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4743	7590	09/17/2020	EXAMINER	
MARSHALL, GERSTEIN & BORUN LLP 233 SOUTH WACKER DRIVE 6300 WILLIS TOWER CHICAGO, IL 60606-6357			HERBERMANN, ERICH G.	
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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* THOMAS EDWARD CLAIBORNE, III  
RICHARD T. SCHOEPHOERSTER, and  
SIOBHAIN LYNN GALLOCHER

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Appeal 2020-001105  
Application 14/601,451  
Technology Center 3700

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Before JENNIFER D. BAHR, CHARLES N. GREENHUT, and  
MICHAEL J. FITZPATRICK, *Administrative Patent Judges*.

BAHR, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant appeals from the Examiner’s decision to reject claims 11, 12, 14, 15, 18–20, 22–24, and 28–32.<sup>1</sup> We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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<sup>1</sup> We use the word “Appellant” to refer to “applicant” as defined in 37 C.F.R. § 1.42(a). Appellant identifies “The Florida International University Board of Trustees” as the real party in interest. Appeal Br. 2.

CLAIMED SUBJECT MATTER

Appellant's invention is directed to "a catheter deliverable artificial heart valve and delivery system therefor." Spec. ¶ 2. Claim 11, reproduced below, is illustrative of the claimed subject matter:

11. A system for intravascular delivery of a heart valve prosthesis, the system comprising:
  - a handle;
  - a flexible elongated sheath having a first end and a second end, the first end connected to and extending from the handle and the second end disposed opposite the handle;
  - a cavity at least partially defined by the second end of the elongated sheath, the cavity adapted to contain a heart valve prosthesis during intravascular delivery of the heart valve prosthesis;
  - a tapered tip coupled to the second end of the elongated sheath adjacent to the cavity, the tapered tip adapted to guide the elongated sheath during intravascular delivery of the heart valve prosthesis, the tapered tip and the elongated sheath being separable such that the heart valve prosthesis can be released from the cavity in the elongated sheath upon proper positioning of the heart valve prosthesis;
  - a stop plug disposed in the elongated sheath and adjacent the cavity;
  - a string fixed to an inside surface of the elongated sheath at a location between the stop plug and the handle and extending through the sheath to the handle such that a user can pull the string to bend the elongated sheath to facilitate navigation of the elongated sheath during intravascular delivery of the heart valve prosthesis.

## REFERENCES

The prior art relied upon by the Examiner is:

Name	Reference	Date
Hammerslag	US 5,372,587	Dec. 13, 1994
Thompson	US 2002/0120322 A1	Aug. 29, 2002
Sakakine	US 2007 /0260225 A1	Nov. 8, 2007

## REJECTIONS

Claims 11, 12, 14, 15, 18–20, 24, and 29–32 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Thompson and Sakakine.

Claims 11, 18, 22, 23, and 28 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Thompson and Hammerslag.

## OPINION

Appellant makes essentially the same arguments against both rejections. Appeal Br. 9–11. Further, Appellant relies solely on the arguments presented against the rejections of independent claim 11 in contesting the rejections of independent claim 18. Appeal Br. 11–12. Appellant does not present any separate arguments for the dependent claims, aside from their dependence from either claim 11 or claim 18. *Id.* Accordingly, we decide the appeal of both rejections on the basis of claim 11, and the remaining claims stand or fall with claim 11.

The Examiner finds that Thompson discloses a system substantially as recited in claim 11, but that

Thompson fails to directly disclose: a string **fixed** to an inside surface of the elongated sheath at a location between the stop plug and the handle and extending through the sheath to the handle such that a user can pull the string to bend the elongated

sheath to facilitate navigation of the elongated sheath during intravascular delivery of the heart valve prosthesis.

Final Act. 2–3, 10–11. The Examiner finds, however, that Sakakine teaches a string (tensioning device 86) fixed to an inside surface of a sheath of a medical device at a location between the stop plug and the handle and extending through the sheath to the handle such that a user can pull the string to bend the sheath to facilitate navigation of the sheath during intravascular delivery of a heart valve prosthesis. *Id.* at 3 (citing Sakakine, Fig. 4; ¶ 37).

The Examiner determines it would have been obvious to modify the outer tube (outer tubular member 16) of Thompson to be bendable and to provide internal pull wires as taught by Sakakine to facilitate steering the device through vasculature. Final Act. 4 (citing Sakakine ¶ 37). According to the Examiner, once the modification is made, at least a portion of the length of the wire, which would be passed through Thompson’s tubular member 16, would be located between the stop plug and the handle because tubular member 16 “passes over the stop plug and the handle in order to manipulate the prosthesis through the vasculature.” *Id.*

In the alternative, the Examiner finds that Hammerslag teaches a string (pull ribbon 234) fixed to an inside surface of a sheath at a location between the stop plug and the handle and extending through the sheath to the handle such that a user can pull the string to bend the sheath to facilitate navigation of the sheath during intravascular delivery of a heart valve prosthesis. Final Act. 11. The Examiner determines it would have been obvious to modify Thompson’s device to be bendable and provide internal pull wires as taught by Hammerslag to facilitate steering the device through

vasculature. *Id.* at 12 (citing Hammerslag 3:17–25; 29:1–12). According to the Examiner, once the modification is made, the wire will be located throughout the length of the device because “the pull wires terminate at the distal tip” as seen in Figure 24 so the user can pull the wires when needed. *Id.* Thus, according to the Examiner, “a portion of the wire will be at a location between the stop plug and the handle since the wire runs the length of the tube 16 which in turn covers the plug.” *Id.*

Appellant does not specifically dispute any of the Examiner’s findings or reasoning. Rather, Appellant contends that “each of the proposed combinations of Thompson and Sakakine and Thompson and Hammerslag would render the stent delivery device of Thompson inoperable for its intended purpose.” Appeal Br. 10. More specifically, Appellant argues that modifying Thompson to include Sakakine’s tensioning device 86 or Hammerslag’s pull ribbon 234 would render Thompson’s stent delivery device

inoperable for its intended purpose by affecting the ability of the interlocking structures 82 and 84 to remain locked when a tensioning device or string (1) pulls the outer tubular member 16 relative to the inner tubular member 14 and fully retracts the outer tubular member 16 before reaching the deployment site, or (2) applies a bending moment to the device 10 and causes the interlocking structures 82 and 84 to move out [of] interlocking engagement.

*Id.*

The Examiner responds by explaining that, in the modified device of Thompson, either in view of Sakakine or in view of Hammerslag, the pull wire, which would be in outer tubular member 16, would not interact with the interlocked portions at all and would not interfere with their ability to

lock in place. Ans. 3, 4. The Examiner also points out that “there is no indication in the disclosure of Thompson that supports the notion that the interlocked portions would not work properly if the device were bent.” *Id.* at 4. The Examiner reasons that one of ordinary skill in the art would know how to incorporate into Thompson a tensioning device as taught by Sakakine or a pull ribbon as taught by Hammerslag for steering to ensure “the device can bend and operate as intended.” *Id.* at 3–4.

Based on the record before us, the Examiner has the better position. “A person of ordinary skill is also a person of ordinary creativity, not an automaton.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421(2007). Such a person would readily appreciate the advantages of providing a means to deflect the distal end of Thompson’s implant delivery system to navigate through tortuous conduits or cavities within the body as taught by Sakakine and to be steerable through body lumens or cavities as taught by Hammerslag. *See* Sakakine ¶¶ 37–39; Hammerslag 1:14–20, 29:3–13. Further, such a person would know how to design Thompson’s interlocking structures 82, 84 to be sufficiently robust that they will remain interlocked even when the distal end of the delivery system is subjected to a degree of deflection necessary to steer the system to facilitate navigation through vasculature and would know how to design outer tubular member 16 and inner tubular member 14 to limit deflection to a degree that will not damage stent 12. Appellant does not provide any evidence or persuasive technical reasoning to show that incorporating a steering means including a pull string in Thompson’s device in a manner to create an operable device would have been beyond the technical grasp of a person having ordinary skill in the art.

The Examiner also explains why applying tension on the tensioning device or pull ribbon would not cause Thompson’s outer tubular member 16 to retract prematurely as Appellant contends. Ans. 4–5. Appellant does not dispute the Examiner’s findings or technical analysis on this issue.

For the above reasons, Appellant fails to apprise us of error in the Examiner’s conclusion that the subject matter of claim 11 would have been obvious, based on either a combination of Thompson and Sakakine or a combination of Thompson and Hammerslag. Accordingly, we sustain the rejection of claim 11, as well as claims 12, 14, 15, 18–20, 24, and 29–32, which fall with claim 11, as unpatentable over Thompson and Sakakine. We also sustain the rejection of claim 11, as well as claims 18, 22, 23, and 28, which fall with claim 11, as unpatentable over Thompson and Hammerslag.

### CONCLUSION

In summary:

<b>Claims Rejected</b>	<b>35 U.S.C. §</b>	<b>Reference(s)/Basis</b>	<b>Affirmed</b>	<b>Reversed</b>
11, 12, 14, 15, 18–20, 24, 29–32	103(a)	Thompson, Sakakine	11, 12, 14, 15, 18–20, 24, 29–32	
11, 18, 22, 23, 28	103(a)	Thompson, Hammerslag	11, 18, 22, 23, 28	
<b>Overall Outcome</b>			11, 12, 14, 15, 18–20, 22–24, 28–32	

Appeal 2020-001105  
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TIME PERIOD FOR RESPONSE

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

AFFIRMED