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. IPR2015-01476
U.S. Patent No. 8,727,773 B2

PETITION FOR *INTER PARTES* REVIEW

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US Endodontics, LLC ("Petitioner") petitions for *Inter Partes* Review ("IPR") under 35 U.S.C. §§ 311-319 and 37 C.F.R., Part 42, of claims 1, 4, 5, 8-10, and 12 of U.S. Patent No. 8,727,773 ("the '773 patent"), filed on April 25, 2012, issued on May 20, 2014, and currently assigned to Gold Standard Instruments, LLC ("GSI" or "Patent Owner"). There is a reasonable likelihood that Petitioner will prevail with respect to at least one claim challenged in this Petition.

I. INTRODUCTORY STATEMENT

This is US Endo's second petition concerning the '773 patent. The first petition—IPR2015-00632 ("the -632 Petition")—explains that the claims of the '773 patent are not entitled to claim the benefit of any earlier filing date because, in their broadest sense, they cover heat-treating a nickel-titanium ("Ni-Ti") endodontic file in *any* type of atmosphere, either reactive or unreactive with the Ni-Ti instrument, to achieve "permanent deformation." IPR2015-00632, Paper 2, at pp. 16-19. In contrast to the claims of the '773 patent, the disclosures in all applications in the claimed priority chain are limited to heat-treating in an *unreactive* atmosphere. ***Id.*** Every example in the specification of the '773 patent (and the priority applications) describes heat-treating at 500°C for 75 minutes in argon, which Patent Owner acknowledges is unreactive with Ni-Ti. *See* IPR2015-00632, Paper 9, at p. 16; *see also* Ex. 1101 at 4:12-19.

Moreover, during prosecution of one of the priority applications, the inventor distinguished heat-treating the instruments in a reactive atmosphere from a non-reactive atmosphere in order to overcome a prior art rejection. IPR2015-00632, Paper 2, at pp. 16-19; Ex. 1102 at pp. 408-14. Specifically, during prosecution of U.S. App. No. 11/628,933 ("the '933 app."), the applicant relied upon a declaration from David Berzins, who compared files heat-treated in air with files heat-treated in an unreactive atmosphere according to the Luebke application, i.e., in argon. *See* Ex. 1102 at pp. 408-14. Berzins informed the PTO that heat-treatment in air produced shanks that remained superelastic at both room temperature and mouth temperature, contrary to the goals of the applicant's invention. *See id.* at pp. 409-410. Berzins further declared that treatment in air, which is reactive with Ni-Ti, would result in a thick oxide layer that "may affect the surface integrity of the file as well as its properties and transformations." *Id*. at p. 411.

Citing the Berzins declaration, and distinguishing the prior art, the applicant, Neill Luebke, argued that "heat-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) when subjected to a bending force after the force is removed. *Id*. at 406. *See, also, id.* at 494 (examiner accepting applicant's

representation, noting that the temperature range and unreactive atmosphere, were critical in distinguishing over the prior art).

Because the '773 patent is not entitled to claim priority to an earlier filing date, the -632 Petition asserts that the claims of the '773 patent are unpatentable over references—including the named inventor's own prior publication—that were published between the filing date of the '773 patent and the filing date of the earliest application in the claimed priority chain. *See* IPR2015-00632, Paper 2, at pp. 21-28.

In its preliminary response to the -632 Petition, the Patent Owner disputes Petitioner's priority date position. The Patent Owner asserts that the '773 patent is entitled to claim the benefit of a 2005 PCT application because that application discloses applying a titanium nitride coating to the endodontic instruments by way of physical vapor deposition ("PVD"). IPR2015-00632, Paper 9, at pp. 16-19. According to the Patent Owner, this PVD process involves inherent heat-treating in a reactive atmosphere, and provides support for claims of the '773 patent. *Id*.

The Patent Owner's assertions regarding the 2005 PCT application and its PVD disclosure lacks merit. As an initial matter, the Patent Owner wrongly asserts that the 2005 PCT application discloses the atmospheric and temperature conditions of the "inherent heat-treatment" associated with the PVD coating process. Patent Owner's Preliminary Response, IPR2015-00632, Paper 9, at p. 16-

17. The 2005 PCT application contains no such disclosure. Ex. 1103, ¶¶ 35-42, Figs. 3-7.

The 2005 PCT application (and all other applications in the priority chain) discloses coating by PVD as a *prior art* coating process that can be performed *separately* from "heat-treating" according to the "inventive" parameters (i.e., heat-treating in an argon atmosphere at 500°C), in order to produce sharper cutting edges and improved resistance to heat-degradation. Ex. 1103 at ¶¶ 30-33. The specification of the 2005 PCT application compares PVD to the "inventive" process of heat-treating in argon (a non-reactive atmosphere) at 500°C and concludes that the "inventive" process was superior in terms of attributes such as flexibility, fatigue life and torsional resistance. Ex. 1103 at ¶¶ 37, 39-41.

There is no disclosure in the 2005 PCT application of applying a coating to a Ni-Ti endodontic file by PVD at a temperature within the claimed range. Indeed, there is no disclosure of *any* of the "inherent heat-treatment" parameters (e.g., atmosphere, time or temperature) at which application of a coating by PVD to a Ni-Ti endodontic file would occur to achieve the claimed result (i.e., permanent deformation), or even how the PVD coating was applied in the disclosed examples.

Nonetheless, and to the extent that PVD coated files, as disclosed in the priority applications, can provide written description support for the broad scope of

the claims of the ’773 patent, as Patent Owner asserts, then those claims are unpatentable over references disclosing the prior art process of coating Ni-Ti endodontic files by way of PVD. The specific grounds of proposed rejection based on PVD prior art references are set forth below.

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

A. Real Party-in-Interest

Petitioner US Endodontics, LLC, Edge Endo, LLC, Guidance Endo, LLC, Charles Goodis, and Bobby Bennett, are the real parties-in-interest.

B. Related Matters

The ’773 patent is currently being asserted against Petitioner by licensee Dentsply International, Inc. and its wholly-owned subsidiary Tulsa Dental Products LLC (d/b/a Tulsa Dental Specialties) 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). US Endo has filed a petition for *inter partes* review of the ’773 patent, IPR2015-00632, which is pending. Additionally, GSI has patent applications pending that might be affected by this proceeding: serial nos. 14/522,013, 14/722,309, 14/722,390, and 14/722,840. Petitioner is not aware of any pending administrative matter 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).

III. PAYMENT OF FEES (37 C.F.R. § 42.103)

The required fee of $23,000 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).

IV. BACKGROUND AND SUMMARY OF THE '773 PATENT

The '773 patent describes a method of modifying a Ni-Ti endodontic instrument for use in root canal therapy, which involves drilling through the hard outer portion of a tooth and removing diseased tissue (pulp) from the inside. A thin

file is needed to remove the tissue from the tooth's root(s). This thin file is the endodontic instrument to which the '773 patent pertains. *See* Ex. 1104 at ¶ 19.

As claimed, the file (or other endodontic instrument) includes a component made from a superelastic Ni-Ti alloy. The file is subjected to heat treatment at a temperature of from at least 400°C up to the melting point of the Ni-Ti alloy. As a result of the heat treatment, the instruments allegedly "exhibit higher resistance to torsion breakage, can withstand increased strain, have higher flexibility, have increased fatigue life and maintain any acquired shape upon fracture better." Ex. 1101 at 9:19-23.

The Ni-Ti alloys described and claimed by the '773 patent were first discovered in the 1960's, and their use to make endodontic files was first disclosed as early as 1988 by Walia et al. *See* Ex. 1105. When appropriately processed, Ni-Ti can exhibit both superelasticity (also known as pseudoelasticity) and shape memory. Superelasticity means that the material is relatively rigid until a threshold stress is applied to it; above that threshold, the material becomes considerably more flexible. When the stress is removed, the material reverts to its original shape. A shape memory material is flexible and does not revert to its original shape immediately after it is deformed. However, when it is heated past a transformation temperature (austenite finish temperature, "A_f"), it reverts to its pre-deformation shape. In other words, it "remembers" its original shape. Ex. 1104 at ¶ 23.

As is relevant to this petition, the specification of the '773 patent describes the results of a flexion test, measuring the angle of permanent deformation after bending ("ADP"), of 3 different groups of endodontic files: (1) an untreated control group; (2) a group heat-treated in a furnace in an argon atmosphere at 500°C for 75 minutes and then slowly cooled; and (3) a group coated with titanium nitride using PVD with an inherent heat-treatment. Ex. 1101 at 8:34-59. The specification does not disclose the "inherent heat-treatment" parameters of the PVD process that was applied to the group of coated files; for example there is no disclosure of the temperature at which the titanium-nitride coating was applied by PVD. The specification does explain that the "ten files that were heat-treated in a furnace in an argon atmosphere at 500°C. for 75 minutes showed the highest ADP of the 3 groups tested. Thus, the heat-treated files maintain the acquired (test deformed) shape rather than the shape memory exhibited in the untreated control (nickel-titanium instruments)." Ex. 1101 at 8:54-59.

V. REQUIREMENTS FOR *INTER PARTES* REVIEW (37 C.F.R. § 42.104)

A. Grounds for Standing (37 C.F.R. § 42.104(b)(1))

Petitioner certifies that the '773 patent is available for IPR. This Petition has been filed within one year after the date on which US Endo was served with a complaint alleging infringement of the '773 patent. No real parties-in-interest or

privies of Petitioner were served with any such complaint. Petitioner is not barred or estopped from requesting IPR.

B. Identification of Challenged Claims and Specific Statutory Ground (37 C.F.R. § 42.104(b)(1)-(2))

Petitioner challenges claims 1, 4, 5, 8-10, and 12 of the '773 patent ("the Challenged Claims") under 35 U.S.C. §103, as set forth below. Cancellation of these claims is requested. Petitioner requests that claims 1, 4, 5, 8-10, and 12 be cancelled on the following ground:

Ground 1: Obviousness Under 35 U.S.C. § 103 of Claims 1, 4, 5, 9-10, and 12 Over Endo in View of Tripi, and in Further View of McSpadden

Ground 2: Obviousness Under 35 U.S.C. § 103 of Claim 8 Over Endo in View of Tripi and in Further View of McSpadden and ISO 3630-1

C. Claim Construction (37 C.F.R. § 42.104(b)(3))

A claim subject to IPR is given its "broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b). Petitioner submits, for the purposes of this IPR petition only, the following claim constructions.

1. <u>"heat-treating the entire shank"/ "entire instrument shank"</u>

This limitation appears in each of the two independent claims, 1 and 13. In the concurrent district court litigation, Petitioner has asserted that this limitation

should be construed to require "heat-treating the entire shank/entire instrument shank in an atmosphere consisting essentially of a gas unreactive with nickel titanium" since, among other reasons, the patent text uniformly states that the atmosphere is one that consists essentially of a gas does not react with the shank component of the instrument. *See* Ex. 1101 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. In IPR2015-00632, Petitioner stated that the broadest reasonable interpretation of this limitation does not require a particular atmosphere for heat treatment. Patent Owner agreed. Petitioner takes the same position in this Petition in light of the applicability of the broadest reasonable interpretation standard in IPR proceedings.

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 claims 1 and 13. As Petitioner explained in the -632 Petition, for the purpose of patentability under 35 U.S.C. §§ 102 and 103, this clause should not be considered a limitation because it only states the intended result of performing the claimed heat treatment process.

A clause in a method claim adds no patentable weight to the claim if it merely states the intended result of a positively recited method step. *See Minton v. Nat'l Assoc. of Sec. Dealers*, 336 F.3d 1373, 1381 (Fed. Cir. 2003); *Baxter Healthcare Corp. v. Millennium Biologix, LLC*, IPR2013-00590, Paper 9, at pp. 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 merely states the intended result of heat treating the instrument: It describes a property of "the heat treated shank," i.e., the shank 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). It is just the intended result.

Step (a) of the claims involves the provision of a known instrument, and step (b) involves the application of a ubiquitous metallurgical technique to that instrument. The "wherein" clause merely recites the result of a known or obvious process—and this is not patentable. *See Bristol Myers-Squibb Co. v. Ben Venue Labs.*, 246 F.3d 1368, 1375-77 (Fed. Cir. 2001); *accord King Pharms. v. Eon Labs*, 616 F.3d 1267, 1274-76 (Fed. Cir. 2010). In fact, the substance of the result was already known, and the inventor merely selected an unorthodox way of measuring it. Neither the intended result nor the particular method of measuring it should be treated as a limitation of the claimed method.

Petitioner's position is consistent with the European Patent Office's

conclusion set forth in its rejection of Patent Owner's foreign counterpart application: "In the previous communication under point 5.3, the examining division objected to claim 11 as being merely directed to a result being achieved. . . . [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. 1106 at p. 4 (emphasis in original).

Petitioner's position is also consistent with the examiner's apparent understanding of this clause during prosecution of the application leading to the '773 patent. Original claim 1 included a shank made of a "titanium alloy," not limited to nickel-titanium, and a "wherein" clause similar to that in the issued claims, requiring the heat-treated shank to have "an angle greater than 10 degrees of permanent deformation after torque at 45 degrees of flexion." Ex. 1107 at p. 16. The examiner rejected the claim, and its dependent claims, for lack of enablement because "not all titanium alloys subjected to this treatment would result in that degree of deformation" and "[t]he dependent claims do not provide further steps that would always result in this degree of permanent deformation." *Id*. at p. 73 (emphasis supplied). In response, the applicant amended the claim to recite a nickel and titanium alloy in a particular ratio, *id*. at p. 100, without asserting any error in the examiner's reasoning. *See id*. at p. 103. Thereafter, the examiner

withdrew the enablement rejection. *See id*. at pp. 125-31. When he eventually allowed the claims (after further prosecution), the examiner reasoned that "while a titanium alloy will not always result in the above [claimed] properties, a shape memory nickel titanium alloy will result from the claimed method distinguished from the superelastic properties of the prior art." *Id*. at pp. 227-28 (emphasis supplied). In other words, the examiner did not treat the "wherein" clause as a limitation on the method, but as a stated goal of the positively recited steps. The examiner evidently believed that the method steps were sufficient to produce a shape-memory alloy without superelasticity, which in turn would meet the "wherein" clause of claim 1.

In another rejection, the examiner explicitly rebutted arguments based on the flexion test in the "wherein clause":

> Applicant argues with respect to the flexion test and Patel having a final superelastic property. First, it is noted that the claims do not currently recite the flexion test actually being performed as part of the method. The test is only referred to inferentially to establish physical properties of the shank, so the prior art references do not currently need to show the conducting of this test (however, Heath has been included to show this being a standard test to make the rejection more complete). Secondly, 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). It is only after Patel's wire is *cold*

> *worked* that it returns to the superelastic state. The flexion test is currently claimed specific to the heat treated shank rather than a cold worked shank.

Ex. 1107 at p. 129 (underline emphasis supplied). Thus, in addition to noting that the prior art need not show the flexion test, the examiner concluded that because the prior art showed the "same material/manufacture steps" as the claimed invention, it also "would have the same properties." *Id*. Following this rejection, the applicant requested an interview with the examiner, agreeing with the examiner's reasoning that the flexion test "is only referred to inferentially" but disagreeing with his conclusion that Patel's heat-treated wire would have the same properties. *See id*. at p. 145. The applicant submitted sixteen pages of notes distinguishing Patel (U.S. Pat. App. Pub. No. 2005/0090844) as "evidence that the Patel device is superelastic and that the subject matter of claim 1 does not have this property." *See id*. at pp. 145-60. The applicant, Neill Luebke, argued that, unlike the prior art, the instrument resulting from his method had a high enough transformation temperature that, during clinical use at body temperature (37°C), the instrument would be in the martensitic phase. *See id*.

Following the interview, the examiner expressed his understanding of the applicant's invention to be heat treatment of a superelastic instrument that results in "non-superelastic properties that allows for some degree of permanent deformation," in contrast to the prior art in which heat treatment was used "to

arrive at a superelastic device." *Id*. at p. 163. Despite the fact that the pending claim included a "wherein" clause requiring post-treatment permanent deformation, the examiner suggested that the applicant amend the claim to distinguish the prior art. *Id*. In other words, the examiner declined to give any weight to the "wherein" clause; if he had considered the "wherein" clause to be a limitation, then the applicant's argument that Patel did not disclose a permanently deformable device (which the Examiner accepted) would have itself been enough. Instead, and in response to the examiner's suggestion, the applicant amended the claim to add the requirement that the starting material, prior to the heat-treatment step, be a "superelastic nickel titanium alloy." *Id*. at pp. 168-70.

In sum, the "wherein" clause describes the intended result; it does not alter the method itself in any way. It therefore does not confer patentable weight and is not limiting for the purpose of determining patentability over the prior art.[1]

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[1] 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). Furthermore, the claims in *Griffin* included the step of "assaying for the presence of a point mutation," and the "wherein" clauses at issue

In the -632 Petition, Petitioner explained that, if the Board disagrees with Petitioner's position that the "wherein" clauses at issue are not limiting, the Board should nevertheless find that the prior art sufficiently satisfies those limitations if it discloses a method of making a heat-treated instrument that "allows for some degree of permanent deformation" (to quote the examiner's understanding of the invention). IPR2015-00632, Paper 2, at pp. 12-13. Petitioner further explained that, if the Board finds that the "wherein" phrase is limiting, it should also find that it is met by the prior art disclosure of a heat-treated file with an austenite finish temperature (or transition temperature) of 37°C or greater. *Id.* at pp. 13-14. Petitioner stands by both of those positions.

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described the 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" clauses in the '773 patent merely state the intended result of the "heat-treating" step, which cannot patentably distinguish the claims over the prior art, even if stated in the claims themselves. *See Minton*, 336 F.3d at 1381.

3. "permanent deformation"

Claims 1 and 13 recite this term within the "wherein" clause discussed above. If the Board concludes that the "wherein" clause is a limitation, Petitioner submits that "permanent deformation" means "deformation remaining after force is removed." Permanent deformation need not be "permanent" in the sense that the instrument never returns to its original shape. *See, e.g.*, Ex. 1107 at p. 110 (applicant explaining that "martensitic Ni-Ti" exhibited permanent deformation). Martensitic Ni-Ti will stay deformed when bent. *See* Ex. 1104 at ¶ 26; *supra* section IV.

4. "diameter of 0.5 to 1.6 millimeters"

Claim 8 recites that "the instrument shank has a diameter of 0.5 to 1.6 millimeters." The diameters of tapered endodontic files are usually measured at the tip, but the specification makes clear that claim 8 refers to the proximate end, i.e., the end that is connected to the handle. Ex. 1101 at 4:1-6; Fig. 1a. Therefore, Petitioner submits that this term means "diameter of 0.5 to 1.6 millimeters at the proximate end."

VI. EFFECTIVE FILING DATE OF THE CHALLENGED CLAIMS

In the -632 Petition, Petitioner argued that the claims should not be entitled to a priority date earlier than April 25, 2012 (the filing date of the '773 patent), for several reasons. Petitioner stands by those arguments; however, the references

relied upon in this Petition are prior art to the '773 patent regardless of the Challenged Claims' effective filing date, since the prior art references were published more than one year before June 8, 2004, the earliest priority date claimed on the face of the '773 patent.[2]

VII. HOW THE CLAIMS ARE UNPATENTABLE UNDER 37 C.F.R. § 42.104(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 understand the structural, chemical, and mechanical properties that can be manipulated in nickel titanium 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 nickel titanium alloy materials used in dental applications. Ex. 1104 at ¶ 28. This level of education and

[2] Patent Owner concedes that the claims are not entitled to the 2004 priority date and instead asserts that the correct priority date is June 7, 2005. IPR2015-00632, Paper 9, at p. 15.

experience applies whether the invention is deemed to have been made in 2004, 2012, or any time in between. *Id*.

B. Ground 1: Obviousness of Claims 1, 4, 5, 9-10, and 12 over Endo in View of Tripi and McSpadden

Endo published in 1994, Tripi published in February 2003, and McSpadden published in 2002. All three references are prior art under § 102(b) (pre-AIA) even if the claims are determined to be entitled to a priority date of June 8, 2004, the earliest priority date claimed by the '773 patent. In view of these references, claims 1, 4, 5, 8-10, and 12 would have been obvious under 35 U.S.C. §103.

1. Overview of Endo

Endo studied the corrosion resistance effects of titanium nitride coatings on a Ni-Ti alloy. The titanium nitride coating was applied to a Ni-Ti alloy composed of 50% atomic nickel by, after removing the surface oxide layer, using arc ion plating physical vapor deposition at 400°C in a nitrogen (N_2) atmosphere for 20 minutes. Ex. 1108 at p. 229.[3] Endo determined that this process improved the corrosion resistance of the Ni-Ti alloy, and that its corrosion rate can be reduced by more than one order of magnitude using titanium nitride coatings. Ex. 1108 at p. 238.

[3] Arc ion plating is a type of PVD. *See, e.g.*, Ex. 1109 at p. 318 ("Arc ion plating is a PVD process ….").

2. Overview of Tripi

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 GT rotary instruments at 300°C. Ex. 1110 at p. 132. Tripi determined that the PVD process deposited a titanium nitride layer on the surface of the file, which "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." Ex. 1110 at p. 134.

3. Overview of McSpadden

McSpadden discloses a superelastic nickel-titanium endodontic file. In particular, McSpadden describes a "typical fluted endodontic file," with a shank and a cutting edge extending from a distal end to a proximal end. *See* Ex. 1111 at Figs. 2A-2G, ¶¶ 32-35. The file "is made from a superelastic alloy, such as SE508," the alloy being "about 56% nickel and about 44% titanium by weight." *Id*. at ¶ 40.

4. Obviousness of claims 1, 4, 5, 8-10, and 12

Endo teaches the use of PVD to apply a titanium nitride coating to Ni-Ti at 400°C in a nitrogen (N_2) atmosphere in order to improve corrosion resistance. Ex. 1108 at pp. 229, 236, 238. Tripi teaches application of a titanium nitride coating

by PVD to Ni-Ti endodontic files in order to improve their cutting efficiency and wear resistance. Improved cutting efficiency and wear resistance are both described as beneficial qualities in endodontic files.

One of ordinary skill would have been motivated to apply a titanium nitride coating to an endodontic file using the PVD process disclosed in Endo. Tripi teaches the feasibility and desirability of depositing a titanium nitride coating on endodontic files comprised of nickel-titanium. A skilled artisan would have been motivated to employ the PVD process described in Endo in an endodontic file application since Endo's arc ion plating PVD process at 400°C provides improved corrosion resistance to a nickel-titanium alloy. Ex. 1108 at p. 238. Corrosion resistance has been shown to be an important quality of endodontic files. *See generally* Ex. 1112 (testing for corrosion of steel and Ni-Ti endodontic files and finding that some files experienced corrosion). It is worth noting that none of the '773 patent or any application in the claimed priority chain distinguishes between different types of PVD, or even recites which type was used for testing purposes.

By applying the teachings of Endo to endodontic files (as per Tripi), the artisan would have arrived at the subject matter of the Challenged Claims. Claim 1 requires "providing an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank." Tripi discloses "endodontic files." Ex. 1110 at p. 132. A person of ordinary skill in the art would

have understood endodontic files to have the claimed "shank" and "cutting edge" extending along the shank; features of a typical of an endodontic file. This is shown, for example, by McSpadden, which describes the basic characteristics of a Ni-Ti endodontic file. *See* Ex. 1111 at ¶¶ 32-35 (describing a "a typical fluted endodontic file" having a "working portion" extending from a "proximal end" to a "distal end," with "helical flutes" and "helical lands" that define a "cutting edge"). It would have been obvious to a person of ordinary skill in the art to apply the PVD coating process to a "typical" endodontic file described by McSpadden.

Claim 1 further requires that the shank "compris[e] a superelastic nickel titanium alloy." Tripi discloses "endodontic files made of NiTi alloy." Ex. 1110 at p. 132. As McSpadden explains, 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. 1111 at ¶ 41. The files described in McSpadden, for example, were made of Ni-Ti SE508, "a superelastic alloy." *Id.* at ¶ 40.

Claim 1 further requires "heat-treating the entire shank at a temperature from 400° C. up to but not equal to the melting point of the superelastic nickel titanium alloy." According to Patent Owner, this includes PVD of titanium nitride with an inherent heat treatment. *See* IPR2015-00632, Paper 9, at pp. 16-19. Endo discloses using "arc ion plating at 400°C under a N_2 atmosphere" to apply a titanium nitride

coating to a nickel-titanium alloy. *See* Ex. 1108 at p. 229. Arc ion plating is a type of PVD. Ex. 1109 at p. 318. For the reasons described above, it would have been obvious to use this process to apply titanium nitride coating to superelastic Ni-Ti endodontic files, such as those disclosed in McSpadden.

Last, claim 1 recites the "wherein" clause described above. Because the "wherein" clause is not a limitation for purposes of patentability (*see supra* section V.C.2), claim 1 is unpatentable as obvious. In any event, according to the '773 patent, using PVD with an inherent heat treatment to apply a titanium nitride coating to a superelastic Ni-Ti endodontic instrument results in an instrument showing more than 10 degrees of permanent deformation after being tested in accordance with ISO 3630-1. *See* Ex. 1101 at Fig. 6, 8:34-59. In particular, Figure 6 shows that these files (the third column in each group, labeled "Ti-N") showed 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.[4] "[T]he discovery of a previously

[4] As set forth above, in the -632 Petition, the Patent Owner falsely asserts that the 2005 PCT application (which includes the same specification as the '773 patent) discloses the atmospheric and temperature conditions of the "inherent heat-treatment" associated with the PVD coating process. IPR2015-00632, Paper 9, at p. 16. A review of the cited passages to the 2005 PCT application and the

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 the combination of Tripi and Endo.

Claim 4 depends from claim 1 and requires that the heat treatment is "performed in any atmosphere." This is not an additional limitation, and according to GSI, PVD is within the scope of the atmospheres allowed by claim 1. *See* IPR2015-00632, Paper 9, at pp. 16-19.

Claim 5 depends from claim 4 and requires that "the atmosphere is unreactive, ambient or any other acceptable heat treatment process." The PVD processes of Endo and Tripi are both "acceptable" within the meaning of claim 5 since they improved the qualities of the endodontic file in terms of cutting efficiency, wear resistance and corrosion resistance.

Claim 9 requires that heat treatment be performed "at a single temperature." Endo states that PVD was performed at 400°C. Ex. 1108 at p. 229. No other heat

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corresponding passages in the '773 patent confirms there is no disclosure of the time, temperature and/or atmosphere at which the files were coated using PVD. Ex. 1103, ¶¶ 35-42, Figs. 3-7.

treatments and no other temperatures were applied. *See id*. Therefore, Endo's heat treatment is "at a single temperature."

Claim 10 depends from claim 9 and requires that the "single temperature" be between 400°C and 525°C. Because Endo discloses PVD at 400°C, this additional limitation is satisfied.

Claim 12 requires that the superelastic nickel titanium alloy have 54-57% nickel and 43-46% titanium, by weight. The files disclosed in McSpadden, having 55.8% nickel and 44.2% titanium by weight, fall within these ranges. Ex. 1111 at ¶ 40, Table 1. And, as McSpadden noted, endodontic files made of the same or "similar NiTi alloys ha[d] been commercially introduced and ha[d] become widely accepted in the industry" by 2002. *Id.* at ¶ 41.

For the foregoing reasons, claims 1, 4, 5, 8-10, and 12 are invalid as obvious in view of Tripi and Endo.

C. Ground 2: Obviousness of Claim 8 over Endo in View of Tripi, McSpadden, and ISO 3630-1

Claim 8 depends from claim 1, which is unpatentable for the reasons described in Ground 1. Claim 8 further requires that "the instrument shank has a diameter of 0.5 to 1.6 millimeters," at the proximal end. *See supra* section V.C.4. The claimed range of sizes constitutes a very large portion of clinically useful sizes; for example, ISO Standard 3630-1 (1992) lists numerous standard diameters,

with a range encompassed by the range of claim 8. *See* Ex. 1113 at 5 (Table 3, listing proximal-end diameters "d_3" from 0.40 to 1.72 mm). In view of ISO 3630-1, it would have been obvious to use any of these standard sizes when constructing an instrument, and it would have been obvious to apply the coating process described in Ground 1 to such a standard-sized file.

Indeed, during prosecution of the '773 patent and its priority applications, the examiner twice rejected claims containing this diameter limitation—in one case, without any specific disclosure in the prior art—and in neither case did Patent Owner dispute the obviousness of that limitation. *See* Ex. 1102 at pp. 82-83 (rejecting claim because "[i]t would have been obvious … to have modified the diameter of the shank in order to drill a hole with a diameter of corresponding size"); *id*. at pp. 105-09 (failing to dispute obviousness of the 0.5 to 1.6 millimeter diameter); Ex. 1107 at 75-76 (rejecting application claim that would become claim 8, stating that "this range of diameters is known for endodontic reamers"); *id*. at pp. 104-07 (failing to dispute the obviousness of the 0.5 to 1.6 millimeter diameter).

VIII. CONCLUSION

For the reasons explained above, Petitioner respectfully requests institution of *inter partes* review of claims 1, 4, 5, 8-10, and 12 of the '773 patent on each of

the grounds presented herein, and cancellation of those claims in a final written decision.

Dated: June 25, 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 42.105, the undersigned certifies that on June 25, 2015, a complete and entire copy of this Petition for *Inter Partes* Review along with complete and entire copies of Petitioner US Endodontics, LLC Exhibits 1101 through 1113 were served via Federal Express on the Patent Owner at the following correspondence address of record for the '773 patent:

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 the Patent Owner in IPR2015-00632:

Steven Lieberman
Rothwell, Figg, Ernst & Manbeck, P.C.
607 14th St. NW, Suite 800
Washington, D.C. 20005

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