

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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US ENDODONTICS, LLC,  
Petitioner,

v.

GOLD STANDARD INSTRUMENTS, LLC,  
Patent Owner.

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Case PGR2015-00019  
Patent 8,876,991 B2

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Before JOSIAH C. COCKS, HYUN J. JUNG, and  
TIMOTHY J. GOODSON, *Administrative Patent Judges*.

GOODSON, *Administrative Patent Judge*.

FINAL WRITTEN DECISION  
35 U.S.C. § 328(a) and 37 C.F.R. § 42.208

## I. INTRODUCTION

US Endodontics, LLC (“Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting post-grant review of claims 12–16 of U.S. Patent No. 8,876,991 B2 (Ex. 1001, “the ’991 patent”). Gold Standard Instruments, LLC (“Patent Owner”) filed a Preliminary Response (Paper 14, “Prelim. Resp.”) to the Petition. On January 29, 2016, we instituted a post-grant review of claims 12–16 on certain grounds of unpatentability alleged in the Petition. *See* Paper 17 (“Dec. on Inst.”).

After institution of trial, Patent Owner filed a Patent Owner Response (Paper 27, “PO Resp.”), and Petitioner filed a Reply (Paper 31, “Pet. Reply”). In addition, Patent Owner filed Observations on Cross Examination (Paper 37), to which Petitioner filed a Response (Paper 45). Both parties also filed motions to exclude evidence, and the briefing on those motions included oppositions and replies. *See* Papers 36, 40, 43, 44, 46, 47. The parties presented oral argument at a hearing held on October 19, 2016. Paper 53 (“Tr.”).

For the reasons explained below, upon consideration of the evidence and arguments of both parties, we determine that Petitioner has shown by a preponderance of the evidence that claims 12–16 of the ’991 patent are unpatentable. *See* 35 U.S.C. § 326(e).

### A. Related Matters

Petitioner has filed two petitions for *inter partes* review challenging U.S. Patent No. 8,727,773 (“the ’773 patent”), which is related to the ’991 patent. We instituted review on several of the grounds presented in the first petition, and issued a Final Written Decision holding all of the challenged claims unpatentable. *US Endodontics, LLC v. Gold Standard Instruments, LLC*, Case IPR2015-00632 (PTAB Aug. 1, 2016) (Paper 78). We denied

institution on any of the grounds presented in the second petition. *US Endodontics, LLC v. Gold Standard Instruments, LLC*, Case IPR2015-01476 (PTAB Oct. 26, 2015) (Paper 13).

In addition, the '773 patent and U.S. Patent No. 8,562,341, another patent related to the '991 patent, are being asserted against Petitioner in an ongoing lawsuit in the U.S. District Court for the Eastern District of Tennessee, *Dentsply International, Inc. v. US Endodontics, LLC*, Case No. 2:14-cv-00196-JRG-DHI. Pet. 1; Paper 52, 3. The parties list a number of pending patent applications owned by Patent Owner that may be affected by this proceeding. *See* Pet. 1; Paper 52, 3–4.

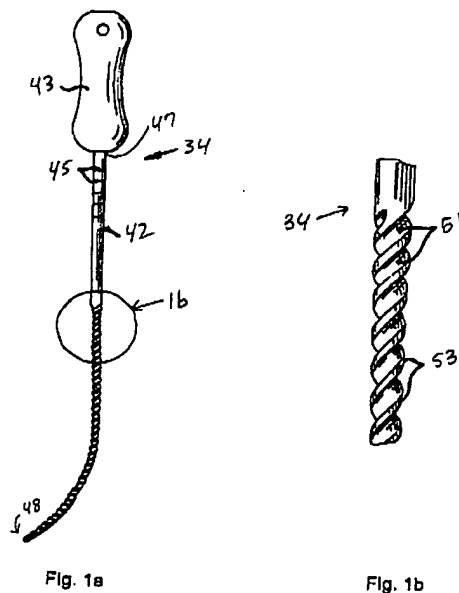
#### *B. The '991 Patent*

The '991 patent is titled “Dental and Medical Instruments Comprising Titanium.” Ex. 1001, Title. The invention is described as serving to “overcome[] the problems encountered when cleaning and enlarging a curved root canal.” *Id.* at 2:59–60. The '991 patent explains that flexibility is a desirable attribute for endodontic files, but that in the prior art, the shank portions of files of larger sizes are relatively inflexible, which impedes the therapy of a root canal. *Id.* at 2:4–26.

The '991 patent also describes that it is known in the art that endodontic files may be formed of “superelastic alloys such as nickel-titanium that can withstand several times more strain than conventional materials without becoming plastically deformed.” *Id.* at 2:43–46. The '991 patent further explains that a property termed “shape memory . . . allows the superelastic alloy to revert back to a straight configuration even after clinical use, testing or fracture (separation).” *Id.* at 2:46–49. According to the '991 patent, there remained a need for endodontic instruments that “have high

flexibility, have high resistance to torsion breakage, maintain shape upon fracture, can withstand increased strain, and can hold sharp cutting edges.”  
*Id.* at 2:50–55.

Figures 1a and 1b, reproduced below, illustrate “a side elevational view of an endodontic instrument” (Fig. 1a), and “a partial detailed view of the shank of the endodontic instrument shown in FIG. 1a” (Fig. 1b). *Id.* at 3:26–29.



The '991 patent describes that the “endodontic instrument . . . shown in FIG. 1a . . . includes an elongate shank 42 mounted at its proximate end 47 to a handle 43.” *Id.* at 4:5–8. The '991 patent also explains that fabricating a medical instrument in accordance with the invention involves selecting a superelastic titanium alloy for the shank and subjecting the instrument to “heat-treatment” so as to “relieve stress in the instrument to allow it to withstand more torque, rotate through a larger angle of deflection, change the handling properties, or visually exhibit a near failure of the instrument.” *Id.* at 6:2–5.

*C. Illustrative Claim*

Claim 12, reproduced below, is the only independent claim among the challenged claims:

12. A method for manufacturing or modifying an endodontic instrument for use in performing root canal therapy on a tooth, the method comprising:

(a) providing an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank, the shank comprising a superelastic nickel titanium alloy, and

(b) after step (a), heat-treating the entire shank at a temperature above 25° C. up to but not equal to the melting point of the superelastic nickel titanium alloy,

wherein the heat treated shank has an angle greater than 10 degrees of permanent deformation after torque at 45 degrees of flexion when tested in accordance with ISO Standard 3630-1.

*D. Instituted Grounds of Unpatentability*

We instituted trial as to claims 12–16 of the '991 on the following grounds:

1. Whether claims 12–16 are unpatentable under 35 U.S.C. § 112(a) for lack of enablement;
2. Whether claims 12–16 are unpatentable under 35 U.S.C. § 112(a) for lack of written description;
3. Whether claims 12–16 are unpatentable under 35 U.S.C. § 102 as being anticipated by Luebke 2008;<sup>1</sup>

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<sup>1</sup> U.S. Patent App. Pub. No. 2008/0032260 A1, published Feb. 7, 2008 (Ex. 1022).

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