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 No. PGR2015-00019
U.S. Patent No. 8,876,991 B2

PETITION FOR POST-GRANT REVIEW

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Prosecution history exhibits are cited in this Petition using page numbers added by Petitioner. Other exhibits are cited by their original page or paragraph numbers.

US Endodontics, LLC ("Petitioner") petitions for post-grant review ("PGR") under 35 U.S.C. §§ 321-329 and 37 C.F.R., Part 42, of claims 12-16 of U.S. Patent No. 8,876,991 ("the '991 patent"). The '991 patent issued on November 4, 2014 from U.S. Patent Application No. 14/167,311, filed on January 29, 2014, and is currently assigned to Gold Standard Instruments, LLC ("Patent Owner").

I. MANDATORY NOTICES (37 C.F.R. § 42.8)

A. Real Parties-in-Interest

Petitioner US Endodontics, LLC; Petitioner's two owners, Charles Goodis and Bobby Bennett; and Edge Endo, LLC and Guidance Endodontics, LLC, both owned by Charles Goodis, are the real parties-in-interest.

B. Related Matters

Petitioner has filed two petitions for *inter partes* review of related U.S. Patent No. 8,727,773 ("the '773 patent"). *See* IPR2015-00632 and IPR2015-01476. The '773 patent and related U.S. Patent No. 8,562,341 are currently being asserted against Petitioner by Patent Owner's licensee Dentsply International, Inc. and Tulsa Dental Products LLC in pending litigation filed on June 24, 2014 in the U.S. District Court for the Eastern District of Tennessee, No. 14-civ-196 (JRG). Additionally, Patent Owner has patent applications pending that might be affected by this proceeding: Ser. Nos. 14/522,013, 14/722,309, 14/722,390, and 14/722,840. Petitioner is not aware of any other pending administrative matter or litigation that would affect, or be affected by, a decision in this proceeding.

C. Counsel and Service Information

Lead Counsel: Jeffrey S. Ginsberg (Reg. No. 36,148)

Back-up Counsel: Matthew G. Berkowitz (Reg. No. 57,215)

Eric T. Schreiber (Reg. No. 58,771)

Electronic Service: jginsberg@kenyon.com; mberkowitz@kenyon.com; and eschreiber@kenyon.com

Post and Delivery: Kenyon & Kenyon LLP, One Broadway, New York, NY 10004

Telephone: 212-425-7200 Facsimile: 212-425-5288

D. Power of Attorney

A power of attorney is filed herewith according to 37 C.F.R. § 42.10(b).

II. PAYMENT OF FEES (37 C.F.R. § 42.203)

The required fee of $30,000 is being paid through the Patent Review Processing System. The USPTO is authorized to charge any fee deficiency, or credit any overpayment, to Deposit Account 11-0600 (Kenyon & Kenyon LLP).

III. SUMMARY OF REASONS WHY THE CHALLENGED CLAIMS ARE UNPATENTABLE

Issuance of the ’991 patent was a mistake; it appears that the examiner reviewed the wrong claim set when issuing the Notice of Allowance and erroneously believed that the claims were limited to heat-treating a nickel titanium (“Ni-Ti”) endodontic instrument at above 400°C. The applicant was actually claiming a much broader temperature range (as low as 25°C), which is not enabled, lacks written description and is otherwise unpatentable as anticipated by and obvious over the prior art.

The specification of the ’991 patent is directed generally to “heat-treating” a Ni-Ti endodontic file (used for root canal procedures) to alter its physical properties. The specification states that certain heat-treating conditions will remove superelasticity from the file and make it permanently deformable (i.e., after heat-treating, a sufficient stress applied to the file will cause it to bend and retain the bent shape after the stress is removed, whereas a superelastic file will return to its original shape). Each of the examples in the ’991 patent describes heat-treating at 500°C. The claims of the ’991 patent, however, recite a method of heat-treating at temperatures as low as 25°C—essentially room temperature—in order to obtain permanent deformation. The specification does not describe or enable how to change the physical properties of nickel titanium by “heat-treating” at room temperature.

The examiner initially recognized this, rejecting the claims for, *inter alia*, lack of enablement, stating that “not all superelastic nickel titanium alloys subjected to a heat treatment at these low of temperatures would appear to result in that degree of deformation.” Ex. 1003 at 82-83. After a response from the applicant in which the claims were not amended, the examiner issued a Notice of Allowance, stating that "[a] method of . . . heat-treating the entire instrument or device ***at 400 C*** or above . . . was neither taught nor suggested by the prior art as a whole." *Id.* at 153 (emphasis added). In other words, the examiner allowed the claims based on the mistaken understanding that they required heat-treating at 400°C or above, and not the 25°C (or 300ºC) actually claimed.

As set forth below, claims 12-16 of the '991 patent are invalid under 35 U.S.C. § 112; heat-treating at from "above 25°C," which is recited as a lower bound in claims 12-13 and 15-16, or "from 300°C," which is recited as a lower bound in claim 14, to obtain permanent deformation is neither enabled nor operable. Further, there is no disclosure of heat-treating at as low as 25°C (or 300°C) to obtain permanent deformation in the chain of priority applications. Accordingly, the claims are not entitled to an effective filing date earlier than the '991 patent's January 29, 2014 filing date and are invalid over the prior art, including applicant's own prior published patent application. Even if entitled to an earlier effective filing date, the claims are invalid as anticipated by and obvious over prior art disclosing heat-treating of nickel titanium within the claimed range. The specific bases of invalidity are set forth in further detail below.

IV. BACKGROUND AND SUMMARY OF THE '991 PATENT

The '991 patent describes a method of modifying a Ni-Ti endodontic instrument for use in root canal therapy. A thin file is used to remove diseased tissue from a tooth's root(s). As described, the instrument includes a shank, comprised of a Ni-Ti alloy, and a handle. The shank includes cutting edge(s) necessary to remove tissue from the root canal. Ex. 1001 at 3:6-10, 4:3-8, Fig. 1a.

When appropriately processed, Ni-Ti can exhibit both superelasticity (also known as pseudoelasticity) and shape memory. Ex. 1002 ¶ 23. Superelasticity means that the material is relatively rigid until a threshold stress is applied, above which the material becomes more flexible. *Id.* When the stress is removed, the material reverts to its original shape. *Id.* A shape memory material is flexible and does not revert to its original shape immediately after it is deformed. *Id.* However, when the material is heated past a transformation temperature, it reverts to its pre-deformation shape. *Id.*

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. *Id.* ¶ 26. In the austenite phase, the material is rigid, whereas in the martensite phase, the material is more flexible. *Id.* The transformation between austenite and martensite depends principally on temperature. Martensite occurs at lower temperatures. *Id.*; *see* Ex. 1004 at 5-6; Ex. 1005 at 25.

When Ni-Ti is in the martensite phase, it exhibits shape memory; when subjected to a bending force it will stay deformed (bent), returning to its original shape when heated above a transformation temperature (austenite finish (A_f) temperature) to form austenite. Ex. 1002 ¶¶ 27-28. When ambient temperatures are higher than the transformation temperature, Ni-Ti is stable as austenite rather than martensite. *Id*. ¶ 29. However, a sufficient applied stress may transform the austenite phase into a more flexible but meta-stable martensite phase, allowing considerably more deformation. *Id*. When the stress is released, Ni-Ti reverts to the austenite phase, returning the object to its previous shape: This is superelasticity. *Id*.; *see also* Ex. 1004 at 5-6; *see* Ex. 1005 at 25.

By 2004, it was well known that heat treatment of a Ni-Ti alloy could change its transformation temperature. Ex. 1002 ¶ 30; *see, e.g.*, Ex. 1006 at 112-15; Ex. 1007 at 3:12-30. The alleged invention of the ’991 patent is to increase the transformation temperature so that a Ni-Ti endodontic file, under conditions of use (i.e., at mouth temperature), is in the martensite phase rather than the austenite phase so that the file can be permanently deformed when subjected to bending forces. *See, e.g.*, Ex. 1003 at 129; *see also* Ex. 1008 at 144-60; Ex. 1002 ¶¶ 31-34.

V. PROSECUTION OF THE ’991 PATENT

U.S. Patent Application No. 14/167,311 (“the ’311 application”) was filed by applicant Neill Luebke on January 29, 2014. The application claims are identical to the claims that ultimately issued with the ’991 patent.

On April 11, 2014, the examiner issued an office action rejecting all claims of the ’311 application for lack of enablement. Ex. 1003 at 82-84. The claims recited subjecting a superelastic, Ni-Ti dental (or endodontic) instrument to heat treatment at a temperature range of from either 25°C or 300°C up to the melting point of Ni-Ti, with the result that the heat-treated instrument would have “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” (or substantially identical language). *See id*. at 23-25. The examiner’s rejection reasoned that “not all superelastic nickel titanium alloys subjected to a heat treatment at these low of temperatures would appear to result in that degree of deformation.” *Id*. at 82-83. The examiner “further noted that 25 C is less than the temperature of the mouth” so that the claimed method would “be broad enough to encompass placing a superelastic nickel titanium archwire in a patient’s mouth.” *Id*. at 83-84.

The examiner’s rejection also relied on the applicant’s own arguments during prosecution of an earlier related application, Ser. No. 12/977,625 (“the ’625 application”), wherein the applicant asserted that the temperature range he was now trying to claim was ineffective for creating a permanently deformable file. Specifically, the examiner noted that during prosecution of the ’625 application, the applicant sought to traverse a prior art rejection over a reference disclosing heat treatment at 350°C based on “the criticality of the temperature being over 400 C.” Ex. 1003 at 83. The examiner quoted the applicant’s prior arguments, which referenced an inventor declaration submitted therewith (“the 2008 declaration”):

> The Inventor’s Declaration explains that the angular deflection was significantly larger for the files heat-treated at 500°C, that the cyclic fatigue data demonstrate the remarkable property of passive flexibility in the files heat-treated at 500°C compared to the files heat-treated at 375°C, that the torque data indicates that the heat did not degrade the metal in the files heat-treated at 500°C, and that the bend test data shows that the files heat-treated at 500°C have improved flexibility compared to the files heat-treated at 375°C. This, heat treatment within the claimed range was <u>critical</u> to improving the beneficial properties of the endodontic instruments.

Id. (quoting the 8/26/2011 amendment in the ’625 application) (emphasis added); *see also* Ex. 1010 at 105-06 (applicant making same argument during prosecution of an earlier priority application).

The examiner noted that, “[i]t is unclear how these temperatures [in the ’311 application] are now sufficient when they had previously been established outside the critical range.” Ex. 1003 at 83.

On July 9, 2014, applicant submitted a response to the outstanding office action in the ’311 application, which included a new declaration (“the 2014 declaration”). Applicant argued that the 2008 declaration and accompanying amendment outlining the “criticality” of 400°C was not relevant to the then-pending independent claims of the ’625 application since they did not include the "angle of permanent deformation" clause, as required by the pending claims of the '311 application. *Id*. at 117. Applicant failed to mention that the <u>dependent</u> claims of the '625 application pending at the time of the 2008 declaration did include such a "permanent deformation" clause. *See* Ex. 1009 at 82. The examiner of the '625 application relied on applicant's representations in ultimately allowing the claims of that application, stating that the claimed temperature range of 400°C and above was "<u>critical</u> in providing distinguishing shape memory qualities." *Id.* at 130 (Statement of Reasons for Allowance) (emphasis added).

Applicant Luebke's 2014 declaration references a new study that he allegedly conducted to demonstrate that 375°C was a sufficient heat treatment temperature to create an instrument with a Ni-Ti shank in the martensitic phase, which applicant argued indicates that such instrument will have "an angle greater than 10 degrees of permanent deformation after torque at 45º of flexion when tested in accordance with ISO Standard 3630-1." Ex. 1003 at 126-27 (¶¶ 4-5). The 2014 declaration does not mention subjecting any of the files to actual testing in accordance with ISO Standard 3630-1 (as claimed) to determine whether permanent deformation is achieved; rather, applicant represented that since the heat-treated files were in the martensitic phase, they satisfied the claims. *See id*.

The 2014 declaration also cites to a graph included in a reference that applicant stated "published after the filing date of his application." Per the applicant, the graph allegedly demonstrated that instruments heat-treated between 300-400°C "will have a phase such that an angle greater than 10 degrees of permanent deformation … will be achieved." *See id*. at 127-28, ¶6.[1]

The examiner ultimately allowed the claims of the '311 application, stating that "a shape memory nickel-titanium alloy will result from the claimed method distinguished from the superelastic properties of the prior art." Ex. 1003 at 153-54. The claimed method, per the examiner, included "heat-treating the entire instrument or device at <u>400 C or above</u> but not [above] the melting temperature." *Id*. (emphasis added). However, none of the claims of the '311 application recites 400°C or above. The examiner's reasons for allowance did not address the applicant's <u>actual</u> claims (with temperature ranges as low as from above 25°C) or the clear inconsistencies between the applicant's 2008 and 2014 declarations.[2] While the applicant submitted comments to the allowance statement, the applicant merely asserted that the examiner's recitation of 400ºC was "underinclusive" given

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1 As further explained in sections VIII.B.2(c) and VIII.J.3, at footnote 28, *infra*, the cited graph actually originated from a 2000 (prior art) publication to Pelton (Ex. 1006 at 114 (Fig. 10)), which applicant failed to mention.

2 The same assistant examiner handled the examination of the '773 patent, which issued just 6 months earlier and <u>did</u> include claims with a 400°C temperature threshold. Ex. 1011; Ex. 1008 at 209-11, 227-28.

the actual claimed temperature ranges. *Id*. at 197-98. The discrepancy was never addressed by the USPTO.

VI. REQUIREMENTS FOR POST-GRANT REVIEW (37 C.F.R. § 42.204)

A. Grounds for Standing (37 C.F.R. § 42.204(a))

Petitioner certifies that the ’991 patent is available for PGR. The ’991 patent issued on November 4, 2014 from an application filed on January 29, 2014. For the reasons discussed below (section VII), at least one claim of the ’991 patent has an effective filing date on or after March 16, 2013 such that PGR is available. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, sec. 3(n)(1)(A), 6(f)(2), 125 Stat. 284, 293, 311 (2011). This Petition is filed less than nine months after the issuance of the ’991 patent. *See* 35 U.S.C. § 321(c). Petitioner is not barred or estopped from requesting PGR.

B. Identification of Challenged Claims and Specific Statutory Grounds (37 C.F.R. § 42.204(b)(1)-(2))

Petitioner challenges claims 12-16 of the ’991 patent (“the Challenged Claims”) under 35 U.S.C. §§ 102, 103, and 112.[3] Claim 12 reads:

> 12. 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

[3] Citations are to the current, post-AIA version of the Patent Act.

> 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 above 25° 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.

Ex. 1001 at 10:35-48. Each of claims 13 through 16 depends from claim 12. Claim 13 recites that step (b) occur in certain atmospheres, including any "acceptable heat treatment process." *Id.* at 10:49-51. Claim 14 specifies that the heat-treatment temperature in step (b) is "from 300° C" up to the melting point of the alloy. *Id.* at 10:52-54. Claim 15 provides that the shank has a diameter of 0.5 to 1.6 millimeters. *Id.*at 10:55-57. Finally, claim 16 recites that the alloy is 54-57 percent nickel by weight. *Id.* at 10:58-60.

Petitioner requests cancellation of claims 12-16 on the following grounds:[4]

Ground 1: Lack of Enablement of Claims 12-16 Under 35 U.S.C. § 112(a)

Ground 2: Lack of Written Description of Claims 12-16 Under § 112(a)

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[4] With respect to § 103 obviousness grounds, Petitioner also relies on the knowledge of one of ordinary skill, as explained in further detail in section VIII.

Ground 3: Anticipation of Claims 12-16 by Luebke 2008 Under § 102(a)

Ground 4: Obviousness of Claim 15 Over Luebke 2008 Either Alone or in View of Heath or ISO 3630-1 Under § 103

Ground 5: Anticipation of Claims 12-16 by Matsutani Under § 102(a)

Ground 6: Anticipation of Claims 12-14 and 16 by Kuhn Under § 102(a)

Ground 7: Obviousness of Claim 15 Over Kuhn Either Alone or in View of Heath or ISO 3630-1 Under § 103

Ground 8: Obviousness of Claims 12-16 Over Kuhn Either Alone or in View of Heath or ISO 3630-1 Under § 103

Ground 9: Obviousness of Claims 12-14 and 16 Over McSpadden and Pelton in View of Kuhn Under § 103

Ground 10: Obviousness of Claim 15 Over McSpadden and Pelton in View of Kuhn and in Further View of Heath and ISO 3630-1 Under § 103

Ground 11: Obviousness of Claims 12-14 and 16 Over Tripi in View of McSpadden Under § 103

Ground 12: Obviousness of Claim 15 Over Tripi in View of McSpadden and in Further View of Heath or ISO 3630-1 Under § 103

C. Claim Construction (37 C.F.R. § 42.204(b)(3))

A claim subject to PGR is given its "broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.200(b).

Petitioner submits, for the purposes of this PGR only, the following claim constructions.

1. "heat-treating the entire shank"

This limitation appears in independent claim 12 of the '991 patent. In the pending district court litigation involving the '991 patent's parent (the '773 patent), Petitioner has asserted that the same limitation should be construed to require "heat-treating the entire shank in an atmosphere consisting essentially of a gas unreactive with nickel titanium" since the specification uniformly states that the atmosphere is one that consists essentially of a gas not reactive with the shank component of the instrument. *See* Ex. 1011 at Abstract, 2:62-65, 4:12-15, 4:17-20, 7:40-43, 7:67-8:2, 8:20-21, 8:47-49, 9:6-9; *see also* Ex. 1001 at 2:65-3:1, 4:16-19, 4:21-24, 7:44-47, 8:4-6, 8:23-24, 9:10-12. Also, during prosecution of an earlier, related application, the applicant made clear that the unreactive atmosphere was an essential part of the invention (see *infra* section VII.C, regarding priority date).

The contrary position is that (i) the '991 patent claim language does not expressly limit heat treatment to an unreactive atmosphere, and (ii) dependent claim 13 of the '991 patent purports to cover treatment in "unreactive, ambient or any other acceptable heat treatment process."[5] For the purposes of this proceeding,

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5 Claims 4-6 and 16 of the '773 patent are the first disclosure, in any of the applications to which the '991 patent claims priority, of heat treatment in anything

the Board must apply the "broadest reasonable construction" ("BRC"). Under this standard, and for purposes of this proceeding only, Petitioner submits that the claims should be construed to include heat treatment in any environment.

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"

The "wherein" clause appears in independent claim 12. 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. Alternatively, if the "wherein" clause is considered a limitation for purposes of patentability, under the BRC, it should be construed to encompass files that (i) allow for some degree of permanent deformation and/or (ii) have A_f temperatures above 37°C, which, as set forth below, matches the applicant's and the examiner's stated understanding of the "wherein" clause during prosecution of applications in the same family as the '991 patent.

(a) The "wherein" clause is not a limitation

A clause in a method claim adds no patentable weight if it merely states the intended result of a positively recited method step. *See Minton v. Nat'l Ass'n of*

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other than "an atmosphere consisting essentially of a gas unreactive with the shank." *See* Section VII.C, *infra*.

Sec. Dealers, 336 F.3d 1373, 1381 (Fed. Cir. 2003) (no limiting effect given to a "whereby" clause requiring execution of a trade "efficiently" because the term "'efficiently' on its face does not inform the mechanics of how the trade is executed"); *Baxter Healthcare Corp. v. Millennium Biologix, LLC*, IPR2013-00590, Paper 9, at 8-9 (PTAB Mar. 21, 2014) (finding "wherein" clause not limiting insofar as it described intended result); M.P.E.P. § 2111.04.

The "wherein" clause at issue here merely states the intended result of heat-treating the "entire shank" of the instrument: It describes a property of "the heat treated shank," i.e., after it has undergone step (b). There are no further steps to be performed on or with the heat-treated shank. Rather, the claims merely state that if a particular test is performed on the shank after the claimed method is performed, a certain range of results will be achieved. The "wherein" clause does not alter the first two steps or require the performance of any additional step(s). [6]

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[6] Petitioner notes that in *Griffin v. Bertina*, 285 F.3d 1029, 1032-34 (Fed. Cir. 2002), "wherein" clauses in an interference count were held to be limiting because they gave "meaning and purpose to the manipulative steps." There, the issue was whether a party had shown reduction to practice, which "does not occur until the inventor has determined that the invention will work for its intended purpose." *Id.* (citation omitted). The claims in *Griffin* included the step of "assaying for the presence of a point mutation," and the "wherein" clauses at issue described the

Petitioner's position regarding the "wherein" clause is consistent with the understanding of various examiners during prosecution of related applications.

First, during prosecution of a European counterpart application, the EPO, in maintaining an objection to a claim with a similar clause, stated: "[C]laim 1, which [recites 'characterized . . . in that the 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'], **still refers to a result to be achieved.**" Ex. 1012 at 127.

Second, Petitioner's position is consistent with the examiner's apparent understanding of the claims during prosecution of the parent '773 patent. For example, in a rejection of then pending claims, the examiner disagreed with the applicant's arguments concerning a prior art reference to Patel, stating "[t]he [ISO 3630-1] test is only referred to inferentially to establish physical properties of the

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properties of the "point mutation" that was to be "assay[ed] for." *See id.* at 1031. The "wherein" clauses did not describe an intended result of the "assaying" step but rather provided information as to how that step must be performed—in particular, what kind of "point mutation" to test for.

By contrast, the "wherein" clause in claim 12 of the '991 patent merely states the intended result of the "heat-treating" step, which cannot patentably distinguish the claim over the prior art, even if stated in the claim itself. *See Minton*, 336 F.3d at 1381.

shank, so the prior art references do not currently need to show conducting of this test." Ex. 1008 at 129. The examiner further stated that "the test is referred to as being conducted on the *heat treated* shank, which Patel's wire after annealing (heat treatment) would have the same properties as the claimed invention (same material/manufacture steps)." *Id.* In other words, the examiner concluded that because the art showed the "same material/manufacture steps" as the claimed invention, it also "would have the same properties." *Id.*

The applicant submitted sixteen pages of notes attempting to distinguish Patel on the basis that the "the Patel device is superelastic." *Id*. at 145-160. The applicant argued that, unlike the Patel device, the device resulting from his method had a high enough transformation temperature that, during clinical use at body temperature (37°C), it would be in the martensitic phase. *See id.*

Thereafter, the examiner suggested that applicant amend the claims to distinguish Patel by requiring that the starting material be superelastic prior to the heat treatment step. *See id.* at 163. The examiner did not consider the "wherein" clause to be a limitation for purposes of patentability; if so, the "wherein" clause alone would have been enough to distinguish the Patel device, which applicant argued was superelastic <u>after</u> heat treatment. *Id.* at 104-05, 172-74. Applicant ultimately amended the claims as suggested by the examiner. *Id.* at 168-70**.**

(b) The prior art does not need to disclose the precise test described in the "wherein" clause

If the Board disagrees with Petitioner's position that the "wherein" clause is not limiting, it should nevertheless find that the prior art sufficiently satisfies such clause if it discloses a heat treated shank that "allows for some degree of permanent deformation" when subjected to bending forces, and/or has an A_f temperature (transition temperature) of 37°C or greater.

First, the "wherein" clause, if deemed limiting, should be construed to cover a method of making a heat-treated instrument that "allows for some degree of permanent deformation." As noted above, during prosecution of the '773 patent—the '991 patent's parent—the applicant argued over a rejection based on the prior art Patel reference. In his summary of a July 26, 2013 interview with the applicant, the examiner used the "some degree of permanent deformation" language to describe his understanding of applicant's alleged invention as distinguished from the device described in Patel. *See* Ex. 1008 at 163. The examiner stated that applicant's invention conducts heat treatment on a superelastic device "resulting in non-superelastic properties that allow for some degree of permanent deformation." *Id*. By characterizing the invention in this manner, the examiner indicated that "some degree of permanent deformation" is sufficient to satisfy the "wherein' clause. Applicant did not dispute this.

Second, the "wherein" clause, if deemed limiting, should be construed to cover a heat-treated file with an A_f temperature (or transition temperature) of 37°C or greater. In his 2014 declaration submitted during the prosecution of the ’991 patent, the applicant “used differential scanning calorimetry (DSC) … to determine the phase of [the] heat treated endodontic instruments.” Ex. 1003 at 126 (¶ 4). The applicant declared that if those instruments were in the martensitic phase, “this indicates” that they will “have an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion when tested in accordance with ISO Standard 3630-1 as recited in pending independent claims 1, 6 and 11 of my patent application.” *See id*. at 127 (¶ 5); *see also id.* (¶ 6). The DSC tests upon which the applicant relied show an austenite finish (A_f) temperature of 37° or greater. Ex. 1002 ¶ 31. The applicant did not indicate any need to subject the files to any testing in accordance with ISO-3630-1 to confirm the claimed permanent deformation. Rather, he indicated that if the files were in the martensite phase during use, the claimed permanent deformation would be achieved. The applicant also defined the “wherein” clause with reference to the A_f (transition) temperature of a heat-treated Ni-Ti instrument during prosecution of the’773 patent (the ’991 patent’s parent). Specifically, applicant Luebke argued that, unlike the prior art Patel reference, his application results in transition temperatures of 39°C, which is above body temperature. Ex. 1008 at 147. The applicant further argued that “the temperature of the body is NOT sufficient to transform the Luebke application instrument or device to austenite," meaning that it remained martensite and was not superelastic. *Id*. at 152. The applicant noted that, by heat-treating for two hours at 500°C, an A_f temperature of 39°C is obtained, and that "[t]his is what this application accomplishes." *Id.* at 159.

(c) The "wherein" clause is relevant to whether the '311 application enabled the claimed invention

Petitioner submits that the "wherein" clause is a limitation for purposes of the enablement requirement of section 112, regardless of whether it is a "limitation" for the purpose of determining patentability over the prior art. A patent's specification must describe the invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, . . . to make and use the same." 35 U.S.C. § 112(a). In order to comply with this requirement, the application must show that the claimed invention will work for its intended purpose. *See Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1322-25 (Fed. Cir. 2005). Accordingly, in order for the specification of the '991 patent and its parent applications to comply with 35 U.S.C. §§ 112 and 120, they must describe and enable an invention in which the claimed heat treatments produce their intended result, i.e., the recited permanent deformation.

3. <u>"permanent deformation"</u>

Claim 12 contains the term "permanent deformation" within the "wherein" clause discussed above. If the "wherein" clause is deemed a limitation, "permanent deformation" means "deformation remaining after force is removed." Permanent deformation need not be "permanent" in the sense that the instrument <u>never</u> returns to its original shape. Ex. 1003 at 129; Ex. 1008 at 110 (applicant explaining that "martensitic Ni-Ti" exhibited permanent deformation). Martensitic Ni-Ti will stay deformed when bent. *See* Ex. 1002 ¶ 28; *supra* section IV, at pp. 5-6.

4. <u>"diameter of 0.5 to 1.6 millimeters"</u>

Claim 15 recites that "the instrument shank has a diameter of 0.5 to 1.6 millimeters." The specification makes clear that claim 15 refers to the proximate end, i.e., the end that is connected to the handle. Ex. 1001 at 4:8-10; Fig. 1a. Therefore, Petitioner submits that this term means "diameter of 0.5 to 1.6 millimeters at the proximate end."

VII. EFFECTIVE FILING DATE OF THE CHALLENGED CLAIMS AND ELIGIBILITY FOR POST-GRANT REVIEW

Patent Owner bears the ultimate burden of demonstrating entitlement to an earlier application's filing date. *See In re NTP, Inc.*, 654 F.3d 1268, 1276-77 (Fed. Cir. 2011). This burden is not satisfied merely because the later application is a "continuation" of the earlier one. *See Research Corp. Techs. v. Microsoft Corp.*, 627 F.3d 859, 865, 869-70 (Fed. Cir. 2010). Patent Owner must show that the claimed invention was "disclosed in the manner provided by the first paragraph of [35 U.S.C.] section 112 (a)" in the earlier application. 35 U.S.C. § 120; *see Anascape, Ltd. v. Nintendo of Am., Inc.*, 601 F.3d 1333, 1334-35 (Fed. Cir. 2010).

If the earlier application is not an immediate parent, the invention must be disclosed in compliance with section 112 in every intervening application. *Lockwood v. Am. Airlines*, 107 F.3d 1565, 1571 (Fed. Cir. 1997). The earlier application(s) must "reasonably convey[ ] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*). The claimed combination, not just its individual elements, must be described. *See Hyatt v. Dudas*, 492 F.3d 1365, 1369-71 (Fed. Cir. 2007).

As long as one claim of the '991 patent is not entitled to an effective filing date earlier than January 29, 2014, PGR is available, even if some of the claims are entitled to an earlier date. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, sec. 3(n)(1)(A), 6(f)(2), 125 Stat. 284, 293, 311 (2011). Petitioner identifies the following non-exhaustive reasons that demonstrate that Patent Owner will not be able to meet its burden of proving that the claims at issue are entitled to a filing date earlier than the '311 application's January 29, 2014 filing date.

A. Prior Applications in the '991 Patent Priority Chain Do Not Support Heat-Treating a Shank at the Claimed Temperature Range of 300°C to the Melting Point of the Alloy

Regardless of whether the Board determines the "wherein" clause is limiting, claim 14 of the '991 patent is not entitled to an effective filing date earlier than January 29, 2014 because none of the earlier-filed priority applications mentions 300°C, whether as an appropriate lower bound for a heat treatment temperature range or otherwise. *See* Ex. 1002 ¶¶ 54-56. When a claimed range is not recited in an application, the application must have some disclosure from which the claimed range can be derived in order to comply with section 112. *See Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575 (Fed. Cir. 1985). No such disclosure exists here. *See* Ex. 1002 ¶¶ 55-56. Indeed, as discussed in section V above, the applicant previously distinguished treatment at 500°C from treatment at 375°C to show the criticality of heat-treating at 400°C or above. *See* Ex. 1010 at 110-14; Ex. 1009 at 93-97.

B. Prior Applications in the ’991 Patent Priority Chain Do Not Support Heat-Treating a Shank at the Claimed Temperature Ranges to Produce the Recited Permanent Deformation

If the Board determines the “wherein” clause to be limiting, the Challenged Claims are not entitled to an effective filing date earlier than January 29, 2014 because earlier-filed applications do not disclose heat treatment in the claimed ranges to produce the recited permanent deformation. Each of the Challenged Claims recites a “heat-treating” step as well as a “wherein” clause indicating that the heat-treated shank will exhibit 10 degrees of permanent deformation after 45 degrees of flexion. Each claim limits the temperature of heat treatment. In claims 12-13 and 15-16, the range is from above 25°C to the melting point of the Ni-Ti alloy; in claim 14, it is from 300°C to the melting point of the Ni-Ti alloy. Earlier applications in the ’991 patent family do not adequately describe heat treatment at these ranges to produce the claimed permanent deformation.

The parent application to the ’991 patent (Application No. 13/455,841, “the ’841 application”) describes five examples. Each example involves three groups of instruments: (1) an untreated control group; (2) one group heat-treated at 500°C for 75 minutes in an argon atmosphere and slowly cooled; and (3) one group given a titanium nitride coating using physical vapor deposition, with an “inherent heat-treatment,” the parameters of which are not described. Ex. 1008 at 12-15. Example 4, which refers to Figure 6, shows that the files heat-treated at 500ºC for 75 minutes and then subjected to a flexion test, had the highest degree of permanent deformation. *See id*. at 14. The ’841 application does not contain any examples at any time and temperature combinations other than 500ºC for 75 minutes.

Although the ’841 application contains a passing reference to “heat-treating the shank at a temperature above 25 C,” there is no mention anywhere in the specification of heat-treating at 25°C, at 300°C, or at any temperature below 400°C, to obtain the claimed permanent deformation.

The disclosure of the ’841 application would not have demonstrated to one of ordinary skill in the art that the inventor was in possession of heat-treating at temperatures as low as 25°C or 300°C to achieve the claimed permanent deformation. *See* Ex. 1002 ¶¶ 47-56; *LizardTech, Inc. v. Earth Resource Mapping,* *Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005).

During prosecution of the related ’625 application and Ser. No. 11/628,933 application (“the ’933 application”), the claims were rejected as anticipated by or obvious in view of, *inter alia*, U.S. Patent No. 6,431,863 (Sachdeva), which discloses heat-treating endodontic instruments at, among other temperatures, 350ºC. Ex. 1010 at 78-90; Ex. 1009 at 62-65. The applicant responded in each case by amending the claims to recite a lower bound of 400°C, which the applicant asserted was “critical to improving the beneficial properties of the endodontic instruments.” Ex. 1010 at 101, 105-06; Ex. 1009 at 81, 89-90.

In allowing the claims of the ’625 and ’933 applications, the examiner agreed that the temperature range of 400°C to the melting point had “been shown to be critical in providing distinguishing shape memory qualities.”[7] Ex. 1010 at 494; Ex. 1009 at 130. This confirms that applicant was not in possession of an invention of heat-treating below 400°C in order to achieve the recited permanent deformation.

For the above reasons, the claims of the ’991 patent are not entitled to a filing date earlier than January 29, 2014.

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7 As discussed in section IV, “shape memory” means susceptibility to deformation that does not reverse after force is removed, but is recoverable by sufficient heating. *See also* Ex. 1002 ¶ 28; Ex. 1010 at 364-65.

C. Applications in the ’991 Patent Family Filed Prior to April 25, 2012 Do Not Support Heat Treatment in a Reactive Atmosphere

Claims 12 and 14-16 recite “heat-treating the entire shank” above a particular temperature, but do not recite whether the atmosphere in which the heat treatment occurs is reactive or unreactive with the Ni-Ti shank. Claim 13 recites performing the step of “heat-treating the entire shank” in an atmosphere that is “unreactive, ambient, or any other acceptable heat treatment process.” Petitioner submits that under the BRC standard, which is the applicable standard in this proceeding, these claims should be construed to cover heat treatment in any environment. *See supra* section VI.C.1.

The disclosures in all applications in the claimed priority chain prior to April 25, 2012 are limited to heat-treating in an atmosphere unreactive with the Ni-Ti instrument or device. Moreover, during prosecution of an application filed prior to April 25, 2012, applicant, in arguing over a prior art rejection, explained that heat-treating in a reactive atmosphere—even at a temperature within the claimed range—was not within the scope of his claimed invention because it did not result in the claimed permanent deformation. Thus, and as described in further detail below, to the extent that claims 12-16 of the ’991 patent are construed to cover “heat-treating the entire shank” in any atmosphere (i.e., reactive or unreactive with Ni-Ti), they are not entitled to a priority date earlier than April 25, 2012.

The disclosure of every application in the priority chain filed prior to April

25, 2012 specifies that the "heat-treating" step is performed in an atmosphere consisting essentially of a gas unreactive with Ni-Ti, and no other atmosphere. Ex. 1002 ¶¶ 58-65, 69. The prosecution of the related '933 application confirms that the applicant did not regard heat-treating in a reactive gas to be part of his original invention. In arguing over a prior art rejection, the applicant submitted a declaration from David Berzins who declared that heat treatment in air, which is reactive with Ni-Ti, Ex. 1002 ¶ 66, would result in a thick oxide layer that "may affect the surface integrity of the file as well as its properties and transformations." Ex. 1010 at 411. Berzins stated that he subjected files with Ni-Ti shanks to the same heat treatment described in the examples of the '991 patent—500°C for 75 minutes—except that the atmosphere was air rather than argon. *See id*. at 409.[8] Berzins declared that such treatment in air produced shanks that remained superelastic at both room temperature and mouth temperature, *id*. at 409-10, contrary to the goals of the applicant's invention.

The applicant relied on the Berzins declaration, arguing that "heat-treatment in air as in the prior art Matsutani reference yields a superelastic file," while "heat-

[8] The examples provided in each application in the claimed priority chain starting with the '933 application, which was filed as PCT/US2005/019947 (the "2005 PCT application") on June 7, 2005, are nearly identical, and each discloses the same temperature, time, and atmosphere for the heat treatment.

treating the instrument in an atmosphere consisting essentially of a gas unreactive with the shank … yields a shape memory file;" that is, one that will stay bent (deformed) after a bending force is removed. *Id*. at 405-06. The examiner accepted the applicant's representations, remarking that the temperature range and treatment environment had "been shown to be critical in providing distinguishing shape memory qualities along the entire length of the shank from the prior art, which teaches heat treatment at temperatures outside this range … and without the described atmosphere." *Id*. at 494; *see also* Ex. 1002 ¶¶ 66-68.

In its preliminary responses to IPR2015-00632 and IPR2015-01476, Patent Owner asserted that one of the "coating" processes disclosed in the pre-2012 applications provides support for heat-treating in a reactive atmosphere. Patent Owner argued that the 2005 PCT application in the claimed priority chain discloses applying a titanium nitride ("TiN") coating to the Ni-Ti endodontic instruments by way of physical vapor deposition ("PVD") with an inherent heat treatment, and that such process occurs in a reactive atmosphere. IPR2015-00632, Paper 9 at pp. 16-19; IPR2015-01476, Paper 9 at pp. 18-20.

However, the earlier applications (as well as the application that resulted in the '991 patent) discuss PVD and other types of "coating" as *prior art* processes that can be performed optionally, in addition to the claimed heat-treating process. The claimed heat treatment is not the "inherent heat-treatment" associated with the

PVD coating process.[9] Notably, there is no disclosure in any of the earlier applications in the priority chain of the temperature range or treatment time for the "inherent heat-treatment" associated with an optional PVD coating process. Nor is there any disclosure as to whether such coating process is performed in an atmosphere reactive with the Ni-Ti instrument itself, such as air.[10] Indeed, as

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9 While the specification alone makes this clear, it is also confirmed by the inventor's testimony in the related district court litigation that, during experiments leading to his filing of the initial application, he perceived "some problems with the [PVD] TiN coating" process, which is why he decided to "remove[] the TiN" coating and "just do the heat." Ex. 1013 at 38:15-39:22.

10 Patent Owner's assertions in the pending '773 petitions that the 2005 PCT application discloses a PVD temperature (500°C) and atmosphere (nitrogen gas and titanium) is wrong; Patent Owner improperly relies on the inventor's recent litigation testimony for these parameters. *See* IPR2015-00632, Paper 9 at pp. 16-17 (citing Exhibit 2001 to that petition); IPR2015-01476, Paper 9 at pp. 19-20 (citing Exhibit 2001 to that petition). Similarly, the "FIREX" process mentioned in the priority applications and the extrinsic evidence Patent Owner alleges discloses the treatment conditions of such process, *see* IPR2015-01476, Paper 9 at p. 21, are irrelevant. None of the priority applications incorporates by reference any specific part of the FIREX process, including its temperature and atmospheric conditions,

discussed above, applicant specifically informed the Patent Office that heat-treating in a reactive, air atmosphere would not achieve the results of his alleged invention. *See, e.g.*, Ex. 1010 at 405-06; *see also* IPR2015-01476, Paper 9 at p. 27 (Patent Owner disputing that "a physical vapor deposition process will always transform a superelastic nickel titanium file into a permanently deformable one").

Given applicant's representations via the Berzins declaration that replacing heat-treating in an atmosphere unreactive with Ni-Ti with an air atmosphere (which is reactive with Ni-Ti) results in a file that is superelastic (i.e., one that is not susceptible to permanent deformation), it is clear that applicant was not in possession of an invention comprising conducting the heat treatment step in an atmosphere reactive with Ni-Ti to achieve the recited permanent deformation prior to the April 25, 2012 filing date of the '841 application.

Claims 12-16 are not entitled to a priority date earlier than April 25, 2012.

D. Prior Applications in the '991 Patent Priority Chain Do Not Satisfy the Written Description or Enablement Requirements of Section 112 for the Same Reasons as the '991 Patent Itself

All of the Challenged Claims are unpatentable because they fail to comply with 35 U.S.C. § 112(a). *See infra* section VIII.B, C. As described below, the '991

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and the applications do not even mention (much less incorporate by reference) the brochure on which Patent Owner relies for the FIREX conditions. *See, e.g.*, *Zenon Envtl., Inc. v. U.S. Filter Corp.*, 506 F.3d 1370, 1378-80 (Fed. Cir. 2007).

patent does not enable one of ordinary skill to obtain permanent deformation using heat treatment temperatures of "above 25°C" or 300°C, or to select the parameters needed to produce permanent deformation at temperatures throughout the claimed temperature range. Nor does it demonstrate that the inventor was in possession of heat treatments throughout the claimed temperature range to obtain permanent deformation. For the same reasons, the applications to which the '991 patent claims priority fail to support the Challenged Claims in the manner required by section 112(a). The descriptions in the priority applications are substantively the same except for their claims; the entire family comprises continuation and divisional applications (but not continuation-in-part applications).[11] Accordingly, none of the Challenged Claims is entitled to an effective filing date earlier than January 29, 2014.

VIII. How the Claims Are Unpatentable Under 37 C.F.R. § 42.204(b)

A. Level of Skill in the Art

A person of ordinary skill in the art at the time the invention was made would have (i) a bachelor's degree or master's degree in materials science, metallurgy, or a related field and at least two years of experience so as to

[11] Nothing in the original claims of the earlier applications provides the enabling or written description disclosure that is lacking from the '991 patent specification.

understand the structural, chemical, and mechanical properties that can be manipulated in Ni-Ti alloy materials used in dental applications, or (ii) a Ph.D. or equivalent degree in materials science, metallurgy, or a related field and at least one year of experience so as to understand the structural, chemical, and mechanical properties that can be manipulated in Ni-Ti alloy materials used in dental applications. Ex. 1002 ¶ 75. This level of education and experience applies regardless of the effective filing date of the alleged invention. *Id*.

B. <u>Ground 1</u>: Lack of Enablement of Claims 12-16 Under § 112(a)

1. <u>Legal Standard for Enablement</u>

"Claims are not enabled when, at the effective filing date of the patent, one of ordinary skill in the art could not practice their full scope without undue experimentation." *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1384 (Fed. Cir. 2013). Undue experimentation factors include "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). These factors are merely illustrative; an individual case must turn on its facts. *See Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991).

The scope of the required enablement depends on the scope of the claims. In order to hold up its end of the patent bargain, a “patentee who chooses broad claim language must make sure the broad claims are fully enabled.” *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008). Accordingly, “when a range is claimed, there must be reasonable enablement of the scope of the range.” *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1244 (Fed. Cir. 2003).

Additionally, inoperative embodiments within the scope of the claims may render such claims unpatentable for lack of enablement. When broad ranges of parameters are claimed, the claims must reasonably bind those parameters to the area in which satisfactory results may be achieved. *See In re Cook*, 439 F.2d 730, 735-36 (C.C.P.A. 1971). It is not enough that a few embodiments within the ranges are disclosed. *See id*. If a large number of inoperative embodiments are within the scope of the claims, it must be obvious to one of ordinary skill whether a given embodiment would be operative, without the need to build and try it. *See id*. at 735.

2. Lack of Enablement of the Challenged Claims

The Challenged Claims all recite heat-treating a superelastic, Ni-Ti dental or endodontic instrument to impart permanent deformability. However, the claimed heat treatment parameters are impermissibly broad. Claims12-13 and 15-16 recite treatment at temperatures of from above 25°C to the melting point of the alloy, while claim 14 recites a lower bound of 300°C. None of the Challenged Claims limit the treatment time.

The claims are unpatentable for lack of enablement under section 112 for at least two reasons. First, the lower bound of as low as 25°C (essentially room temperature) is not operable; heat treatments at or near 25°C will not have the claimed effect on a superelastic file. Second, even if temperatures just above the claimed thresholds of either 25ºC or 300ºC would actually work (which Petitioner does not concede), it would require undue experimentation to select the necessary combinations of parameters required to practice the full scope of the claimed invention. One of ordinary skill would not be able to determine whether certain embodiments would be effective without trying them.

(a) Heat treatment at or near 25°C to achieve the claimed permanent deformation is not enabled

The process of "heat-treating" at from "above 25°C" (per claims 12-13 and 15-16) encompasses simply placing the instrument in an environment at or just above room temperature. Indeed, simply performing the ISO test referenced by the claims themselves could subject the files to that temperature. *See* Ex. 1014 at 10 ("Apparatus and root-canal instruments shall be conditioned in accordance with ISO 554 at (23±2)°C for a period of at least 1 h prior to testing."). Further, as the examiner noted during prosecution, using an endodontic instrument for its intended purpose would amount to "heat-treating" it because the temperature inside the mouth is greater than 25°C. *See* Ex. 1003 at 83-84; Ex. 1002 ¶¶ 100, 108.

In any event, "heat-treating" a superelastic, nickel-titanium endodontic instrument at as low as 25°C, or at mouth temperature (37°C), will not result in a file that exhibits the recited level of permanent deformation. Ex. 1002 ¶¶ 101-02.[12] This is confirmed by testing commissioned by Petitioner, which shows that endodontic files "heat-treated" at 25°C do not have the claimed effect. Commercially available, ProFile brand Ni-Ti, endodontic instruments were obtained and tested.[13] Ex. 1002 ¶ 103 (citing Ex. 1015 ¶ 3). These files are endodontic files, with a composition of 54-57wt% nickel and 43-46wt% titanium. Ex. 1016 at 759, Table II; Ex. 1017 at 1294; Ex. 1038 at 567; Ex. 1002 ¶ 104. The

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[12] The applicant effectively conceded as much during prosecution of the European counterpart application. The EPO rejected claims reciting a lower heat-treatment bound of "above 25°C" based on "serious doubt" that such treatment would result in the claimed permanent deformation. Ex. 1012 at 127. In his June 25, 2015 response, the applicant did not dispute the EPO's conclusion that 25°C would not work; instead he amended the claims by replacing the 25°C lower bound with 400°C, and argued the EPO's "doubts no longer are justified in view of the Amendment." *Id*. at 129, 132. Applicant's concession in the EPO regarding essentially the same limitation at issue here is relevant. *See, e.g.*, *Apple Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1312-13 (Fed. Cir. 2014).

[13] Such files are sold and distributed by Patent Owner's licensee. *See* Ex. 1035.

handles of the instruments were removed, and 10 of the shanks were placed in a furnace at 25°C. Ex. 1002 ¶ 105 (citing Ex. 1015 ¶¶ 4-5).The duration of treatments was 75 minutes, 2 hours, 4 hours, 8 hours, and 12 hours (two shanks were heat-treated at each of the times). *Id*. The 10 shanks treated at 25ºC as well as the two non-treated, control shanks were then tested in accordance with ISO 3630-1 for stiffness. The shanks were deflected by 45 degrees, per the ISO 3630-1 test recited in the claims, and their permanent deformation was measured afterward. *Id*. (citing Ex. 1018, Ex. A, at 2-3).

The shanks that were "heat treated" at 25°C showed between 0.04 and 2.19 degrees of permanent deformation, averaging 0.87 degrees, far below the 10 degrees stated in the claims. *Id*. (citing Ex. 1018, Ex. A, at 2, 8).[14] This confirms that heat treatment of superelastic, Ni-Ti files at from above 25°C is inoperable to achieve the claimed permanent deformation. *See* Ex. 1002 at ¶¶ 106-07.

The examiner originally rejected the claims based on this very enablement problem, stating that the 25°C lower bound is less than mouth temperature (37°C)

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[14] By comparison, the shanks of the same ProFile brand files that were not heat-treated showed 0.15 and 0.38 degrees of permanent deformation, *id*., values that Patent Owner's licensees have argued in the pending district court litigation meet the "superelastic" limitation of the claims of the related '773 patent. *See* Ex. 1019 ¶¶ 44, 52.

and that “the 112 issue” with the claims is that one would not expect to achieve the claimed permanent deformation from placing a Ni-Ti orthodontic archwire in the mouth. Ex. 1003 at 83-84. The applicant responded by asserting that the mechanism by which Ni-Ti orthodontic wires move teeth was different from how the device he was “attempting to create” in the present application would behave. *Id*. at 128-29. The applicant never addressed the actual enablement issue: whether placing an untreated, superelastic Ni-Ti file inside a patient’s mouth would, despite the low temperature of the mouth (i.e., 37ºC), result in a permanently deformable file. *See* Ex. 1002 ¶¶ 108-10. It would not. *See id.* ¶¶ 100-02, 110.

The examiner ultimately allowed the claims, but, in doing so, made a mistake about the scope of the claims. The examiner’s statement of reasons for allowance indicates that he believed the lower temperature bound to be 400°C, and that heat-treating above this temperature would produce “a shape memory alloy with the prescribed deformation characteristics.” Ex. 1003 at 153-54. However, the claimed range was not limited to just “400°C to the melting point;” it included temperatures with a lower threshold of just above 25°C (claims 1-5, 12-13, and 15-16), and a lower threshold of from 300ºC (claims 6-11 and 14).[15] The applicant

[15] The examiner’s apparent confusion may have resulted from the fact that he had, just 6 months earlier, allowed claims of the parent ’841 application that included a 400° lower temperature threshold. Ex. 1008 at 209-11, 227-28.

submitted comments in response, calling the examiner's statement "underinclusive," *see id*. at 197-98, but the fundamental enablement problem relating to the actual claimed temperature ranges was never resolved.

Although the examiner did not respond to applicant's comments, that silence "does not give rise to any implication." 37 C.F.R. § 1.104(e). The Board should not deny consideration of the above enablement arguments on the basis of any argument that they "previously were presented to the Office." 35 U.S.C. § 325(d).

(b) Heat treatment at 300°C to achieve the claimed permanent deformation is not enabled

Testing also demonstrates that the '991 patent lacks an enabling disclosure for heat treatment at 300°C—the lower bound in Challenged Claim 14—to achieve the claimed permanent deformation. Commercially available ProFiles were obtained and tested in the same manner and time durations as described above in section VIII.B.2(a), except that the temperature was 300°C. *See* Ex. 1002 ¶¶ 103-05 (citing Ex. 1015 ¶¶ 3-5). Ten of the shanks treated at 300ºC were then tested in accordance with ISO 3630-1 for stiffness. *See* Ex. 1002 ¶¶ 103, 105 (citing Ex. 1018, Ex. A at 2-3). The 300°C-treated shanks showed permanent deformation between 0.07 and 2.73 degrees, averaging 1.17 degrees—similar to the 25°C-treated shanks and still far below the 10 degrees stated in the claims. *See id*. ¶ 107 (citing Ex. 1018, Ex. A at 1, 2, 8). This testing demonstrates that there is no enabling disclosure for heat treatment at 300°C to achieve the claimed permanent deformation. *Id.* at ¶¶ 106-07.

Given the insufficient effect from heat treatment at either 25ºC or 300ºC, it can be inferred that at least the entire range of 25-300°C lacks an enabling disclosure to achieve the claimed permanent deformation. *Id*. ¶ 107.[16] Therefore, claims 12-16 are unpatentable for lack of enablement. *In re Corkill*, 771 F.2d 1496, 1501 (Fed. Cir. 1985) ("Claims which include a substantial measure of inoperatives . . . are fairly rejected under 35 U.S.C. § 112").

(c) Undue experimentation would be required to practice the full scope of the claimed invention

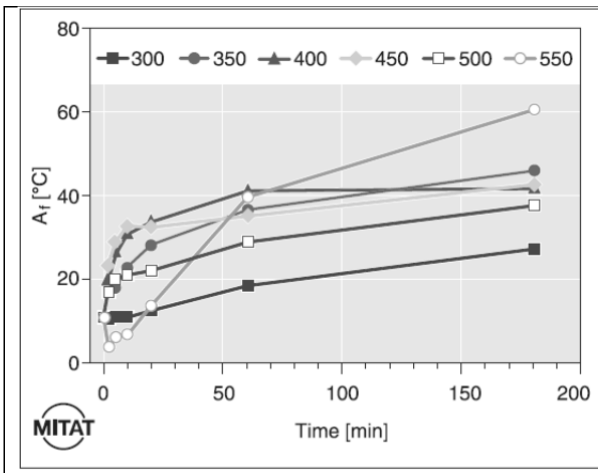
As set forth below, the relevant *Wands* factors—including, for example, the quantity of experimentation necessary, the amount of direction or guidance presented, the nature of the invention, the unpredictability of the art and the breadth of the claims—all support Petitioner's position that undue experimentation

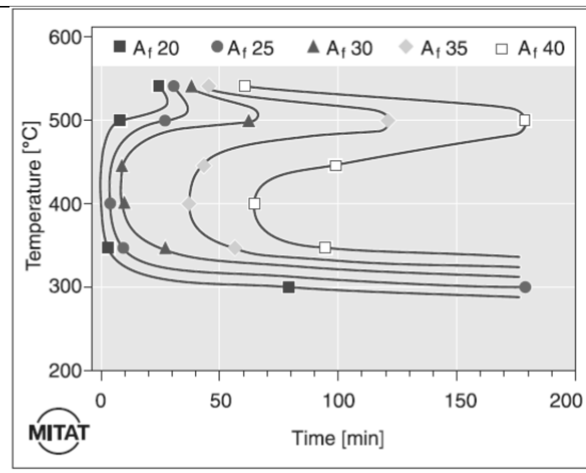
[16] As noted above, the applicant recently amended claims in the European counterpart application by replacing a lower heat-treatment bound of "above 25°C" with a lower bound of 400°C, in an attempt to overcome the EPO's "serious doubt" that treatment at 25°C would result in the claimed deformation. *Supra* section VIII.B.2.(a), at footnote 12. By choosing 400°C for this amendment (rather than 300°C), the applicant effectively acknowledged that 300°C is insufficient to achieve the claimed result.

would be required to practice the full scope of the claimed invention, rendering the claims unpatentable for lack of enablement under 35 U.S.C. § 112(a).

An appropriate starting point for this analysis is the single example provided by applicant Luebke for achieving permanent deformation (Example 4). According to the applicant, the tested files were comprised of 54-57% nickel and 43-46% titanium, and were heat-treated for 75 minutes in argon at a temperature of 500°C resulting in files that were permanently deformable. *See* Ex. 1003 at 20-21. But, as Patent Owner acknowledged, "[n]ot all heat treatments will necessarily result in a shank having the claimed permanent deformation." IPR2015-00632, Paper 9 at p. 12; *see also id.* at p. 30; IPR2015-01476, Paper 9 at p. 12. Practicing the full scope of the claimed invention would require undue experimentation as the results of heat treatment depend on several variables, including temperature, time, alloy composition and alloy treatment history. *See* Ex. 1002 ¶ 111. For example, even altering the alloy composition within the identified range (between 54-57% nickel and 43-46% titanium) could yield very different results after heat-treating under the same conditions, as could varying the time and temperature. *Id*. ¶¶ 112-13. Indeed, as mentioned above, heat-treating superelastic, Ni-Ti files in the range of the claimed lower bounds (25º or 300ºC) resulted in files that did not come close to meeting the level of permanent deformation recited in the "wherein" clause of the claims. To the extent that heat-treating at those temperatures could achieve the recited permanent deformation (which testing demonstrates it could not), undue experimentation would be required.

The complexities inherent in heat-treating Ni-Ti are evidenced by comparing Example 4 of the ’991 patent with a 2000 article published by Pelton (Ex. 1006). The Pelton article, which was indirectly cited by the applicant during prosecution,[17] discusses the results of heat-treating a particular superelastic, Ni-Ti alloy at temperatures from 300°C to 550°C for times up to three hours. The following graphs show the results, with respect to the austenite finish temperature of the heat-treated Ni-TI wire:





Ex. 1006 at 114, Figs. 9, 10.

The A_f temperature of the starting material was 11°C, confirming it was superelastic, and its composition was 50.8at%, which is equivalent to 55.8%wt%

[17] *See infra* section VIII.J.3, at footnote 28.

nickel, Ex. 1002 ¶¶ 185, 195-96, and within the range described by Example 4 in the ’991 patent.[18] *Id*. Treatment at 300°C had the least effect, raising A_f to only 25°C after three hours. Increasing treatment temperature up to about 400-450°C increased A_f, but further increases up to about 500°C reduced the final A_f. Beyond 500°C, A_f increased again. Short treatments at 550°C actually reduced A_f below its starting value, while longer treatments at 550°C increased A_f more than any other treatment temperature. *See* Ex. 1002 ¶ 114.

The results of Pelton are inconsistent with the results outlined in Example 4 of the ’991 patent for the same heat treatment times and temperatures. Specifically, the Pelton graphs show that treatment of the particular alloy tested at 500°C for approximately 75 minutes (as in Example 4) resulted in an A_f temperature of about 32ºC, and treatment at that same temperature for 2 hours increased the A_f temperature to 35ºC. Ex. 1002 ¶ 117. Applicant indicated during prosecution of the related ’773 patent that heat treatment according to his invention would produce an A_f temperature of about 39°C (which is above mouth temperature of 37ºC). *Id*.; Ex. 1008 at 159 (applicant incorrectly represented that the Pelton graph was consistent with his invention, but it is not, as just explained).

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[18] The designation of “at%” means atomic percentage. That is, 50.8% of the atoms in the alloy are nickel atoms. Ex. 1002 ¶ 84. The ’991 patent, by contrast, refers to weight percentage, which may be designated “wt%.”

The discrepancy between the results of Pelton and Example 4 of the ’991 patent may be a result of differences in the tested alloy composition. Pelton only describes heat treatment of a particular alloy, containing 50.8at% nickel (55.8wt% Ni, Ex. 1002 ¶¶ 195-96). The range of 54-57 percent nickel by weight described in Example 4 and dependent claim 16 of the ’991 patent is broad; the A_f temperature of an alloy may vary by 100°C based solely on a 1% change in nickel content within that range. Ex. 1002 ¶¶ 112-13, 120; *see* Ex. 1020 at 33-34, Fig. 2; *see also* Ex. 1021 at 256-57.

The history of the alloy prior to final heat treatment can also impact its properties. Ex. 1002 ¶¶ 121-24. For example, in a 1982 publication by Miyazaki, a Ni-Ti alloy treated at 400°C showed markedly different properties depending on whether it was first treated at 1000°C and then cooled. *Id*. ¶ 122; Ex. 1021 at 258-59.

As demonstrated, there are many variables that determine the resulting shape memory characteristics of a heat-treated, superelastic, Ni-Ti alloy. Ex. 1002 ¶¶ 111-25. While a person of ordinary skill in the art may have been able to, through experimentation, arrive at an appropriate treatment time and temperature for a particular alloy that had certain treatment history before final heat treatment, such that the file would satisfy the “wherein” clause of the ’991 patent, doing so for all Ni-Ti alloy compositions within the claimed range would require undue experimentation. *Id.* ¶ 125. The specification of the ’991 patent provides almost no guidance to one of ordinary skill as to how to achieve the intended result—permanent deformation—using the claimed heat treatment parameters. The specification gives only a single time and temperature combination, but does not identify with any specificity the particular composition of the tested alloy. The specification does not provide any guidance as to how variations in time and temperature, or alloy composition, may affect the results one way or another. The only disclosed time constraints—1 to 2 hours, or more preferably 75 minutes—were shown to be inoperable to achieve the intended result on the Ni-Ti alloy tested by Pelton at 500°C, the only temperature for which the ’991 patent discloses any permanent deformation data.

For the foregoing reasons, Challenged Claims 12-16 are invalid under 35 U.S.C. § 112(a) for lack of enablement.

C. <u>Ground 2</u>: Lack of Written Description of Claims 12-16 Under § 112(a)

Section 112(a) contains a written description requirement separate from the enablement requirement. *Ariad*, 598 F.3d at 1344. For the following reasons, if the “wherein” clause of the Challenged Claims is deemed limiting, such claims are invalid for failing to satisfy the written description requirement.

1. <u>Legal Standard for Written Description</u>

In order to satisfy the written description requirement, an application must "reasonably convey[ ] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Id*. at 1351. In appropriate circumstances, a lack of adequate written description may be found even though the issued claims were in the original patent application. As explained by the *en banc* Federal Circuit, this is particularly true of generic claims defined in terms of their desired results:

> Although many original claims will satisfy the written description requirement, certain claims may not. For example, a generic claim may define the boundaries of a vast genus of chemical compounds, and yet the question may still remain whether the specification, including original claim language, demonstrates that the applicant has invented species sufficient to support a claim to a genus. The problem is especially acute with <u>genus claims that use functional language to define the boundaries of a claimed genus</u>. In such a case, the functional claim may <u>simply claim a desired result</u>, and may do so without describing species that achieve that result. But the specification must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant <u>has invented species sufficient to support a claim to the functionally-defined genus</u>.

Id. at 1349 (emphasis added).

2. <u>Lack of Adequate Written Description for the Challenged Claims</u>

The Challenged Claims are far broader than any invention described in the

’311 application; they purportedly cover any heat treatments in the claimed temperature ranges that produce the desired result of permanent deformability, and exclude any treatments in those ranges that do not produce this transformation. *See* IPR2015-00632, Paper 9 at p. 12; IPR 2015-01476, Paper 9 at p. 12. However, the specification discloses just one example of a heat treatment that may result in the claimed permanent deformation: 500°C for 75 minutes (without disclosing the exact alloy composition). The ’311 application does not provide other examples of heat treatments that will produce the intended “permanent deformation” result, or any guidance on how to modify the one example and still produce that result. Ex. 1002 ¶¶ 128-31. The application fails to convey that the inventor possessed the entire class of heat treatments that might result in the recited permanent deformation (from above 25°C or from 300°C all the way to the melting temperature of Ni-Ti (1310°C), and on an unbounded or broad range of alloy compositions and heat treatment times). *Id.* ¶ 132.

This is not a case in which the “original claim language … discloses the subject matter that it claims.” *Ariad*, 598 F.3d at 1349; Ex. 1002 at ¶ 133. Rather, this is a case in which a “functional claim … simply claim[s] a desired result.” *Id*. The ’311 application does not “demonstrate that the applicant has made a generic invention that achieves the claimed result … by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus.”

Id. As set forth in section VIII.B.2(c), numerous factors impact the effectiveness of heat treatment in imparting permanent deformability. There is no indication, in the specification itself, that the inventor was in possession of the nearly unbounded set of parameters claimed (i.e., claims to the genus of all heat treatment process within the scope of steps (a) and (b) that result in permanent deformation as recited in the "wherein" clause). Ex. 1002 ¶¶ 128-33.

For foregoing reasons, the '311 application fails to demonstrate that the inventor possessed the broad class of heat treatments claimed by the '991 patent. Therefore, Challenged Claims 12-16 are unpatentable for failure to comply with the written description requirement of section 112.

D. <u>Ground 3</u>: Anticipation of Claims 12-16 by Luebke 2008

Claims 12-16 are anticipated by Luebke 2008.

Luebke 2008 published February 7, 2008 and is one of the underlying applications that is part of the priority chain for the '991 patent. Because the claims of the '991 patent are not entitled to an effective filing date earlier than January 29, 2014 (*see supra* sections VII.A, B, D) or, alternatively, the April 25, 2012 filing date of the '841 application (*see supra* section VII.C), Luebke 2008 is prior art under § 102(a)(1). Petitioner's arguments regarding the claims' lack of entitlement to an earlier filing date are based on the failure of earlier applications in the priority chain to describe or enable the claims in their full scope. As such, Petitioner's argument that Luebke 2008 anticipates the Challenged Claims is consistent with its argument that the Challenged Claims are not entitled to the filing date of Luebke 2008. *See, e.g.*, *Chester v. Miller*, 906 F.2d 1574, 1577 (Fed. Cir. 1990).

Claim 12, step (a), of the ’991 patent recites “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.” Luebke 2008, in Example 4, discloses endodontic files with “an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank.” Ex. 1022 ¶ 41. The files “are made from a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium.” *Id*. This composition is superelastic as it “avoid[s] the inclusion of elements that affect the superelastic properties of the alloy.” *Id.* ¶ 28.

Step (b) in claim 12 recites “heat-treating the entire shank at a temperature above 25° C. up to but not equal to the melting point of the superelastic nickel titanium alloy.” Luebke 2008 discloses heat-treating the endodontic files at 500°C. *Id*. ¶ 41. This is below the melting point of the alloy, Ex. 1002 at ¶ 138. One of ordinary skill in the art would understand that the entire file was heat-treated, such that the entire shank (which is part of the instrument) would also have been heat-treated. *Id.*. The inventor has acknowledged as much. *See* Ex. 1009 at 85-86; Ex. 1010 at 454-55.

Claim 12 then recites, “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.” Example 4 in Luebke 2008 states that the files “were used in a study of angle of permanent deformation after the flexion test (ADP) reported in degrees of deflection performed in accordance with ‘ISO Standard 3630-1 Dentistry—Root-canal instruments—Part 1: General requirements’ and ‘ANSI/ADA Specification No. 28, Endodontic files and reamers.’” Ex. 1022 ¶ 41. Example 4 does not specify “torque at 45 degrees of flexion,” but this is a requirement of the cited ISO 3630-1 test.[19] *See* Ex. 1014 at 13; Ex. 1023 at 13. Additionally, claim 11 of Luebke 2008 specifies the “45° of flexion” parameter. The results of the test are shown in Figure 6; the heat-treated files (group labeled “TT”) show an angle of permanent deformation of about 26-30 degrees.

The ISO 3630-1 standard referenced in Luebke Example 4 requires removing the handle from the instrument before testing it. Ex. 1014 at 13; Ex. 1023 at 13. That is, the shank is tested in accordance with ISO 3630-1.[20] Therefore,

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19 The flexion test recited in ISO 3630-1 is used to test torque, not permanent deformation; Luebke 2008 and the ’991 patent both use the test unconventionally.

20 The ISO standard uses the word “shank” differently from Luebke 2008 and the ’991 patent. The “shank” in ISO 3630-1 is “part of the root-canal instrument to

claim 12 is anticipated by Luebke 2008. Ex. 1002 ¶¶ 136-41.

Claim 13, which depends from claim 12, further recites that "step (b) is performed in an atmosphere that is unreactive, ambient or any other acceptable heat treatment process." Example 4 in Luebke 2008 describes heat treatment in an argon atmosphere. Ex. 1022 ¶ 41. Luebke 2008 also makes clear that argon is unreactive. *Id.* ¶ 27; *see also* Ex. 1001 at 4:16-24; *see also* 1002 ¶ 142. The treatment process disclosed by Luebke 2008 is also "acceptable"; the '991 patent touts the results of such heat treatment. *Compare* Ex. 1001 at 9:22-33 *with* Ex. 1022 ¶ 43.

Claim 14, which depends from claim 12, sets the lower temperature bound at 300°C. Because Luebke 2008 discloses heat treatment at 500°C, claim 14 is anticipated for the same reasons as claim 12.

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be connected to a handpiece," Ex. 1014 at 2; *see* Ex. 1023 at 3. That is, it may be present instead of a handle so that the instrument can be used with a mechanical handpiece instead of being handled directly by the practitioner. Ex. ¶ 141. Thus, when the standard directs that the "handle or shank" should be removed "at the point at which the handle or shank is attached to the shaft of the root-canal instrument," Ex. 1014 at 13; *accord* Ex. 1023 at 13, the remaining portion (the "shaft") is part of the Ni-Ti "shank" within the meaning of the '991 patent, *see* Ex. 1002 ¶ 141.

Claim 15, which depends from claim 12, further requires that "the instrument shank has a diameter of 0.5 to 1.6 millimeters." Luebke 2008 discloses that the "proximate end" of the shank "may have a diameter of about 0.5 to about 1.6 millimeters." Ex. 1022 ¶ 26; *see supra* section VI.C.4. Example 4 also discloses that the treated instruments are "ISO size[d]," Ex. 1022 ¶ 41, and ISO 3630-1 discloses numerous standard sizes, which include sizes that fall within the claimed range. *See* Ex. 1014 at 5; Ex. 1023 at 5; Ex. 1002 ¶ 144.

Claim 16, which depends from claim 12, further recites that "the instrument shank consists essentially of a titanium alloy comprising 54-57 weight percent nickel." Luebke 2008 describes files "made from a titanium alloy comprising 54-57 weight percent nickel and 43-46 weight percent titanium." Ex. 1022 ¶ 41.

For the above reasons, claims 12-16 are anticipated by Luebke 2008.

E. <u>Ground 4</u>: Obviousness of Claim 15 Over Luebke 2008 Either Alone or in View of Heath or ISO 3630-1

Heath issued in 1997. ISO 3630-1 published originally in 1992 and again in 2008. Both Heath and ISO3630-1 are prior art under § 102(a)(1).

Claim 15, which depends from claim 12, limits the diameter of the shank, at the proximal end (*see supra* section VI.C.4), to 0.5 to 1.6 millimeters. To the extent Luebke 2008 does not disclose that the files in Example 4 had such a diameter, this is an obvious modification of such files. Heath discloses the exact range of 0.5 to 1.6 millimeters for the diameter at the handle end of a shank. Ex.

1024 at 3:49-53. Additionally, most of the “standard” sizes in ISO 3630-1 fall within the claimed range. *See* Ex. 1014 at 5; Ex. 1023 at 5. Moreover, practitioners use multiple sizes of instruments in root canal procedures, including those within the claimed range, thereby providing motivation to design instruments according to Luebke 2008 with the claimed diameter range. *See* Ex. 1002 ¶¶ 146-47. Additionally, during prosecution of the related ’933 application, the examiner stated that it would have been obvious to use this diameter as corresponding to the size of the hole. Ex. 1010 at 83. The applicant never challenged this point. Accordingly, claim 15 is unpatentable as obvious over Luebke 2008 either alone or in combination with Heath or ISO 3630-1.

F. Ground 5: Anticipation of Claims 12-16 by Matsutani

Matsutani published as U.S. Patent App. Publication 2006/0115786 from an application filed in 2005. Matsutani claims priority to Japanese Patent App. No. 2004-344717, filed on November 29, 2004, which published as Japanese Unexamined Patent App. Publication No. 2006-149675. Based on the 2004 Japanese priority date, Matsutani is prior art under § 102(a)(2) and (d)(2).[21] Claims 12-16 are anticipated by Matsutani.

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[21] Petitioner provides herein parallel citations to the certified English translations of the Japanese patent application publication and corresponding original application.

1. Overview of Matsutani

Matsutani describes a Ni-Ti endodontic instrument. Matsutani notes that superelastic Ni-Ti instruments were known in the prior art, but that the rotation of such instruments while inside a curved root canal would cause the tip of the instrument to repeatedly bend back and forth, causing cyclic fatigue and eventual fracture. Ex. 1025 ¶¶ 8, 9; Exs. 1027 & 1029 ¶¶ 7, 8. Matsutani proposed solving this problem by applying heat treatment to a part or all of the entire working portion of the file in order remove the superelastic characteristic and allow it to be permanently deformed, just like the ’991 patent. Ex. 1025 ¶¶ 10, 11, 23, 24, 27; Exs. 1027 & 1029 ¶¶ 9, 10, 19, 20, 23. Matsutani explains that the A_f temperature is increased to allow the file to exhibit shape memory. Ex. 1025 ¶ 27; Exs. 1027 & 1029 ¶ 23. This allowed an endodontist to pre-curve the instrument to extend the life of the file. Ex. 1025 ¶ 28; Exs. 1027 & 1029 ¶ 24.

2. Anticipation of Claims 12-16 by Matsutani

Claim 12, step (a), recites “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.” Figure 1 of Matsutani shows an endodontic file having an “elongate shank,” and a cutting edge is shown extending from the distal end (tip) along the length. Ex. 1025, Fig. 1, ¶¶ 18-23; Exs. 1027 & 1029, Fig. 1, ¶¶ 14-19; Ex. 1002 ¶ 150. Matsutani teaches that the needle (shank) should be made of Ni-Ti "previously provided with a superelastic characteristic." Ex. 1025 ¶¶ 56, 57; Exs. 1027 & 1029 ¶¶ 52, 53.

Step (b) in claim 12 recites "heat-treating the entire shank at a temperature above 25° C. up to but not equal to the melting point of the superelastic nickel titanium alloy." Matsutani teaches heat-treating the shank at a temperature of 400°C to 450°C for 30 to 45 minutes, such that the material has an elevated A_f temperature and is no longer superelastic, but rather exhibits shape memory. *See* Ex. 1025 ¶¶ 10, 27, 45, 53; Exs. 1027 & 1029 ¶¶ 9, 23, 41, 49. Matsutani discloses performing the heat treatment step after the cutting edges are formed in the shank. *See* Ex. 1025 ¶¶ 57, 58; Exs. 1027 & 1029 ¶¶ 53, 54.

Matsutani teaches that part of or the entire working portion of the shank should be heat-treated, and the entire working portion may be treated "by inserting the needle portion [] composed of Ni-Ti alloy into an electric furnace." Ex. 1025 ¶¶ 10, 24, 27, 37*; see also id.* ¶¶ 38-40; Exs. 1027 & 1029 ¶¶ 10, 20, 23, 33; *see also id.* ¶¶ 34-36. A person of ordinary skill would have understood "inserting the needle portion . . . into an electric furnace" to mean that the entire shank was heat-treated.[22] Ex. 1002 ¶ 152.

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[22] What the '991 patent calls a "shank," Matsutani calls a "needle portion." Matsutani uses "shank" to refer to the portion of the "needle" that has no cutting edge.

Finally, claim 12 recites, "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." As explained above (section VI.C.2(a)), this is not a limitation. However, even if it were a limitation, it would be satisfied by Matsutani. Matsutani teaches that the heat-treated portion of the instrument "can exhibit a shape memory function" and, after a bending stress is removed, "keeps a bent shape." Ex. 1025 ¶¶ 27-30; Exs. 1027 & 1029 ¶¶ 23-26. Therefore, the dentist can "precurve" the file. Ex. 1025 ¶ 28; Exs. 1027 & 1029 ¶ 24. Matsutani also discloses testing the heat-treated shank using a bend test equivalent to the ISO 3630-1 test recited in the "wherein" clause. Ex. 1025 ¶ 38; Exs. 1027 & 1029 ¶ 34; *see also* Ex. 1002 ¶ 153. Accordingly, Matsutani teaches that heat treatment would accomplish the permanent deformability claimed by the '991 patent. Ex. 1002 ¶ 153.

Additionally, Matsutani teaches that the shank should be heat-treated to change the material so that it has an elevated A_f temperature to impart shape memory. *See* Ex. 1025 ¶¶ 10, 27; Exs. 1027 & 1029 ¶¶ 9, 10, 23. The inventor of the '991 patent described his invention as one that raises the A_f temperature to above body temperature so that it is martensitic during use. *See supra* section VI.C.2(b). When Ni-Ti is in the martensite phase, it exhibits shape memory such that when it is subjected to a bending force it will stay deformed, returning to its original shape when heated above a transformation temperature to form austenite. Ex. 1002 ¶ 154. Matsutani states that "[a]fter the [root canal] treatment is finished," the heat-treated shank "can be returned to its original shape by force applied thereto by the dentist" or "by increasing the temperature thereof to a temperature higher than the Af temperature set by the durable heat treatment." Ex. 1025 ¶ 28; Exs. 1027 & 1029 ¶ 24. By implication, the Af temperature must be greater than mouth (body) temperature, or else the shank would return to its shape during treatment. Ex. 1002 ¶ 154. As such, Matsutani discloses the "wherein" clause. Accordingly, Matsutani anticipates claim 12.

Claim 13, which depends from claim 12, recites that the heat-treating step "is performed in an atmosphere that is unreactive, ambient or any other acceptable heat treatment process." While this does not appear to add any meaningful limitation to claim 1, Matsutani discloses performing the "heat-treating" step in an "acceptable" atmosphere as reflected by the results achieved. Ex. 1025 ¶ 28; Exs. 1027 & 1029 ¶ 24; Ex. 1002 ¶ 153.

Claim 14, which depends from claim 12, further requires that "the temperature is from 300°C. up to but not equal to the melting point of the superelastic nickel titanium alloy." Matsutani discloses a heat treatment temperature of 400°C to 450°C. Ex. 1025 ¶¶ 45, 53; Exs. 1027 & 1029 ¶¶ 41, 49.

Claim 15, which depends from claim 12, further requires that the diameter of the shank (at the proximal end, *see supra* section VI.C.4) be 0.5-1.6 millimeters. Matsutani discloses a shank having a tip diameter of about 0.3 millimeter, a tapered working portion of 4/100, a length and working portion of about 25 millimeters and 15 millimeters, respectively. Ex. 1025 ¶¶ 30, 35; Exs. 1027 & 1029 ¶¶ 15, 31. Matsutani therefore discloses a file having a diameter of 0.9 millimeter at the proximal end of the working length. Ex. 1002 ¶ 157.[23] Matsutani also explains that the shank is made from 1.0 millimeter wire, Ex. 1025 ¶ 35; Exs. 1027 & 1029 ¶ 31, which means the shank has a maximum diameter (at any point) of 1.0 millimeter, Ex. 1002 ¶ 157. Therefore, the diameter of the proximal end of the shank is between 0.9 and 1.0 millimeter, within the claimed range.

Claim 16, which depends from claim 12, further recites that "the instrument shank consists essentially of a titanium alloy comprising 54-57 weight percent nickel." Matsutani studied five different Ni-Ti alloys, all within the claimed range, including a material having 55.91wt% nickel, with the balance being titanium. *See* Ex. 1025 ¶¶ 35, 44; Exs. 1027 & 1029 ¶¶ 31, 40.

For the above reasons, claims 12-16 are anticipated by Matsutani.

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[23] A taper of "4/100" means that the diameter increases .04 mm for each 1 mm of length. Ex. 1002 ¶ 157. Therefore, over a 15 mm working length, the diameter increases by 0.6 mm. Adding this to the tip diameter of 0.3 mm, the result is 0.9 mm. *Id.*

G. <u>Ground 6</u>: Anticipation of Claims 12-14 and 16 by Kuhn

Kuhn published in 2002 and is prior art to the ’991 patent under § 102(a)(1). It anticipates claims 12-14 and 16.

1. <u>Overview of Kuhn</u>

Kuhn explores the effects of mechanical fatigue and, in relevant part, heat treatment on superelastic, Ni-Ti endodontic files. Files made from Ni-Ti were treated at various temperatures between 350°C and 700°C, and their bending properties were tested. Ex. 1030 at 717. It was found that treatment at 400°C for 10 minutes produced “good results,” including an increase in the transformation temperature and an increase in flexibility. *Id*. at 716, 719-20.

2. <u>Anticipation of Claims 12-14, and 16</u>

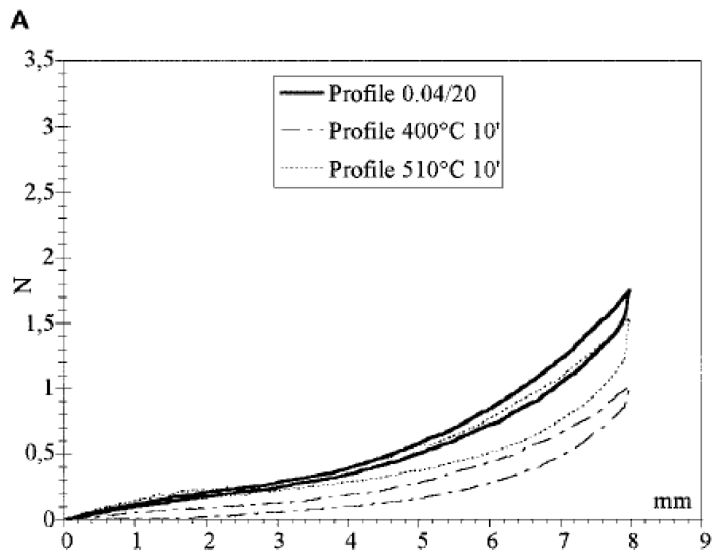
Claim 12, step (a), recites “providing an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank, the shank comprising a superelastic nickel titanium alloy.” Kuhn discloses “endodontic instruments” or “engine-driven rotary files,” including Hero- and ProFile-branded instruments. Ex. 1030 at 716-17. One of ordinary skill would have understood such files, which are 25 mm long and 0.2-0.4 mm in diameter at the tip, to have the claimed “elongate shank” and “cutting edge.” *Id*.; Ex. 1002 ¶ 160. Kuhn’s objective was “to show fatigue characteristics of superelastic NiTi” because “[s]hape memory alloys are increasingly used in superelastic conditions under complex cyclic deformation situations." Ex. 1030 at 716.

Further, Kuhn notes that superelasticity and shape memory are properties that may be exhibited by Ni-Ti, but specifies that superelastic alloys "have a transition temperature range (TTR) lower than mouth temperature." *Id.* at 716. The pre-treated files had a transition temperature of 35°C, which is below mouth temperature (37°C), and thus were superelastic per the definition provided in Kuhn. *Id*. at 719; Ex. 1002 ¶ 161. Further, when the non-heat-treated ProFile instruments were bent, they returned to their original shape. Ex. 1030 at 720; Ex. 1002 ¶ 161. And ProFile instruments are known to have superelastic Ni-Ti shanks. Ex. 1002 ¶ 161; Ex. 1038 at 567; Ex. 1034 at 518, 519.

Claim 12, step (b), requires "heat-treating the entire shank at a temperature above 25° C. up to but not equal to the melting point of the superelastic nickel titanium alloy." Kuhn discloses treatments at various temperatures, including 350°C, 400°C, 510°C, 600°C, and 700°C. Ex. 1030 at 717. Kuhn does not mention heat-treating only a portion of the instruments, so one of ordinary skill would have understood that at least the "entire shank" was heat-treated. Ex. 1002 ¶ 162.[24]

[24] Patent Owner's argument in IPR 2015-00632 that Kuhn only discloses heat-treating a portion of the shank (IPR2015-00632, Paper 9 at p. 29) confuses heat-treating the entire files, which one of skill in the art would have understood Kuhn to disclose, with Kuhn's mention of cutting files <u>after</u> heat treatment to perform

Because the "wherein" clause is not a limitation (*see supra* section VI.C.2(a)), claim 12 is anticipated by Kuhn. In any event, even if the "wherein" clause is determined to be a limitation, Kuhn discloses the same. Figure 6(A) shows bend-test results of both heat-treated and untreated files:



Ex. 1030 at 720. As can be seen, the file heat-treated at 400°C for 10 minutes exhibited permanent deformation; the lower portion of the bending curve returns to

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DSC testing to determine the transformation temperature of the heat-treated files. Ex. 1002 ¶ 163. Indeed, Patent Owner's position is belied by Kuhn's description of the bend test results that were performed. *Id*.; Ex. 1030 at 718 ("At first, and until 3 mm of strain, only the tip of the instrument is bent. Then, between 3 and 6 mm, the curvature is in the middle of the file. Finally, above 6 mm, the part that has the maximum cross-sectional area near the handle becomes deformed in turn.").

the x-axis to the right of the origin. Ex. 1002 ¶ 165. In particular, the file showed about 1.8 mm of permanent deformation after being deflected 8 mm. *Id*.[25] This is considerably greater than the untreated file, *id*., and shows that the shank took on the general condition claimed by the ’991 patent. *See K-Swiss Inc. v. Gilde N Lock GmbH*, 567 F. App’x 906, 913 (Fed. Cir. 2014) (finding claims obvious even though prior art did not disclose specifically claimed “deformation percentage”). The results are consistent with the identified ISO 3630-1 test; permanent deformability undoubtedly increased with the 400ºC heat treatment. Ex. 1002 ¶¶ 165-6. Furthermore, Kuhn discloses that the treatment increased the transformation temperature from 35°C to 40°C, above oral temperature. Ex. 1030 at 719; Ex. 1002 ¶ 167. Under these conditions, the “wherein” clause is satisfied. Ex. 1002 ¶ 167; *see supra* section VI.C.2(b).[26]

Claim 13, which depends from claim 12, recites that the heat-treating step “is performed in an atmosphere that is unreactive, ambient or any other acceptable heat treatment process.” While this does not appear to add any meaningful

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[25] That the curve continues leftward along the x-axis to the origin does not mean that the file ultimately returned to its original shape. Ex. 1002 ¶165 n.7.

[26] In IPR 2015-00632, Patent Owner misreads Kuhn’s statement that non-heat-treated files “recover[ed] their original” state after bending as applying to the heat-treated files. *See* Ex. IPR2015-00632, Paper 9 at pp. at 30-31; Ex. 1002 ¶ 168.

limitation to claim 1, Kuhn discloses performing the "heat-treating" step in an "acceptable" atmosphere as reflected by the "good results" achieved. Kuhn at 716; *see also* Ex. 1002 ¶ 170.

Claim 14, which depends from claim 12, sets the lower temperature bound at 300°C. The relevant heat treatment temperature from Kuhn is 400°C. Ex. 1030 at 719-720; Ex. 1002 ¶ 171.

Claim 16, which depends from claim 12, further recites that "the instrument shank consists essentially of a titanium alloy comprising 54-57 weight percent nickel." The "Profile" endodontic instruments tested in Kuhn, *see* Ex. 1030 at 720, had a composition of 54-57wt% nickel and 43-46wt% titanium. Ex. 1016 at 759, Table II; Ex. 1017 at 1294; Ex. 1002 ¶ 172.

H. __Ground 7__: Obviousness of Claim 15 Over Kuhn Either Alone or in View of Heath or ISO 3630-1

Claim 15, which depends from claim 12, further requires that the diameter of the shank (at the proximal end, *see supra* section VI.C.4) be 0.5-1.6 millimeters. Kuhn specifies the heat-treated instruments' size at the tip (0.2 mm), length (25 mm), and taper (0.04). Ex. 1030 at 717. The taper would be understood to apply over the entire standard ISO working length of the shank (16 mm), in which case the diameter would be 0.84 mm. *See* Ex. 1014 at 4-6; Ex. 1023 at 4-5; Ex. 1002 ¶ 173. Alternatively, the taper could apply to the entire length of the shank, in which case the diameter would be 1.2 mm. Ex. 1002 ¶ 173. In either case, the diameter is within the claimed range.

To the extent Kuhn is not found to disclose the claimed diameter, this would be an obvious modification. Heath discloses the exact range of 0.5 to 1.6 millimeters for the diameter at the handle end of a shank. Ex. 1024 at 3:49-53. Additionally, most of the "standard" sizes in ISO 3630-1 fall within the claimed range. *See* Ex. 1014 at 5; Ex. 1023 at 5. Moreover, practitioners use multiple sizes of instruments in root canal procedures, including those within the claimed range, thereby providing motivation to design instruments according to Kuhn with the claimed diameter range. *See* Ex. 1002 ¶ 174. Additionally, during prosecution of the related '933 application, the examiner stated that it would have been obvious to use this diameter as corresponding to the size of the hole. Ex. 1010 at 83. The applicant never challenged this point. *See, e.g.*, *id*. at 107.

Accordingly, claim 15 is unpatentable as obvious over Kuhn either alone or in combination with Heath or ISO 3630-1.

I. <u>Ground 8:</u> Obviousness of Claims 12-16 over Kuhn Either Alone or in View of Heath or ISO 3630-1

Claims 12-16 each requires "heat-treating the entire shank." To the extent it is determined that Kuhn's mention of cutting the instruments, Ex. 1030 at 717, means that less than the "entire shank" was heat-treated, it would have been obvious to a person of ordinary skill in the art to heat-treat the entire shank. Even if Kuhn, for testing purposes, cut the shank before heat-treating it, one would not cut the shank of an instrument intended for clinical use, since this would render the instrument inoperable. Ex. 1002 ¶¶ 175-76. And, with the shank intact, it would have been obvious to heat-treat the entire shank. *Id*. A person skilled in the art would expect that heat-treating the entire shank would lead to the same beneficial effects seen by Kuhn, and Kuhn gives no reason to believe otherwise. *Id*. Therefore, a person of ordinary skill in the art would have been motivated to modify the method taught by Kuhn to heat-treat the entire shank if it is determined that Kuhn discloses heat-treating less than the "entire shank."

Thus, claims 12-16 are unpatentable for the reasons stated in Grounds 6 and 7, and for the additional reason that it would have been obvious to heat-treat the entire shank.

J. Ground 9: Obviousness of Claims 12-14 and 16 Over McSpadden and Pelton in View of Kuhn

Pelton and McSpadden published in 2000 and 2002, respectively, and so are prior art under § 102(a)(1).

1. Overview of Pelton

As discussed above with respect to Ground 1 (section VIII.B.2(c)), Pelton describes the relationship among temperature, time, and final A_f temperature in the heat treatment of a particular Ni-Ti alloy. *See* Ex. 1006 at 114. As described above (section IV), the transformation temperatures of Ni-Ti determine whether it is superelastic at a given testing temperature.[27]

2. Overview of McSpadden

McSpadden discloses a superelastic Ni-Ti endodontic instrument and a method of manufacturing the same. *E.g.*, Ex. 1031 Abstract, Figs. 1-2, ¶¶ 8, 14-17. McSpadden teaches that heat treatment should be applied after machining: (1) because residual stress in the material improves machinability; and (2) "in order to achieve the desired degree of superelasticity or other material properties and/or to set a desired file shape (straight**,** pre-curved or pre-twisted)." *Id*. ¶ 52 (emphasis added).

3. Obviousness of Claims 12-14 and 16

As noted above, Kuhn discloses that heat treatment of superelastic Ni-Ti files under certain conditions provided "good results," including an increase in the transformation temperature (A_f temperature) and an increase in flexibility. Ex. 1030 at 716, 719-20. It would have been obvious to use the Ni-Ti instrument

[27] In IPR2015-00632, Patent Owner argues that Pelton was seeking to "optimize" rather than "lessen" Ni-Ti's superelastic properties. But an increase in transformation temperature—which applicant Luebke describes as his invention, *see supra* section VI.C.2(b)—does not "lessen" superelastic properties; rather, it changes them, so that superelasticity is observed at higher test temperatures. Ex. 1002 ¶ 192.

disclosed by McSpadden, and apply the heat treatment parameters of Pelton, which discloses a Ni-Ti alloy with the same composition, in order to obtain a file exhibiting the "good results" disclosed by Kuhn. Ex. 1002 at ¶ 178. By doing so, a person of ordinary skill in the art would have arrived at the invention recited in claims 12-14 and 16. *Id.*

A skilled artisan would have been motivated to apply Kuhn's teaching—using heat treatment to raise the Ni-Ti transformation temperature and increase flexibility—to other instruments, including the commercially available instrument disclosed by McSpadden. *Id.* ¶ 179. McSpadden discloses a file comprised of superelastic "NiTi SE508"; as McSpadden itself explained in 2002, "[f]luted endodontic instruments fabricated from NiTi SE508 and similar NiTi alloys ha[d] been commercially introduced and ha[d] become widely accepted in the industry." *Id*.; Ex. 1031 ¶¶ 40, 41. In addition to using an industry-standard alloy, McSpadden describes benefits of its manufacturing process, including files having improved cutting edges. *E.g.*, Ex. 1031 ¶ 52; Ex. 1002 ¶ 180. McSpadden also teaches that heat treatment of the instruments after they are machined allows one "to achieve the desired degree of superelasticity or other material properties and/or to set a desired file shape (straight, <u>pre-curved</u> or pre-twisted)." Ex. 1031 ¶ 52 (emphasis added). Therefore, the McSpadden instrument would have been a natural choice to which to apply a heat treatment to obtain the "good results" touted by Kuhn. Ex.

1002 ¶ 180.

In order to replicate those "good results" seen by Kuhn after heat treatment at 400°C for 10 minutes, *see* Ex. 1030 at 716, 720, one of ordinary skill in the art would have relied on Kuhn's disclosure that the transformation temperature of the heat-treated instrument increased from 35°C to 40°C, *id*. at 719, and so would have looked for a treatment that increased the A_f temperature at least that far. Ex. 1002 at ¶ 183.

Pelton describes heat treatment of the same Ni-Ti alloy taught by McSpadden, namely a superelastic N-Ti alloy having 55.8wt% Ni. *Compare* Ex. 1031 ¶ 40 (disclosing SE508 Ni-Ti alloy, which comprises 55.8wt% Ni) *with* Ex. 1006 at 108, 114 (disclosing composition of 50.8at% Ni, which is equivalent to 55.8wt% Ni); *see also id.* at 113 (Fig. 6, showing "superelastic window" that includes room temperature and body temperature); Ex. 1002 ¶¶ 185, 195-96. Because the Ni-Ti alloy composition disclosed in McSpadden is the same as that disclosed in Pelton, and Pelton relates treatment time and temperature of that alloy to transformation temperature, Ex. 1006 at 113-15, Ex. 1002 ¶ 185, it would have been obvious to use Pelton as a guide for heat treatment of the McSpadden file. Ex. 1002 ¶ 186.[28] Figure 10 of Pelton (reproduced *supra*, page 42) shows that

[28] In IPR2015-00632, Patent Owner seeks to distinguish Pelton because it did not study heat treatments on finished products, but rather Ni-Ti wire. *See, e.g.*,

treating Pelton's Ni-Ti alloy at 400°C for 1 hour or about 450°C for 2 hours would result in an A_f temperature of 40°C. Therefore it would have been obvious to use either of these heat treatments.[29] *Id*.

In doing so, the artisan would arrive at the subject matter of claims 12-14 and 16. Claim 12, step (a), requires "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." McSpadden discloses a "fluted endodontic file" having a "shank portion" and an "elongated working portion." Ex. 1031 ¶ 32. Together, these portions comprise the "elongate shank" of

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IPR2015-00632, Paper 9 at p. 35. However, the applicant himself relied on the figure from Pelton discussed above, *see supra* section VIII.B.2(c), to support his argument that "endodontic instruments" heat-treated at certain temperatures will satisfy the "wherein" clause. Ex. *See* Ex. 1003 at 127-28 (¶¶ 5, 6) (emphasis added).

29 While Pelton does not express a preference for a particular treatment, the prior art as a whole need only suggest the desirability of the treatment. *See In re Fulton*, 391 F.3d 1195, 1200-01 (Fed. Cir. 2004). Viewed together, Kuhn, McSpadden, and Pelton provide the necessary suggestion.

claim 12.[30] Ex. 1002 ¶ 188. McSpadden further discloses that the "working portion" extends from a "proximal end" to a "distal end," with "helical flutes" and "helical lands" that define a "cutting edge." Ex. 1031 ¶¶ 32-35; Ex. 1002 ¶ 188. McSpadden teaches that the file should be made from "a superelastic alloy, such as … nickel-titanium wire." Ex. 1031 ¶ 40.

Claim 12, step (b), requires "heat-treating the entire shank at a temperature above 25° C. up to but not equal to the melting point of the superelastic nickel titanium alloy." Step (b) would be satisfied by performing the heat treatments at 400°C for 1 hour or about 450°C for 2 hours as disclosed by Pelton. Ex. 1002 ¶¶ 186, 189. McSpadden makes clear that such treatment should be performed after machining the file, since machining before heat-treating "improve[s] the machining characteristics of the material." *Id*. ¶ 182; Ex. 1031 ¶¶ 50-52. McSpadden also teaches treating "the formed endodontic file," *id.*, which one of ordinary skill would have understood to include the "entire shank." Ex. 1002 ¶ 190.

Finally, the "wherein" clause would be satisfied by the A_f temperature of 40°C obtained by heat-treating the McSpadden file in accordance with Pelton,

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[30] The "shank" in the '991 patent is the "shaft" in McSpadden, which includes the "working portion." *Compare* Ex. 1001 at 4:5-15, Fig.1a *with* Ex. 1031 ¶ 32, Fig. 2A; *see* Ex. 1002 ¶ 188 n.8.

because (i) it is above body temperature, and (ii) it is high enough that, under ISO testing conditions (21-25°C), the martensite present in the material would permit the requisite permanent deformation. Ex. 1002 ¶ 191; *see also supra* section VI.C.2.(b).

Claim 13, which depends from claim 12, further recites that "step (b) is performed in an atmosphere that is unreactive, ambient or any other acceptable heat treatment process." The heat treatment process of Pelton is "acceptable" because it results in the material having a satisfactory A_f temperature. *See* Ex. 1002 ¶ 193.

Claim 14, which depends from claim 12, further requires that "the temperature is from 300° C. up to but not equal to the melting point of the superelastic nickel titanium alloy." As explained above, Pelton discloses heat-treating for 400°C for 1 hour or about 450°C for 2 hours to obtain an A_f temperature of 40°C, which a skilled artisan would have been motivated to achieve.

Claim 16, which depends from claim 12, further recites that "the instrument shank consists essentially of a titanium alloy comprising 54-57 weight percent nickel." The Pelton alloy composition is 50.8at%, which is 55.8wt% nickel and within the claimed range. Ex. 1006 at 108, 114; Ex. 1002 ¶¶ 195-96. McSpadden discloses the use of SE508 Ni-Ti to make an endodontic file and that such alloy comprises 55.8% nickel and 44.2% titanium by weight, the same composition of the Pelton alloy. Ex. 1031 ¶ 40 & Table 1; Ex. 1002 ¶¶ 195-96.

K. Ground 10: Obviousness of Claim 15 Over McSpadden and Pelton in View of Kuhn and in Further View of Heath or ISO 3630-1

Claim 15, which depends from claim 12, further requires that the diameter of the shank (at the proximal end, *see supra* section VI.C.4) be 0.5-1.6 millimeters. This is an obvious modification of the McSpadden file, and therefore claim 15 is obvious for the reasons stated in the previous ground regarding claim 12. Ex. 1002 ¶ 197. Heath discloses the exact range of 0.5 to 1.6 millimeters for diameter at the handle end of a shank. Ex. 1024 at 3:49-53. Additionally, most of the "standard" sizes in ISO 3630-1 fall within the claimed range. *See* Ex. 1014 at 5; Ex. 1023 at 5. Moreover, practitioners use multiple sizes of instruments in root canal procedures, including those within the claimed range, thereby providing the motivation to design a file with the claimed diameter range. *See* Ex. 1002 at ¶¶ 174, 197. Finally, during prosecution of the related '933 application, the examiner stated that it would have been obvious to use this diameter as corresponding to the size of the hole. Ex. 1010 at 83. The applicant never challenged this point. *See, e.g., id*. at 107. Accordingly, claim 15 is obvious over McSpadden and Pelton in view of Kuhn and in further view of Heath and ISO 3630-1.

L. **<u>Ground 11</u>: Obviousness of Claims 12-14 and 16 Over Tripi in View of McSpadden**

As noted in section VII.C above, Patent Owner has argued that the claims in the ’773 patent (the ’991 patent’s parent), which cover heat-treating in an atmosphere reactive with Ni-Ti, are entitled to priority to the 2005 PCT application because that application discloses applying a titanium nitride coating to the Ni-Ti shank of an endodontic instrument by way of physical vapor deposition (PVD) with an inherent heat treatment. Petitioner disagrees. *See supra* section VII.C.

Nonetheless, to the extent that PVD-coated files, as disclosed in the priority applications, can provide written description support for the broad scope of the Challenged Claims, those claims are unpatentable over references disclosing the prior art process of coating Ni-Ti endodontic files by way of PVD, such as Tripi, which published in February 2003 and is prior art under § 102(a)(1).

1. <u>Overview of Tripi</u>

Tripi studied the surface layers obtained by coating Ni-Ti endodontic files using arc evaporation PVD, and thermal metal organic chemical vapor deposition (CVD). For the PVD process, titanium was physically deposited in the presence of nitrogen on Maillefer Ni-Ti endodontic instruments at 300°C. Ex. 1032 at 132. Tripi determined that the PVD process deposited a titanium nitride layer on the surface of the file “can increase the cutting efficiency and wear resistance in that the instrument becomes harder on the surface and thus more effective in its shaping ability." *Id*. at 134.

2. Obviousness of Claims 12-14 and 16

The combination of Tripi and McSpadden renders claims 12-14 and 16 unpatentable. Claim 12, step (a), requires "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." Tripi discloses "endodontic files made of NiTi alloy," and, in particular, Maillefer GT Rotary instruments. Ex. 1032 at 132. McSpadden discloses a "fluted endodontic file" having a "shank portion" and an "elongated working portion." Ex. 1031 ¶ 32. Together, these portions comprise the "elongate shank" of claim 12.[31] Ex. 1002 ¶ 188. McSpadden further discloses that the "working portion" extends from a "proximal end" to a "distal end," with "helical flutes" and "helical lands" that define a "cutting edge." Ex. 1031 ¶¶ 32-35; Ex. 1002 ¶ 188. Further, McSpadden discloses that, by 2002, "[f]luted endodontic instruments fabricated from NiTi SE508 and similar NiTi alloys ha[d] been commercially introduced and ha[d] become widely accepted in the industry." *See* Ex. 1031 ¶ 41. The files described in McSpadden, for example, were made of Ni-Ti SE508, "a superelastic alloy." *Id.* ¶

[31] The "shank" in the '991 patent is the "shaft" in McSpadden, which includes the "working portion." *Compare* Ex. 1001 at 4:5-15, Fig.1a *with* Ex. 1031 ¶ 32, Fig. 2A.

40. It would have been obvious to apply Tripi's PVD to McSpadden's Ni-Ti endodontic files since such treatment would be expected to increase cutting efficiency and wear resistance. Ex. 1032 at 134; Ex. 1002 ¶¶ 199-201.[32]

Claim 12, step (b), requires "heat-treating the entire shank at a temperature above 25° C. up to but not equal to the melting point of the superelastic nickel titanium alloy." Tripi discloses coating Ni-Ti files with titanium nitride using PVD at 300ºC. Ex. 1032 at 132.

Claim 12 concludes, "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." Because the "wherein" clause is not a limitation for purposes of patentability (*see supra* section VI.C.2(a)), claim 12 is unpatentable as obvious. In any event, according to the '991 patent, using PVD with an "inherent heat treatment" to apply a titanium nitride coating to a superelastic, Ni-Ti shank of an endodontic instrument results in a

[32] In IPR2015-01476, Paper 9 at p. 30, Patent Owner asserts that McSpadden is "incompatible" with Tripi's coating process because McSpadden discloses heat treatment in which the surface of the shank is kept cool while its core is heated. However, that argument relates to a different embodiment of McSpadden than the embodiment on which Petitioner relies, which is not a selective heat-treatment process. *See* Ex. 1002 ¶ 190.

shank showing more than 10 degrees of permanent deformation after being tested in accordance with ISO 3630-1. *See* Ex. 1001 at Fig. 6, 8:35-62. In particular, Figure 6 shows that such file shanks (the third column in each group, labeled "Ti-N") exhibited about 15-24 degrees of permanent deformation. Nothing in Example 4 suggests that particular heat treatment conditions are required to achieve the claimed result; PVD with an inherent heat treatment is enough. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999). Therefore, the "wherein" clause is inherently disclosed by Tripi, either alone, or in combination with McSpadden.

Claim 13, which depends from claim 12, further recites that "step (b) is performed in an atmosphere that is unreactive, ambient or any other acceptable heat treatment process." The PVD process of Tripi is "acceptable" because it improved the qualities of the endodontic file in terms of cutting efficiency and wear resistance.

Claim 14, which depends from claim 12, further requires that "the temperature is from 300° C. up to but not equal to the melting point of the superelastic nickel titanium alloy." The PVD temperature is 300°C. Ex. 1032 at 132.

Claim 16, which depends from claim 12, further recites that "the instrument shank consists essentially of a titanium alloy comprising 54-57 weight percent nickel." McSpadden discloses the use of SE508 Ni-Ti to make an endodontic file and such alloy has 55.8% nickel and 44.2% titanium, by weight. Ex. 1031 ¶ 40 & Table 1. As discussed above (pp. 74-75), it would have been obvious to apply Tripi's PVD process to the files described in McSpadden. Ex. 1002 ¶¶ 199-201.

M. Ground 12: Obviousness of Claim 15 Over Tripi in View of McSpadden and in Further View of Heath or ISO 3630-1

Claim 15, which depends from claim 12, further requires that the diameter of the shank (at the proximal end, *see supra* section VI.C.4) be 0.5-1.6 millimeters. This is an obvious modification of McSpadden for the same reasons stated above in Ground 10 (*see supra* section VIII.K). Ex. 1002 ¶ 202. Accordingly, claim 15 is unpatentable over Tripi in view of McSpadden in further view of Heath or ISO 3630-1.

IX. THE GROUNDS IN THE PETITION ARE NOT REDUNDANT

The Board should institute inter partes review on all of the grounds presented in this petition.

Grounds 1 and 2, for lack of enablement and lack of written description, respectively, are distinct issues of patentability under § 112.

Grounds 3 and 4 based on Luebke 2008 depend on the Board's determination as to the effective filing date of the Challenged Claims (*see supra* sections VII, VIII.D, VIII.E). Luebke 2008 is otherwise a comprehensive reference that anticipates the Challenged Claims and also renders obvious Claim 15.

The grounds based on earlier prior art references (Grounds 5-12) are not redundant of the Luebke 2008 grounds or one another. The references at issue in Grounds 6 through 12 are prior art regardless of the effective filing date of the Challenged Claims, and the Matsutani reference (Ground 5) is prior art provided the claims are not entitled to the provisional filing date of June 7, 2004. Ground 5 is an anticipation ground based on Matsutani. Ground 6 is an anticipation ground based on Kuhn; it is not redundant of Ground 5 because Matsutani and Kuhn satisfy the "wherein" clause based on different types of disclosures. Matsutani discloses the "wherein" clause by teaching that heat-treated instruments should have an elevated A_f temperature such that they stay bent after a stress is removed, allowing a dentist to pre-curve the file (*see supra* section VIII.F). Meanwhile, Kuhn discloses the "wherein" clause by providing that a particular A_f temperature above the body temperature is achieved by heat-treating at a particular temperature and time (*see supra* section VIII.G). Grounds 7 and 8 are obviousness grounds based on Kuhn. Ground 7 addresses claim 15, which Ground 6 (anticipation) does not; Ground 8 addresses an argument against anticipation made by Patent Owner in IPR2015-00632. Neither is redundant.

Grounds 9 and 10 are obviousness grounds based on McSpadden and Pelton in view of Kuhn. They are not redundant of Grounds 6-8 because they are provided in the event that the Board accepts Patent Owner's previous and disputed argument that Kuhn's heat-treated instruments returned to their original shape after bending force is applied and, therefore, do not satisfy the "wherein" clause. *See supra* section VIII.G, footnotes 25-26. Further, Patent Owner has lodged arguments against McSpadden and Pelton that are inapplicable to Kuhn. *See supra* section VIII.J, footnotes 27-28.

Finally, Grounds 11 and 12 are obviousness grounds related to Patent Owner's disputed arguments in pending IPR2015-00632 and IPR2015-01476 that PVD-coated files with an inherent heat treatment, as disclosed in the priority applications, can provide written description support for the broad scope of the Challenged Claims. *See supra* sections VIII.L, VIII.M. Petitioner expects that Patent Owner will rely on a similar argument in this proceeding despite the fact that the applications in the priority chain for the '991 patent make no mention of the necessary parameters for performing PVD to achieve permanent deformation. In the interest of fairness, these grounds should not be denied as redundant for this would permit Patent Owner's to rely on its specious PVD argument without consequence.

In Petitioner's view, Patent Owner's previous arguments lack merit; but, because the Board's institution decision is only preliminary in nature, Petitioner requests institution on all the grounds in this petition. These grounds, both individually and collectively, "demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable" as required by 35 U.S.C. § 324(a).

X. CONCLUSION

For the reasons explained above, Petitioner respectfully requests institution of post-grant review of claims 12-16 of the '991 patent on each of the grounds presented herein, and cancellation of those claims in a final written decision.

Dated: August 3, 2015

/Jeffrey S. Ginsberg/
Jeffrey S. Ginsberg (Reg. No. 36,148)
Lead counsel for Petitioner US Endodontics, LLC

Matthew G. Berkowitz (Reg. No. 57,215)
Eric T. Schreiber (Reg. No. 58,771)
Back-up counsel for Petitioner US Endodontics, LLC

Kenyon & Kenyon LLP
One Broadway
New York, NY 10004-1007
Tel.: (212) 425-7200

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.205, the undersigned certifies that on August 3, 2015, a complete and entire copy of this Petition for Post-Grant Review along with complete and entire copies of Petitioner US Endodontics, LLC Exhibits 1001 through 1038 were served via FedEx Express on the Patent Owner at the following correspondence address of record for U.S. Patent No. 8,876,991:

Quarles & Brady LLP
Attn: IP Docket
411 E. Wisconsin Avenue
Suite 2350
Milwaukee, WI 53202-4426

A courtesy copy was also provided to counsel representing Patent Owner in IPR2015-00632 and IPR 2015-01476 and litigation counsel for Patent Owner's licensee:

Steven Lieberman
Joseph Hynds
R. Elizabeth Brenner-Leifer
Derek Dahlgren
Jason Nolan
Rothwell, Figg, Ernst & Manbeck, P.C.
607 14th St. NW, Suite 800
Washington, D.C. 20005

/Eric T. Schreiber/
Eric T. Schreiber (Reg. No. 58,771)

Kenyon & Kenyon LLP
One Broadway
New York, NY 10004-1007
Tel.: (212) 425-7200