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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/405,820	01/13/2017	Michael G. Fisher	4394.548US6	3684
104326	7590	11/01/2019	EXAMINER	
Schwegman Lundberg & Woessner / Zimmer			HOBAN, MELISSA A	
P.O. Box 2938			ART UNIT	PAPER NUMBER
Minneapolis, MN 55402			3774	
			NOTIFICATION DATE	DELIVERY MODE
			11/01/2019	ELECTRONIC

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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* MICHAEL G. FISHER, ANTHONY K. HEDLEY,  
MICHAEL HOWARD, KEVIN M. CORDES, and  
TOSHINOBU KATSUYA

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Appeal 2019-002906  
Application 15/405,820  
Technology Center 3700

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Before EDWARD A. BROWN, MICHAEL L. HOELTER, and  
LISA M. GUIJT, *Administrative Patent Judges*.

BROWN, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant<sup>1</sup> appeals from the Examiner's decision to reject claims 2–9, 14–19, 22, and 23. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

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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. Zimmer Biomet is identified as the real party in interest. Appeal Br. 2.

### CLAIMED SUBJECT MATTER

Appellant’s disclosure “relates generally to medical/surgical devices, systems and methods. More specifically, the invention relates to devices, systems and methods for enhancing a knee surgery procedure.” Spec. ¶ 2.

Claims 2, 14, and 22 are independent. Claim 2 illustrates the claimed subject matter.

2. A method for conducting a surgical procedure on a knee joint, the method comprising:

temporarily attaching a trial femoral component to a distal end of a femur, the trial femoral component including at least one positioning feature to provide position information for an implant;

adjusting the trial femoral component to modify a position of the at least one positioning feature relative to the distal end of the femur;

sensing the position of the at least one positioning feature;

communicating position information corresponding to the sensed position to a robotic surgery system; and

shaping the distal end of the femur with the robotic surgery system in response to the position information, wherein the shaping the distal end of the femur comprises at least one of cutting, milling, or burring the distal end of the femur with the robotic surgery system.

Appeal Br. 23 (Claims App.).

### REJECTION

Claims 2–9, 14–19, 22, and 23 are rejected under 35 U.S.C. § 103(a) as unpatentable over Hershberger (US 5,470,354, issued Nov. 28, 1995) and Applicant’s Admitted Prior Art (“AAPA”).

## ANALYSIS

### *Claims 2–9*

As for claim 1, the Examiner finds that Hershberger discloses temporarily attaching a trial femoral component 54 including at least one positioning feature to a distal end of a femur. Final Act. 3. The Examiner finds that the positioning feature includes “at least one of a surface marker or a fiducial and/or a plurality of fiducials or markers (any of the convex bearing portions, the patella guide recess, and the central ridge)”. *Id.* (citing Hershberger, col. 6, ll. 8–23). The Examiner also finds that the trial femoral component is adjusted and the position of the positioning feature “is inherently sensed (viewed and/or felt) at least by the surgeon and the distal end of the femur is shaped (trimmed) in response to the position information.” *Id.* (citing Hershberger, col. 4, ll. 6–16, col. 8, ll. 59–64).

The Examiner acknowledges that Hershberger does not teach using a robotic surgery system to shape the distal end of a femur, and relies on AAPA as teaching this feature. *Id.* at 3–4. The Examiner concludes that it would have been obvious to one of ordinary skill in the art to use this teaching, reasoning that “it is a well-known improvement in the art to use a robotic surgery system in place of a surgeon for making bone cuts, as taught by [AAPA].” *Id.* (citing Spec. ¶¶ 11, 67). According to the Examiner, there is a lack of any disclosed criticality for this limitation because paragraph 67 “states that the positioning feature may provide positional information to a surgeon, computer, robotic system, and/or the like, to help facilitate completion of the TKA procedure.” *Id.* at 4.

Appellant contends that Hershberger does not disclose or suggest the claimed positioning feature. Appeal Br. 12. Regarding the Examiner's position that "convex bearing portions, the patella guide recess, and the central ridge" of trial femoral component 54 disclosed in Hershberger correspond to the claimed positioning features, we note Figure 1 of Hershberger shows that trial femoral component 54 includes convex bearing portions 68, 70, guide recess 72, and central ridge 74. Appellant contends that these elements do not provide "position information," as claimed. Appeal Br. 12. Appellant also contends that the term "position information" is defined in the Specification as "[information that may] be used to guide a robotic surgical system, to enhance the procedure via a navigational system, or the like." *Id.* (citing Spec. ¶ 58). Appellant asserts that the anatomical portions of Hershberger's device do not provide position information for an implant. *Id.* at 13.

The Examiner disagrees with Appellant, stating,

the convex bearing portions (a plurality of positioning features) of the trial implant (54) are meant to interact with the distal portion of the femur and therefore provide positional information (for example, whether the implant is placed in a proper position) to the surgeon when placing the implant on the bone.

Ans. 4–5.

Appellant's contentions are persuasive. Even if at least one of the convex bearing portions 68, 70, guide recess 72, and central ridge 74 of Hershberger's trial femoral component 54 interacts with the distal end of a patient's femur, the Examiner does not identify any disclosure in Hershberger that such interaction provides positional information to a surgeon that is then used to shape the distal end of the femur.

Moreover, claim 2 requires “adjusting the trial femoral component to modify a position of the at least one positioning feature relative to the distal end of the femur,” “sensing the position of the at least one positioning feature,” and “communicating position information corresponding to the sensed position to a robotic surgery system.” Appeal Br. 23 (Claims App.). Regarding the Examiner’s position that, in Hershberger, the position of the at least one positioning feature is adjusted and “inherently sensed” by the surgeon, the passages in Hershberger cited to support these findings do not describe adjusting the trial femoral component, in particular. To the contrary, Appellant contends, Hershberger’s device is not adjustable relative to the distal end of the femur. Appeal Br. 13. Rather, Appellant contends, Hershberger discloses anatomical adjustments. *Id.* We agree with Appellant that the Examiner has not established by a preponderance of the evidence that, in the cited portions of Hershberger, the position of convex bearing portions 68, 70, guide recess 72, or central ridge 74 of trial femoral component 54 is modified after attaching trial femoral component 54 to a distal end of a femur, that the modified position is inherently (i.e., necessarily) sensed by a surgeon, or that a surgeon uses such “sensed” position information to shape the distal end of the femur.

Appellant also contests the Examiner’s position on AAPA. First, Appellant points out that paragraph 67 is not in the Background section of the Specification and cannot be considered prior art *per se*, and furthermore, nothing in this paragraph is admitted as being prior art. Appeal Br. 10. Rather, Appellant contends, sending positional information from an adjustable femoral trial component to a robotic system to adjust resections subsequently made by the robotic system is new, even assuming that using a

robotic system in a total or partial knee replacement procedure is old and well known. *Id.* at 10–11.

Second, Appellant contends that paragraph 11 of the Specification merely describes robotic surgical systems as one proposed alternative to the cutting block technique. Appeal Br. 11. Appellant points out that paragraph 11 does indicate whether the robotic surgical system is better than other techniques and subsequent paragraph 12 discusses potential problems with robotic surgical systems. *Id.* Appellant contends that, from this disclosure, one of ordinary skill would not have been motivated to make the Examiner’s proposed modifications to Hershberger. *Id.*

Paragraph 11, which is included in the Background of the Invention section of the Specification, describes “the use of robotic surgical systems for making distal femoral bone cuts” as a proposed alternative to the cutting block technique for making bone cuts on a femur, and explains:

With robotic surgery and surgical navigation, a surgical saw blade or bur is still used, but the bone cuts are positioned as a result of fiducial-based or shape-based registration of the patient’s anatomy. In fiducial-based approaches, fiducials, or markers are attached to pertinent anatomical structures prior to imaging. During surgery, the markers are exposed, and a sensor system conveys their location to the computer.

Spec. ¶ 11.

Claim 2 recites that “the trial femoral component *includ[es]* at least one positioning feature to provide position information for an implant.” Appeal Br. 23 (Claims App.) (emphasis added). Claim 8 depends from claim 2 and recites that “the at least one positioning feature includes at least one of . . . a fiducial . . . .” *Id.* at 24. Accordingly, claim 2 encompasses the trial femoral component including at least one fiducial. Paragraph 11 of the

Specification does not appear to describe that sending positional information *from an adjustable femoral trial component to a robotic system* to shape the distal end of the femur is known. Rather, paragraph 11 describes attaching fiducials to “pertinent anatomical structures” and conveying the sensed locations of the markers to a computer. Paragraph 11 does not appear to describe attaching fiducials to a femoral component that is attached to an anatomical structure. Accordingly, this paragraph does not describe communicating positional information corresponding to the sensed position of at least one positioning feature *of a trial femoral component* to a robotic surgical system, as required by claim 2.

The Examiner explains that paragraph 67 of Appellant’s Specification is relied on “to show that there is a lack of disclosed criticality for providing positional information to the claimed robotic system versus a surgeon.”

Ans. 4. However, paragraph 67 is not part of the background of the invention, and furthermore, does not describe or suggest that including at least one positioning feature on an adjustable femoral member to provide position information to a robotic surgery system is prior art. Accordingly, the Examiner’s reliance on paragraphs 11 and 67 does not cure the deficiencies of Hershberger.

We are persuaded by Appellant’s contentions that the Examiner has not established with sufficient evidence that the proposed combination of Hershberger and AAPA discloses or suggests all limitations recited in claim 2, or articulated an adequate reason why one of ordinary skill in the art would have modified the applied combination to result in the claimed method. Thus, we do not sustain the rejection of claim 2, or dependent claims 3–9, as unpatentable over Hershberger and AAPA.

*Claims 14–19*

Claim 14 recites a method for conducting a surgical procedure on a knee joint, comprising, *inter alia*, “coupling a trial femoral component to a distal end of a femur, the trial femoral component *including a plurality of positioning features*,” “adjusting the trial femoral component to modify *an orientation of the plurality of positioning features* relative to the distal end of the femur,” “sensing *the orientation of the plurality of positioning features* to obtain position information for the trial femoral component relative to the distal end of the femur,” and “shaping the distal end of the femur with the robotic surgery system in response to the position information.” Appeal Br. 25 (Claims App.) (emphasis added).

The Examiner’s findings and reasoning in rejecting claim 14 are similar to those for claim 2 discussed above. Final Act. 4–5. For reasons similar to those for claim 2, we do not sustain the rejection of claim 14, or dependent claims 15–19, as unpatentable over Hershberger and AAPA.

*Claims 22 and 23*

Claim 22 recites a method for conducting a surgical procedure on a knee joint, comprising, *inter alia*, “sensing at least one position *of at least one fiducial incorporated into the trial femoral component*,” “communicating position information corresponding to *the at least one position* to a robotic surgery system,” and “shaping the distal end of the femur with the robotic surgery system *in response to the position information*.” Appeal Br. 26–27 (Claims App.) (emphasis added).

The Examiner’s findings and reasoning as to these limitations of claim 22 are similar to those for similar limitations in claims 2 and 14 discussed above. Final Act. 5–6. Accordingly, we do not sustain the rejection of

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claim 22, or dependent claim 23, as unpatentable over Hershberger and AAPA.

CONCLUSION

In summary:

<b>Claims Rejected</b>	<b>Basis</b>	<b>Affirmed</b>	<b>Reversed</b>
2-9, 14-19, 22, 23	§ 103(a) Hershberger, AAPA		2-9, 14-19, 22, 23

REVERSED