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Paper 29
Date: August 5, 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 IPR2015-00632
Patent 8,727,773 B2

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

COCKS, *Administrative Patent Judge.*

DECISION
Institution of *Inter Partes* Review
37 CFR § 42.108

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"). 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.

To institute an *inter partes* review, we must determine that the information presented in the Petition shows "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). For the reasons set forth below, we conclude that the information presented in the Petition establishes a reasonable likelihood that Petitioner will prevail in showing that claims 1–17 of the '773 patent are unpatentable. Pursuant to 35 U.S.C. § 314, we hereby authorize an *inter partes* review to be instituted as to claims 1–17.

Our factual findings and conclusions at this stage of the proceeding are based on the evidentiary record developed thus far (prior to Patent Owner's Response). This is not a final decision as to patentability of claims for which *inter partes* review is instituted. Our final decision will be based on the record, as fully developed during trial.

A. Related Matters

The '773 patent is stated to be the subject of a litigation 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.). Paper 5, 2[1]; *see* Paper 8, 1.

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 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

[1] GSI also identifies four patents, 8,562,341; 8,083,873; 8,062,033, and 8,876,991 as "related matters" to this proceeding. *Id*. at 2–3.

detailed view of the shank of the endodontic instrument shown in FIG. 1a" (Fig. 1b). *Id*. at 3:21–24.

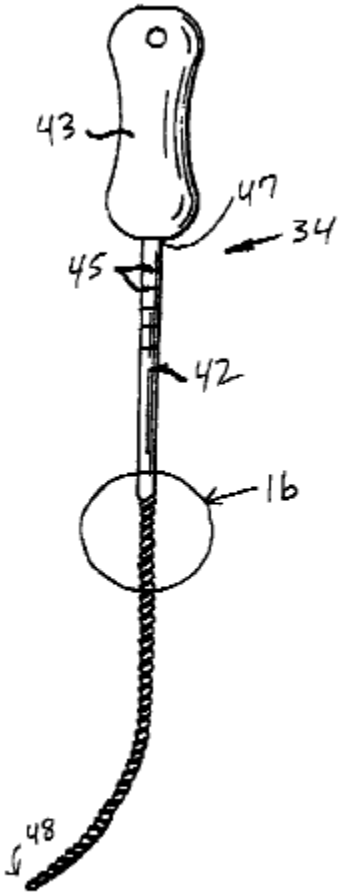


Fig. 1a

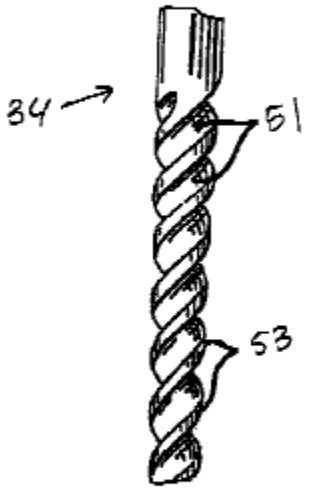


Fig. 1b

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. 1002), and prior art of record (Exs. 1004 and 1005) provides the following explanation of the effect of heat-treatment on structures made of a superelastic material, such as Nickel-Titanium (“Ni-Ti”):

> The superelastic and shape memory properties result from the microscopic structure of Ni-Ti crystals, which can take on at least two relevant solid phases: austenite and martensite. In the austenite phase, the individual atoms in the crystal are arranged rigidly, whereas in the martensite phase, the atoms can shift within the lattice, making the material more flexible. The transformation between austenite and martensite depends principally on temperature, with martensite occurring at lower temperatures. Ex. 1002 at ¶ 28-29; *see* Ex. 1004 at 5-6; Ex. 1005 at 25.
>
> When Ni-Ti is in the martensite phase at ambient temperatures, it exhibits shape memory; when subjected to a bending force it will stay deformed, returning to its original shape when heated above a transformation temperature to form austenite. When ambient temperatures are higher than the transformation temperature, Ni-Ti is stable as austenite rather than martensite. However, a sufficient applied stress may

> transform the austenite phase into a more flexible but meta-stable martensite phase despite being above its transformation temperature, allowing considerably more deformation. When the stress is released, Ni-Ti reverts quickly to the austenite phase, returning the object to its previous shape. This is superelasticity. Ex. 1002 at ¶¶ 30-31; Ex. 1004 at 5-6; Ex. 1005 at 25.

Pet. 3–4.

C. 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.

D. References Relied Upon

US Endo relies upon the following references:

Luebke 2008	US 2008/0032260 A1	Feb. 7, 2008	Ex. 1012
Gao	US 2011/0271529 A1	Nov. 10, 2011	Ex. 1014
McSpadden	US 2002/0137008 A1	Sep. 26, 2002	Ex. 1022
Matsutani	US 7,713,815 B2	Nov. 21, 2006	Ex. 1023

Alan R. Pelton et al., *Optimisation of Processing and Properties of Medical-Grade Nitinol Wire*, 9 MINIMALLY INVASIVE THERAPIES & ALLIED TECHS. 107 (2000) ("Pelton")	Ex. 1006
International Standard ISO 3630-1, 1st ed. (1992) ("ISO 3630-1")	Ex. 1016
Salwa E. Khier et al., *Bending properties of superelastic and nonsuperelastic nickel-titanium orthodontic wires,* 99 AM. J. ORTHODONTICS & DENTOFACIAL ORTHOPEDICS 310 (1991) ("Khier")	Ex. 1018
Grégoire Kuhn & Laurence Jordan, *Fatigue and Mechanical Properties of Nickel-Titanium Endodontic Instruments,* 28 J. ENDODONTICS 716 (2002) ("Kuhn")	Ex. 1019
S. Miyazaki et al., *Characteristics of Deformation and Transformation Pseudoelasticity in Ti-Ti Alloys,* 53 J. PHYSIQUE COLLOQUES C4-255 (1982) ("Miyazaki")	Ex. 1024

E. The Proposed Grounds of Unpatentability

US Endo contends that claims 1–17 of the '632 patent are unpatentable under 35 U.S.C. on the following grounds:

Ground	References	Basis	Claim(s) challenged
1	Luebke 2008	§ 102	1–17
2	Gao	§ 102	1–7 and 9–12
3	Gao and ISO 3630-1	§ 103	8 and 13–17
4	Gao, ISO 3630-1, and Khier	§ 103	1–17
5	Kuhn	§ 102	1, 2, and 9–12
6	Kuhn and ISO 3630-1	§ 103	8, 13, 15, and 17
7	Kuhn, ISO 3630-1, McSpadden, and Pelton	§ 103	1–17
8	Kuhn, ISO 3630-1, and Khier	§ 103	1–17
9	Kuhn, ISO 3630-1, McSpadden, Pelton, and Khier	§ 103	1–17
10	McSpadden, Miyazaki, and ISO 3630-1	§ 103	1–17
11	Matsutani, Pelton, and ISO 3630-1	§ 103	1–17
12	Matsutani, Pelton, ISO 3630-1, and Khier	§ 103	1–17

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); *In re Cuozzo Speed Techs., LLC*, No. 2014–1301, ___ F.3d ___, 2015 WL 4097949, at *5–*8 (Fed. Cir. July 8, 2015). 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). However, 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).

Neither party contends that the '773 patent sets forth any lexicographic definition for any claim term. For purposes of this Decision, we have given all claim terms their ordinary and customary meaning as would be understood by a skilled artisan in light of the Specification of the '773 patent. Nevertheless, we address expressly the meaning of the following claim terms/phrases: (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."

1. "heat treating"

Each of claims 1 and 13 is drawn to a method of manufacturing or modifying an endodontic instrument and includes a step of providing an elongate shank. Each claim also includes a step of "heat treating" that shank. US Endo contends that, in the context of an *inter partes* review proceeding, the claimed act of heat-treating the shank "should be construed to include heat treatment in any environment." Pet. 7. GSI expresses agreement with US Endo's construction. Prelim. Resp. 10.

Although the Specification of the '773 patent describes heat treating of an endodontic instrument's shank only in connection with an atmosphere

that is "unreactive with the shank" (*see, e.g.*, Ex. 1001, 2:62–65), we observe that neither claim 1 nor claim 13 makes explicit any requirement as to the characteristics of the atmosphere in which the claimed heat-treating occurs. Furthermore, other claims that depend from claim 1 or claim 13 make clear that the act of heat-treating may be performed in "any atmosphere" (claim 4) or in an atmosphere that is "unreactive, ambient, or any other acceptable heat treatment process" (claims 5, 6, and 16). Accordingly, for purposes of this Decision, we construe claims 1 and 13 as permitting the step of heat-treating the shank in any atmosphere or environment.

2. The "wherein" clause

Each of claims 1 and 13 includes a concluding "wherein" clause that specifies that a shank, once heat-treated, will exhibit a particular level of permanent deformation (i.e. "an angle greater than 10 degrees") after being subjected to a particular level of torque (i.e., "45 degrees of flexion") upon being "tested in accordance with ISO Standard 3630-1." US Endo contends the following with respect to the "wherein" clauses of claims 1 and 13:

> Petitioner submits that, for the purpose of patentability under 35 U.S.C. §§ 102–103, this clause should not be considered a limitation because it only states the intended result of performing the claimed heat treatment process. However, if the "wherein" clause is determined to be a limitation, then, based on the applicant's representations and arguments during prosecution, it is met by a prior art reference disclosing "some degree of permanent deformation" and/or by a heat-treated file with an austenite finish temperature about mouth temperature.

Pet. 7–8.

GSI responds that the noted "wherein" clauses may not be discounted and, instead, "constitute material limitations of the claimed methods,"

(Prelim. Resp. 11). According to GSI, that is so because the clauses establish the means for determining whether a heat treatment process is encompassed by the claims. In that respect, GSI submits that a given heat treatment process is outside the scope of the claims if it does not transform a superelastic nickel titanium material into one that exhibits greater than 10 degrees of permanent deformation after the application of 45 degrees of torque upon testing in the ISO Standard 3630-1 bend test. *Id.*

On this record, we do not agree with US Endo that the pertinent "wherein" clause should be disregarded as a limiting aspect of claims 1 and 13. We recognize that the Federal Circuit has declined to give weight to phrases in "whereby" clauses of method claims that simply expressed the intended result of a process step that has been positively recited. *See, e.g.*, *Minton v. Nat'l Ass'n of Sec. Dealers, Inc.*, 336 F.3d 1373, 1381 (Fed. Cir. 2003) (holding that the district court was correct in not giving weight to the phrase "traded efficiently" because the term "efficiently" did not inform the mechanics of how the trade is executed and was instead a laudatory term characterizing the result of the executing step). The inquiry, however, in that regard is fact-specific and determined on a case-by-case basis. Here, the noted "wherein" clauses provide a means of assessing the efficacy of the act of heat-treating a shank to determine if the resulting physical transformation of the shank places the heat treating process within the confines of the claims. In circumstances such as those present here, the "wherein" clause sets forth a necessary purpose of a claim step, and should, therefore, be regarded as a material limitation of the claim. *See Griffin v. Bertina*, 285 F.3d 1029, 1034 (Fed. Cir. 2002) (determining that "wherein" clauses of a claim were limiting because they "provide the necessary purpose for the

steps" of a method.) Further, unlike the merely laudatory term to which the court declined to give weight in *Minton*, the "wherein" clause in this case sets forth a specific, quantitative test.

We are cognizant that US Endo proposes an alternative approach that, should the "wherein" clauses of claims 1 and 13 be considered limiting, then "some" degree of permanent deformation should suffice for the expression "greater than 10 degrees" of permanent deformation that now appears in those claims. US Endo, however, provides no meaningful explanation as to why that should be the case. To that end, US Endo does not articulate a reason why "some degree" of deformation somehow forms a meaning or construction of "greater than 10 degrees." We decline, on this record, to so construe that aspect of the wherein clauses in the proffered manner.

At this time, we regard the "wherein" clause in each of claims 1 and 13 as a limitation of the claims that lays out a metric for determining if a heat treatment process falls within the scope of the claims.

B. Discussion

US Endo, in its Petition, advances twelve grounds that it contends establish the unpatentability of the claims of the '773 patent. Of those grounds, four are premised on the assertion that the claims of the '773 patent are entitled only to a filing date of April 25, 2012, which is the actual filing date of the application that became the '773 patent. GSI, on the other hand, contends that the effective filing date of the claims of the '773 patent are June 7, 2005, which is the filing date of PCT application PCT/US2005/019947 ("the PCT application"), to which the '773 patent claims priority. Prelim Resp. 15; *see* Ex. 1001.

1. The effective filing date of the '773 patent

US Endo contends that all the applications on which the '773 patent claims priority lack support under 35 U.S.C. § 112 for heat treatment in a "reactive" atmosphere. Pet. 15–16. According to US Endo, because the claims of the '773 patent encompass within their scope the act of heat-treating a shank in any atmosphere, including one that is reactive to the shank, the claims of the '773 patent are not entitled to the benefit of the filing date of any of the earlier applications. To that end, US Endo is of the view that, with respect to the application that became the '773 patent, "it cannot be said that applicant possessed an invention comprising conducting the heat treatment step in atmospheres that are both reactive and unreactive with Ni-Ti prior to the April 25, 2012 filing date." *Id*. at 18–19.

GSI does not agree. In disputing US Endo's assertions, GSI maintains that the PCT application describes at least two embodiments of the invention, including one in which "superelastic nickel titanium files [] were coated by heat-treatment at 500 ºC in a non-inert, or reactive, atmosphere—nitrogen gas and titanium" citing the PCT application (Ex. 2003) at paragraphs 35–42 and Figures 3–7. Prelim. Resp. 16. We observe that US Endo seemingly recognizes that the PCT application describes a heat treatment process performed in an environment that is reactive, but discounts that description as being applied only to "coated instruments." Pet. 16 (emphasis omitted). US Endo, however, does not articulate why the "coated" aspect of the instruments has significance with respect to the type of atmosphere employed, i.e., in this case, one that is reactive to the instrument.

To satisfy 35 U.S.C. § 112, the written description must convey with reasonable clarity to those skilled in the art that the inventor was in possession of the claimed invention. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563–64 (Fed. Cir. 1991). One shows "possession" of the invention by describing the invention using such descriptive means as words, structures, figures, diagrams, formulas, etc. that fully set forth the claimed invention. *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). Here, US Endo does not explain adequately why the above-noted heat treatment procedure involving a "nitrogen gas and titanium" atmosphere described in the PCT application is insufficient to convey the use of a reactive atmosphere.[2] On this record, we are not persuaded that the inventors of the '773 patent did not demonstrate that they possessed the use of a heat treatment process employing a reactive atmosphere at the time of the filing of the PCT application.

Therefore, at this time, we are persuaded that the '773 patent is entitled to an effective filing date that is the filing date of the PCT application.

2. Proposed Grounds 1–4

Each of the grounds designated 1–4 in the Petition and in this Decision includes either Luebke 2008 or Gao. US Endo's position that those references are available as "prior art" in the context of the '773 patent is predicated on a determination that the claims of the '773 patent are entitled only to the filing date of April 25, 2012. For the reasons discussed above,

[2] We understand that description in the PCT application to carry forward through all applications intervening the PCT application and the '773 patent to which the '773 patent claims priority.

we do not discern that the claims of the '773 patent find inadequate support in the PCT application so as to deprive those claims of the effective filing date of that PCT application, i.e., June 7, 2005.

Accordingly, we conclude that, in light of the record before us, Luebke 2008 and Gao are not considered properly as prior art to the '773 patent. We are not persuaded, therefore, that US Endo has shown a reasonable likelihood of prevailing in its challenge to any of the claims in connection with proposed grounds 1–4.

3. Proposed Grounds 5, 6, and 7

Each of proposed grounds 5, 6, and 7 is based on Kuhn. In particular, ground 5 applies Kuhn as anticipating claims 1, 2, and 9–12, ground 6 applies Kuhn and ISO 3630-1 as rendering obvious claims 8, 13, 15, and 17, and ground 7 applies Kuhn, ISO 3630-1, McSpadden, and Pelton as rendering obvious claims 1–17.

a. 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.[3] 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 ºC, 400 ºC,

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

450 ºC, 510 ºC, 600 ºC and 700 ºC in salt baths for 10 min and at 600 ºC and 700 ºC 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*.

b. Anticipation of claims 1, 2, and 9–12 by Kuhn

US Endo contends that Kuhn discloses all the features required by claims 1, 2, and 9–12, such that the reference anticipates those claims. Pet. 29–33. GSI challenges US Endo's contention on the theory that Kuhn lacks three features required by those claims. In particular, according to GSI, Kuhn does not disclose: (1) heat treating the "entire" shank as set forth in claim 1 (Prelim. Resp. 28); (2) a "greater than 10 degrees of permanent deformation" after bend testing (*id*. at 28–31); and (3) the composition limitation of claim 12 pertaining to a make-up of 54–57% nickel and 43–46% titanium for the material of the shank (*id*. at 30).

i. Heat-treating the "entire" shank

US Endo contends that Kuhn's disclosure accounts for the requirement that an entire shank is heat-treated. In that respect, US Endo proposes that Kuhn does not limit its heat treatment disclosures to only a portion of the instruments, and maintains that "Kuhn performed bend-testing on the entire shank, confirming that the entire shank was treated," citing to Kuhn at page 718. Pet. 30. US Endo also relies on the testimony of Dr. Goldberg, who testifies, based on the content of Kuhn, it is his opinion that Kuhn contemplates heat-treating the entirety of a shank. Ex. 1002 ¶ 132.

GSI disputes that Kuhn contemplates the step of heat-treating the entirety of a shank. Instead, GSI urges that Kuhn discloses applying heat treatments only to portions of a file, specifically the "working or active part of the file," and, thus, does not disclose heat-treating the entire shank of an endodontic instrument. Prelim. Resp. 29 (citing Ex. 1019 (Kuhn), 717).

The portion of Kuhn at page 717 that is referenced by GSI does disclose that an exemplary tested file is one measuring 25 mm in length, but is "cut to separate [the] working or active part of the file from the inactive part." Ex. 1019, 717, first column. In further describing the methodologies of a thermal treatment process, Kuhn sets forth that the file is cut into segments measuring 5 mm in length. *Id*. In later explaining the nature of "bending tests," however, Kuhn describes that "bending of files" occurs and that those files constitute "[n]ew instruments, instruments used in the clinic, and instruments that have been heat-treated." *Id*. at 717, second column. Kuhn also sets forth that the bending tests involve bending the "tip of the instrument" (*id*. at 718, second column), and that aspects of the bending tests involve bending the instruments by as much as 8 mm (*see id*. at 719, Fig. 6A).

Although Kuhn does set forth that heat treatment may be performed on portions of a file that have been cut, we observe that Kuhn also seemingly contemplates that bend testing is performed on instruments as a whole that have been subjected to heat treatment (e.g., bending the "tip of the instrument" (*id*. at 718, second column)). We also are mindful that, in bending or deforming files by as much as 8 mm as a part of the bending tests (e.g. as shown in Fig. 6A), Kuhn clearly contemplates that some samples undergoing those tests must be larger in length than the samples that were

"cut" so as to be 5 mm in length. In considering the record before us, and for purposes of this Decision, we are persuaded that Kuhn conveys that the entirety of an instrument file or shank may be heat-treated.

ii. "greater than 10 degrees of permanent deformation"

Claim 1 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 Kuhn 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 400ºC-treated file depicted in Kuhn's Figures 6A; (2) the declaration testimony of Dr. Goldberg at paragraphs 135–137; and (3) and representations made by the applicants during the prosecution of the patent application that became the '773 patent. *Id*.

According to Dr. Goldberg, the curve shown in Figure 6A that corresponds to a file heat treated at 400 ºC 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 ºC, the transformation temperature, i.e., the temperature at which the file transitions between martensite and austenite, was increased from 35 ºC to 40 ºC. 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 generally discounts Kuhn's teachings as satisfying the requirement of claim 1's "wherein" clause. Prelim. Resp. 30–31. On this record, however, GSI does not explain why Dr. Goldberg's above-noted testimony should be discredited. GSI also generally argues that Kuhn does not convey that its bending test is the ISO Standard 3630-1 bend test; however, we do not discern that claim 1 requires that the ISO Standard 3630-1 bend test must be employed. Rather, the claim simply requires particular resulting deformation properties of a treated shank, and specifies that the ISO Standard 3630-1 bend test is a way to ascertain that the shank has the desired characteristics. On this record, GSI does not explain why we should disregard Dr. Goldberg's testimony that the bend test used in Kuhn conveys that the disclosed heat treatment of a file at 400 ºC also establishes a

file with the required deformation, or point to evidence serving to undermine Dr. Goldberg's testimony. We are mindful, however, that, at this stage of the proceeding, GSI has not yet had opportunity to submit any new testimony evidence to countervail that testimony. *See* 37 C.F.R. § 41.107(c).

Accordingly, at this time, we are persuaded that US Endo has demonstrated for purposes of the institution of trial that Kuhn discloses the requirement of the pertinent "wherein" clause of claim 1.

iii. The composition limitations of claim 12

Claim 12 depends from claim 1 and provides that "the superelastic nickel titanium alloy comprises 54–57 weight percent nickel and 43–46 weight percent titanium." In accounting for that composition, US Endo makes reference to Kuhn's disclosure that a type of file tested is one known in the art as "Profile," and points to content of the record that conveys that "Profile" instruments are understood in the art as being composed of 54.26% nickel and 45.42% titanium. Pet. 33 (citing Ex. 1021 at 759, and Ex. 1002 ¶ 144).

GSI urges that "Petitioner has not addressed this limitation in ground 5," but does not account for the above-noted disclosure that Kuhn describes the heat treatment and testing of a "Profile" endodontic instrument. In reviewing the record, we are persuaded, at this time, that endodontic instruments known in the art as a "Profile" type were recognized as having a composition of nickel and titanium that meets claim 12.

iv. Conclusion

We have considered US Endo's Petition, its underlying supporting evidence, and GSI's Patent Owner Preliminary Response. On the record

before us, we are persuaded that US Endo has established a reasonable likelihood of success in its challenge to claims 1, 2, and 9–12 as anticipated by Kuhn.

c. Obviousness of claims 8, 13, 15, and 17 over Kuhn and ISO 3630-1

US Endo proposes that claims 8, 13, 15, and 17 are unpatentable over Kuhn and ISO 3630-1. Claim 8 depends from claim 1 and adds the feature "the instrument shank has a diameter of 0.5 to 1.6 millimeters." Claim 13, from which claims 15 and 17 depend, is independent and, like claim 1, is drawn to a method for manufacturing or modifying an endodontic instrument. Claim 13 includes a feature of "the instrument being in accordance with ISO Standard 3630-1." US Endo applies ISO 3630-1 as teaching an endodontic instrument with a shank within the range of 0.5 to 1.6 millimeters, and the use of endodontic instruments construed in accordance with ISO Standard 3630-1. Pet. 31–33.

In challenging the grounds based on Kuhn and ISO 3630-1, GSI relies on the same arguments it advanced with respect to claims 1, 2, and 9–12. Prelim. Resp. 32–33. For the same reasons discussed above, we are not persuaded, at this time, that the arguments are correct.

We have considered the Petition, its supporting evidence, and GSI's Preliminary Response, and conclude that US Endo has shown a reasonable likelihood of success in this challenge to claims 8, 13, 15, and 17 as unpatentable over Kuhn and ISO 3630-1.

d. Obviousness of claims 1–17over Kuhn, ISO 3630-1, McSpadden, and Pelton

US Endo proposes that claims 1–17 are unpatentable over Kuhn, ISO 3630-1, McSpadden, and Pelton. Pet. 34–43. As discussed above, we are satisfied, on the record now before us, that US Endo has shown a reasonable likelihood of succeeding in its challenge to claims 1, 2, and 9–12 as anticipated by Kuhn, and claims 8, 13, 15, and 17 as unpatentable over Kuhn and ISO 3630-1. McSpadden and Pelton present additional teachings in the art with respect to the manufacture of endodontic instruments (McSpadden) or other medical instruments (Pelton) from alloys of nickel and titanium. We do not discern those additional teachings disrupt the teachings of Kuhn and ISO 3630-1, and also conclude that US Endo has shown a reasonable likelihood of succeeding in its proposal that claims 1, 2, 8–13, 15, and 17 are unpatentable over Kuhn, ISO 3630-1, McSpadden, and Pelton.

With respect to claims 3–7, 14, and 16, these claims ultimately depend from one of claims 1 or 13, and add the following limitations:

"the shank is heat-treated for 1 to 2 hours" (claims 3 and 14);

"step (b) is performed in any atmosphere" (claim 4);

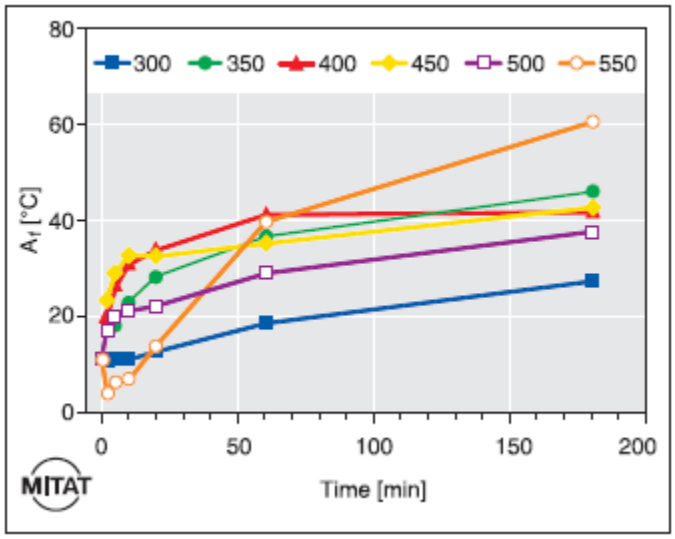
"the atmosphere is unreactive ambient or any other acceptable heat treatment process" (claims 5 and 6);

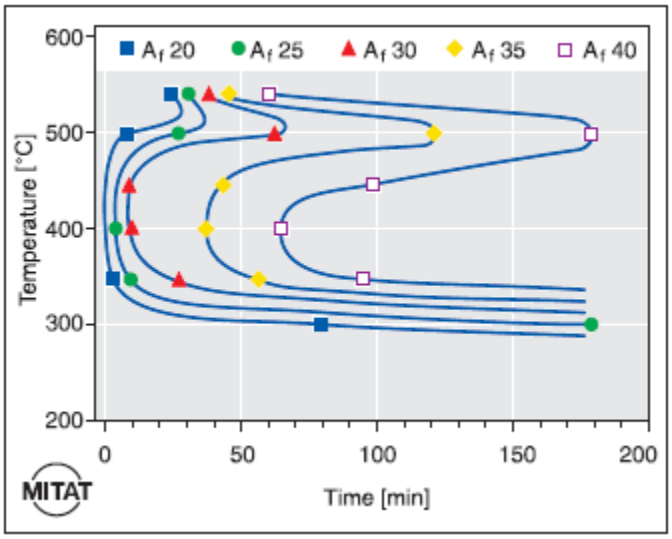
"the instrument shank consists essentially of a superelastic nickel titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium, the temperature is 500° C., and the shank is heat-treated for 1 to 2 hours" (claim 7); and

"step b is performed in an atmosphere that is unreactive ambient or any other acceptable heat treatment process" (claim 16).

US Endo contends 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. GSI argues that some of the above-noted added features, such as heat treating for 2 hours (*see*, *e.g.*, Prelim. Resp. 34–35), or heat treating for 1–2 hours at 500 ºC (*see*, *e.g.*, *id.* at 36) are not found in the prior art.

In reviewing the record it is apparent that the art conveys readily that there are a variety of known, viable options in terms of heat treatment duration and temperature. For instance, the following is a reproduction of Pelton's Figures 9 and 10:





The figures 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). Ex. 1006, 114.[4] US Endo contends that those figures demonstrate the heat treatment of nickel-titanium wire for periods ranging from 2 to 180 minutes at temperatures ranging from 300 ºC to 600 ºC. Pet. 34–35. Given Pelton's teachings, we are persuaded that a person of ordinary skill in the art would have appreciated that heat treating at various temperatures, e.g., 475 ºC to 525 ºC, for various periods of time, e.g., 1 to 2 hours, were options available for selection. That Pelton, itself, is not concerned specifically with endodontic instruments does not end the obviousness inquiry, contrary to the view of GSI. *See* Prelim. Resp. 36. Rather, in an obviousness analysis, it is not necessary to find precise teachings in the prior art directed to the specific subject matter claimed because inferences and creative steps that a person of ordinary skill in the art

[4] Pelton is paginated as pages 107 to 118 in the "Min Invas Ther & Allied Technol 2000" journal. Ex. 1006. That pagination sequence is referenced in this Decision.

would employ can be taken into account. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). Here, US Endo has shown sufficiently, on this record, that a skilled artisan would have inferred reasonably that Pelton's teachings that are directed to the treatment of wire made of nickel-titanium would have been applicable to other devices composed of that material, such as the endodontic instrument in Kuhn.

We also are persuaded, at this time, that one of ordinary skill in the art would have had adequate reason to combine the teachings of the prior art to arrive at the invention set forth in claims 1–17. To that end, we do not discern why applying known heat treatment techniques to a known structure, i.e., an endodontic instrument, would have been more than simply the routine exercise of the ordinary skill of a skilled artisan. *See KSR*, 550 U.S. at 421.

Having considered the record before us, we are persuaded that US Endo has shown a reasonable likelihood of prevailing in its challenge to claims 1–17 as unpatentable based on the combined teachings of Kuhn, ISO 3630-1, McSpadden, and Pelton.

4. Proposed Ground 11

US Endo submits 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:

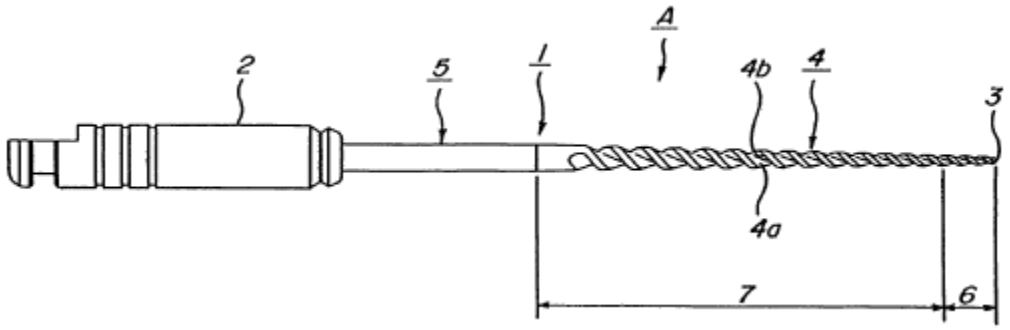


Figure 1 above depicts a tool according to Matsutani's invention. *Id.* at 3:14–15. Matsutani characterizes the tool as "Reamer A," which includes needle portion 1 and grip 2. *Id*. at 3:61–64. Needle portion 1 includes straight shank 5, tapered work portion 4, and tip 3. Needle portion 1 is "made of 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.

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 ¾ 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. Obviousness of claims 1–17 over 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. For the reasons set forth below, we are persuaded, on this record, that US Endo has shown a reasonable likelihood of prevailing in its challenge to claims 1–17 as unpatentable over Matsutani, Pelton, and ISO 3630-1.

At the outset, we are cognizant that Matsutani was a reference before the examiner during the prosecution of the application that became the '773 patent. GSI argues that, as such, we should deny institution of trial with respect to Ground 11 on that basis alone. Prelim. Resp. 47. US Endo argues that, in support of its Petition, it has provided "additional evidence of the knowledge of one of ordinary skill" that was not available to the Examiner. Pet. 50, n.11. To that end, we observe that US Endo relies on evidence, such as the declaration testimony of Dr. Goldberg, that was not part of the earlier prosecution. In this case, we decline to deny institution of a trial on Ground 11 simply because Matsutani was a reference previously of record.

GSI primarily focuses its challenge to Ground 11 on two premises. Specifically, GSI contends that Matsutani does not teach heat treating the entire shank, and that neither Matsutani nor Pelton teach that the shank exhibits greater than 10 degrees of permanent deformation upon being subject to a bending test after heat treatment. Prelim. Resp. 48–50.

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 ¾ of the working portion of its endodontic instrument out of a concern that the 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 (U.S.A) LLC v. Apotex, Inc.*, 407 F.3d 1371, 1380 (Fed. Cir. 2005). Indeed, in evaluating the teachings of the prior art, the inferences of one ordinary skill in the art would employ should be taken into account. *See KSR*, 550 U.S. at 418.

Here, although Matsutani may discount heat treating the entirety of the shank, we are not persuaded that a skilled artisan would have regarded that practice as unworkable or unobtainable. To that end, and for purposes of this Decision, 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* ¶¶ 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 treatment of a structure. *See* Pet. 53.

Thus, we conclude that the current record demonstrates that it was understood in the art that various extents of the shank of an endodontic instrument may be heat-treated. Although 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, that potential problem may be balanced 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. 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, for purposes of this Decision, that such requirement is derived from the teachings of Matsutani. 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 4 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 also 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 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. For purposes of this Decision, we credit Dr. Goldberg's testimony in that regard. In crediting that testimony, we conclude that a skilled artisan following the teachings of Matsutani and Pelton would have appreciated that a bend test, as described in Matsutani, may be performed upon the Ni-Ti shank of an endodontic instrument heated for the duration and to the temperatures disclosed in Pelton. We also conclude that the art conveys circumstances where a transformation temperature of the shank is altered to be above body temperature. In such circumstances, we are persuaded, at this time, that the deformation resulting from the bend test would account for that required by the claims.

iii. Conclusion

We have considered the record before us, and, at this time, we are persuaded that US Endo has established a reasonable likelihood of succeeding in its challenge to claims 1–17 as unpatentable over Matsutani, Pelton, and ISO 3630-1.

5. Remaining Grounds

Grounds 8, 9, and 12 are presented as alternative grounds that are premised on a construction of "heat treating" that requires an unreactive environment. As discussed above in § II.A.1, we do not construe the claims

has having such a requirement. Accordingly, we do not institute trial based on grounds 8, 9, and 12.

Ground 10 is an additional ground proposed for claims 1–17 based on McSpadden, Miyazaki, and ISO 3630-1. There is no requirement that an *inter partes* review proceeding must proceed on all grounds of unpatentability asserted by a petition. *See* 37 C.F.R. § 42.108(a) ("When instituting inter partes review, the Board may authorize the review to proceed on all or some of the challenged claims and on all or some of the grounds of unpatentability asserted for each claim."). Furthermore, we construe our rules "to secure the just, speedy, and inexpensive resolution of every proceeding." 37 C.F.R. § 42.1(b); *see also* 35 U.S.C. § 316(b) (regulations for post-grant proceedings take into account "the efficient administration of the Office" and "the ability of the Office to timely complete [instituted] proceedings").

Thus, whether to institute trial on a particular ground of unpatentability proposed is our discretion. We have determined that US Endo has shown a reasonable likelihood of success with respect claims 1–17 based on other prior art. In this case, we exercise our discretion and decline to institute trial in this *inter partes* review proceeding based on the ground of unpatentability involving McSpadden, Miyazaki, and ISO 3630-1 (ground 10).

III. CONCLUSION

For the foregoing reasons, we determine that the information presented in the Petition establishes a reasonable likelihood that US Endo would prevail in showing that claims 1–17 are unpatentable. We have not

made a final determination with respect to the patentability of those claims or the construction of any claim term.

IV. ORDERS

After due consideration of the record before us, it is

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted on the grounds that:

A. Claims 1, 2, and 9–12 are unpatentable under 35 U.S.C. §102(b) as anticipated by Kuhn;

B. Claims 8, 13, 15, and 17 are unpatentable under 35 U.S.C. §103(a) over Kuhn and ISO 3630-1;

C. Claims 1–17 are unpatentable under 35 U.S.C. §103(a) over Kuhn, ISO 3630-1, McSpadden, and Pelton;

D. Claims 1–17 are unpatentable under 35 U.S.C. §103(a) over Matsutani, Pelton, and ISO 3630-1;

FURTHER ORDERED that no other grounds are authorized for *inter partes* review; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial. The trial will commence on the entry date of this decision.

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