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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* BRUCE M. FRANKEL and MARK EVALD SEMLER

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Appeal 2019-004638  
Application 13/957,190  
Technology Center 3700

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Before MICHAEL J. FITZPATRICK, LISA M. GUIJT, and  
LEE L. STEPINA, *Administrative Patent Judges*.

GUIJT, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellant<sup>1</sup> seeks our review under 35 U.S.C. § 134(a) of the rejection of claims 1–12, 23, and 33–37. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM IN PART.

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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. Appellant identifies MUSC Foundation for Research Development as the real party in interest. Appeal Br. 3.

## THE INVENTION

Appellant's invention relates to "A Skeletal Bone Fixation Mechanism." Spec., Title. Claims 1 and 37 are the independent claims on appeal. Claim 1 is reproduced below as illustrative of the subject matter of the present invention, with paragraph indentations added for clarity and disputed limitations italicized for emphasis.

1. A skeletal fixation apparatus, comprising:

two or more fixation rod receiving "U" shaped bodies that are attached to two or more screws that are adapted to be inserted into vertebral bodies associated with a patient, each screw having a screw axis;

two or more cylindrical tower members that are attached to the two or more bodies to control the movement or alignment of the two or more bodies when the skeleton fixation apparatus is being installed in the patient, each tower member having a tower axis; and

a fixation rod

manufactured with a plurality of curvatures extending along a length of the fixation rod,

said fixation rod of sufficient strength or rigidity to stabilize the patient's spine extending between adjacent screws of the two or more screws,

said fixation rod being manufactured having a first bend radius or arc corresponding to a predetermined medical curvature extending along the length of the fixation rod and two or more second bend radii or arcs, each second bend radius or arc defining a local curvature,

*each local curvature* having an attachment segment with a generally straight portion *having a local axis that is parallel to each other local axis* and approximately perpendicular with each respective screw axis,

the first bend radius or arc being different than the two or more second bend radii or arcs,

the fixation rod with the predetermined medical curvature being selected based on a medical diagnosis

associated with stabilizing the two or more vertebral bodies,  
the local curvatures being at two or more locations on the fixation rod while preserving the medical curvature in relation to the two or more cylindrical tower members, the local curvature overlaying the medical curvature, and the local curvature configured to immovably fasten the two or more bodies to the fixation rod and configured to preclude the two or more cylindrical tower members from contacting each other when the skeletal fixation apparatus is installed in the patient, and wherein when the body is immovably attached to the fixation rod, the screw axis associated with the body aligns with the tower axis associated with the tower to which the body is attached, such that the approximate alignment of each local axis causes the two or more cylindrical tower members to be approximately parallel.

### THE REJECTIONS

The Examiner relies upon the following as evidence in support of the rejections:

NAME	REFERENCE	DATE
Prevost	US 2011/0106179 A1	May 5, 2011
Peukert	US 2011/0196426 A1	Aug. 11, 2011

The following rejections are before us for review:

- I. Claims 33, 35, and 36 stand rejected under 35 U.S.C. § 112(d) for being in an improper dependent form.
- II. Claims 1–12, 23, 33, 34, and 37 stand rejected under 35 U.S.C. § 102(a)(1) as anticipated by Peukert.
- III. Claims 35 and 36 stand rejected under 35 U.S.C. § 103 as unpatentable over Peukert and Prevost.

OPINION

*Rejection I*

The Examiner correctly finds that claims 33, 35, and 36 depend from cancelled claim 30, and therefore, are in improper dependent form. Final Act. 3. Appellant acknowledges the necessity of amending the claims to overcome the Examiner’s rejection. Appeal Br. 10. For purposes of Rejection II, we consider claims 33, 35, and 36 to depend from independent claim 1.

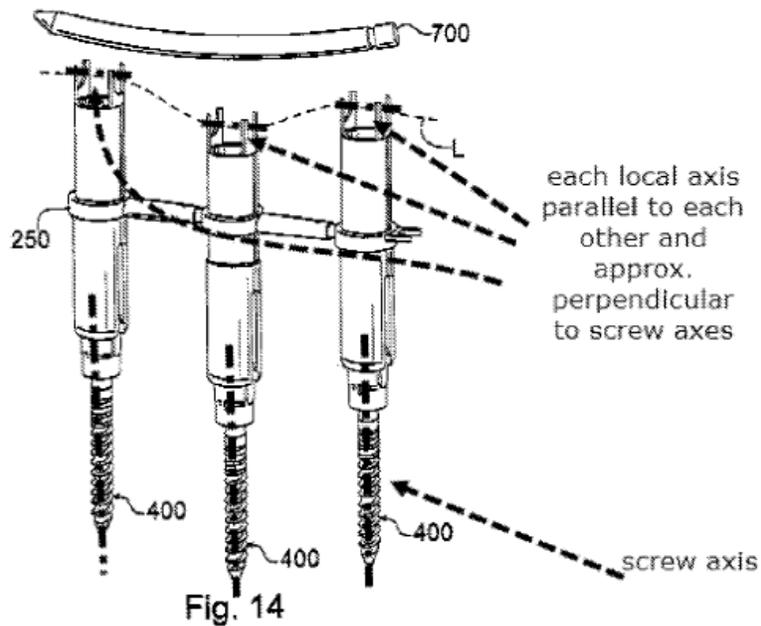
Accordingly, we sustain the Examiner’s rejection of claims 33, 35, and 36 under 35 U.S.C. § 112(d).

*Rejection II*

*Independent claim 1 and dependent claims 2–12, 23, 33, and 34*

Regarding independent claim 1, the Examiner finds that Peukert discloses, *inter alia*, a skeletal fixation apparatus comprising fixation rod receiving “U” shaped bodies (i.e., rod receivers 420), each attached to a screw (i.e., polyaxial bone screws 410), and also cylindrical tower members (i.e., extension tubes 210) attached to the bodies. Final Act. 4 (citing, *e.g.*, Peukert ¶¶ 51, 52, Figs. 2, 4, 14). The Examiner also finds that Peukert discloses a fixation rod 600 made with a plurality of curvatures along its length, including: (i) a first bend radius corresponding to a predetermined medical curvature extending along its length (i.e., “dotted line L” as depicted in Figure 14); and (ii) two or more second bend radii each defining a local curvature having an attachment segment with a generally straight portion and a local axis parallel to each other local axis and approximately perpendicular with each respective screw axis (i.e., Figure 14 “shows three

channel markers rendering three local curvatures in the rod”), as claimed. *Id.* at 5 (citing Peukert, *e.g.*, ¶ 67, Fig. 14); *see also* Ans. 3 (“Fig. 14 of Peukert coupled with the disclosure of [Peurkert’s paragraph 67] and the concept that the tube connectors are maintained parallel to one another as described in [Peurkert’s paragraph 31] reasonably teaches all the limitations of claim 1 to one of ordinary skill in the art”). The Examiner provides an annotated Figure 14 of Peukert, reproduced below. Final Act. 8.



The Examiner’s annotated Figure 14 of Peukert is “a perspective view of a series of pedicle screws with extension tubes and other components . . . , the pedicle screws shown with a contoured guide member,” wherein the Examiner has identified local axis as being parallel to each other and approximately perpendicular to screw axes. Peukert ¶ 21; Final Act. 8.

Appellant argues, *inter alia*, that “[r]egardless of what shape the hypothetical path “L” has, persons having skill in the art would understand that a curved rod following a path can take on any number of different shapes,” and that “[t]he guide member 700 of Peukert merely has to pass

through each of the channel markers of the pedical screw assemblies 400.”

Appeal Br. 13. Appellant submits that “Peukert merely states that a ‘fixation rod may be bent and shaped to *follow a curved path* defined by channel markers,’ however, “[n]owhere does Peukert provide a guide member 700 that has the exact curvature of path ‘L,’ or a guide member 700 [having a general curvature with discrete attachment segments that have a longitudinal axis that does not align with the general curvature,]” as claimed. *Id.*

Appellant submits, therefore, that Peukert fails to disclose a fixation rod with local curvatures having an attachment segment with a generally straight portion, as claimed, let alone straight portions with local axes parallel to one another. *Id.*; *see also* Reply Br. 2 (“dashed line ‘L’ does not possess any straight segments, and the actual depiction of the guide member 700 only has a single *global* curvature while the dashed line ‘L’ has at least three roughly defined undulations.”); *id.* at 3 (“persons having skill in the art understand that there are infinite paths between two points”).

To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either expressly or inherently. *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1341 (Fed. Cir. 2016).

Peukert discloses that “tube connectors . . . secure the extension tubes in a fixed relationship in which the tubes are maintained parallel to one another,” such that “the proximal ends of the tubes represent the relative positions of the corresponding implant because the extension tubes have the same length,” and wherein “[t]he proximal ends of the parallel tubes can incorporate templates, which represent the rod receiving channels of each corresponding implant from which the tube extends,” for example, “the templates are in the form of U-shaped notches at the proximal ends of the

extension tubes.” Peukert ¶ 31; *see also id.* ¶ 51 (“[r]od receiver 420 is generally cylindrical, but interrupted at two sections, forming diametrically opposed U-shaped channels 26,” which collectively form a transverse conduit through rod receiver 420 to receive a section of a spinal fixation rod”). Peukert also discloses that

[c]hannel markers provide a visual representations of the rod receiving channels on spinal implants. When channel markers are used together on a series of extension tubes, the channel markers provide a visual outline of how the rod needs to be shaped in order to pass through each implant. *In many cases the spinal implants and their rod receiving components are not arranged in a straight line, but instead follow a curved path, such as the curved path shown by the dashed line “L” in FIG. 14.* Because the channel markers indicate the relative positions of the rod receiving channels on the spinal implants, the channel markers form a template that can be used to shape a fixation rod prior to insertion. *The fixation rod may be bent and shaped to follow a curved path defined by channel markers.* During the shaping process, the rod can be set periodically into the channel markers to monitor the shaping and confirm a proper shaping.

*Id.* ¶ 67 (emphasis added).

We find that a preponderance of evidence supports the Examiner’s reliance on Peukert for disclosing a fixation rod with a first bend radius extending along the length of the fixation rod, because—as discussed *supra*—Peukert discloses that rod receiving components may be arranged in a curved path (i.e., dashed line “L”), and that the fixation rod may be bent to follow the curved path, for example, fixation rod 600 may be bent to have a general curvature that mimics the curvature of guide rod 700, as depicted in Figure 14. *Cf.* Spec. ¶ 4 (acknowledging that, with reference to Figure 1, that “[c]onventional fixation rod 120 may include a predetermined bend

radius or arc (hereinafter, a ‘medical curvature’) based on a medical diagnosis”).

However, we are persuaded by Appellant’s argument that Peukert’s Figure 14 fails to disclose a fixation rod with two or more bend radii defining a local curvature, as compared to the first bend radius. In other words, we agree with Appellant that Peukert merely discloses a general curvature with respect to fixation rod 600, as fixation rod 600 is shaped to conform to the shape of guide member 700 (for example, as guide rod 700 is depicted with a general curvature in Figure 14), wherein guide member 700 is shaped to be placed within Peukert’s rod receivers. As argued by Appellant, Peukert teaches that guide member 700 (and therefore, fixation rod 600) is shaped *to pass through* the channel markers, or *to follow a curved path such as shown by dashed line L*, but does not disclose that guide member 700 (and therefore, fixation rod 600) is shaped specifically into dashed line “L” as drawn in Figure 14.

Notably, although Peukert discloses, with respect to *conventional* rod insertion systems, that rod receiving channels are known to form “a complex serpentine or other non-linear path to which the rod must conform,” Peukert does not disclose how Peukert’s rod insertion system, which relies on threading a guide rod through consecutive rod receiving channels, may be executed when rod 600 has a serpentine shape, as opposed to having a general curvature.<sup>2</sup> Peukert ¶ 28. In sum, Peukert’s disclosure of offset U-

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<sup>2</sup> See Reply Br. 5 (arguing that “a rod with multiple local curvatures would be physically impossible to navigate in [Peukert’s] minimally invasive procedure,” wherein “tandem movements of the rod and guide member are limited to two dimensions making it impossible to thread through multiple curvatures through multiple parallel points”).

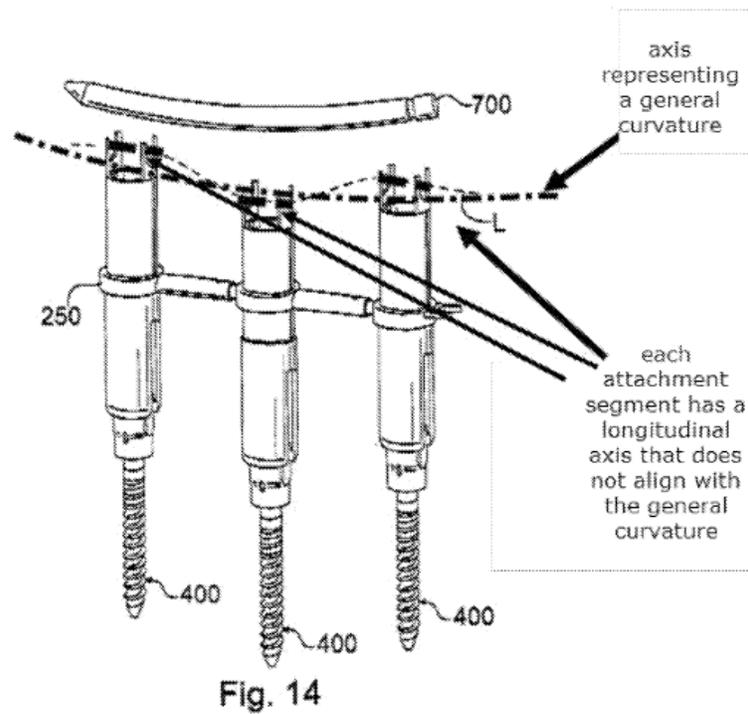
shaped channels of rod receivers and also of bending a fixation rod to follow a curved path defined by the rod receivers does not support, by a preponderance of the evidence, a finding that Peukert's *fixation rod* is bent into a shape having local curvatures as claimed, rather than being bent merely into a generally curved shape suitable for receipt in a path defined by rod receiving channels.

Further, although Peukert depicts *straight* transverse conduits between each of the U-shaped channels of the rod guidance assemblies 200 of extensions tubes 210, Peukert does not disclose that fixation rod 600 is shaped to exhibit straight segments in the portions of fixation rod 600 that pass through such conduits, as required by claim 1.

Accordingly, we cannot sustain the Examiner's rejection of independent claim 1, and claims 2–12, 23, 33, and 34 depending therefrom.

*Independent claim 37*

Independent claim 37 recites, in relevant part, “a fixation rod having a length, a general curvature along the entire length, and a plurality of segments along the length and within the general curvature, wherein the attachment segments each have a longitudinal axis that does not align with the general curvature.” Appeal Br. 27 (Claims App.). The Examiner relies on Peukert for disclosing fixation rod 600, as claimed. Final Act. 15 (citing Peukert ¶ 77, Fig. 14). The Examiner refers to the annotated Figure 14 of Peukert, reproduced below. *Id.* at 16.



Appellant argues that Peukert “fails to describe, implicitly or explicitly, that guide member 700 has a length, a general curvature along the entire length, and a plurality of attachment segments along its length, wherein the attachment segments each have a longitudinal axis that does not align with the general curvature.” Appeal Br. 17.

Similar to the rejection of claim 1, we agree with Appellant that a preponderance of the evidence fails to support the Examiner’s finding that Peukert’s fixation rod 600 is disclosed to have attachment segments having a curvature that is different from the general curvature of the rod, as required by claim 37.

Accordingly, we also do not sustain the Examiner’s rejection of independent claim 37.

*Rejection III*

The Examiner's reliance on Previst for disclosing changing the rod's cross-section does not cure the deficiencies in the Examiner's rejection of independent claims 1 and 37 *supra*. Final Act. 18.

Accordingly, for the reasons set forth *supra*, we also do not sustain the Examiner's rejection of dependent claims 35 and 36.

CONCLUSION

In summary:

<b>Claims Rejected</b>	<b>35 U.S.C. §</b>	<b>Reference(s)</b>	<b>Affirmed</b>	<b>Reversed</b>
33, 35, 36	112(d)		33, 35, 36	
1-12, 23, 33, 34, 37	102(a)(1)			1-12, 23, 33, 34, 37
35, 36	103			35, 36
<b>Overall Outcome</b>			33, 35, 36	1-12, 23, 34, 37

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 IN PART