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Paper 13
Date: October 26, 2015

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 IPR2015-01476
Patent 8,727,773 B2

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

COCKS, *Administrative Patent Judge.*

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 325(d) and *37 CFR § 42.108*

I. INTRODUCTION

Petitioner, US Endodontics, LLC ("US Endo" or "Petitioner"), filed a Petition (Paper 1, "Pet.") requesting *inter partes* review of claims 1, 4, 5, 8–10, and 12 of U.S. Patent 8,727,773 B2 ("the '773 patent"). Patent Owner, Gold Standard Instruments, LLC ("GSI" or "Patent Owner"), filed a Preliminary Response (Paper 9, "Prelim. Resp.") requesting that *inter partes* review of the above-noted claims not be instituted. We have jurisdiction under 35 U.S.C. § 314 and 37 C.F.R. § 42.4(a).

A. Related Matters

The '773 patent is stated to be the subject of a lawsuit styled *Dentsply International, Inc. and Tulsa Dental Products LLC d/b/a Tulsa Dental Specialties v. US Endodontics, LLC*, Case No. 2:14-cv-00196-JRG-DHI (E.D. Tenn.). Pet. 1, 5; Paper 4, 2[1].

The '773 patent also is the subject of an *inter partes* review trial currently pending before the Board, and involving the same parties, *US Endodontics, LLC v. Gold Standard Instruments, LLC*, Case IPR2015-00632 (or "the '632 IPR"). In that proceeding, we instituted review of claims 1–17 on August 5, 2015 based on the following grounds of unpatentability:

A. Claims 1, 2, and 9–12 are unpatentable under 35 U.S.C. §102(b) as anticipated by Kuhn[2];
B. Claims 8, 13, 15, and 17 are unpatentable under 35 U.S.C. §103(a) over Kuhn and ISO 3630-1[3];

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[1] GSI also identifies four patents (8,562,341; 8,083,873; 8,062,033; and 8,876,991) and four patent applications (14/522,013; 14/722,309; 14/722,390; 14/722,840) as "related matters" to this proceeding. *Id*. at 2–3.

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

[3] International Standard ISO 3630-1, 1st ed. (1992).

C. Claims 1–17 are unpatentable under 35 U.S.C. §103(a) over Kuhn, ISO 3630-1, McSpadden[4], and Pelton[5]; [and]
D. Claims 1–17 are unpatentable under 35 U.S.C. §103(a) over Matsutani[6], Pelton, and ISO 3630-1[.]

IPR2015-00632, Paper 29, 32.

B. 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. 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

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[4] US 2002/0137008 A1 issued September 26, 2002.

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

[6] US 7,713,815 B2 issued November 21, 2006.

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 2:47–52.

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 3:21–24.

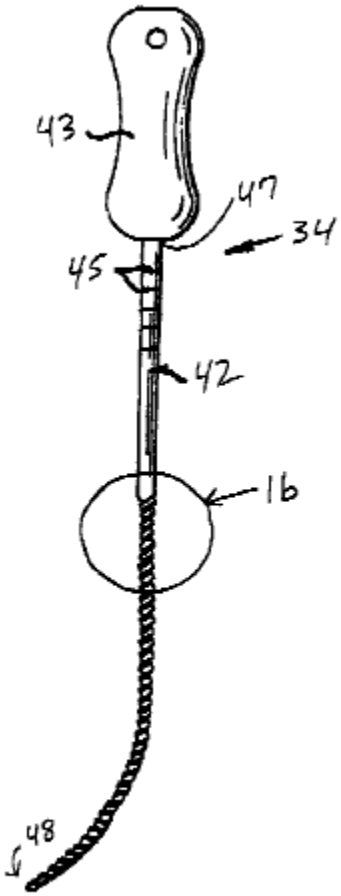

Fig. 1a

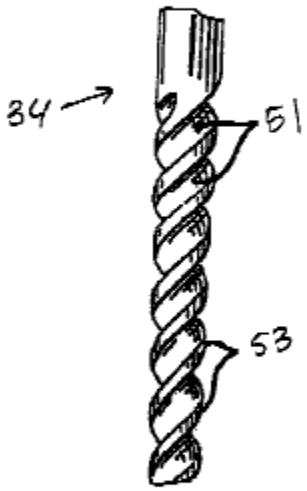

Fig. 1b

The figures above depict an endodontic instrument according to the invention. 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 helical 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.

By way of background, the Petition, through recourse to the declaration testimony of Dr. A. Jon Goldberg (Ex. 1104), and prior art of record (Ex. 1105) provides the following explanation of the effect of heat-treatment on structures made of a superelastic material, such as Nickel-Titanium (“Ni-Ti”):

> The Ni-Ti alloys described and claimed by the ’773 patent were first discovered in the 1960’s, and their use to make endodontic files was first disclosed as early as 1988 by Walia et al. *See* Ex. 1105. When appropriately processed, Ni-Ti can exhibit both superelasticity (also known as pseudoelasticity) and shape memory. Superelasticity means that the material is relatively rigid until a threshold stress is applied to it; above that threshold, the material becomes considerably more flexible. When the stress is removed, the material reverts to its original shape. A shape memory material is flexible and does not revert

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