

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.

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)

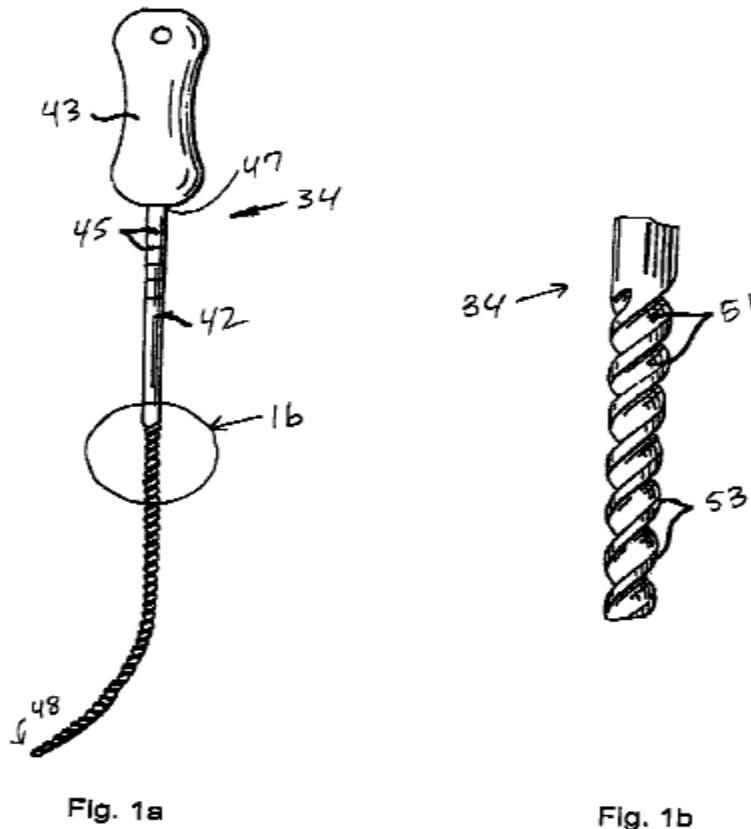
The '773 patent is titled “Dental and Medical Instruments Comprising Titanium.” Ex. 1001, Title. The invention is described as serving to “overcome[] the problems encountered when cleaning and enlarging a curved root canal.” *Id.* at 2:56–57. In that respect, the '773 patent explains that flexibility 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:



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. 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

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 4:1–11.

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.

13. 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 helical flutes defining a cutting edge extending from a distal end of the shank along an axial length of the shank, the instrument being in accordance with ISO Standard 3630-1, the shank consisting essentially of a superelastic nickel titanium alloy; and

(b) after step (a), heat-treating the entire instrument shank at a temperature from 475° C. to 525° C.,

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

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see Cuozzo Speed Techs. LLC v. Lee*, No. 15–446, 2016 WL 3369425, at *12 (U.S. June 20, 2016). Under the broadest reasonable construction standard, claim terms usually are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Nevertheless, a “claim term will not receive its ordinary meaning if the patentee acted as his own lexicographer” and clearly set forth a definition of the claim term in the specification. *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002).

For purposes of our Decision instituting trial in this *inter partes* review, we determined that no terms of the ’773 patent acquired any special

meaning. Thus, we gave all terms their broadest reasonable meaning as would be understood by a person of ordinary skill in the art in light of the Specification. Inst. Dec. 9. We discussed the meaning of certain terms/phrases appearing in claims 1 and 13: (1) “heat-treating”; and (2) “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.” *Id.* at 9–12. Our expressed constructions of those terms/phrases is set forth below.

Claim Term/Phrase	Construction
“ <i>heat-treating</i> ”	“[W]e construe claims 1 and 13 as permitting the step of heat-treating the shank in any atmosphere or environment.” <i>Id.</i> at 10.
The “ <i>wherein</i> ” clause	“[W]e regard the “wherein” clause in each of claims 1 and 13 as a limitation of the claims and lays out a metric for determining if a heat treatment process falls within the scope of the claims.” <i>Id.</i> at 12.

Neither party disputes that all claim terms of the ’773 patent should be given their ordinary meaning. Nor does either party offer any alternative constructions for the terms/phrases noted above. We do not discern that the record developed during trial gives reason to alter the constructions expressed above. Accordingly, for the reasons set forth in the Decision instituting trial, and in the absence of any challenge from the parties, we maintain the constructions set forth above.

*B. The Ground of Unpatentability
Based on Anticipation*

Anticipation is established only when a single prior art reference discloses all elements of the claimed invention. *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990). US Endo contends that claims 1, 2, and 9–12 are anticipated by Kuhn.

1. Overview of Kuhn

Kuhn is an article in the Journal of Endodontics titled “Fatigue and Mechanical Properties of Nickle-Titanium Endodontic Instruments.” Ex. 1019, Title. Kuhn sets forth that the “aim” of its disclosure is “to show fatigue characteristics of superelastic NiTi, and subsequently, the effect of the process history on fracture life.” *Id.* at 716.⁷ Kuhn describes the study of “files” measuring 25 mm in length and a taper ranging between 0.04 and 0.06 mm per mm length. *Id.* at 717. Kuhn explains that the files were subjected to heat treatments that consist of “anneals at 350 °C, 400 °C, 450 °C, 510 °C, 600 °C and 700 °C in salt baths for 10 min and at 600 °C and 700 °C for 15 min.” *Id.* Kuhn also explains that “bending tests” were performed on “[n]ew instruments, instruments used in the clinic, and instruments that have been heat-treated” to obtain “information about the elastic behavior (flexibility) of the files.” *Id.*

2. Discussion—Anticipation

In its Petition, US Endo urges that Kuhn discloses all the features required by claims 1, 2, and 9–12. Pet. 29–33. GSI does not agree. PO

⁷ Kuhn is paginated as 716–720 in volume 28, number 20 of the Journal of Endodontics. That pagination scheme is referenced in this Decision.

Resp. 19–34.⁸ In particular, GSI urges that that Kuhn lacks certain features required by those claims. Namely, GSI focuses our attention on the requirements of claim 1 pertaining to: (1) heat-treating the “entire” shank; and (2) obtaining a “greater than 10 degrees of permanent deformation” after bend testing.

a. Heat-treating the “entire” shank

We instituted trial in this *inter partes* review proceeding on the ground that Kuhn anticipates claim 1. In that regard, we determined, at that time, that US Endo had shown a reasonable likelihood of success in showing that Kuhn disclosed all the features of claim 1, including that Kuhn accounts for heat treatment of the “entire” shank. In making that determination we credited the testimony of US Endo’s declarant, Dr. A. Jon Goldberg (Ex. 1002). Inst. Dec. 16–17. GSI maintains that Kuhn’s disclosure is insufficient to convey the practice of heat-treating the entirety of a shank. In

⁸ We are cognizant that in its Reply submitted in response to GSI’s Patent Owner’s Response, US Endo now contends the following:

In light of the Board’s finding that the “wherein” clause is a limitation, and for the purposes of this Reply only, Petitioner acknowledges that the reasons provided in Ground 5 of the Petition do not support a finding that claims 2 and 11 are anticipated by Kuhn, and that the reasons provided in Ground 6 do not support a finding that claims 13, 15, and 17 are obvious over Kuhn and ISO 3630-1.

Pet. Reply 11 n.6.

More to that contention, at oral argument, US Endo represented to the panel that it did not believe that a preponderance of the evidence supported a determination that claims 2, 11, 13, 15, and 17 were unpatentable over Kuhn or Kuhn taken with ISO 3630-1. *See* Tr. 31–32.

taking that position, GSI points to specific disclosure in Kuhn as to the extent of heat treatment that it contemplates and also to the testimony of its own declarant, Dr. Robert Sinclair (Ex. 2006). PO Resp. 17–20. With the benefit of the record now before us that has been developed during trial, we revisit the question of whether Kuhn, itself, contemplates heat-treating the entire shank of an endodontic instrument.

There is no dispute that Kuhn discloses heat-treating at least some portion of the shank of an endodontic instrument, such as a file. For instance, in describing “Thermal Treatments,” Kuhn clearly provides that “heat treatments” are applied in some fashion to the file specimens that it discloses. Ex. 1019, 717. Before discussing those treatments, however, Kuhn describes that the specimens were “cut” to separate “active” parts from “inactive” parts of the file. *Id.* We do observe that, in connection with a discussion of “bending tests,” Kuhn proposes that “instruments that have been heat-treated” are subjected to those tests. *Id.* Yet, Kuhn provides no additional qualifier as to what extent of the “instruments” were heat-treated.

Dr. Goldberg testifies that “Kuhn says nothing about treating only portions of the instruments,” and concludes that “[b]ecause Kuhn is silent on the subject, one of ordinary skill in the art would have understood that the ‘entire shank’ was treated.” Ex. 1002 ¶ 132. Dr. Goldberg also infers that the entire shank is heat-treated based on Kuhn’s mention of bending an instrument “near the handle” as a part of a bending test. *Id.* In view of that testimony, US Endo concludes that Kuhn discloses heat treatment of the entire shank. Pet. 30. Both GSI and Dr. Sinclair, however, contend that such conclusion is unwarranted. PO Resp. 18–20; Ex. 2026 ¶¶ 65–71. In

that respect, GSI and Dr. Sinclair urge that Kuhn only contemplates heat-treating portions of a file that are less than the entirety of a shank of the file.

The involved ground, here, is one premised on anticipation. The “hallmark of anticipation is prior invention” which means that to anticipate, a prior art reference must disclose all elements of the claim “within the four corners of the document” and “arranged as in the claim.” *Net MoneyIn, Inc. v. VeriSign Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008). In this case, that means that Kuhn, itself, must disclose heat-treating the entirety of a file’s shank. It is not enough that a skilled artisan, based on the knowledge of the art they carry with them, may have “understood” that the entire shank is available for heat treatment. Indeed, that one of ordinary skill in the art might have selected between a limited number of heat treatment options based on their knowledge in the art is not the proper inquiry when considering anticipation.

We do not discern that Kuhn’s description of providing heat treatment to its file specimens is of suitable specificity to glean from that description that it is the entirety of the shank portion of a file that is subjected to heat treatment. It also is unclear what portions of a shank Kuhn contemplates for heat treatment in its disclosure that portions “near the handle” are deformed when subjected to a bending test. *See* Ex. 1019, 718. Although Dr. Goldberg points to that disclosure as “confirm[ing] that the ‘entire shank’ is treated,” he does not explain adequately why that is so. *See* Ex. 1002 ¶ 132.

b. Conclusion—Anticipation

Having considered the record as has now been developed during trial, we conclude that Kuhn does not disclose that the entire shank of an endodontic instrument is subjected to heat treatment. That is a requirement

of claim 1, and, thus, is also a requirement of claims 2 and 9–12, which ultimately depend from claim 1. Accordingly, we are not persuaded that a preponderance of the evidence demonstrates that claims 1, 2, and 9–12 are anticipated by Kuhn.

*C. The Grounds of Unpatentability
Based on Obviousness*

A claim is unpatentable for obviousness under § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) where in evidence, so-called secondary considerations. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). We also recognize that prior art references must be “considered together with the knowledge of one of ordinary skill in the pertinent art.” *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994) (citing *In re Samour*, 571 F.2d 559, 562 (CCPA 1978)).

Trial was instituted on the following grounds premised on obviousness: (1) claims 8, 13, 15, and 17 as obvious over Kuhn and ISO 3630-1; (2) claims 1–17 as obvious over Kuhn, ISO 3630-1, McSpadden, and Pelton; and (3) Claims 1–17 as obvious over Matsutani, Pelton, and ISO 3630-1.

1. Level of Ordinary Skill in the Art

In determining the level of skill in the art, various factors may be considered, including the “type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field.” *In re GPAC, Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) (citing *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986)). Here, the parties are in general agreement as to the level of ordinary skill in the art. In that respect, declarants for both parties opine that one of ordinary skill in the art would have an underlying educational background in “materials science, metallurgy, or a related field,” and would have an understanding of the structural and mechanical properties of NiTi endodontic instruments. *See* Ex. 1002 ¶ 63; *see* Ex. 2026 ¶ 22. We adopt the above-noted contention of the parties as to the level of ordinary skill. Furthermore, we observe that the prior art of record in this proceeding also is indicative of the level of ordinary skill in the art. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *GPAC*, 57 F.3d at 1579; *In re Oelrich*, 579 F.2d 86, 91 (CCPA 1978).

2. Ground Based on Kuhn, ISO 3630-1, McSpadden, and Pelton

US Endo explains in detail where it believes all of the features of claims 1–17 are found in Kuhn, ISO 3630-1, McSpadden and Pelton, and why a person of ordinary skill in the art would have combined the teachings of those references. *See* Pet. 34–43.

a. Overview of ISO 3630-1

As a part of its “Introduction,” ISO 3630-1 describes its content as follows:

This International Standard covers significant features of hand- and power-operated dental root canal instruments which are used by the dentist for the mechanical preparation of roots canals for treatment. In dentistry these instruments are also referred to as endodontic instruments.

Part 1, in addition to the specific instruments indicated, includes general specifications, requirements and test methods which are applicable to all types of root-canal instruments.

Ex. 1016, 5.⁹

b. Overview of McSpadden

McSpadden is titled “Endodontic Instrument.” Ex. 1022, Title. The reference is directed generally to “nickel-titanium endodontic instruments used for performing root canal therapy.” *Id.* ¶ 3. McSpadden describes the following in connection with the use of nickel-titanium for such instruments:

Nickel-titanium has several peculiar properties that make it very useful in endodontic applications. In particular, the alloy has the unusual ability to reversibly change its crystalline structure from a hard, high-modular “austenitic” crystalline form to a soft, ductile “martensitic” crystalline form upon application of pressured and/or by cooling. This results in a highly elastic material having a very pronounced pseudo-elastic strain characteristic. This pseudo-elastic elastic strain characteristic is often described as “superelasticity.”

Id. ¶ 8. McSpadden also summarizes its invention as follows:

It is therefore an object of the present invention to provide an improved class of superelastic alloy materials particularly

⁹ In this Decision, the referenced pagination of ISO 3630-1 is that appearing at the lower center of each page of the document.

adapted for use in endodontic files. It is another object of the invention to provide an endodontic instruments having improved manipulation control, sharp cutting edges, and a reduced tendency to break during use.

Id. ¶ 14.

In further describing the formation of an endodontic instruments from a NiTi alloy, McSpadden explains the following:

[T]he drawn NiTi wire is first heat treated and fully annealed to relieve most if not all of the latent stress and crystalline deformation in the material and to set a permanent straightened shape to the wire prior to machining. Such heat treatment and annealing is typically required to optimize the material's super[e]lasticity and other desired properties.

Id. ¶ 51.

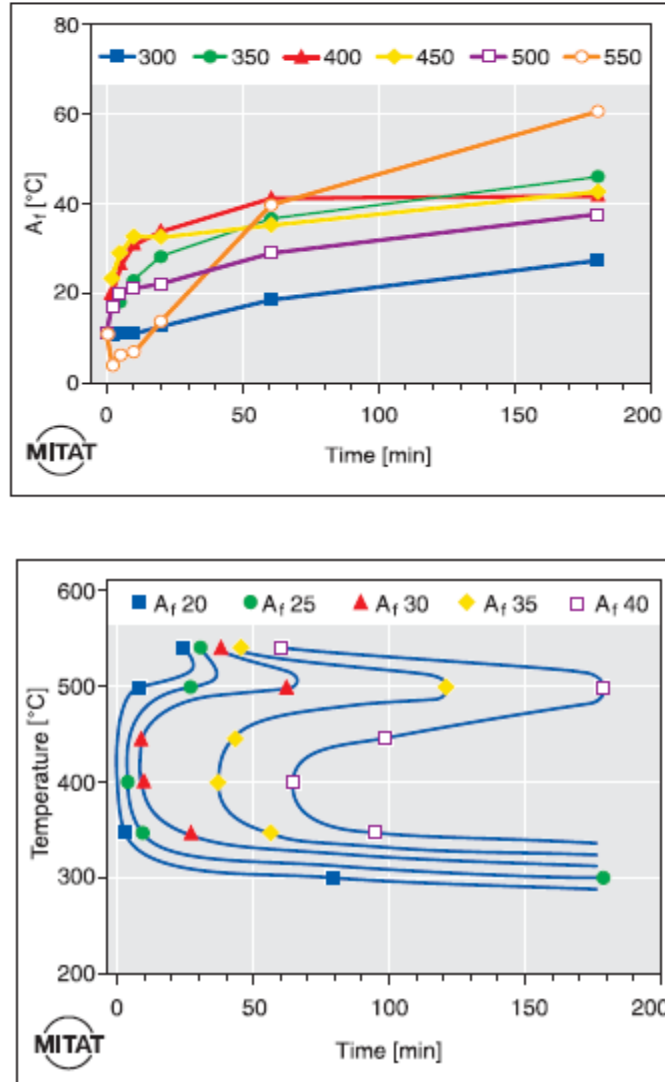
c. Overview of Pelton

Pelton is titled "Optimisation of processing and properties of medical grade Nitinol wire." Ex. 1006, Title. Pelton summarizes its content as follows:

The purpose of this paper is to review the current processing and resultant properties of standard Nitinol wire for guide-wire applications. Optimised Ti-50.8at%Ni wire was manufactured according to industry standards by precise control of the composition, cold work and continuous strain-age annealing. Mechanical properties of this wire are reported from -100°C to 200°C to demonstrate the effects of test temperature. Within the 'superelastic window' the plateau stresses are linearly related to test temperature. Additional ageing treatments can be used as a tool to fine-tune transformation temperatures and mechanical properties. A review of the fatigue properties of thermomechanically-treated Nitinol wire shows that they are affected by test temperature, stress and strain.

Id. at 107.¹⁰

The following is a reproduction of Pelton's Figures 9 and 10:



Figures 9 and 10 above depict the effect of ageing temperature and time on the transformation temperature of Nitinol wire (i.e., a wire made of nickel and titanium). *Id.* at 114. As evident from the figures, and as

¹⁰ Pelton is paginated 107 to 118 of the Minimally Invasive Therapies & Allied Techs. Journal. That pagination sequence is referenced in this Decision.

explained, Pelton contemplates heat treatment of various Nitinol wires ranging from 300°C to 550°C for durations between 0 and 200 minutes. *Id.* Pelton also contemplates that its disclosed Nitinol wire is used in medical applications such as for endodontic instruments. *Id.* at 107.

d. Discussion—Kuhn, ISO 3630-1, McSpadden, and Pelton

As was the case in the context of the anticipation ground based on Kuhn, the dispute between the parties primarily centers on two features required by the claims: (1) heat-treating the “entire” shank; and (2) obtaining a “greater than 10 degrees of permanent deformation” after bend testing.

i. Heat-treating the “entire” shank

Although, as discussed above, it is not apparent that Kuhn discloses the act of heat-treating the entire shank of a file, that does not end the inquiry into whether a person of ordinary skill in the art would have recognized that such practice was an available option. The record is replete with description of heat-treating medical tools, including endodontic instruments. Indeed, that is a practice described, for instance, in each of Kuhn, McSpadden, and Pelton.

We agree with US Endo (Pet. Reply 4–5) that there are a finite and predictable number of options for heat-treating the extent of an endodontic instrument, i.e., heat-treating a portion of the shank or heat-treating the entire shank. In such scenarios, a skilled artisan has good reason to pursue known options within their technical grasp. *See KSR*, 550 U.S. at 421 (2007). We are mindful of GSI’s arguments (PO Resp. 17–20) and Dr. Sinclair’s testimony (Ex. 2026 ¶¶ 63–71) urging that Kuhn, itself, does not disclose heat-treating the entirety of a shank. Indeed, as discussed above, we

agree there is some question in that regard. Here, however, we do not discern that GSI or Dr. Sinclair consider appropriately what a person of ordinary skill and creativity in the art would have understood from the teachings of the prior art beyond simply Kuhn's disclosure. We conclude that a skilled artisan practicing the teachings of the prior art in connection with heat-treating a nickel-titanium instrument would have had the background knowledge, creativity, and common sense to heat-treat the entirety of a shank, as opposed to some partial portion, if so desired. *See Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1329 (Fed. Cir. 2009). In that respect, we observe that none of Kuhn, McSpadden, and Pelton suggests a prohibition to any particular heat treatment approach, and we do not discern that a skilled artisan would have viewed heat-treating the entire shank of a file as unknown or unworkable. Indeed, it simply is not evident why a person of ordinary skill in the art practicing the heat treatment of an endodontic instrument based on the teachings of the prior art would have viewed heat treatment of the entire shank of such an instrument as some type of barrier. In reaching that conclusion, we also credit Dr. Goldberg's testimony that a skilled artisan would have known that heat-treating the entire shank would "avoid the difficulties and added expense associated with partial heat treatment." Ex. 1002 ¶ 201.

Accordingly, we determine that, on the record at hand, a person of ordinary skill in the art would have known heat-treating the "entire shank" of an endodontic instrument as required by the claims of the '773 patent was an available option, and that selecting such an option would have been obvious.

ii. “*greater than 10 degrees of permanent deformation*”

Each of claims 1 and 13 culminates in a recitation that “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.” US Endo contends that the bending tests described in the prior art satisfy the above-noted requirement, including that, at least in one example, a shank that underwent heat-treating, and subsequently subjected to a bending test, displayed the required 10 degrees of permanent deformation. Pet. 30–31. In support of that contention, US Endo points to: (1) results of bend tests of a 400°C-treated file depicted in Kuhn’s Figures 6A; (2) the teachings of Pelton and McSpadden concerning the materials of the instruments and wires they disclose; (3) the declaration testimony of Dr. Goldberg at paragraphs 135–137; and (4) representations made by the applicants during the prosecution of the patent application that became the ’773 patent. *Id.* at 30–31, 34–38.

According to Dr. Goldberg, the curve shown in Figure 6A that corresponds to a file heat-treated at 400 °C indicates that the file exhibited permanent deformation of “about 1.8 millimeters” after undergoing 8 millimeters of deflection. Ex. 1002 ¶ 135. Although characterized as a “rough estimate,” Dr. Goldberg testifies that such disclosure relays “10.125 degrees” of deformation for the treated file. *Id.* Dr. Goldberg further provides the following testimony:

Kuhn also discusses the effect of treatment on the material’s transformation temperature. The 400°C treatment, per Kuhn, raised the instrument’s transformation temperature from 35°C to 40°C, which is above mouth temperature. Ex. 1019 (Kuhn) at 719. Thus, it was no longer superelastic by Kuhn’s definition; this increase in the transformation temperature confirms that the

treated instrument would satisfy the “wherein” clause. *See supra* section V; *see also supra* section VI-B; Ex. 1008 (’773 patent prosecution history) at 147, 151-52, 159. Kuhn discloses this very property with respect to the 400°C-treated instrument, which per Kuhn gave “good results.” As such, in my opinion, Kuhn not only discloses the feature that Dr. Luebke used to distinguish his invention, but also teaches it to be a desirable one.

Id. ¶ 137. Thus, Dr. Goldberg testifies that, as determined from the bending test applied to the file treated at 400 °C, the transformation temperature, i.e. — the temperature at which the file transitions between martensite and austenite—was increased from 35 °C to 40 °C. Dr. Goldberg also testifies that such an increase in the transformation temperature was a desired result of the invention of the ’773 patent, as represented by Dr. Luebke during prosecution of the application that became the ’773 patent.

GSI is generally of the view that Kuhn’s disclosure in conjunction with its described bending tests is of insufficient specificity to account for the testing procedure set forth in claims 1 and 13. In particular, GSI argues that Kuhn does not identify the bend test it employs, and, as a result, one of ordinary skill would have been unable to “correlate the results obtained by Kuhn with the permanent deformation (if any) that would be exhibited by the file if it were tested in accordance with the ISO Standard 3630-1 bend test.” PO Resp. 20–22. GSI also contends that the heat treatment described in Kuhn results in endodontic files that maintain superelasticity. *Id.* at 27–32. In that respect, according to GSI, Kuhn’s approach to heat treatment would not result in permanent deformation when bent, and specifically the “greater than 10 degrees of permanent deformation” as claimed. *Id.* at 28. GSI also is of the view that the teachings of the pertinent prior art—i.e., Kuhn, McSpadden, and Pelton—convey only files or instruments that are

“stiffer” and, thus, allegedly not flexible or permanently deformable, such that those references “teach away” from the deformation set forth in the claims. *Id.* at 33, 36–47.

We do not agree with GSI. At the outset, GSI does not explain persuasively why the deformation required by the claims of the ’773 patent is a characteristic that the prior art viewed as inferior or impractical. It is evident from the teachings of the prior art that a skilled artisan appreciated that there were a variety of considerations that factor in to the formation of an endodontic instrument. For instance, McSpadden recognizes that “rubber-like elasticity” is a material property that is “very desirable for endodontic files” to overcome “breakage problems.” Ex. 1022 ¶ 9. In that respect, McSpadden disparages certain materials, such as stainless steel, with respect to endodontic applications because of “limited flexibility.” *Id.* ¶ 7. Kuhn, too, places “emphasis on flexibility of endodontic instruments.” Ex. 1019, 716.

We are cognizant that McSpadden notes that a “drawback” to certain files made of NiTi material is “reduced manipulation control” due to “reduced stiffness and extreme torsional flexibility” Ex. 1022 ¶ 12. GSI, however, does not articulate why the deformation characteristics set forth in the claims are those that would have been regarded by skilled artisans as “extreme torsional flexibility.” McSpadden also advises that objectives of its invention include providing an endodontic instrument “having improved manipulation control, sharp cutting edges, and a reduced tendency to break during use.” *Id.* ¶ 14. We note that those objectives are in accord with the objectives expressed in the ’773 patent, which include “high resistance to torsion breakage, maintain shape upon fracture, can withstand increased

strain, and can hold sharp cutting edges.” Ex. Ex. 1001, 2:50–52. GSI does not explain adequately why the deformation characteristics of the claims of the ’773 patent would be outside the type of characteristics a skilled artisan would have recognized as desirable from the teachings of the prior art.

References only teach away when they suggest that the developments flowing from their disclosures are unlikely to produce the objective of a claimed invention. *Syntex (U.S.A) LLC v. Apotex, Inc.*, 407 F.3d 1371, 1380 (Fed. Cir. 2005). Moreover, a reference does not teach away if it merely expresses a general preference for an alternative invention but does not “criticize, discredit, or otherwise discourage” investigation into the claimed invention. *DePuy Spine Inc. v. Medtronic Sofamor Danek*, 567 F.3d 1314, 1327 (Fed. Cir. 2009) (quoting *In re Fulton*, 391 F.3d 1195, 1201 (Fed Cir. 2004)). Here, we determine that the prior art does not convey endodontic instruments that would be unlikely to fulfill the objectives of the ’773 patent, or criticize, discredit, or discourage investigation into formation of endodontic instruments with deformation characteristics encompassed by the claims.

It is clear from the teachings of the prior art, e.g., Kuhn, McSpadden, and Pelton, that instruments made of nickel-titanium alloys were known to be heat-treated at various temperatures between 300°C and 550°C for various periods of time ranging between 0 and 200 minutes. It also is evident that the materials and heat treatment processes were selected to balance issues of strength, manipulation control, flexibility, and suitable cutting edges during use in an endodontic procedure. Furthermore, it was also known that various bending tests routinely were employed to measure deformation characteristics of endodontic instruments. Lastly, the record

conveys that a skilled artisan also would have been aware of the ISO Standard 3630-1. Accordingly, we are not persuaded that the limitation of “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” distinguishes the claims of the ’773 patent over the combined teachings of Kuhn, McSpadden, ISO 3630-1, and Pelton.

iii. Claims 3, 7, 6, and 14

GSI also separately argues claims 3, 7, 6, and 14. PO Resp. 42–43. Claims 3, 6, and 7 ultimately depend from claim 1, and claim 14 depends from claim 13. Each of claims 3 and 14 adds that “the shank is heat-treated for 1 to 2 hours.” Claim 6 adds that “the atmosphere is unreactive, ambient or any other acceptable heat treatment process.” Claim 7 adds that “the instrument shank consists essentially of a superelastic nickel titanium alloy comprising 54–57 weight percent nickel and 43-46 weight percent titanium, the temperature is 500° C., and the shank is heat-treated for 1 to 2 hours.” According to GSI, the recited heat-treatment times and temperatures distinguish those claims over the prior art. *Id.*

US Endo urges that, as evidenced by the prior art, all of those features would have been appreciated as available options in manufacturing an instrument from nickel-titanium alloys, and one of ordinary skill in the art would have had adequate reason to select those options as desired. *See* Pet. 34–43. In support of that contention, US Endo also makes reference to the declaration testimony of Dr. Goldberg. *Id.*

It is apparent that the art conveys readily that there are a variety of known, viable options in terms of heat treatment environment, duration, and

temperature. For instance, as discussed above, it is clear from Pelton's teachings that it was well known to apply heat treatment in a suitable atmosphere to Nitinol wire for time periods between 0 and 200 minutes, i.e., periods encompassing 1 to 2 hours. Ex. 1006, Figs. 9 and 10. As also explained above, Pelton contemplates temperatures ranging between 300 and 550 °C. *Id.* We further observe that Pelton recognizes that the Nitinol wire that is the subject of its heat treatment techniques is the type of material used in "endodontic instruments." *Id.* at 107. We conclude that applying known heat treatment temperatures, duration, and environment to known structures, e.g., Kuhn's endodontic instruments, would have been nothing more than the routine exercise of the ordinary skill of a skilled artisan. *See KSR*, 550 U.S. at 418.

iv. Conclusion—Grounds Based on Kuhn, ISO 3630-1, McSpadden, and Pelton

Having considered the record before us, we conclude that a preponderance of the evidence supports US Endo's contention that all of the features of claims 1–17 of the '773 patent are accounted for by the combined teachings of Kuhn, ISO 3630-1, McSpadden, and Pelton, and that the record conveys adequate reason to combine their teachings.¹¹ We are mindful, however, that GSI has introduced evidence of non-obviousness, which we consider below.

¹¹ Because we reach this conclusion based on the combined teachings of Kuhn, ISO 3630-1, McSpadden, and Pelton, we discern that it is not necessary to reach the merits of the ground of unpatentability offered for claims 8, 13, 15, and 17 based on only Kuhn and ISO 3630-1.

3. *Ground Based on Matsutani, ISO 3630-1, and Pelton*

Before we consider GSI's evidence of non-obviousness, we first address US Endo's position that claims 1–17 also are unpatentable over the teachings of Matsutani taken with Pelton and ISO 3630-1.

a. *Overview of Matsutani*

Matsutani is titled “Root Canal Treatment Tool and Method for Manufacturing the Same.” Ex. 1023, Title. Matsutani's Figure 1 is reproduced below:

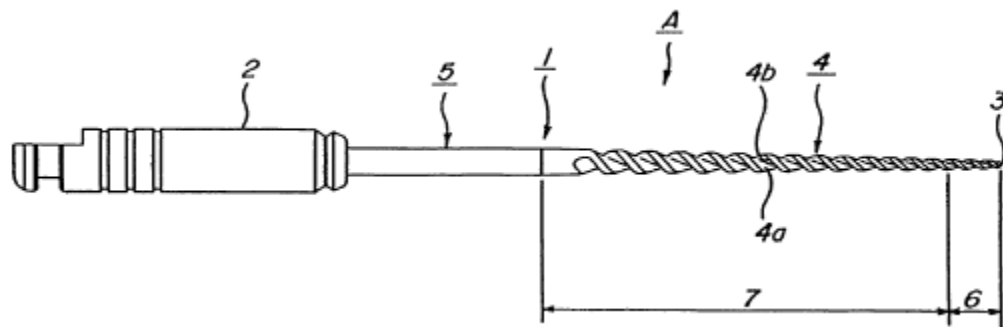


Figure 1 above depicts a tool according to Matsutani's invention. *Id.* at 3:14–15. Matsutani characterizes the tool as “Reamer A,” which includes needle portion 1 and grip 2. *Id.* at 3:61–64. Needle portion 1 includes straight shank 5, tapered work portion 4, and tip 3. Needle portion 1 is “made of a metal having a shape memory characteristic, for example, nickel-titanium (Ni–Ti).” *Id.* at 4:21–23. A segment of work portion 4 in the vicinity of tip 3 forms “shape memory portion 6” that “is provided with such a characteristic by performing heat treatment on the Ni–Ti alloy, so as to cause the Ni–Ti alloy to not recover a memory shape in the range of a room temperature or a body temperature.” *Id.* at 4:31–35. In that regard, Matsutani explains: “it is preferable that the shape recovery temperature of the shape memory portion 6 is sufficiently higher than room temperature and

body temperature.” *Id.* at 8:46–49. Matsutani also explains that “the shape memory portion 6 does not exhibit the characteristic of returning to its original shape, but can be deformed in a preferable shape.” *Id.* at 4:42–44.

With respect to the length of shape memory portion 6, Matsutani notes that such length is variable and “is not limited to a special value.” *Id.* at 5:20–33. Matsutani, however, advises that:

if the length of the shape memory portion 6 is larger than $\frac{3}{4}$ of the work portion, at the time of inserting the tip 3 into the root canal and rotating it, a problem may occur in that the position of a rotational axis is not fixed, but is made eccentric to make it difficult to cut the root canal well.

Id. at 5:37–42.

b. Discussion—Matsutani, Pelton, and ISO 3630-1

US Endo contends that claims 1–17 would have been obvious to a person of ordinary skill in the art when considering the teachings of Matsutani, Pelton, and ISO 3630-1. Pet. 49–57. GSI disagrees. As was the case with the grounds based on Kuhn, GSI contends that Matsutani does not teach heat-treating the entire shank, and that neither Matsutani nor Pelton teaches that the shank exhibits greater than 10 degrees of permanent deformation upon being subject to a bending test after heat treatment. PO Resp. 47–54.

i. Heat-treating the “entire” shank

With regard to the requirement of treating the “entire” shank, we are mindful that, as noted above, Matsutani, itself, does not seek to heat-treat more than $\frac{3}{4}$ of the working portion of its endodontic instrument out of a concern that doing so may cause the “rotational axis” of the instrument not to be “fixed.” Ex. 1023, 5:37–42. Nevertheless, it also is clear from

Matsutani's teachings that the extent of heat treatment of a shank of such an instrument is known to be variable. *See, e.g.*, Ex. 1023, 5:20–21. Moreover, what a reference suggests is taken in the context of the knowledge, skill and reasoning ability of one with ordinary skill in the art. *Syntex*, 407 F.3d 1380. Indeed, in evaluating the teachings of the prior art, the inferences and creative steps one of ordinary skill in the art would employ should be taken into account. *See KSR*, 550 U.S. at 418; *see also Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (“[O]bviousness must be determined in light of all the facts, and there is no rule that a single reference that teaches away will mandate a finding of nonobviousness.”).

Here, although Matsutani cautions that “a problem may occur” if more than $\frac{3}{4}$ of the working portion of the instrument is heat-treated, we are not persuaded that a skilled artisan would have regarded heat-treating the entirety of the shank as unworkable or unobtainable. To that end, we credit the testimony of Dr. Goldberg that a person of ordinary skill in the art would have inferred that Matsutani's heat-treating procedures may be used for the entire shank, and that such practice would “avoid the difficulties and added expense associated with partial heat-treatment.” Ex. 1002 ¶ 201; *see id.* ¶¶ 203–206. For instance, as suggested by US Endo, heat-treating the entire shank would omit the requirement of the particular steps and components disclosed in Matsutani (Ex. 1023, 7:14–19) to accomplish only partial heat-treating of a structure. *See* Pet. 53.

Thus, we conclude that the current record demonstrates that it is understood in the art that various extents of the shank of an endodontic instrument may be heat-treated. Consistent with the view that heat-treating an entire shank was simply one of the known options for how much of the

shank to treat, GSI's counsel agreed that the disclosure of the '773 patent does not attribute any significance to heat-treating the entire shank rather than only a portion of it. Tr. 36:23–37:6.

While Matsutani suggests that heat-treating the entirety of a shank may lead to a potential problem associated with the non-fixation of a rotational axis of the shank, the record before us does not include any evidence that the problem Matsutani prophesied ever actually materialized when the entire shank was heat-treated. Dr. Luebke's testimony indicates that he never experienced the problems Matsutani forecasted when heat-treating the entire shank. See Ex. 1038, 167:8–15, 164:18–21. Moreover, a skilled artisan would have recognized that the potential problem Matsutani identifies may be offset by other factors, such as ease and expense of the heat-treating procedure. That Matsutani expresses a preference for one approach over another, does not mean that a person of ordinary skill in the art would have understood that only one approach, i.e. partial heat treatment, is available. See *Medichem*, 437 F.3d at 1165 (“[A] given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine.”). On this record, we are persuaded that one of ordinary skill would have known that the entire shank of an endodontic instrument may be heat-treated.

ii. “*greater than 10 degrees of permanent deformation*”

With regard to the requirement that the treated shank exhibit greater than 10 degrees of permanent deformation upon testing, we also are persuaded that such requirement is derived from the teachings of the prior art, including Matsutani, Pelton, and ISO 3630-1. Matsutani describes the following in connection with a testing procedure:

In the bending test, the work portion 4 was gripped at a position about 3 mm from the tip 3, and torque when the work portion was bent about 45 degrees in this state was measured. . . . Therefore, even if the shape memory portion 6 is forcibly bent, and then the bending force is released, the bent shape of the shape memory portion 6 can be maintained. For this reason, at the time of treating the root canal, it is possible to bend the shape memory portion 6 previously according to the shape of the patient's root canal, to insert the tip 3 into the root canal, and to perform treatment with this maintained bent shape. That is, it is possible to make the shape memory portion 6 conform to the shape of the root canal before and during treatment.

Ex. 1023, 8:15–39.

Thus, Matsutani discloses that a bending test is performed on a treated shank in which torque is applied to bend the shank about 45 degrees. Matsutani further discloses that the intent of its heat-treating process is to create an instrument that maintains its deformation “before and during treatment” of a root canal. Dr. Goldberg also testifies that Matsutani's disclosure, including that noted above, taken with Pelton's disclosure of various known heat-treating temperatures and durations to achieve a shape recovery temperature above body temperature, accounts for the “wherein” clause of claims 1 and 13. Ex. 1002 ¶¶ 211–214.

GSI disputes US Endo's arguments and Dr. Goldberg's testimony in that respect. PO Resp. 52–54. To that end, GSI contends that Dr. Goldberg based his testimony on the belief that a NiTi endodontic file will exhibit the deformation of the claims of the '773 patent if the shape recovery temperature (“ A_f ”) is above body temperature (e.g., in situations of 0 and 10° stress strain curves). *Id.* According to GSI, there may be occasions in which NiTi may be below its A_f but still be “superelastic.” *Id.* GSI, thus, contends that Dr. Goldberg's testimony should be rejected or discredited.

Even assuming that GSI is correct, and there are situations in which NiTi's A_f is above body temperature but remains superelastic, GSI does not explain that a skilled artisan would not recognize that the corollary is also true, i.e., that in other circumstances the NiTi is not superelastic and would exhibit permanent deformation when flexed. Indeed, we observe that Matsutani discloses that such a scenario is known in describing that its “shape memory portion 6” is provided with a shape memory characteristic “by performing heat treatment on the Ni–Ti alloy, so as to cause the Ni–Ti alloy to not recover a memory shape in the range of a room temperature or a body temperature.” *Id.* at 4:31–35. GSI does not explain why, in that exemplary situation, the deformation requirement of claims 1 and 13 is not satisfied.

In any event, the record is replete with disclosure of heat-treating various NiTi instruments over particular ranges of temperatures for specific time periods. For instance, Pelton discloses that wire made of nickel-titanium alloys were known to be heat-treated at various temperatures between 300°C and 550°C for various periods of time ranging between 0 and 200 minutes. Ex. 1006, Figs. 9 and 10. Pelton also discloses that such wires are tested by bending them to a prescribed strain. *Id.* at 109. As noted above, Matsutani describes that various Ni-Ti alloys may be heat-treated such that “shape memory portion 6 does not exhibit the characteristic of returning to its original shape, but can be deformed in a preferable shape” where it remains at room or body temperature. *Id.* at 4:31–44. Finally, as we have already concluded, one of ordinary skill in the art would have been aware of the ISO Standard 3630-1. Accordingly, we determine that the limitation of “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” does not distinguish the claims of the ’773 patent over the combined teachings of Matsutani, Pelton, and ISO 3630-1.

iii. Conclusion—Matsutani, Pelton, and ISO 3630-1

We have considered the record before us, and, as with the grounds of unpatentability based on Kuhn, we conclude that a preponderance of the evidence supports US Endo’s position that all of the features of claims 1–17 are accounted for by the combined teachings of Matsutani, Pelton, and ISO 3630-1 and the record presents adequate reasons for combining their teachings. We turn now to GSI’s proffered evidence of non-obviousness.

D. Objective Evidence of Non-Obviousness

GSI asserts that the record establishes objective evidence of non-obviousness that confirms the patentability of the claims of the ’773 patent. Specifically, according to GSI, that evidence conveys: “(1) teaching away by others; (2) long-felt but unresolved need; (3) failure of others; (4) skepticism by experts; (5) the invention’s commercial success[;] (6) copying of the invention by competitors; and (7) praise by others.” PO Resp. 55 (citing Ex. 2027 ¶¶ 37–46; Ex. 2028 ¶¶ 33–49).¹²

1. Teaching away by others

GSI takes the view that the prior art “teaches away” from endodontic files “with less superelasticity,” as allegedly required by the claims of the ’773 patent. PO Resp. 55. For the reasons discussed above, however, we

¹² Exhibit 2027 is a Declaration of the inventor of the ’773 patent, Dr. Neill H. Luebke. Exhibit 2028 is a Declaration of Dr. Ronald R. Lemon.

conclude that the amount of permanent deformation called for in the claims does not demonstrate characteristics of an endodontic file beyond those that a skilled artisan would have recognized from the files taught in the prior art.

2. Long-felt but unresolved need/Failure of others

GSI contends that it has provided evidence of a long-felt need for an endodontic file that navigates a canal better and fractures less, and that those were problems that others failed to solve. PO Resp. 56–58. In particular, GSI points to the Declarations of Dr. Luebke and Dr. Lemon (citing Ex. 2027 ¶¶ 19, 22, and 27–32 and Ex. 2028 ¶¶ 26 and 33–45).

We have reviewed the cited testimony of Dr. Luebke and Dr. Lemon. Dr. Luebke’s testimony at ¶¶ 19, 22, and 27–32 is directed to the following: (1) a general background of NiTi files (¶ 19); (2) generic and non-specific statements that the industry recognized a problem of fracture in NiTi files, and that others failed to solve that problem (¶ 22); and (3) a description of the steps that Dr. Luebke took in developing endodontic files according to the ’773 patent (¶¶ 27–32). Dr. Lemon’s testimony provides the following: (1) general statements that breakage of NiTi files was known to occur (¶ 26); (2) Dr. Lemon’s description of some reasons he believes lead to the breakage problem (¶¶ 33–37); and (3) Dr. Lemon’s background and discussion of his personal and professional experience with “Vortex Blue®” heat-treated files (¶¶ 38–45).

To establish a long-felt but unresolved need, one must demonstrate that widespread efforts of skilled workers having knowledge of the prior art had failed to find a solution to the problem. *In re Allen*, 324 F.2d 993, 997, 139 USPQ 492, 495 (CCPA 1963). Also, a showing of failed attempts of others requires that others making the attempt had knowledge of the prior art

and thus failed despite having guidance from the prior art. *See, e.g., In re Sneed*, 710 F.2d 1544, 1550 (Fed. Cir. 1983).

Absent from the testimony of Dr. Luebke and Dr. Lemon is evidence tending to show what “widespread” efforts were employed by skilled workers in the art, and that such efforts had only resulted in failure. Also absent from the testimony is suitable evidence and explanation that others knew of the prior art—for example McSpadden and Matsutani—but despite the guidance provided therein could not solve the purported problem. Indeed, we note that each of McSpadden and Matsutani recognizes a need for a NiTi endodontic file with enhanced durability and a reduced tendency to break during use. Each of those references also offers a solution to the problem. Neither GSI nor its proffered evidence explain why the solutions described in McSpadden and Matsutani were inadequate and that workers in the art, even following the practices of, for instance, McSpadden and Matsutani, nevertheless, were unsuccessful in implementing the proposed solutions of those references.

3. Skepticism by experts

GSI contends the following:

Dr. Luebke’s invention was initially met with skepticism—he was told by companies, colleagues, and focus groups that his files were “too soft,” “too weak”—they were not interested. Ex. 2027, ¶¶37-38. Indeed, Dr. Luebke struggled for several years just to find a manufacturer to make files for him. Ex. 2027, ¶39.

PO Resp. 58.

In reviewing the cited evidence, we discern that Dr. Luebke testifies that he spoke with “Pierre-Luc Maillefer, the General Manager of Maillefer,

and Jean-Charles Giachetto, the Head of Laboratory Testing at Maillefer” concerning commercialization of Dr. Luebke’s files. Ex. 2027 ¶ 37. Evidently, according to Dr. Luebke, they indicated concern that the files may be “too soft.” *Id.* Dr. Luebke also testifies that a single focus group arranged by Maillefer composed of a “group of practitioners” expressed doubt that the files were “strong enough.” *Id.* Furthermore, Dr. Luebke urges that feedback from two other unidentified colleagues in connection with the files was “disappointing.” *Id.* ¶ 38. In particular, Dr. Luebke testifies that “one of them said he did not like the files and the other said he thought the files were ‘just okay.’” *Id.* Lastly, Dr. Luebke testifies that he generally had difficulty in attempting to commercialize his files. *Id.* ¶ 39.

We have considered Dr. Luebke’s testimony offered in an effort to show skepticism in the industry that the files would be successful. We observe, however, that Dr. Luebke’s recounting of somewhat limited interactions with unidentified colleagues—one of whom apparently thought the files were “okay”—tells us little in connection with assessing obviousness. Moreover, Dr. Luebke provides little by the way context surrounding his representation that two employees of Maillefer and some practitioners generally questioned some aspects pertaining to the strength of his files. Such is also the case concerning Dr. Luebke’s brief description of the challenges he experienced in attempting to commercialize his files.

4. Commercial Success

GSI urges that the invention of the ’773 patent has enjoyed commercial success. In support of that position, GSI contends the following:

Dr. Luebke had discussions with several different companies in the industry. Ex. 2027, ¶¶39-44. In fact, Mr. Bobby Bennett, a co-founder of Petitioner, tried to license Dr. Luebke's invention for his former employer D&S in 2010. Ex. 2027, ¶¶41-43; Ex. 2040. After having met with several different companies, Dr. Luebke successfully licensed his patents to Dentsply in 2014. Ex. 2027, ¶44; Ex. 2006, ¶¶10-11. Dentsply manufactures a heat-treated file known as the Vortex Blue file, which is covered by the '773 patent. Ex. 2006, ¶9. Dentsply's licensing and sales of Vortex Blue files are evidence of commercial success. Ex. 2027, ¶45.

PO Resp. 58.¹³

Thus, GSI contends that the sale of a type of file known as a "Vortex Blue file" coupled with licensing of several patents including the '773 patent demonstrates commercial success. Notably absent from the evidence on which GSI relies is any indication of how many files were sold, or what market share GSI enjoyed as a result of those sales. Indeed, GSI provides little, if any, elucidation as to the significance of the sales of the "Vortex Blue" files. Without the benefit of such information, it is difficult to discern the significance of the proffered evidence. *See In re Applied Materials, Inc.*, 692 F.3d 1289, 1300 (Fed. Cir. 2012) ("An important component of the commercial success inquiry in the present case is determining whether Applied had a significant market share relative to *all* competing pads based on the merits of the claimed invention, which Applied did not show.").

Moreover, the fact that a patent has been licensed generally is insufficient for purposes of showing commercial success. *See Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1539 (Fed. Cir. 1983). Indeed, that an entity chooses to license a patent may be for reasons beyond the merits of

¹³ Dentsply is identified by GSI as a real-party-in-interest. Paper 5, 2.

the claimed invention. *See Iron Grip Barbell Co. v. USA Sports Inc.*, 392 F.3d 1317, 1324 (Fed. Cir. 2004) (“Our cases specifically require affirmative evidence of nexus where the evidence of commercial success presented is a license, because it is often ‘cheaper to take licenses than to defend infringement suits.’”).

5. Copying

GSI contends that Dr. Luebke’s heat treatment process was copied by others, including Petitioner US Endo. PO Resp. 58–59. GSI, however, provides scant evidence in support of that contention. For instance, GSI makes vague reference to e-mail between a co-founder (Bennett) and partner (Goodis) of US Endo identified in the “Transcript of Motion Hearing Before the Honorable J. Ronnie Greer United States District Judge” (Ex. 2002). According to GSI, Bennet and Goodis discussed making a heat-treated file that could “actually compete in the marketplace.” *Id.* at 59. Even assuming that such statement was made, GSI does not explain how it demonstrates that US Endo sought to copy anything, much less a particular endodontic instrument or process covered by the ’773 patent.

GSI also urges the following:

Petitioner’s sister company, Edge Endo has built its entire endodontic file business on making heat-treated files that are advertised as “interchangeable” with Dentsply’s and even provides customers with a compatibility chart showing which EdgeFile to use instead of Dentsply’s. Ex. 2012. Indeed, in advertising its heat-treated NiTi files, EdgeEndo describes this patented advance as “revolutionary” and specifically markets its files as having improved strength, durability, and flexibility caused by the heat treatment of those files:

Our revolutionary heat treated Fire-Wire Niti yields performance enhancing durability (PED) that

provides not only incredible flexibility, but far out performs even the most expensive files on the market in cyclic fatigue testing; a key indicator of file strength and durability.

Id. (emphasis added).

Id. GSI, however, does not explain why advertised interchangeability and comparison of particular files by US Endo's sister company somehow indicates copying of a particular product or process.

6. *Praise by others*

GSI points to Dr. Lemon's testimony (Ex. 2028) at paragraphs 34–45 and 48 as evidence that “Dr. Luebke's invention significantly advanced the endodontic industry.” PO Resp. 59–60. That testimony reflects that Dr. Lemon views the “Vortex Blue” endodontic file favorably. *Id.* GSI also directs our attention to Exhibit 2043, which appears to be an advertisement for “The Vortex Blue® Family of Products.” More particularly, GSI points to a statement therein which reads as follows:

I really love the Vortex Blue files. They are my favorite file system ever. In my experience, Vortex Blue files are far more likely to follow the shape of the canal without breaking – and since they cut dentin like butter, I can negotiate the most wicked of curves with complete confidence.”).

Id. Evidently, that statement is attributed to a Dr. Nathan Baker. Ex. 2043, 1. We have considered the testimony and Exhibit 2043. Dr. Lemon and Dr. Baker credit “Vortex Blue®” files for their control and an ability not to break. As noted above, however, art of record, such as McSpadden and Matsutani, describe endodontic instruments that also are geared towards improving manipulation control and reducing breakage. It is not generally apparent that Dr. Lemon and Dr. Baker would not also have been impressed

equally with endodontic files formed based on the teachings of the prior art, apart from the “Vortex Blue®” files.

E. Conclusion—Obviousness

We have evaluated the record before us, including US Endo’s Petition, with its underlying supporting evidence, and GSI’s Patent Owner Response, with its proffered evidence of non-obviousness. On balance we conclude that the strong evidence of obviousness outweighs the weak evidence of non-obviousness. Accordingly, we conclude that US Endo has established by a preponderance of the evidence that claims 1–17 are unpatentable as obvious under 35 U.S.C. § 103.

F. Motions to Exclude Evidence

1. US Endo’s Motion to Exclude

US Endo moves to exclude the following “Exhibits 2006, 2040, 2043, 2044, and 2050–2052, and certain paragraphs of declarations of Patent Owner’s witnesses.” Paper 62, 1. We observe that with respect to all of the noted evidence, we have either not relied upon it in reaching this Final Written Decision, or we were unpersuaded that the evidence undermined US Endo’s contentions of obviousness. Accordingly, we *dismiss as moot* US Endo’s Motion to Exclude.

2. GSI’s Motion to Exclude

GSI presents the following in connection with its Motion to Exclude (Paper 63, “PO Mot. to Excl.”):

Pursuant to 37 C.F.R. § 42.64(c), Patent Owner Gold Standard Instruments, LLC (“Patent Owner”) moves to exclude Exhibits 1005, 1014 and 1037. Patent Owner further moves to strike Exhibits 1038, 2045 and 2046 at 154:12–155:2; 157:20–

158:15; 161:21–163.5; 66:18–67:14; and 68:3–17. Finally Patent Owner moves to strike the first full paragraph on page 10 in Petitioner’s Reply in Support of the Petition for *Inter Partes* Review (Paper 57) that relies on Exhibits 1005, 1014, and 1037.

PO Mot. to Excl. 2.

We observe that this Final Written Decision does not rely upon any of the content that GSI seeks to exclude. In that respect, we conclude that GSI’s Motion is moot. We take this opportunity, however, to consider GSI’s statement that “Exhibit 1005 should be excluded to prevent unnecessary prejudice to Patent Owner and to avoid confusion as to its state as non-prior art.” PO Mot. to Excl. 3. Exhibit 1005 was not considered prior art in reaching a Final Written Decision in this proceeding. Therefore, it is not clear what perceived “prejudice” exists to GSI that would be remedied were Exhibit 1005 to be excluded.

We dismiss as moot GSI’s Motion to Exclude.

III. CONCLUSION

For the foregoing reasons, we conclude that US Endo has not shown by a preponderance of evidence that claims 1, 2, and 9–12 are anticipated under 35 U.S.C. § 102 by Kuhn. We, however, conclude that US Endo has shown by a preponderance of evidence that claims 1–17 are unpatentable under 35 U.S.C. § 103 over: (1) Kuhn, McSpadden, ISO 3630-1, and Pelton; and (2) Matsutani, Pelton, and ISO 3630-1.¹⁴

IV. ORDERS

After due consideration of the record before us, it is

¹⁴ We determine that it is unnecessary to address the proposed ground of obviousness for claims 8, 13, 15, and 17 based on Kuhn and ISO 3630-1.

ORDERED that claims 1–17 of the '773 patent are held unpatentable;

FURTHER ORDERED that US Endo's Motion to Exclude (Paper 62) is *dismissed as moot*;

FURTHER ORDERED that GSI's Motion to Exclude (Paper 63) is *dismissed as moot*; and

FURTHER ORDERED that, because this is a Final Written Decision, the parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

IPR2015-00632
Patent 8,727,773 B2

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