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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.

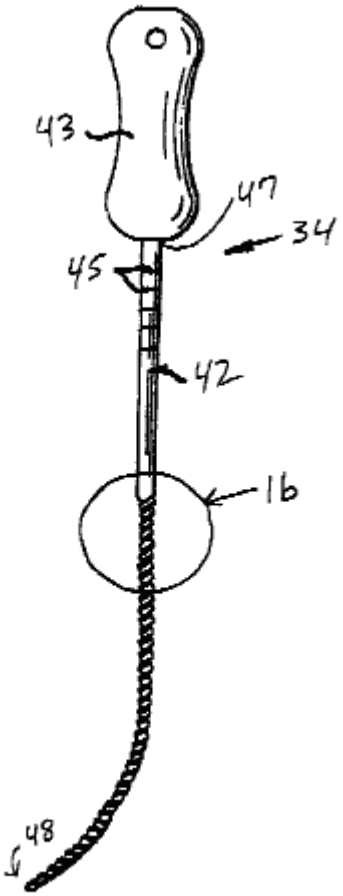

Fig. 1a

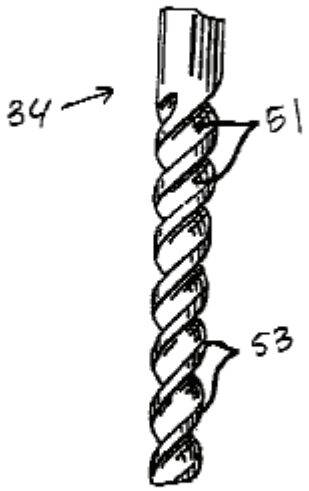

Fig. 1b

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

> to its original shape immediately after it is deformed. However, when it is heated past a transformation temperature (austenite finish temperature, "Af"), it reverts to its pre-deformation shape. In other words, it "remembers" its original shape. Ex. 1104 ¶ 23.

Pet. 7.

C. Illustrative Claim

Claim 1 is independent, and is 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.

D. References Relied Upon

US Endo relies upon the following references:

Kazuhiko Endo et al., *Effects of Titanium Nitride Coatings on Surface and Corrosion Characteristics of Ni-Ti Alloy*, DENTAL MATERIALS JOURNAL 13(2): 228–239 (1994) ("Endo").			Ex. 1108
Teresa Roberta Tripi et al., *Fabrication of Hard Coatings on NiTi Instruments*, JOURNAL OF ENDODONTICS, Vol. 29, No. 2, 132–134 (February 2003) ("Tripi").			Ex. 1010
McSpadden	US 2002/0137008 A1	Sep. 26, 2002	Ex. 1111

International Standard ISO 3630-1, 1st ed. (1992) ("ISO 3630-1") Ex. 1113

E. The Proposed Grounds of Unpatentability

US Endo contends that claims 1, 4, 5, 8–10, and 12 of the '773 patent are unpatentable under 35 U.S.C. on the following grounds:

Ground	References	Basis	Claim(s) challenged
1	Endo, Tripi, and McSpadden	§ 103	1, 4, 5, 9, 10, and 12
2	Endo, Tripi, McSpadden, and ISO 3630-1	§ 103	8

II. ANALYSIS

A. Statutory Discretion to Institute

The authority to institute *inter partes* reviews is established by 35 U.S.C. § 314, the relevant portions of which are reproduced below.

> § 314. Institution of inter partes review
>
> (a) Threshold.—The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

As the Board has recognized, in stating that the Director "may not" institute review unless certain circumstances are met, Congress made institution of *inter partes* review discretionary. *See Butamax Advanced Biofuels LLC, v. Geno, Inc.*, IPR2014-00581, slip op. at 6 (PTAB Oct. 14, 2014) (Paper 8); *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, Case IPR2013-00324, slip op. at 4 (PTAB Nov. 21, 2013) (Paper 19). The Director has delegated the decision to institute *inter partes* review to the

Board. *See* 37 C.F.R. § 42.4 ("[t]he Board institutes the trial on behalf of the Director.").[7] Thus, the Board, at its discretion, may determine whether to institute an *inter partes* review.

Furthermore, in determining whether to institute an *inter partes* review, "the Board may authorize the review to proceed . . . on all or some of the grounds of unpatentability asserted for each claim." 37 C.F.R. § 42.108. 35 U.S.C. § 325(d) also provides that: "In determining whether to institute or order a proceeding under this chapter, chapter 30, or chapter 31, the Director may take into account whether, and reject the petition or request because the same or substantially the same prior art or arguments previously were presented to the Office."

Accordingly, whether to institute an *inter partes* review is at our discretion, and, in exercising that discretion, we may take into account whether "the same or substantially the same prior art or arguments" have been presented previously to the Board.

B. Discussion

As discussed above, this proceeding, IPR2015-01476, involves the same patent (i.e., the '773 patent) and the same parties as IPR2015-00632, in which trial was instituted on August 5, 2015. Furthermore, all of the claims of the '773 patent that US Endo seeks *inter partes* review in connection with IPR2015-01476 (i.e., claims 1, 4, 5, 8–10, and 12) are involved in the '632 IPR. In that respect, trial already is underway in the '632 IPR based on grounds proposed by US Endo to each of claims 1, 4, 5, 8–10, and 12. More particularly, as set forth above, those proposed grounds include: (1) claims

[7] "The term trial includes . . . an *inter partes* review under Chapter 31 of title 35, United States Code." 37 C.F.R. § 42.2.

1, 2, and 9–12 are anticipated by Kuhn; (2) claims 8, 13, 15, and 17 are unpatentable over Kuhn and ISO 3630-1; (3) claims 1–17 are unpatentable over Kuhn, ISO 3630-1, McSpadden, and Pelton; and (4) claims 1–17 are unpatentable under 35 U.S.C. §103(a) over Matsutani, Pelton, and ISO 3630-1.

Here, US Endo proposes two additional grounds of unpatentability that involve two additional references, namely Endo and Tripi.[8] US Endo, however, does not explain why those additional grounds are better than any of the prior art involved in the '632 IPR. In that regard, US Endo does not present Endo and Tripi as constituting prior art that somehow more closely or more effectively accounts for limitations of the pertinent claims of the '773 patent beyond, for instance, any of Kuhn, Pelton, or Matsutani. To that end, US Endo does not explain why the grounds based on Endo and Tripi are not understood reasonably as being based on "substantially the same prior art or arguments" that were presented in the '632 IPR. Indeed, like each of Kuhn, Pelton, and Matustani, Endo and Tripi discuss various types of heat treatment techniques for tools or instruments made of a Ni-Ti shape memory alloy.

US Endo also does not articulate a reason why it could not have offered the proposed grounds based on Endo and Tripi earlier as a part of its Petition in the '632 IPR. To the extent that the grounds are offered in some capacity to respond to arguments made by GSI in its Preliminary Response in the '632 IPR, we observe that generally a petitioner is not permitted to respond to arguments presented by a patent owner in a preliminary response

[8] The proposed grounds also involve McSpadden and ISO 3630-1 which, as noted above, already are of record in the '632 IPR.

until after a trial has been instituted. *See* 77 Fed. Reg. 48702, Response to Comment 54 (Aug. 14, 2012). ("The statutes provide for only a petition and a patent owner preliminary response prior to institution. Allowing a reply as a matter of right would negatively impact the ability of the Office to meet the time requirements of 35 U.S.C. 314(b), as amended, and 35 U.S.C. 324(c).")

On the record before us, we conclude that the two proposed grounds based on Endo and Tripi amount simply to additional, parallel challenges of the claims of the '773 patent, without explanation as to why such challenges are improvements upon grounds for which *inter partes* review already has been instituted. GSI requests that we deny institution on those two grounds because they are "redundant," and so as to "secure a just, speedy, and inexpensive resolution of the proceedings" citing to 37 C.F.R. § 42.1. Prelim. Resp. 33. We exercise our discretion and deny institution of *inter partes* review on any of the grounds proposed by US Endo in connection with IPR2015-01476.

III. CONCLUSION

For the foregoing reasons, we deny institution based on any of the grounds presented in conjunction with US Endo's Petition in IPR2015-01476 pursuant to our authority arising under 35 U.S.C. §§ 314 and 325(d), and 37 C.F.R. §§ 42.4 and 42.108.

IV. ORDER

It is

ORDERED that institution of *inter partes* review is *denied* with respect to all grounds of unpatentability presented in US Endo's Petition in IPR2015-01476.

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