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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte CHRISTOPHER FOLK and
JACOB KEARNS

Appeal 2019-003381
Application 14/758,754
Technology Center 3700

Before ANTON W. FETTING, PHILIP J. HOFFMANN, and
AMEE A. SHAH, *Administrative Patent Judges.*

HOFFMANN, *Administrative Patent Judge.*

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject claims 9–22 and 24–35. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

Appellant's "disclosure generally relates to medical systems and methods." Spec. ¶ 1. Claims 9, 27, and 30 are the independent claims on appeal. Below, we reproduce claim 9 as illustrative of the appealed claims:

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[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as Ford Global Technologies, LLC. Appeal Br. 2.

9. A method for performing a diagnostic or therapeutic procedure on an aneurysm, the method comprising:

introducing an intravascular device through a parent vessel and adjacent an aneurysm or within the aneurysm to reduce blood flow from the parent vessel into the aneurysm;

introducing a guide into the parent vessel and advancing the guide through the parent vessel past a proximal neck of the aneurysm, wherein a sensor is on the guide;

positioning the sensor one of upstream or downstream of the aneurysm and measuring, with the sensor and while the sensor is on the guide and within the parent vessel, at least one of a first pressure, a first volume, or a first blood flow velocity; and

after measuring the at least one of the first pressure, the first volume, or the first blood flow velocity, positioning the sensor the other one of upstream or downstream of the aneurysm and measuring, with the sensor and while the sensor is on the guide and within the parent vessel, at least one of a second pressure, a second volume, or a second blood flow velocity to determine the effectiveness of the intravascular device in minimizing blood flow from the parent vessel into the aneurysm.

REJECTIONS AND PRIOR ART

The Examiner rejects the claims as follows:

I. Claim 21 under 35 U.S.C. § 112, second paragraph, as indefinite;

II. Claims 9–12, 15, 18–22, 24, 30, and 32–34 under 35 U.S.C. § 103(a) as unpatentable over Evans et al. (US 7,666,220 B2, iss. Feb. 23, 2010) ("Evans), Letort et al. (US 2003/0199772 A1, pub. Oct. 23, 2003) ("Letort"), and Hayashi et al. (US 2003/0229388 A1, pub. Dec. 11, 2003) ("Hayashi");

III. Claims 27, 28, and 35 under 35 U.S.C. § 103(a) as unpatentable over Evans, Letort, and Escamilla et al. (US 2004/0059407 A1, pub. Mar. 25, 2004) ("Escamilla");

IV. Claims 13, 14, 16, 17, 25–29, 31, and 35 under 35 U.S.C. § 103(a) as unpatentable over Evans, Letort, Hayashi, and Escamilla.

ANALYSIS

Rejection I—Indefiniteness rejection

As set forth above, the Examiner rejects claim 21, which depends from claim 9, as indefinite. Below, we reproduce relevant portions of independent claim 9, and claim 21 in its entirety.

> 9. A method for performing a diagnostic or therapeutic procedure on an aneurysm, the method comprising:
>
> introducing an intravascular device through a parent vessel and adjacent an aneurysm or within the aneurysm to reduce blood flow from the parent vessel into the aneurysm;
>
> introducing a guide into the parent vessel and *advancing the guide through the parent vessel past a proximal neck of the aneurysm*, wherein a sensor is on the guide; [and]
>
> *positioning the sensor one of upstream or downstream of the aneurysm* and measuring, with the sensor and while the sensor is on the guide and within the parent vessel, at least one of a first pressure, a first volume, or a first blood flow velocity . . . .
>
> 21. The method according to claim 9, *wherein advancing the guide through the parent vessel past the proximal neck of the aneurysm comprises* advancing the guide from a first position in which the sensor is upstream of the aneurysm to a second position in which the sensor is downstream of the aneurysm.

Appeal Br., Claims App. (emphases added). According to the Examiner, claim 21 is indefinite based on the following:

> Claim 21 requires that advancing the guide comprises advancing the guide from a first position in which the sensor is upstream of the aneurysm to a second position in which the sensor is downstream of the aneurysm. Claim 9, from which [claim] 21 depends, requires both advancing the guide, as well as positioning the sensor upstream/downstream and then downstream/upstream. *It is unclear if the advancing steps required in claim 21 are the same as the positioning steps of 9 or are different from the positioning steps of claim 9*.

Final Action 6–7 (emphases added). Based on our review of the record, we disagree with the Examiner, and instead agree with Appellant that claim 21 is not indefinite. Appeal Br. 6–7. Claim 21 expressly recites that it is claim 9's step of "advancing the guide through the parent vessel past the proximal neck of the aneurysm" that comprises advancing the guide from the first to the second position, as claim 21 further recites.

> *Rejection II—Obviousness rejection of claims 9–12, 15, 18–22, 24, 30, and 32–34 based on Evans, Letort, and Hayashi*
>
> Independent claim 9, and its dependent claims 10–12, 15, 18–22, 24, and 34
>
> As set forth above, independent claim 9 recites the following:
>
> 9. A method for performing a diagnostic or therapeutic procedure on an aneurysm, the method comprising:
>
> introducing an intravascular device through a parent vessel and adjacent an aneurysm or within the aneurysm to reduce blood flow from the parent vessel into the aneurysm;
>
> introducing a guide into the parent vessel and advancing the guide through the parent vessel past a proximal neck of the aneurysm, wherein a sensor is on the guide;

> *positioning the sensor one of upstream or downstream of the aneurysm and measuring, with the sensor* and while the sensor is on the guide and within the parent vessel, at least one of *a first pressure, a first volume, or a first blood flow velocity*; and
>
> after measuring the at least one of the first pressure, the first volume, or the first blood flow velocity, *positioning the sensor the other one of upstream or downstream of the aneurysm and measuring, with the sensor* and while the sensor is on the guide and within the parent vessel, at least one of a second pressure, *a second volume, or a second blood flow velocity* to determine the effectiveness of the intravascular device in minimizing blood flow from the parent vessel into the aneurysm.

Appeal Br., Claims App. (emphases added). Restated, claim 9's method uses a sensor to measure either pressures, volumes, or blood-flow velocities both upstream and downstream of an aneurysm. For the reasons set forth below, the Examiner does not support adequately that the proposed combination of Evans, Letort, and Hayashi would provide a method where sensors measure properties both upstream and downstream of an aneurysm. Thus, we do not sustain the Examiner's obviousness rejection of independent claim 9.

The Examiner's rejection relies on Evans's double-walled filling structure 12 to disclose the claimed intravascular device. *See, e.g.*, Final Action 7. Consistent with Appellant's argument (Appeal Br. 11), Hayashi discloses measuring properties with sensors 18 that are disposed at ends of graft 10 (*see, e.g.*, Hayashi ¶ 20, Fig. 1). The Examiner proposes, in part, to modify Evans, to "measure the upstream/downstream pressure" as "taught by Hayashi." Answer 8.

We agree with Appellant, however, that "Hayashi does not describe that pressure measurements should be taken upstream and downstream of an aneurysm in order to detect endoleaks. Instead, Hayashi describes that the positioning of sensors relative to the ends of . . . graft 10 enables detection of endoleaks." Appeal Br. 11 (citing Hayashi ¶ 23) (underlining omitted). Thus, a modification of Evans based on Hayashi would result in an arrangement in which sensors measure properties at the ends of Evans's double-walled filling structure 12. Appeal Br. 11–12.

If Evans's double-walled filling structure 12 extends upstream and downstream of the aneurysm, then measuring properties at the ends of structure 12 would result in an arrangement where sensors measure properties both upstream and downstream of an aneurysm, consistent with claim 9's recitations. The reason that we do not sustain the rejection, however, is because the Examiner does not support adequately that Evans's structure 12 extends upstream or downstream of an aneurysm.

Evans describes that its

> methods for treating an aneurysm comprise positioning at least one double-walled filling structure across the aneurysm. By "across" the aneurysms, it is meant generally that the filling structure will extend axially from one anatomical location, which has been identified by imaging or otherwise as *the beginning of the aneurysm*, to a space-part location (or locations in the case of bifurcated aneurysm) where it has been established that *the aneurysm ends*.

Evans col 6, l. 61–col. 7, l. 2 (emphases added). This is consistent with the arrangement shown in Evans's Figure 5C, for example, in which structure 12 extends from a top-right end of aneurysm AAA to bottom-left and bottom left end of the aneurysm. It is not clear to us that even measuring properties

at structure 12's top-left and bottom-left ends, for example, would be measurements upstream and downstream of the aneurysm.

According to the Examiner, Evans's "[Figure] 5C . . . shows ends of the device extending slightly upstream and downstream of the aneurysm." Answer 6. This finding is not supported adequately in view of Evans's express description that its method uses structures that extend from the beginning to the end of the aneurysm.

The rejection further references Evans's Figure 5D, which, according to the Examiner, "shows the device extending even further from the limits of the aneurysm." Answer 6–7 (citing Evans col. 18, ll. 10–13, Fig. 5D). To the extent that it would have been obvious to measure properties at the end of "seals, anchors, stents, or other additional prosthetic components" (Evans col. 18, ll. 10–12) that are attached to Evans's structure 12, rather than at the ends of structure 12 itself, consistent with Appellant's argument, Evans discloses that such components are "position[ed] . . . at *either* . . . proximal end 52 *or* distal end 50 of the graft" (*id.* at col. 18, ll.10–13 (emphases added)). That is, this portion of Evans does not state that the components are positioned at *both* ends of structure 12, so that measuring characteristics at both ends of structure 12 with any additional component would result in a method where sensors measure properties *both upstream and downstream* of an aneurysm. This is consistent with Evans's Figure 5D, which shows "a stent-like structure . . . planted in . . . upper proximal opening 52 of the tubular lumen of . . . filling structure 12"—i.e., in only one end of structure 12. *Id.* at col. 18, ll. 13–15. No other figure appears to disclose prosthetic components in one end (or more importantly both ends) of structure 12.

Thus, based on the foregoing, we do not sustain the Examiner's rejection of independent claim 9. Further, we do not sustain the Examiner's rejection of claims 10–12, 15, 18–22, 24, and 34 that depend from claim 9.

Independent claim 30, and its dependent claims 31–33

Independent claim 30 recites the following:

> 30. A method comprising:
>
> delivering an intravascular device through a parent vessel of a patient to a treatment site adjacent an aneurysm or within the aneurysm to reduce blood flow from the parent vessel into the aneurysm;
>
> introducing a guide into the parent vessel and advancing the guide within the parent vessel past a neck of the aneurysm to *position a sensor* on the guide *one of upstream or downstream of the aneurysm*;
>
> *measuring, with the sensor* and while the sensor is on the guide, *at least one of a first pressure, a first volume, or a first blood flow velocity* within the parent vessel;
>
> after measuring the at least one of the first pressure, the first volume, or the first blood flow velocity, *positioning the sensor the other one of upstream or downstream of the aneurysm* and *measuring, with the sensor* and while the sensor is on the guide, *at least one of a second pressure, a second volume or a second blood flow velocity* within the parent vessel to determine an effectiveness of the intravascular device in minimizing blood flow from the parent vessel into the aneurysm.

Appeal Br., Claims App. (emphases added). Thus, claim 30 includes recitations similar to those discussed above with respect to independent claim 9. Accordingly, we do not sustain claim 30's obviousness rejection for reasons similar to the reasons we do not sustain claim 9's rejection.

Further, we do not sustain the Examiner's obviousness rejection of claims 31–33 that depend from claim 30.

Rejection III—Obviousness rejection of claims 27, 28, and 35

Independent claim 27 recites the following:

> 27. A method comprising:
>
> *introducing an intravascular device through a parent vessel* and adjacent an aneurysm or *within the aneurysm to reduce blood flow from the parent vessel into the aneurysm*, wherein *introducing the intravascular device comprises* delivering a stent adjacent the aneurysm such that the stent assumes a deployed configuration in which the stent extends from a position upstream of the aneurysm to a position downstream of the aneurysm, or *positioning a plurality of microcoils within the aneurysm*;
>
> introducing a guide into the parent vessel and advancing the guide within the parent vessel past a neck of the aneurysm to position a sensor on the guide at least adjacent to the aneurysm;
>
> with the guide at least partially within the parent vessel and the sensor on the guide, measuring at least one of pressure, volume or blood flow velocity adjacent the aneurysm with the sensor to determine an effectiveness of the intravascular device in minimizing blood flow from the parent vessel into the aneurysm; and
>
> after measuring the at least one of pressure, volume or blood flow velocity adjacent the aneurysm with the sensor, moving the sensor within the patient by at least moving the guide.

Appeal Br., Claims App. (emphases added). The Examiner's proposed combination of references includes Evans and Escamilla. As set forth below, we agree with Appellant that the Examiner's proposed modification

changes Evans's principle of operation, and, therefore, is improper. *See* Appeal Br. 23–24; *see also* Answer 12–15.

Almost Evans's entire disclosure is directed to describing a double-walled filling structure that is positioned across an aneurysm, and then filled with a filling medium so that the structure's outer wall conforms to the aneurysm and the inner wall forms a lumen through which blood may flow. *See, e.g.*, Evans Abstract, col. 2, ll. 52–56. The Examiner's proposed combination does not rely on Evans's double-walled filling structure to fill an aneurysm, but instead fills the aneurysm with Escamilla's embolic coils 60 from microcatheter 58. Final Action 14. Thus, as we state above, we agree with Appellant that combining Evans with Escamilla, such that an aneurysm is treated by filling the aneurysm with coils rather than conforming a double-walled filling structure's outer wall to the aneurysm and then filling the double-walled structure, impermissibly changes Evan's principle of operation.

Therefore, based on the foregoing, we do not sustain the Examiner's obviousness rejection of independent claim 27. Further, we also do not sustain the obviousness rejection of claims 28 and 35 that depend from claim 27.

Rejection IV—Obviousness rejection of claims 13, 14, 16, 17, 25–29, 31, and 35

Each of claims 13, 14, 16, 17, 25–29, 31, and 35 depends from one of independent claims 9, 27, and 30. In the dependent claims' rejection, the Examiner does not rely on any reference to disclose anything that would remedy the above-discussed deficiencies in the independent claims'

rejections. Thus, we do not sustain the Examiner's obviousness rejection of dependent claims 13, 14, 16, 17, 25–29, 31, and 35.

CONCLUSION

We REVERSE the Examiner's indefiniteness and obviousness rejections of claims 9–22 and 24–35.

In summary:

Claims Rejected	35 U.S.C. §	Basis/Reference(s)	Affirmed	Reversed
21	112, second paragraph	Indefiniteness		21
9–12, 15, 18–22, 24, 30, 32–34	103(a)	Evans, Letort, Hayashi		9–12, 15, 18–22, 24, 30, 32–34
27, 28, 35	103(a)	Evans, Letort, Escamilla		27, 28, 35
13, 14, 16, 17, 25–29, 31, 35	103(a)	Evans, Letort, Hayashi, Escamilla		13, 14, 16, 17, 25–29, 31, 35
Overall Outcome:				9–22, 24–35

REVERSED