simon compares measured features to a previously determined set of features in a fingerprint to determine the location of an inserted medical device. We are not persuaded, however, that the Examiner has explained adequately how or why Simon's disclosure of determining a device's location using physical properties at anatomical locations or physiological conditions, such as "multiple features in the fingerprint [which] may include a measured position (but may also include a pulsative pressure, velocity, etc.) during a physiological cycle, such as a cardiac cycle" (*id.* at 5:65–6:1), teaches or suggests using a characterizing feature of the device's appearance, such as shape, to determine the device's location, even when viewing Simon in light of Markowitz.

We acknowledge, as the Examiner contends, that Simon teaches that multiple measured features may be used to create the location-determining fingerprint, including "instrument motion [which] can include acceleration, velocity, position, or other information" (*id.* at 7:56–57), "fluid motion . . . such as the direction, turbulence, velocity or other fluid motion information" (*id.* at 8:18–20), "electrical activity" (*id.* at 8:25), "pressure information [which] can include fluid pressure, tissue pressure, pulsative pressure, or

other pressure measurements" (*id.* at 8:35–37), and "tissue stiffness or density" (*id.* at 8:46). The Examiner, however, does not explain specifically why any of the features disclosed in Simon as providing the location-determining fingerprint would have taught or suggested Appellants' claimed use of a characterizing feature of *the appearance* of the inserted device, such as its shape, as an indication of the anatomical location of an inserted device.

Accordingly, because we are not persuaded that the Examiner has explained with adequate specificity why the combination of Simon and Markowitz teaches or suggests using a feature of the appearance of an inserted medical device as an indication of the anatomical location of the device, as required by each of Appellants' independent claims 1, 7, and 14, we reverse the Examiner's rejection of those claims, and their dependents, over Simon and Markowitz.

As to the remaining obviousness rejections, the Examiner relies on Brummer, Solem, and Wittenbrink as evidence that features in certain dependent claims would have been obvious variations on the subject matter recited in independent claims 1, 7, and 14. *See* Ans. 10–15. Accordingly, because the Examiner does not explain why Brummer, Solem, and Wittenbrink remedy the deficiencies discussed above of Simon and Markowitz as to independent claims 1, 7, and 14, we reverse the Examiner's obviousness rejections based on the combinations of Simon and Markowitz with Brummer, Solem, and Wittenbrink.

SUMMARY

For the reasons discussed, we affirm the Examiner's rejection of claims 1–5, 7–12, and 14–28, as being directed to a patent-ineligible judicial exception;

For the reasons discussed, we affirm the Examiner's rejection of claim 3, under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement;

For the reasons discussed, however, we reverse the Examiner's rejection of claim 27, under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement;

For the reasons discussed, we affirm the Examiner's rejection of claims 1–5, 19, 20–24, and 27, under 35 U.S.C. § 112, second paragraph, as being indefinite;

For the reasons discussed, however, we reverse each of the Examiner's rejections for obviousness under 35 U.S.C. § 103(a).

TIME PERIOD

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