Trials@uspto.gov
571-272-7822

Paper 78
Date: August 1, 2016

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 IPR2015-00632
Patent 8,727,773 B2

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

COCKS, *Administrative Patent Judge.*

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

I. INTRODUCTION

Petitioner, US Endodontics, LLC ("US Endo" or "Petitioner"), filed a Petition (Paper 2, "Pet.") requesting *inter partes* review of claims 1–17 of U.S. Patent 8,727,773 B2 ("the '773 patent"). We issued a Decision to institute an *inter partes* review (Paper 29, "Inst. Dec.") of the '773 patent on the following proposed grounds of unpatentability: (1) claims 1, 2, and 9–12 under 35 U.S.C. §102(b) as anticipated by Kuhn;[1] (2) claims 8, 13, 15, and 17 under 35 U.S.C. §103(a) as obvious over Kuhn and ISO 3630-1;[2] (3) claims 1–17 under 35 U.S.C. §103(a) as obvious over Kuhn, ISO 3630-1, McSpadden,[3] and Pelton;[4] and (4) claims 1–17 under 35 U.S.C. §103(a) as obvious over Matsutani,[5] Pelton, and ISO 3630-1. Inst. Dec. 31–32.

After institution of trial, Patent Owner, Gold Standard Instruments, LLC ("GSI" or "Patent Owner"), filed a Patent Owner's Response (Paper 44, "PO Resp."), to which US Endo replied (Paper 57, "Pet. Reply"). Oral argument was conducted on April 5, 2016. A transcript of that argument has been made of record in this proceeding. Paper 77 ("Tr"). Both parties have filed Motions to Exclude. Papers 62, 63.

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[1] Grégoire Kuhn & Laurence Jordan, *Fatigue and Mechanical Properties of Nickel-Titanium Endodontic Instruments*, 28 J. ENDODONTICS 716 (2002) (Ex. 1019).

[2] International Standard ISO 3630-1, 1st ed. (1992) (Ex. 1016).

[3] US 2002/0137008 A1 issued Sep. 26, 2002 (Ex. 1022).

[4] Alan R. Pelton et al., *Optimisation of Processing and Properties of Medical-Grade Nitinol Wire*, 9 MINIMALLY INVASIVE THERAPIES & ALLIED TECHS. 107 (2000) (Ex. 1006).

[5] US 7,137,815 B2 issued Nov. 21, 2006 (Ex. 1023).

We have jurisdiction under 35 U.S.C. § 318(a). We have considered the evidence and arguments of both parties, and, for the reasons set forth below, we determine that US Endo has met its burden of showing, by a preponderance of the evidence, that claims 1–17 of the '773 patent are unpatentable.

A. The '773 Patent (Ex. 1001)

The '773 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 2:56–57. In that respect, the '773 patent explains that flexibility is a desirable attribute for endodontic devices such as "files," but that, in the prior art, for files of larger sizes, the "shank" portions of the files become "relatively inflexible," which impedes the therapy of a root canal. *Id.* at 2:1–24.

The '773 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 2:39–43.[6] The '773 patent further explains that such "property is termed shape memory, which allows the superelastic alloy to revert back to a straight configuration even after clinical use, testing or fracture (separation)." *Id.* at 2:43–46. Nevertheless, the '773 patent represents that there is a need for endodontic instruments that "have high flexibility, have high resistance to torsion

[6] "Nickel-titanium" is also referenced in this Decision as "Ni-Ti" or "NiTi."

breakage, maintain shape upon fracture, can withstand increased strain, and can hold sharp cutting edges." *Id.* at 2:47–52.

Figures 1a and 1b are reproduced below:

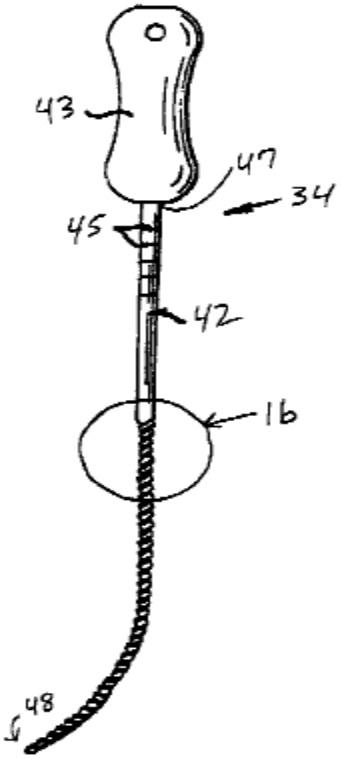

Fig. 1a

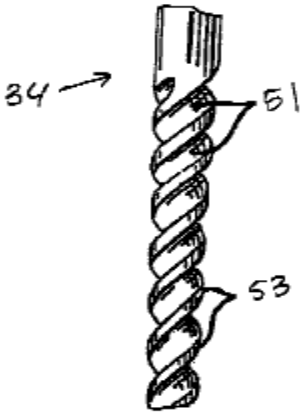

Fig. 1b

Figures 1a and 1b above 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 3:21–24. With respect to those figures, the '773 patent conveys the following:

> This embodiment of the invention is an endodontic instrument as shown in FIG. 1*a* 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

> flutes 51 as shown in FIG. 1*b* 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. 1*b*.

Id. at 4:1–11.

The '773 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 5:64–6:1. Thus, according to the '773 patent, after undergoing such heat treatment, the resulting shank has "high flexibility, high resistance to torsion breakage, maintains shape upon fracture, can withstand increased strain, and can hold sharp cutting edges." *Id.* at 2:65–3:1.

B. Illustrative Claims

Claims 1 and 13 are independent, and are reproduced below:

> 1. 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 from 400° 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.

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