UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ORTHOPEDIATRICS CORP., Petitioner,

v.

K2M, INC., Patent Owner.

Case IPR2018-00429 Patent 9,532,816 B2

Before LYNNE H. BROWNE, MICHAEL L. WOODS, and ROBERT L. KINDER, *Administrative Patent Judges*.

BROWNE, Administrative Patent Judge.

DOCKET

FINAL WRITTEN DECISION 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

Orthopediatrics Corp. ("Petitioner"), on January 8, 2018, filed a Petition requesting *inter partes* review of claims 16, 18, 19, 21, and 22 of U.S. Patent No. 9,532,816 B2 ("the '816 patent"). Paper 1 ("Pet."). We issued a Decision to Institute an *inter partes* review (Paper 8, "Dec.") of all challenged claims (16, 18, 19, 21, and 22) under all grounds, namely Grounds 1–4 discussed below.

After institution of trial, K2M, Inc. ("Patent Owner") filed a Patent Owner Response (Paper 24, "PO Resp."), to which Petitioner replied (Paper 30, "Pet. Reply"), and a Sur-Reply (Paper 35, "PO Sur-Reply).

Oral argument was concurrently conducted on February 21, 2019, for this and related proceeding IPR2018-00521, and the transcript of the hearing has been entered as Paper 41.

We have jurisdiction under 35 U.S.C. § 318(a). After considering the evidence and arguments of both parties, and for the reasons set forth below, we determine that Petitioner has not met its burden of showing, by a preponderance of the evidence, that any of claims 16, 18, 19, 21, and 22 are unpatentable.

II. BACKGROUND

A. Related Proceedings

Petitioner is a defendant in a lawsuit involving the '816 patent. Pet. 1 (referencing *K2M*, *Inc. v. OrthoPediatrics Corp. & OrthoPediatrics US Distribution Corp.*, Case No. 1:17-cv-00061-GMS (D. Del.)).

On the same day that the Petition in the instant proceeding was filed, Petitioner filed a second petition requesting *inter partes* review also challenging claims 16, 18, 19, 21, and 22 of the '816 patent. IPR201800521. Subsequently, Petitioner filed three petitions challenging claims 1, 3, 5, 6, 8–10, 12, and 15–19 of U.S. Patent No. 9,655,664 B2, which is a divisional of the '816 patent. IPR2018-01546, 1547, 1548.

B. The '816 Patent

The '816 patent is directed "to devices for stabilizing and fixing the bones and joints of the body. Particularly, the present invention relates to a manually operated device capable of reducing a rod into position in a rod receiving notch in the head of a bone screw with a controlled, measured action." Ex. 1001, 1:14–19. The device described in the '816 patent achieves this objective by grasping "the head of a bone screw and reduc[ing] a rod into the rod receiving recess of the bone screw using a single manual control that can be activated in a controlled and measured manner." *Id.* at 2:23–27.

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Figure 4 reproduced below illustrates the device:

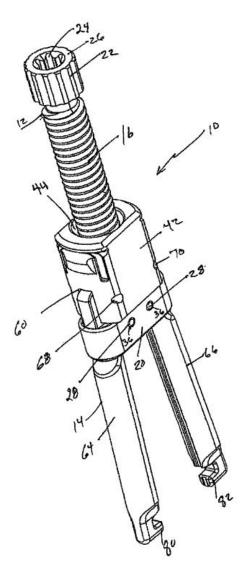




Figure 4 is an isometric view of the rod reducing device with the screw jack mechanism fully retracted and the two elongated grasping members in an open configuration. Ex. 1001, 3:27–30.

The '816 patent states that

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The device . . . is a rod reduction device capable of reducing a rod into position in a rod receiving notch in the head of a bone screw with a controlled, measured action. The device

is an elongated rod reduction device 10 that includes a screw jack mechanism 12 moveably engaged with an elongated grasping fork assembly 14. The screw jack mechanism 12 includes an elongated threaded screw shaft 16 that terminates at its most proximal end with a controlling member 18 and terminates at its most distal end with a rod contact member 20.

Id. at 3:63-4:5.

C. Illustrative Claim

Petitioner challenges claims 16, 18, 19, 21, and 22 of the '816 patent.

Claim 16, reproduced below, is the only challenged independent claim and illustrative of the claims at issue.

16. A rod reducing device comprising:

a housing defining a longitudinal axis, the housing including first and second grasping members configured to grasp a portion of a bone anchor therebetween, the first and second grasping members defining a plane;

a rotatable member extending through the housing along the longitudinal axis; and

a rod contact member positioned at a distal end of the rotatable member, the rod contact member translatable along the longitudinal axis in response to rotation of the rotatable member about the longitudinal axis, wherein the rod contact member and the rotatable member are translatable within the plane defined by the first and second grasping members.

Ex. 1001, 10:22–35.

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