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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte NATHAN T. LEE

Appeal 2014-009930
Application 13/074,948¹
Technology Center 3700

Before JOSEPH A. FISCHETTI, MICHAEL C. ASTORINO, and
KENNETH G. SCHOPFER, *Administrative Patent Judges*.

SCHOPFER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the rejection of claims 1–5, 8–12, and 14–29. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

BACKGROUND

According to Appellant, the application “relates to fixation techniques for implantable medical devices.” Spec. 1.

¹ According to Appellant, the real party in interest is Medtronic, Inc. Appeal Br. 2.

CLAIMS

Claims 1–5, 8–12, and 14–29 are on appeal. Claim 1 is illustrative of the appealed claims and recites:

1. A kit for implanting an implantable medical device within a patient, the kit comprising:

a delivery catheter including an inner member and an outer member;

the implantable medical device, wherein the implantable medical device is adjacent the inner member and constrained by the outer member;

a force sensor in mechanical communication with the implantable medical device via the inner member, wherein the force sensor collects force feedback data representing force applied by the inner member on the implantable medical device; and

a user communication module configured to deliver force feedback information corresponding to the force feedback data collected by the force sensor to a user.

Appeal Br. 28.

REJECTIONS

1. The Examiner provisionally rejects claims 1, 3, 14, and 16 on the ground of non-statutory obviousness-type double patenting over claims 11, 19, 20, 22, and 23 of U.S. Patent Application No. 13/096,881 and claims 12, 16, 19, 21, and 22 of U.S. Patent Application No. 13/284,761.

2. The Examiner rejects claims 1–3, 5, and 8–12 under 35 U.S.C. § 103(a) as unpatentable over Hastings² in view of Blumenkranz³ and Cioanta.⁴
3. The Examiner rejects claim 4 under 35 U.S.C. § 103(a) as unpatentable over Hastings in view of Blumenkranz, Cioanta, and Verma.⁵
4. The Examiner rejects claims 14–16 and 18–29⁶ under 35 U.S.C. § 103(a) as unpatentable over Hastings in view of Blumenkranz.
5. The Examiner rejects claim 17 under 35 U.S.C. § 103(a) as unpatentable over Hastings in view of Blumenkranz and Verma.

DISCUSSION

Rejection 1

Appellant does not appeal the double patenting rejection of claims 1, 3, 14, and 16. Accordingly, we summarily sustain this rejection.

Rejection 2

Claim 1

With respect to claim 1, the Examiner finds that Hastings discloses a device for implanting a medical device including a delivery catheter with inner and outer members and an implantable medical device. Final Act. 4 (citing Hastings Figs. 7–9, ¶¶ 81, 84, 89). The Examiner finds that Blumenkranz teaches a force sensor that would be in mechanical

² Hastings et al., US 2006/0085041 A1, pub. Apr. 20, 2006.

³ Blumenkranz et al., US 2009/0157092 A1, pub. June 18, 2009.

⁴ Cioanta et al., US 2002/0082610 A1, pub. June 27, 2002.

⁵ Verma, US 2009/0234367 A1, pub. Sept. 17, 2009.

⁶ Although the Examiner lists claim 17 in the heading for this rejection, the body of the rejection does not include claim 17. See Final Act. 8–12.

communication with the implant of Hastings in the proposed combination⁷ and that measures data representing force applied by the inner member; and the Examiner also finds that Blumenkranz teaches a user communication module. *Id.* at 5 (citing Blumenkranz Figs. 1C, 4B, ¶¶ 36, 40).

Further, with respect to Hastings and Blumenkranz, the Examiner concludes:

Therefore it would have been obvious to one of ordinary skill in the art to have a force sensor, as taught by Blumenkranz, to be in mechanical communication with the implantable medical device of Hastings for purposes of providing feedback to the surgeon as to how much force is being applied on the instrument or the implantable medical device as it is being deployed into the body; as such the surgeon, with that information, can accordingly adjust the force being applied in order to prevent tissue damage inside the body cavity.

Blumenkranz is analogous art and one of ordinary skill in the art would be motivated to combine the teachings of said reference with primary reference because it is directed towards solving the same problem – implanting medical device in a body such that it provides force sensor communication to the operating physician to regulate the force he is exerting on the device in order to prevent injury or inaccurate deployment of the device inside the body cavity.

Final Act. 5–6. Finally, the Examiner concludes that it would have been obvious to include the combination of Hastings and Blumenkranz in a kit as claimed, based on the teachings of Cioanta. *Id.* at 6 (citing Cioanta Fig. 11, ¶ 80).

⁷ Although the Examiner states that Blumenkranz teaches a force sensor in mechanical communication with an implantable medical device, we understand the Examiner to mean that the sensor in the proposed combination would be in mechanical communication with Hastings' implantable medical device. *See* Final Act. 5.

Appellant argues that the art does not teach or suggest a force sensor that measures the force applied by the inner member on the medical device and that the Examiner has not adequately explained why it would have been obvious to do so. Appeal Br. 10–16.

We begin our analysis by construing the relevant claim language. We note that the claimed structure relevant to the arguments presented is only a force sensor in mechanical communication with the implantable medical device via the inner member. The remaining portion of this limitation, i.e. the “wherein” clause, is functional language, which may be interpreted to only require that the claimed force sensor is capable of collecting data representing the force applied by the inner member on the implantable device. Further, contrary to Appellant’s assertions, the claim only requires that the force sensor collects data *representing* the force applied by the inner member on the implantable medical device, which may include force exerted by tissue on the device, noting Newton’s third law. *See* Ans. 12–13. Moreover, the claim does not require the capability of directly measuring the force on the implantable device. Thus, Appellant’s argument that the claim requires that “the force measured is the force applied by the inner member to the device” (*id.* at 12), is not commensurate with the scope of the claim.

In light of the claim construction above, we are persuaded by the Examiner’s findings that the art of record renders the claimed structure obvious. Hastings discloses a delivery catheter with inner members and outer members for delivering an implantable medical device adjacent to the inner member as claimed. *See* Hastings Fig. 7, ¶ 81; *see also* Final Act. 4. Hastings does not disclose a force sensor in mechanical communication with the implant via the inner member or a user communication module.

However, Blumenkranz discloses a catheter including a force sensor in mechanical communication with a surgical tool via an inner member. *See* Blumenkranz Figs. 3B, 4B; *see also* Final Act. 5. Blumenkranz also discloses a user module, surgeon's console 90, that transmits position, force, and tactile sensations from the surgical instrument back to the surgeon, i.e. it is configured to transmit force data collected from the force sensors on the inner member back to the user. *See* Blumenkranz ¶ 36; *see also* Final Act. 5. Further, Blumenkranz discloses that the device is intended to provide a means for sensing forces applied to tissue and "to provide accurate feedback of forces and torques to the surgeon to improve user awareness and control of . . . instruments." Blumenkranz ¶¶ 6, 34.

Based on these disclosures and the reasoning provided by the Examiner, we agree with the Examiner's findings that because both devices are in the same field of endeavor and use relatively the same movement mechanisms, i.e. for pushing and pulling a catheter in order to perform a desired surgical procedure, one of ordinary skill would have found it desirable to include force sensors in Hastings device. *See* Ans. at 5–6, 8–9.

Finally, we also find that because the inner member, force sensor(s), and implant are working in unison, the device would be capable of collecting force feedback data representing the force applied by the inner member on the implant. For example, we agree with the Examiner that where the combined device contacts or abuts patient tissue, and specifically in the situation where the combined device is perpendicular to and contacts patient tissue, the force sensors would provide force feedback that is representative of the force applied by the inner member on the implant. *See* Ans. 12–13.

Thus, we find that the Examiner's findings and conclusions regarding the proposed combination of Hastings and Blumenkranz are supported by a preponderance of the evidence before us. For these reasons, we sustain the rejection of claim 1. Appellant does not provide separate arguments with respect to dependent claims 2, 5, and 8–12, and thus, we sustain the rejection of those claims for the same reasons.

Claim 3

With respect to claim 3, the Examiner relies on the combination of Hastings, Blumenkranz, and Cioanta as discussed above, and the Examiner also finds that the force feedback data provided by Blumenkranz would also allow the user to determine whether an implant is adequately fixated within a patient as claimed. Final Act. 5–6 (citing Blumenkranz ¶ 36). Further with respect to this claim, the Examiner also finds that “it would be advantageous and necessary to add a force feedback sensor on Hastings as force is applied to [the implantable] medical device such that [the] surgeon does not apply too much or unnecessary force resulting in tissue damage.” *Id.* at 5.

In addition to the arguments raised with respect to claim 1, Appellant raises additional arguments with respect to this claim. First, Appellant argues that Hastings inner tube is used to push the implant into tissue and the force required to push the implant into tissue is not the force required to pull it out and thus does not provide a measure of the adequacy of the device's securement as claimed. Appeal Br. 17. Second, Appellant argues:

there is no reason to believe it would actually work even to perform the argued desired function of avoiding “tissue damage”. The express purpose of the device in Hastings is to cause tissue damage. Tissue damage is necessary in order for the device to work. If tissue damage were avoided, the device could

not be forcibly implanted into the tissue as is required for it to function at all.

Id. at 18. Third, Appellant also argues that the Examiner's rejection of this claim refers to other embodiments of Hastings and the Examiner has not provided enough detail to indicate which elements of these other embodiments are relied upon in the rejection. *Id.* at 18–19.

For the reasons discussed below, we are not persuaded of error.

As an initial matter, we note that this claim includes an additional wherein clause, which we again interpret as functional language that requires only that the claimed force sensor be capable of providing data to the user to allow the user to evaluate whether an implantable medical device is adequately fixated within the patient.

Regarding Appellant's first argument, we agree with the Examiner that both Hastings and Blumenkranz teach devices that involve pulling and pushing mechanisms used to perform a desired surgical procedure. *See* Ans. 8. Thus, contrary to Appellant's assertion, one of ordinary skill in the art would understand that Hastings is not only concerned with providing a pushing force for implanting a device, but Hastings is also concerned with directing the catheter to the desired cite and removing said catheter using various pushing and pulling forces. Further, as indicated above with respect to claim 1, we agree that it would have been obvious to include force sensors on Hastings' device in order to provide haptic feedback to the surgeon. Thus, we are not persuaded, as Appellant indicates, that including force sensors in Hastings' device would only measure the pushing force required to insert the medical implant into tissue. Further, based on this analysis, we find that the proposed combination of art would be capable of providing information to the user to evaluate whether the device is adequately fixated

within the patient by providing a measurement of the force applied to the force sensors when the catheter is being pulled before the implant is permanently released.

Regarding Appellant's second argument, we agree with the Examiner's conclusion that preventing tissue damage would have motivated one of ordinary skill in the art to include force sensors in Hastings' device as claimed. Appellant's argument is focused on the necessary tissue damage required by implanting the medical device in tissue. However, the Examiner explains that one of ordinary skill in the art would recognize that it would be advantageous to include force feedback sensors such that the "surgeon does not apply too much or unnecessary force." We agree with the Examiner that avoiding *unnecessary* tissue damage would have motivated one of ordinary skill in the art to add feedback sensors to Hastings' device.

With respect to Appellant's third argument (Appeal Br. 16), we understand that the Examiner has only relied on the embodiment of Figure 11F of Hastings to show that Hastings teaches applying a force on a delivery catheter to deliver an implant to a desired implantation cite (Final Act. 5). We are not persuaded that the rejection is in error based on the Examiner's additional citation to this embodiment.

For these reasons, we sustain the rejection of claim 3.

Rejection 3

Claim 4 depends from claim 1 and further requires "wherein the force feedback information includes an indication that a holding force of the implantable medical device at least meets a predetermined threshold." With respect to this claim, the Examiner finds that Hastings, Blumenkranz, and Cioanta are "silent on [a] clear teaching of including a holding force that

meets a predetermined threshold level.” Final Act. 8. However, the Examiner finds that Verma teaches a force assessment device providing an indication that a holding force meets a predetermined level, and the Examiner concludes “it would be obvious to have a holding force that meets a predetermined threshold level for purposes of using such measures as guidelines for limits of pressure that can be tolerated by a tissue or organ where the implantable medical device is being placed.” *Id.* (citing Verma Figs. 5–8, ¶ 27).

With respect to this rejection, Appellant raises the following arguments: 1) that the Examiner’s finding that the art relied upon with respect to claim 1 is silent regarding measuring a holding force as claimed is inconsistent with the Examiner’s findings regarding claim 3; 2) that Verma’s force transducer would not measure holding force unless it were attached as in Verma; 3) that there is no reason suggested in Hastings that Hastings’ device can “be removed by pulling force without exceeding the limits of the tissue”; and 4) that the rejection is defective because it does not cite to Cioanta, which was cited with respect to independent claim 1. Appeal Br. 21–22.

For the reasons discussed below, we are not persuaded of error by Appellant’s argument.

With respect to Appellant’s first argument, Appellant has not adequately explained any inconsistency in the Examiner’s findings at least because the language of claim 4 regarding a predetermined threshold is different than the language of claim 3 regarding an evaluation of whether the device is adequately fixated. With respect to claim 3, the Examiner did not

find that the art teaches or suggests comparing the holding force to a predetermined threshold.

Regarding Appellant's second argument, "[t]he test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference Rather, the test is what the combined teachings of those references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425 (CCPA 1981). The rejection does not rely on the physical incorporation of Verma's force transducer into Hastings' device. Rather, we understand the rejection to rely on Verma's teaching of predetermined thresholds relating to limits of pressure that can be tolerated by different tissues. Appellant does not point, with particularity, to any error in the Examiner's reliance on Verma for this teaching.

Next, for reasons discussed previously, we are not persuaded by Appellant's third argument. Specifically, we find that the combination of art shows that the capability required by claim 4 would have been obvious for the reasons discussed with respect to claims 1 and 3 because one of ordinary skill would have found it obvious to employ force sensors in Hastings' device in order to prevent unnecessary tissue damage and one of ordinary skill in the art would recognize that unnecessary tissue damage could be prevented by ensuring that the pulling force measured when the adequacy of fixation is tested falls below the threshold amounts taught by Verma.

With respect to Appellant's final argument, we find that the rejection of claim 4 does cite to Cioanta, contrary to Appellant's assertion. *See* Final Act. 8.

For these reasons, we sustain the rejection of claim 4.

Rejections 4 and 5

With respect to the rejections of the remaining claims, Appellant relies on substantially the same arguments as those discussed above. *See* Appeal Br. 23–26. We find those arguments unpersuasive here for the same reasons identified above. Accordingly, we sustain the rejections of claims 14–29.

CONCLUSION

For the reasons set forth above, we AFFIRM the rejections of claims 1–5, 8–12, and 14–29.

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