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EXAMINER

COLEY, ZADE JAMES

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte NICHOLAS J. KATRANA, NATHAN A. WINSLOW,
and JOHN M. MCDANIEL

Appeal 2014-005802
Application 13/089,595
Technology Center 3700

Before LINDA E. HORNER, ERIC C. JESCHKE, and
PAUL J. KORNICZKY, *Administrative Patent Judges*.

HORNER, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Nicholas J. Katrana et al. (Appellants) seek our review under 35 U.S.C. § 134 of the Examiner's decision, as set forth in the Final Action, dated July 17, 2013, ("Final Act."), rejecting claims 1–25 and 30–33.¹

Claims 26–29 are canceled. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

¹ Appellants identify the real party in interest as Biomet Manufacturing, LLC. Appeal Br. 3.

CLAIMED SUBJECT MATTER

Appellants' claimed subject matter relates to "patient-specific instruments for reducing fractures and facilitating internal fixation." Spec., para. 1. Claims 1, 16, and 30 are the independent claims on appeal. Claim 1 is reproduced below.

1. An instrument for internal bone fracture fixation comprising:

a first elongated shaft having a first distal portion; and

a first patient-specific bone holder coupled to the first distal portion, the first bone holder having a three-dimensional curved and patient-specific bone engagement surface designed during a preoperative plan based on a medical scan of a patient and configured to match as an inverse surface to an outer surface of a first bone fragment of a fractured bone of the patient.

EVIDENCE

The Examiner relied upon the following evidence:

Gundlapalli	US 5,697,933	Dec. 16, 1997
Robie	US 6,159,217	Dec. 12, 2000
Schoenefeld	US 2008/0114370 A1	May 15, 2008
Abou El Kheir	US 2008/0287926 A1	Nov. 20, 2008
Turner	WO 2009/001109 A1	Dec. 31, 2008

REJECTIONS

The Final Action included the following rejections:

1. Claims 1–7, 9–11, 13–17, 19, 20, 22–25, and 30 under 35 U.S.C. § 102(b) as anticipated by Turner.²

² The Examiner's statement of the ground of rejection in the Final Action includes claim 21; however, the detailed explanation that follows contains

2. Claims 8, 32, and 33 under 35 U.S.C. § 103(a) as unpatentable over Turner and Schoenefeld.
3. Claims 12 and 18 under 35 U.S.C. § 103(a) as unpatentable over Turner and Gundlapalli.
4. Claim 21 under 35 U.S.C. § 103(a) as unpatentable over Turner and Robie.
5. Claim 31 under 35 U.S.C. § 103(a) as unpatentable over Turner and Abou El Kheir.

ANALYSIS

First Ground of Rejection

Each of independent claims 1, 16, and 30 calls for a patient-specific bone holder having “a three-dimensional curved and patient-specific bone engagement surface designed during a preoperative plan based on a medical scan of a patient and configured to match as an inverse surface to an outer surface of a first bone fragment of a fractured bone of the patient.” Appeal Br. 22, 25, and 27 (Claims App.). The Examiner found that Turner discloses an instrument capable of being used for internal bone fracture fixation having a patient-specific bone holder 12 with a three-dimensional curved and patient-specific bone engagement surface. Final Act. 2, 4, and 5 (citing Turner, Figs. 1, 3). The Examiner construed “designed during a preoperative plan based on a medical scan of a patient” as a product-by-

no discussion of claim 21. Final Act. 2–6. As such, we understand the inclusion of claim 21 in the first ground of rejection to be a typographical error by the Examiner.

process limitation and found that the bone engagement surface of Turner is “capable of being designed [as claimed].” *Id.* at 2, 4, and 5–6. The Examiner further found that the bone holder of Turner is “capable of matching as an inverse surface to an outer surface of a first bone fragment of a fractured bone of the patient.” *Id.* at 2–3, 4, and 6 (citing Turner, Figs. 1, 3, 8a, 9, and 14) (finding that this limitation “depends on how the fractured bone is shaped” and “bones can come in a very wide variety of shapes and sizes”); *see also* Ans. 2 (finding that “Turner clearly designs the device to match the bone of a specific patient” and that “[t]he clamping jaws have a concave surface that matches an inverse surface (i.e.,] a convex surface) of a bone”) (citing Turner, para. 104, Figs. 8–10, and 13).³

Appellants contend that the Examiner erred because “Turner’s instrument has jaws 12, 13 for clamping an intact femoral neck 54” and that, “[a]s can be clearly seen in FIG. 12 of Turner, the jaws are not patient-specific, i.e., the jaws are not custom made for a specific patient and do not have a patient-specific bone engagement surface configured to match as an inverse surface to an outer surface of a first bone fragment of a fractured bone of the patient.” Appeal Br. 10, 11. Appellants contend that “[m]atching the surface as an inverse is not a matter of just matching size and overall shape but also matching the peculiarities of the bone surface of a

³ The Examiner cited to the paragraph numbers found in the pre-grant publication of the U.S. counterpart application to Turner (US 2011/0257657 A1, published October 20, 2011). We cite to the U.S. publication in this Decision for consistency with the record.

specific patient, such as idiosyncratic protrusions, dimples, osteophytes and the like.” *Id.* at 11.

With regard to examination of product-by-process claim limitations, the Manual of Patent Examining Procedure (MPEP) provides:

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product.” MPEP § 2113(I) (citing *In re Garner*, 412 F.2d 276, 279 (CCPA 1979)); *see also* MPEP § 2113(II) (describing that the examiner must “provide a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process”).

Appellants’ Specification describes that “[t]he patient-specific instrument components have an engagement surface that is made to conformingly contact and match a three-dimensional image/model of the patient’s bone surface (with or without cartilage or other soft tissue), by the computer-assisted image methods.” *Spec.*, para. 22; *see also id.* at para. 40 (describing that the bone-engaging surface is designed to “closely match, as mirror or inverse image, the outer surfaces of the corresponding bone fragments and/or bone portions”). We understand the “patient-specific bone engagement surface” to be defined in the claims by the process step used to make it, e.g., it is “designed during a preoperative plan based on a medical scan of the patient.” This surface is further defined in the claims by the resulting structure of the design process, which provides an engagement

surface that is “configured to match as an inverse surface to an outer surface of a first bone fragment of a fractured bone of the patient.” As such, the structure implied by the process step and explicitly recited in the claims is a bone engagement surface that is made to conformingly contact and match a three-dimensional outer surface of the patient’s bone fragment.

Turner does not disclose the claimed “patient-specific bone engagement surface.” Turner is directed to “devices for aligning guide wires with respect to bones.” Turner, para. 1. Turner’s device 1 is in the form of a scissor clamp 2 with two arms 3, 4, each arm having a jaw 12, 13 disposed at its distal end for attaching the device to a bone. Turner, para. 77, Fig. 1. In use, the jaws 12, 13 are attached to the neck of the femur, for example, which results in an alignment guide being naturally aligned with a center point of the neck of the femur for placement of the guidewire. Turner, para. 89, Fig. 11. Figure 12 of Turner is reproduced below:

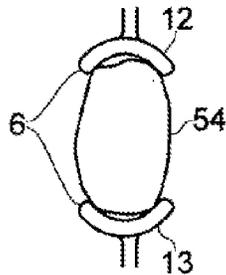


FIG. 12

“FIG. 12 shows a cross-section through the neck (54) of a femur (53), with the jaws (12, 13) of the device attached to the neck (54) in an opposed position.” Turner, para. 90 (emphasis omitted). As can be seen in Figure 12, the inner surface of each jaw 12, 13 that comes in contact with the femur

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is not configured to match as an inverse surface to an outer surface of the femur. As such, Turner does not disclose a “patient-specific bone engagement surface designed during a preoperative plan based on a medical scan of a patient and configured to match as an inverse surface to an outer surface of a first bone fragment of a fractured bone of the patient” as called for in claims 1, 16, and 30. For these reasons, we do not sustain the rejection of independent claims 1, 16, and 30, and their dependent claims 2–7, 9–11, 13–15, 17, 19, 20, and 22–25 under 35 U.S.C. § 102(b) as anticipated by Turner.

Second through Fifth Grounds of Rejection

The remaining grounds of rejection are based on the same finding as to Turner’s disclosure that we found deficient in the first ground of rejection. Final Act. 6–9. Thus, we likewise do not sustain the remaining grounds of rejection under 35 U.S.C. § 103(a): of claims 8, 32, and 33 as unpatentable over Turner and Schoenefeld, of claims 12 and 18 as unpatentable over Turner and Gundlapalli, of claim 21 as unpatentable over Turner and Robie, and of claim 31 as unpatentable over Turner and Abou El Kheir.

DECISION

The decision of the Examiner to reject claims 1–25 and 30–33 is REVERSED.

REVERSED