

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

US ENDODONTICS, LLC,
Petitioner,

v.

GOLD STANDARD INSTRUMENTS, LLC,
Patent Owner.

Case PGR2015-00019
Patent 8,876,991 B2

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

GOODSON, *Administrative Patent Judge*.

DECISION
Institution of Post-Grant Review
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 (“the ’991 patent”). Gold Standard Instruments, LLC (“Patent Owner”) filed a Preliminary Response (Paper 14, “Prelim. Resp.”) to the Petition.

We have jurisdiction under 35 U.S.C. § 324(a), which provides that a post-grant review may be instituted only if “the information presented in the petition . . . demonstrate[s] that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable.” For the reasons explained below, upon consideration of the Petition and the Preliminary Response, we conclude that the information presented in the Petition demonstrates that it is more likely than not that at least one of the challenged claims is unpatentable. Accordingly, we authorize a post-grant review to be instituted as to claims 12–16 of the ’991 patent.

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. *US Endodontics, LLC v. Gold Standard Instruments, LLC*, Case IPR2015-00632 (PTAB Aug. 5, 2015) (Paper 29). 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.

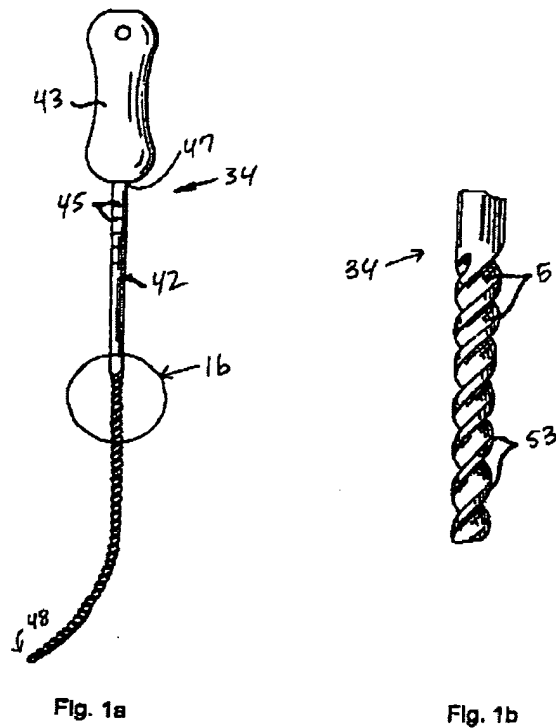
2:14-cv-00196-JRG-DHI. Pet. 1; Paper 13, 3.

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 devices such as “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 remains 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, which are 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 figures above depict an endodontic instrument according to the invention. With respect to those figures, the '991 patent conveys the following:

This embodiment of the invention is an endodontic instrument as shown in FIG. 1a that includes an elongate shank 42 mounted at its proximate end 47 to a handle 43. The shank 42 may be about 30 millimeters long. The proximate end 47 may have a diameter of about 0.5 to about 1.6 millimeters. The shank 42 may include calibrated depth markings 45 and further includes a distal end 48. The shank 42 includes two continuous helical flutes 51 as shown in FIG. 1b that extend along its lower portion. The flutes 51 define a cutting edge. A helical land 53 is positioned between axially adjacent flutes as shown in FIG. 1b.

Id. at 4:5–15.

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 is independent, and is reproduced below:

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. References Relied Upon

The Petition relies on the following references:

Luebke 2008	US 2008/0032260 A1	Feb. 7, 2008	Ex. 1022
Heath	US 5,628,674	May 13, 1997	Ex. 1024
Matsutani	US 2006/0115786 A1	June 1, 2006	Ex. 1025
McSpadden	US 2002/0137008 A1	Sept. 26, 2002	Ex. 1031
Alan R. Pelton et al., <i>Optimisation of Processing and Properties of Medical-Grade Nitinol Wire</i> , 9 MINIMALLY INVASIVE THERAPIES & ALLIED TECHS. 107 (2000) (“Pelton”)			Ex. 1006
International Standard ISO 3630-1, 1 st ed. (1992) (“ISO 3630-1”)			Ex. 1023
Grégoire Kuhn & Laurence Jordan, <i>Fatigue and Mechanical Properties of Nickel-Titanium Endodontic Instruments</i> , 28 J. ENDODONTICS 716 (2002) (“Kuhn”)			Ex. 1030

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