UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDGE ENDO, LLC,
Petitioner

v.

MAILLEFER INSTRUMENTS HOLDING S.A.R.L.
Patent Owner

Case No. IPR2018-01349
U.S. Patent No. 9,801,696

PETITION FOR *INTER PARTES* REVIEW

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Submitted Electronically via the PTAB E2E System

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Edge Endo, LLC ("Edge Endo" or "Petitioner") respectfully requests *inter partes* review ("IPR") under 35 U.S.C. §§311-319 and 37 C.F.R., Part 42 of claims 1, 2, 5, and 8-10 ("the challenged claims") of U.S. Patent No. 9,801,696 (Ex. 1001, "the '696 patent"). There is a reasonable likelihood that Petitioner will prevail with respect to at least one challenged claim.

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

A. Real Party in Interest (37 C.F.R. §42.8(b)(1))

Petitioner Edge Endo, LLC, as well as US Endodontics, LLC, Charles Goodis, Bobby Bennett, Edge Holdings, LLC and Guidance Endodontics, LLC are real parties-in-interest. Petitioner does not believe that any other entity is a real party-in-interest, but nonetheless identifies that Edge Endo, LLC and US Endodontics, LLC are owned by Edge Holdings, LLC, which is majority owned by Peter Brasseler Holdings, LLC, which is majority owned by SG Healthcare Corp., which is owned by Henry Schein, Inc.

B. Related Matters (37 C.F.R. §42.8(b)(2))

The '696 patent is asserted in *Dentsply Sirona, Inc., et al. v. Edge Endo, LLC, et al.*, No. 1:17-CV-01041 (D.N.M.). Patent Owner, Maillefer Instruments Holding S.a.r.l., has a related pending patent application that might be affected by this proceeding: U.S. Pat. Appl. Ser. No. 15/710,869. Petitioner has also filed IPR petitions for the other three patents at issue in the district court case. *See* Case Nos. IPR2018-001320, -01321, and -01322. While such patents are not in the same family as the '696 patent, the subject matter is similar and Petitioner relies on common prior art references in support of its unpatentability positions. 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. Lead and Back-Up Counsel (37 C.F.R. §42.83(b)(3)) and Service Information (37 C.F.R. §§42.8(b)(4))

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Pursuant to 37 C.F.R. §42.8(b)(4), counsel agrees to service by mail, and to electronic service by e-mail. Pursuant to 37 C.F.R. §42.10(b), a Power of Attorney accompanies this Petition.

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

In accordance with 37 C.F.R. §§42.15(a) and 42.103, Petitioner authorizes the Commissioner to charge all fees due to Attorney Deposit Account No. 506642.

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

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

Petitioner certifies that the '696 patent is available for IPR. This Petition has been filed less than one year after the date on which Petitioner was served with a complaint alleging infringement of the '696 patent. Petitioner is not barred or estopped from requesting IPR on the grounds identified herein.

B. Identification of Challenge (37 C.F.R. §42.104(b)(1)-(2)) and Relief Requested (37 C.F.R. §42.22(a)(1))

Petitioner requests that claims 1, 2, 5, and 8-10 of the '696 patent (Ex. 1001) be cancelled as unpatentable because they are anticipated under 35 U.S.C. §102 and/or obvious under 35 U.S.C. §103 in view of prior art on the following grounds:

Ground 1	**Challenged Claims**
Anticipation by U.S. Pat. Appl. No. 2004/0023186 to McSpadden ("McSpadden," Ex. 1004)	1, 2, 5, 8
Ground 2	
Obviousness over McSpadden	1, 2, 5, 8, 10
Ground 3	**Challenged Claims**
Obviousness over McSpadden in view of U.S. Pat. No. 6,299,445 to Garman ("Garman," Ex. 1005)	9
Ground 4	**Challenged Claims**
Obviousness over U.S. Pat. Appl. No. 2006/0228669 to Scianamblo ("Scianamblo," Ex. 1006)	1, 2, 5, 8, 10
Ground 5	**Challenged Claim**
Obviousness over Scianamblo in view of Garman	9

Ground 6	Challenged Claims
Obviousness over WO 01/19279 to Badoz ("Badoz," Exs. 1007 and 1008)[1] in View of U.S. Pat. No. 5,882,198 to Taylor et al. ("Taylor," Ex. 1009)	1, 2, 5, 10
Ground 7	**Challenged Claims**
Obviousness over Badoz in view of Taylor and in further view of Garman	8, 9

For purposes of this IPR only, Petitioner assumes that the earliest effective filing date of the '696 patent is January 30, 2013, which is the filing date for PCT/IB2013/000108, to which the '696 patent claims priority. Ex. 1001, p. 1.

McSpadden published on February 5, 2004, and thus qualifies as prior art under pre-AIA 35 U.S.C. §102(b).

Scianamblo published on October 12, 2006, and thus qualifies as prior art under pre-AIA 35 U.S.C. §102(b).

Badoz published on March 22, 2001, and thus qualifies as prior art under pre-AIA 35 U.S.C. §102(b).

Taylor issued on March 16, 1999, and thus qualifies as prior art under pre-AIA 35 U.S.C. §102(b).

Garman issued on October 9, 2001, and thus qualifies as prior art under pre-AIA 35 U.S.C. §102(b).

[1] Exhibit 1007 is the original references in the French language. Exhibit 1008 is the certified translation. Citations herein are to the latter.

IV. BACKGROUND AND SUMMARY OF THE '696 PATENT

A. Overview of the '696 Patent

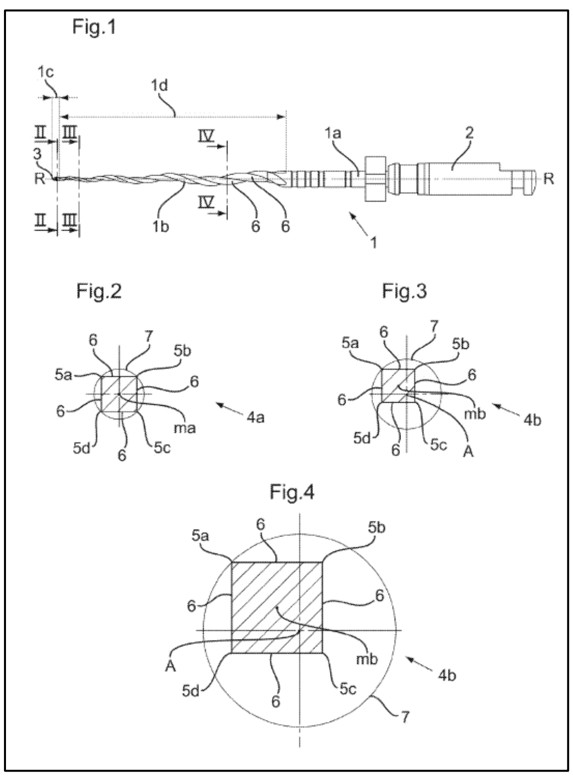
The '696 patent relates to an instrument for drilling dental root canals. Ex. 1001, 2:15-16; Ex. 1003, ¶¶33.[2] The '696 patent identifies two drawbacks with a conventional instrument. Ex. 1001, 1:25-33; Ex. 1003, ¶33. First, it "may have a tendency to screw itself into the canal." Ex. 1001, 1:25-26; Ex. 1003, ¶33. Second, it is either too flexible, resulting in bending or breaking of the instrument, or too rigid, resulting in difficulty in the instrument following the curvature of the root canal. Ex. 1001, 1:29-33; Ex. 1003, ¶33.

The '696 patent attempts to address the alleged drawbacks associated with instruments for drilling dental root canals. Ex. 1003, ¶¶34, 35. In one embodiment, it describes an instrument comprising a rod fitted with a handle that permits actuation of the instrument either manually or in a hand-held device that drives the instrument. Ex. 1001, 2:56-62; Ex. 1003, ¶36. The rod has an active part that is preferably tapered and conical, narrowing to a point. Ex. 1001, 2:63-67; Ex. 1003, ¶36. The active part has a square cross-section forming four cutting edges. Ex. 1001, 3:1-7; Ex. 1003, ¶36. The active part is defined by an envelope that is substantially tapered and has its longitudinal axis coinciding with the instrument's

[2] Citations are to the column and line number for patents, and either paragraph number or page and line numbers for other patent publications.

rotational axis. Ex. 1001, 3:7-10; Ex. 1003, ¶36.

As illustrated in Figures 1-4 (reproduced below), the "active part 1b has a first portion 1c extending from the point 3 towards the rear of the active part 1b and of which the centre of mass is located on the axis of rotation R of the instrument and a second portion 1d extending from the end of the first portion 1c to the rear of the active part 1b and of which at least one cross-section has a centre of mass which is not located on the axis of rotation R of the instrument but is offset with respect to said axis R." Ex. 1001, 3:11-48; Ex. 1003, ¶¶37-38. Preferably, for any cross-section 4b of the second portion 1d, a single cutting edge is 5a located on the envelope 7, while the other cutting edges 5b, 5c and 5d are located inside the envelope 7. Ex. 1001, 3:37-42; Ex. 1003, ¶38.



Ex. 1001, Figs. 1-4.

The '696 patent discloses a second embodiment, which is similar to the first, Ex. 1001, 4:22-50, except that for any cross-section of the second portion, two cutting edges are located on the envelope, and two cutting edges are located inside the envelope, Ex. 1001, 4:50-55; Ex. 1003, ¶¶40-41.

In a third disclosed embodiment, the active part has cross-sections of a parallelogram shape, and the second portion of the active part has an alternating arrangement of zones that have off-center cross-sectional centers of mass and zones that have centered cross-sectional centers of mass. Ex. 1001, 4:62-5:32, 6:46-59; Ex. 1003, ¶¶42-44. Preferably, the off-center zones have one cutting edge on the envelope, while the centered zones have two cutting edges on the envelope. Ex. 1001, 5:38-51; Ex. 1003, ¶44.

B. Prosecution History of the '696 Patent

While McSpadden, Scianamblo and Badoz were identified in an Information Disclosure Statement submitted during prosecution of the application that resulted in issuance of the '696 patent, U.S. Pat. Appl. Ser. No. 14/651,677 (the '677 application"), they were never discussed.[3] A reference related to McSpadden,

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[3] Notably, McSpadden, Scianamblo, and Badoz were disclosed in an Information Disclosure Statement that identified 46 references and that was submitted after an original notice of allowance had already issued. Ex. 1002, pp. 321-325, 350-356.

however, was discussed during prosecution. But, as noted below, key disclosures in that reference appear to have been overlooked. Grounds 1-3 of this Petition are based on these critical disclosures and present arguments and supporting testimony not previously considered by the United States Patent and Trademark Office ("PTO").

In a non-final office action, dated January 30, 2017, the examiner rejected then-pending claims 1-7, 9, and 10 under 35 U.S.C. §102(b) as anticipated by U.S. Pat. Appl. Pub. No. 2006/0228668 (Ex. 1010, "the related McSpadden reference")[4] and then-pending claim 8 as rendered obvious by the related McSpadden reference. Ex. 1002, pp. 245-249. The examiner referenced portions of the related McSpadden reference that correspond to Figures 3A, 3C, 3D, and 4A-4I and Paragraph 58 of McSpadden, Ex. 1002, pp. 245-247, 249, but did not cite or refer to several key disclosures that correspond to those of McSpadden upon which Petitioner relies in this Petition, *e.g.*, Ex. 1004, ¶¶36, 49, 51-53, 59, and 60, which are discussed in detail below. *See infra* Sections VII.B. and VII.C. (Grounds 1-3).

In an April 26, 2017 response, the applicants argued that "McSpadden does not disclose or suggest that an active part terminates by a point and is defined by an envelope of a cylindrical or conical shape along its entire length" and that

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[4] The related McSpadden reference is a continuation-in-part of, and in substantial part includes the disclosures of, McSpadden. *Compare* Ex. 1004 *with* Ex. 1010.

"McSpadden does not disclose or suggest a tapered rod having a single continuous taper function." Ex. 1002, pp. 315-316. Thereafter, the claims were allowed.

In advancing these arguments, the applicants misunderstood and/or misrepresented the teachings of the related McSpadden reference. Notably, the applicants discussed and attempted to distinguish only the embodiment depicted in Figures 2A and 2C of the related McSpadden reference, while ignoring the remainder of the reference, including Figures 3A and 3C (which correspond to Figures 3A and 3C of McSpadden) and the descriptions of the embodiment depicted therein. With respect to that embodiment, as discussed in detail below, McSpadden clearly discloses "a tapered rod defined by a single continuous taper function," as well as an "active part terminating by a point and being defined by an envelope of a cylindrical or conical shape along its entire length." *See infra* Sections VI.A. and VII.B.1.

For at least the foregoing reasons, none of the grounds in this Petition raises "substantially the same" arguments previously considered by the PTO. The unpatentability arguments presented in this Petition are based on disclosures in the identified references that have never been addressed by the PTO, and are accompanied by new evidence, including the declaration of Gary Garman, that confirms the unpatentability of the challenged claims. Accordingly, the Board should decline to exercise its discretion under 35 U.S.C. §325(d), and should institute review on all grounds presented. *See, e.g., Limelight Networks, Inc. v. Akamai Techs., Inc*., Case IPR2016-01711, slip op. at 21-22 (PTAB Mar. 6, 2017) (Paper 10); *Acclarent, Inc. v. Ford Albritton, IV*, Case IPR2017-00498, slip op. at 5-6 (PTAB July 10, 2017) (Paper 12); *Google, Inc. v. Blackberry Ltd*., Case IPR2017-00914, slip op. at 21 (PTAB Sept. 11, 2017) (Paper 7); *Edwards Lifesciences Corp. v. Boston Scientific Scimed, Inc*., Case IPR2017-01295, slip op. at 27 (PTAB Oct. 25, 2017) (Paper 9).

V. LEVEL OF ORDINARY SKILL IN THE ART

The art to which the '696 patent relates is the field of endodontic instruments. Ex. 1001, 1:7-8, 2:15-16. A person of ordinary skill in the art as of January 2013 (a "POSITA") would have had at least a Bachelor's degree in mechanical engineering or a related field, and at least two years of work experience in the design and/or operation of endodontic instruments so as to understand the characteristics of the same. Ex. 1003, ¶¶65-66.

VI. CLAIM CONSTRUCTION (37 C.F.R. §42.104(B)(3))

A claim subject to IPR is to be given its broadest reasonable construction in light of the specification. 37 C.F.R. §42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131 (2016). Petitioner submits, for the purposes of this proceeding only, the following claim constructions.[5]

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[5] Petitioner may seek additional and/or alternate claim constructions in district

A. "a tapered rod defined by a single continuous taper function"

Claim 1 recites that the claimed instrument has "a tapered rod defined by a single continuous taper function." To a POSITA, "taper" generally means the change of the diameter of an instrument per unit length of the file. Ex. 1003, ¶49. A typical endodontic instrument has, across the length of its tapered portion, a gradual decrease in the diameter of the instrument, *i.e.*, a continuous taper. Ex. 1003, ¶50.This gives such an instrument a uniform, conical shape from a profile view. *Id.*

The '696 patent specification does not discuss the concept of "a single continuous taper function." In fact, this phrase is not even mentioned in the specification. As noted above, *see supra* Section IV.B., during prosecution of the '677 application, the examiner rejected then-pending claims 1-7, 9, and 10 under 35 U.S.C. §102(b) as anticipated by the related McSpadden reference, Ex. 1002, pp. 245-247, and rejected then-pending claim 8 as rendered obvious by the related McSpadden reference, Ex. 1002, 249. In response, the applicant added the words "defined by a single continuous taper function" to claim 1 in an attempt to distinguish it from the embodiment depicted in Figures 2A and 2C of the related

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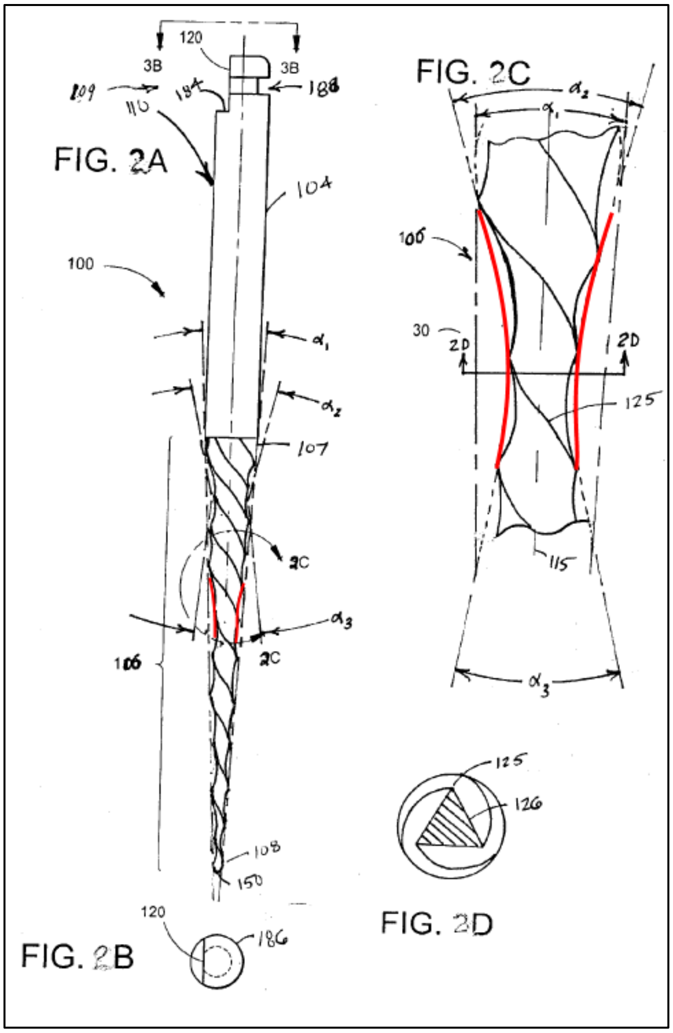
court. Further, Petitioner does not concede that the challenged claims are definite, but only that the scope of the claims, as asserted by Patent Owner, extends at least to the prior art as described herein.

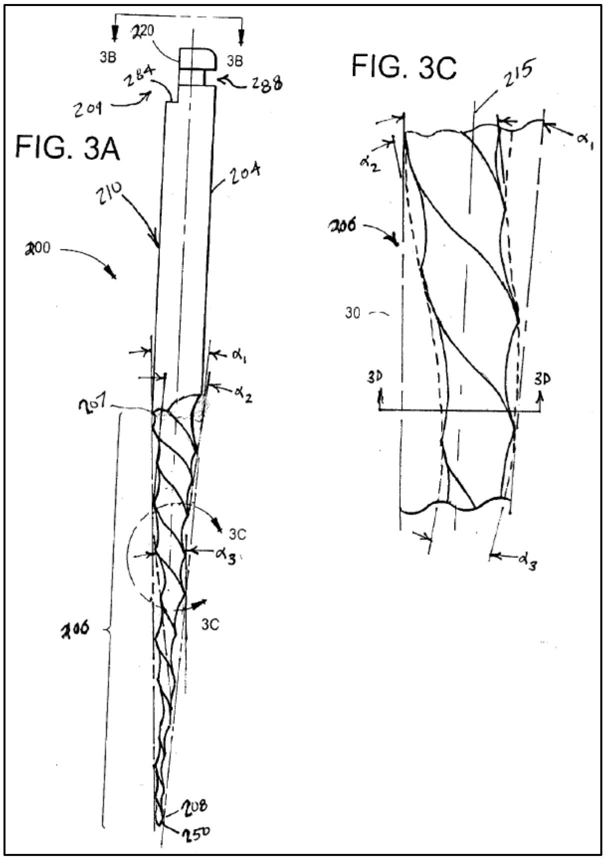
McSpadden reference. In that embodiment, the diameter of the instrument gets smaller, but the contours of the instrument are defined by an undulating shape that bulges inward and outward. Ex. 1010, Figs. 2A-2B; Ex. 1003, ¶¶51-52.

The related McSpadden reference explains that in such embodiment the envelope is defined by a "a second taper function—different from the first—that preferably varies from a positive taper angle (α_2) to negative taper angle (α_3)." Ex. 1010, ¶34; Ex. 1003, ¶53. This results in an instrument that has a diameter that "alternatingly expands and contracts from the proximal end 107 to the distal end 108 within an envelope defined by the first and second taper functions while remaining essentially concentric with the central axis 115 of the instruments 00." Ex. 1010, ¶40; Ex. 1003, ¶53. As shown in Figures 2A and 2C of the related McSpadden reference (reproduced below with annotations in red), the instrument's diameter alternatingly contracts and expands towards the tip end.



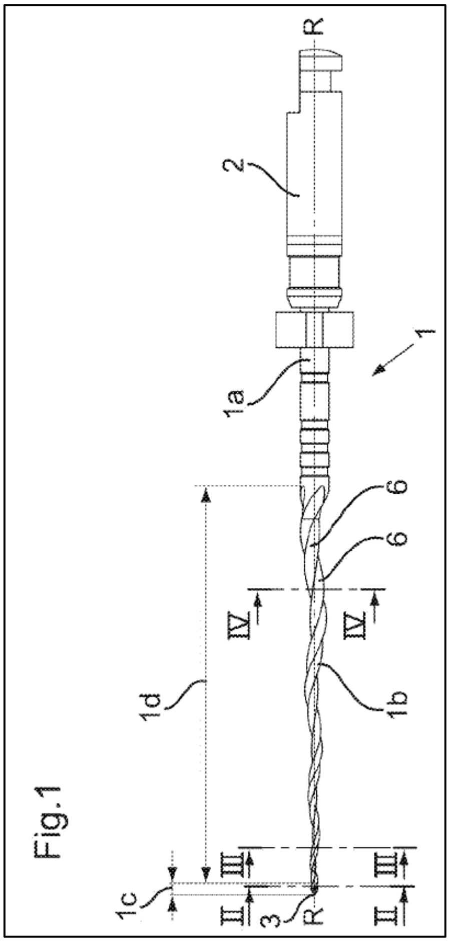
Ex. 1003, ¶53. The taper of this embodiment is therefore not defined by a single function that tapers continuously, as the taper is disrupted by portions of the instrument that bulge outward. *Id.*

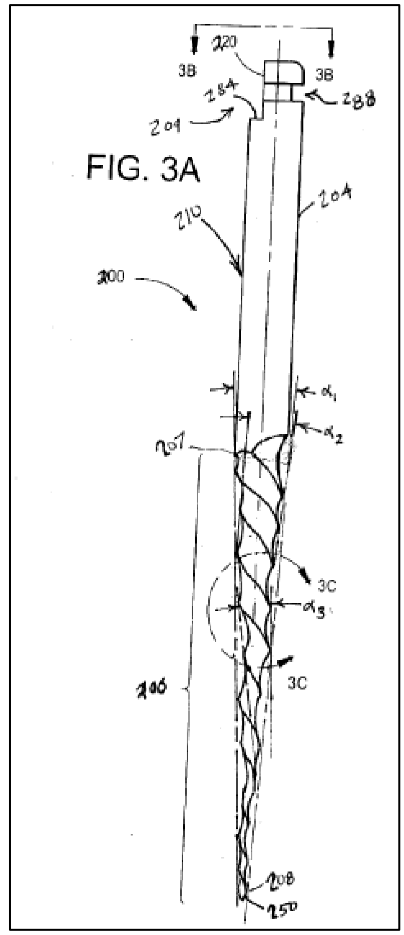
In contrast, the embodiment depicted in Figures 3A and 3C of the related McSpadden reference, has a diameter that tapers substantially continuously from one end of the working portion toward the tip end:



Ex. 1003, ¶¶54-56. Therefore, Figures 3A and C depict a "tapered rod defined by a single continuous taper function," notwithstanding that the related McSpadden reference describes this embodiment as having a second taper function (which defines its "cork-screw-like shape"). Ex. 1010, ¶¶48-54, 56; Ex. 1003, ¶¶54-56.

"A tapered rod defined by a single continuous taper function" would not, to a POSITA, mean simply that the entire shape of the instrument is defined by only a single taper function. Ex. 1003, ¶¶57-58. An endodontic instrument defined entirely by a single taper function would be flat and simply narrow to a point, similar to a nail or toothpick. Ex. 1003, ¶57. However, the embodiments described in the '696 patent have a decreasing taper, a polygonal cross-sectional shape and, just like in Figures 3A and 3C of the related McSpadden reference, a corkscrew shape that winds in a sinusoidal manner across the length of the active part of the instrument. *Id.* at ¶59.





Ex. 1001, Fig. 1.

Ex. 1010, Ex. 3A.

Accordingly, the term "a tapered rod defined by a single continuous taper function" should be construed as "a rod having a diameter that gets gradually smaller toward one end." Ex. 1003, ¶60.

B. "a polygonal cross-section"

Claim 1 further recites that the tapered rod has "over at least an active part of its length a polygonal cross-section forming at least two cutting edges." The specification states: "The embodiments presented above describe polygonal cross-section with straight sides. It is clear that said sides could be curved. Consequently, the term 'polygonal' should be understood in its general sense meaning 'which has a plurality of sides' and covering equally a geometric shape with straight or curved sides." Ex. 1001, 6:65-7:3; Ex. 1003, ¶61. Thus, "a polygonal cross-section" should be construed as "a cross-section having a geometric shape with a plurality of straight or curved sides." *Id*.

VII. DETAILED EXPLANATION OF UNPATENTABILITY GROUNDS

The challenged claims are unpatentable in view of the prior art for the reasons discussed below.

A. Overview of the Prior Art

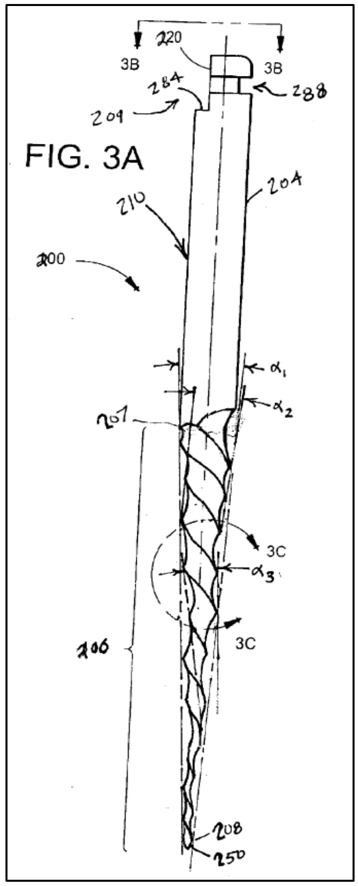
1. McSpadden

McSpadden attempts to solve the same problems identified in the '696 patent and the other prior art references discussed herein. Ex. 1004, ¶33, 60, 61; Ex. 1003, ¶69. Endodontic files having twisting or helically spiraling cutting edges often bind with, or burrow into, the root canal, potentially causing the file to inadvertently drive deep into the root canal, to puncture the apical seal of the canal, and to otherwise transport through the canal wall. Ex. 1004, ¶¶8, 10, 11, 13, 33, 44, 61; Ex. 1003, ¶70. McSpadden and the '696 patent are both concerned with increasing the flexibility of the instrument, without sacrificing overall strength. Ex. 1004,

¶¶44, 60; Ex. 1003, ¶¶71-72. McSpadden additionally identifies the problem of heavy torque loading caused by inefficient cutting or high surface area engagement of the file with the inner canal wall, leading to "catastrophic failure." Ex. 1004, ¶8, 10, 44, 60; Ex. 1003, ¶72.

McSpadden discloses an endodontic instrument formed from a shaft having a generally twisted or fluted prismatic shape defined by three or more side surfaces and three or more interposed corners. Ex. 1004, ¶11; Ex. 1003, ¶73. The shaft includes a working portion having one or more helical cutting edges, the working portion tapered along its length in accordance with a first predetermined taper function and further tapered in accordance with a second taper function. Ex. 1004, ¶11; Ex. 1003, ¶73.

In one embodiment, depicted in Figures 3A through 3D, the corners of the shaft assume a helical or spiraling shape. Ex. 1004, ¶13; Ex. 1003, ¶74.



Ex. 1004, Fig. 3A.

McSpadden explains that the second taper function modulates the center axis of the cross-sectional polygon (*e.g.*, triangular or square) relative to the central axis of the instrument such that the cross-sectional polygon winds "cork-screw-like" from the proximal end to the distal end within an envelope defined by the first and second taper functions. Ex. 1004, ¶¶52, 59, 61; Ex. 1003, ¶74; *see also* Ex. 1003, ¶63.

McSpadden further explains that "[t]hose skilled in the art will readily appreciate that a wide variety of alternative taper functions and cross-sections having various constant or non-constant phase angles, wave lengths and frequencies may be used and combined together to produce any variety of desired performance characteristics." Ex. 1004, ¶64; Ex. 1003, ¶75. McSpadden also teaches that "[t]he tip 150 of the instrument 100 may assume any number of a variety of possible configurations (e.g., chisel, cone, bullet, multifaceted and/or the like), depending upon the preference of the endodontist and manufacturing conveniences." Ex. 1004, ¶42; Ex. 1003, ¶76.

2. Scianamblo

Scianamblo's goal, similar to that of the '696 patent and the other prior art references discussed herein, is to create instruments that "can provide more efficient endodontic cleaning which is safer for a patient. An instrument that is both flexible and strong resists breaking and injuring the patient." Ex. 1006, ¶27; Ex. 1003, ¶77; *see also* Ex. 1006, ¶58.

Scianamblo broadly describes endodontic instruments for treatment of root canals, which are known as endodontic cavity spaces, or ECS. Ex. 1006, ¶112; Ex. 1003, ¶78. Scianamblo describes a number of variations on the shape and geometry of endodontic instruments that, according to Scianamblo, "swagger," *i.e.*, move in a wave-like manner, when used in an endodontic cavity. Ex. 1006, ¶¶109-112, 199; Ex. 1003, ¶¶78-82. Scianamblo describes the behavior of these files: "[W]hen the center of mass of the system corresponds to the axis [of] rotation, the system is in equilibrium and the instrument turns evenly around the axis. When the center of mass or the centroid [of] the system is at a distance from the center of rotation, similar to an endodontic instrument of singly symmetric cross section, the system is out of equilibrium and will tend to swagger." Ex. 1006, ¶125; Ex. 1003, ¶80.

Figure 31A depicts the endodontic instrument described in Scianamblo "at two different locations at two different points in time while the instrument rotates." Ex. 1006, ¶235; Ex. 1003, ¶¶83-84.

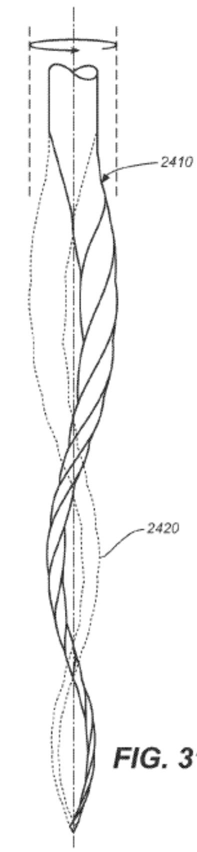


FIG. 31A

Ex. 1006, Fig. 31A. The rotating instrument presents "a mechanical wave 2420, or multiples of a half of a mechanical wave" pattern when the instrument is rotated that "may appear to form helical waves that propagate up and down within the canal." Ex. 1006, ¶235; Ex. 1003, ¶84. These waves propagate in three dimensions in the ECS. Ex. 1006, ¶235; Ex. 1003, ¶84. "As the wave propagates, different portions of the instrument extend from the axis of rotation varying amounts (not shown) and may appear as a spiraling body to a human viewer when the instrument is rotating very fast." Ex. 1006, ¶235; Ex. 1003, ¶84.

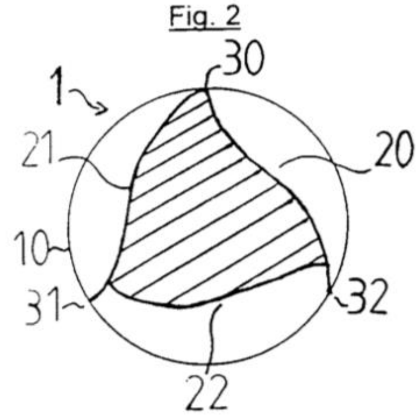
Scianamblo's endodontic instruments can be formed with a cutting tip. Ex. 1006, Figs. 22A-22D; ¶49; Ex. 1003, ¶85. Figure 27 depicts a file with an offset center of mass. Ex. 1003, ¶85. Scianamblo teaches that the offset center of mass and cutting tip features can be combined. Ex. 1006, ¶233; Ex. 1003, ¶85. Moreover, Scianamblo explains that the instrument shown in Figure 27 can display "a change in cross section geometry" such that the cross sections of the portion of the instrument for cutting the curved portion of the ECS "are asymmetrical while the cross sections of the tip and end portions are symmetrical." Ex. 1006, ¶234; Ex. 1003, ¶85.

3. Badoz

Badoz attempts to solve the same problem as the '696 patent and the other prior art references discussed herein where "the forces applied during the preparation of the canal are no longer balanced and the trajectory of the instrument may deviate with respect to the axis of the root canal," which can have "very serious consequences, since it can lead to the creation of a directional mishap or even a perforation of the canal." Ex. 1008, 1:15-19; Ex. 1003, ¶86. Badoz describes an endodontic instrument that alleviates these concerns by "intentionally breaking the circular symmetry of the instrument, so that the tip of the instrument is able to search for the root canal and penetrate it naturally, since the bending resistance of the blade is no longer the same in all directions." Ex. 1008, 1:21-24; Ex. 1003, ¶87.

A cross-section of an instrument described in Badoz is shown in Figure 2, reproduced below. Ex. 1008; Ex. 1003, ¶88.

Fig. 2



The instrument is "of the root-canal reamer type, comprising a working section (10) including three flutes (20, 21, 22) forming three cutting lips (30, 31, 32). It is characterized by the fact that the three cutting lips (30, 31, 32) are located at the apices of an isosceles triangle." Ex. 1008, 2:12-15; Ex. 1003, ¶89. The instrument in Badoz "possesses a working section (10), also known as a 'blade', whose active part is obtained by grinding and has a conical shape also obtained by grinding. The conical shape is obtained most frequently by gradually moving the grinding wheel away from the axis of the instrument as one moves away from the tip of the instrument." Ex. 1008, 2:16-20; Ex. 1003, ¶90.

4. Taylor

Similar to the '696 patent, and the other prior art references discussed herein, Taylor describes the problem of conventional endodontic instruments "hav[ing] a tendency to straighten out the canal or to proceed straight into the root canal wall," thereby "sometimes transporting completely through the canal wall." Ex. 1009, 1:48-51; Ex. 1003, ¶92; *see also* Ex. 1009, 2:20-27. Also similar to several of the prior references discussed above, Taylor describes the concern of conventional endodontic instruments being "able to withstand the torsional load necessary to penetrate and enlarge the canal opening without breaking the instrument." Ex. 1009, 1:53-56; Ex. 1003, ¶93; *see also* Ex. 1009, 2:5-19.

Referring to another patent, which names McSpadden as the inventor, Ex. 1011, Taylor discloses that one prior attempt to solve the transportation problem was to provide an instrument having "a smooth-walled, non-cutting pilot tip for guiding the file or reamer into the curved root canal," but that while this was "a significant improvement in the art at the time, the design has several significant drawbacks." Ex. 1009, 2:27-34; Ex. 1003, ¶94. One drawback with that design, Taylor explains, "is that the pilot tip, being blunt and smooth, has little or no cutting ability," making it difficult, in highly calcified root canals, "to penetrate through the calcified material to a depth sufficient to allow cutting to begin." Ex. 1009, 2:36-43; Ex. 1003, ¶95. A file with a blunt tip must grind its way into the calcified material, which "generates significant heat and friction," which, in turn, "can cause pain and heating of the tooth," as well as "increase the risk of breakage [of the instrument] in the canal." Ex. 1009, 2:43-51; Ex. 1003, ¶95.

Taylor attempts to solve these and other problems by providing an instrument with a tip having improved cutting ability based on the discovery that some cutting ability on the tip can increase the overall cutting efficiency of the instrument without significantly increasing the likelihood of canal wall transportation and instrument breakage . Ex. 1009, 5:36-50; Ex. 1003, ¶96.

5. Garman

Garman is a U.S. patent naming Petitioner's expert as the sole inventor. Ex. 1003, ¶97. Similar to the '696 patent and the other prior art references discussed herein, Garman's goal is to provide instruments that have "optimize[d] flexibility, strength and other operating characteristics of the instrument." Ex. 1005, 2:5-7; Ex. 1003, ¶98; *see also* Ex. 1005, 2:7-16, 2:36-38, 2:51-54, 4:52-55.

Garman describes that conventional endodontic instruments have helical cutting edges formed by grinding or twisting a ground blank (also referred to as a "wire"). Ex. 1005, 1:30-50; Ex. 1003, ¶99. Garman teaches that conventional files have a major diameter or cross-sectional dimension and a tapered minor diameter or cross-sectional dimension along their working portion. Ex. 1005, 1:30-52. In such instruments, the tapers of these two dimensions are generally the same, with the minor diameter being purely a function of the major diameter. *Id*.; Ex. 1003, ¶100. With instruments that have a greater taper along the working portion, certain undesirable consequences of this type of design become significant. Ex. 1005, 1:52-55; Ex. 1003, ¶100. Specifically, "these instruments become much stiffer toward the proximal end or handle of the instrument. This can cause the instrument to be difficult to maneuver within curved root canals because the instrument may not flex enough to conform to the shape of the canal." Ex. 1005, 1:55-59; Ex. 1003, ¶100.

Garman describes an endodontic instrument comprising an "elongate member" with a "longitudinal axis," "a proximal end, a distal end, and a working length generally between the proximal and distal ends." Ex. 1005, 2:13-20; Ex. 1003, ¶101. The working length is formed with an outer surface comprising a plurality of twisted or curved surface portions defining at least one cutting edge. Ex. 1005, 2:20-23; Ex. 1003, ¶101. The working length is physically twisted to form helical cutting edges extending around the longitudinal axis. Ex. 1005, 2:28-30; Ex. 1003, ¶101. Notably, the size of one diameter or cross-sectional dimension is formed independently of another, in order to optimize flexibility, strength, and other operating characteristics of the instrument. Ex. 1005, 2:1-7; Ex. 1003, ¶101. Since the taper of one diameter may be different than the taper of the other, Ex. 1005, 2:46-57, 4:41-63, the geometry of the cross-sections across the length of the working portion will change, Ex. 1005, 6:43-51, 7:5-16. Ex. 1003, ¶101. In this manner, instruments of greater taper may be formed with greater flexibility for maneuvering within curved root canals, while retaining sufficient strength to resist breakage during use. Ex. 1005, 2:7-10; Ex. 1003, ¶101.

This is depicted in, for example, Figure 2 of Garman, where "a minor diameter or cross-sectional dimension 'd' and a major diameter or cross-sectional dimension 'D' are evident along the working length 22. Minor diameter 'd' preferably remains substantially constant along working length 22, while major diameter 'D' becomes progressively larger in a direction extending from distal end 40 to proximal end 42 of working length 22. Due to the substantially constant minor diameter 'd' extending along the working length 22, the flexibility of working length 22 is maintained generally constant along working length 22." Ex. 1005, 4:45-55; Ex. 1003, ¶102.

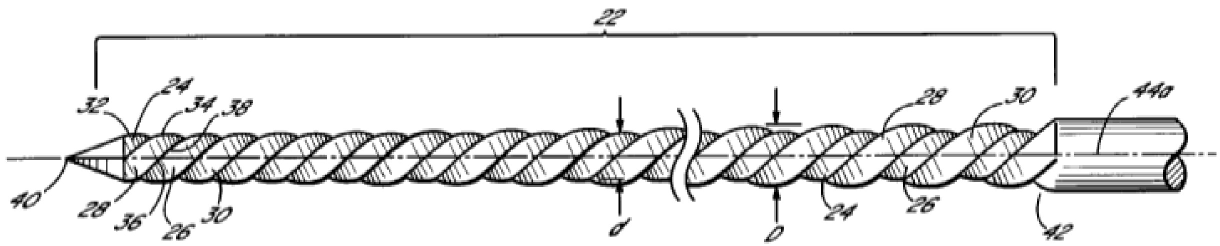
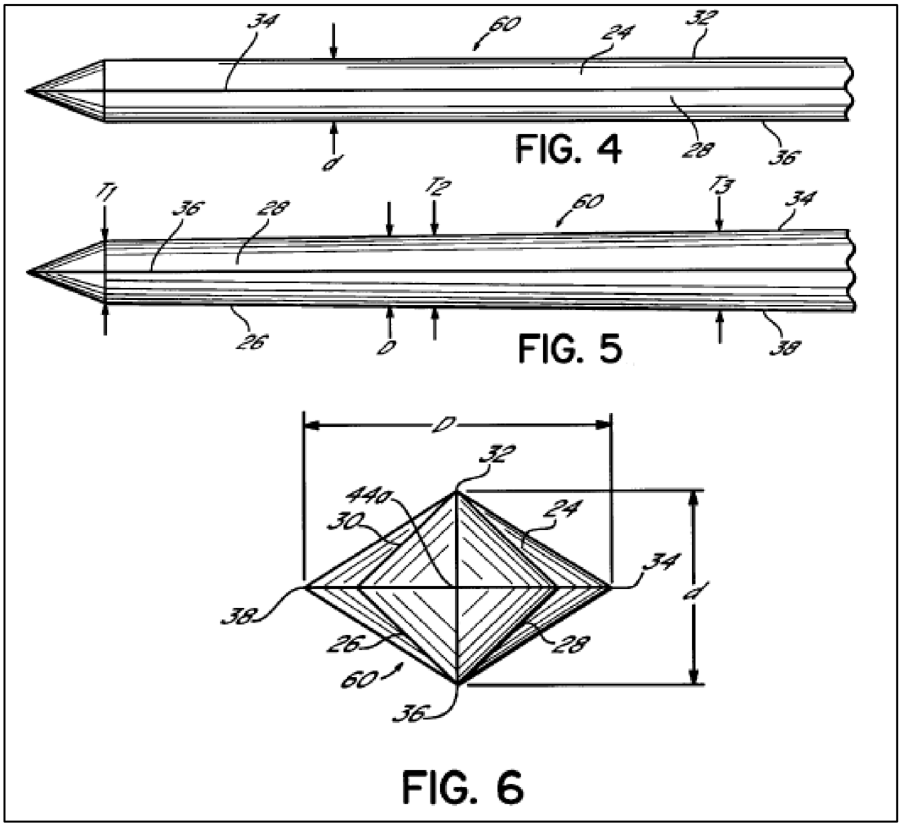


FIG. 2

Figures 4-6 show, reproduced below, that a "ground blank 60 will have a minor diameter 'd', as shown in FIG. 4, which may be substantially constant or slightly tapered along working length 22. A major diameter 'D', as shown in FIG. 5, tapers more significantly as shown by dimensions T1, T2, T3 . . . . The cross section of ground blank 60, in this embodiment, transforms from a relatively square cross section proximate distal end 40 to a rhomboid cross section at proximal end 42. As further evidenced in FIG. 6 edges 34, 38 will be sharper at proximal end 42 than at distal end 40. Distal end 40 may be of rhomboid cross section, however, "the rhomboidal shape at distal end 40 will not be as exaggerated as at proximal end 42." Ex. 1005, Fig. 6; 5:44-59; Ex. 1003, ¶103.



Ex. 1005, Figs. 4-6.

B. Ground 1: Claims 1, 2, 5, and 8 are Anticipated by McSpadden; Ground 2: Claims 1, 2, 5, 8, and 10 are Obvious Over McSpadden

Claims 1, 2, 5, and 8 are anticipated by McSpadden. Alternatively, to the extent the Board determines that McSpadden does not disclose one or more of the limitations of these claims, they are obvious over McSpadden. Further, claim 10 is obvious over McSpadden.

1. Independent claim 1

a. "An instrument for drilling dental root canals comprising"

To the extent the Board determines that the preamble of claim 1 is limiting, McSpadden explains that "[t]he present invention relates generally to the field of dentistry and more particularly to an endodontic instrument" that "is highly efficacious in cleaning and expanding root canal openings." Ex. 1004, ¶¶3, 42-44; Ex. 1003, ¶107; *see also* Ex. 1004, ¶29.

b. [1.a] "a tapered rod defined by a single continuous taper function and having over at least an active part of its length a polygonal cross-section forming at least two cutting edges, said active part terminating by a point and being defined by an envelope of a cylindrical or conical shape along its entire length, the longitudinal axis of the envelope coinciding with the axis of rotation of the instrument"

Figures 3A and 3C of McSpadden depict an instrument having "a tapered rod defined by a single continuous taper function." Ex. 1003, ¶109. McSpadden explains, "In the particular embodiment shown, the first taper function is an elongated cone having a substantially uniform angle of conicity α_1—that is, the rate of taper or cone angle is substantially constant along the working portion 206. A preferred first taper function ranges from a constant taper rate about 0.01 mm/mm to about 0.08 mm/mm." Ex. 1004, ¶51; Ex. 1003, ¶110. The diameter of the rod of the instrument gets gradually smaller from the rear toward the tip end. Ex. 1003, ¶110. This satisfies the "single continuous taper function" limitation. Ex. 1003, ¶¶109-11; *see also supra* Section VI.A.

McSpadden discloses the rod of the instrument "having over at least an active part of its length a polygonal cross-section forming at least two cutting edges." Ex. 1003, ¶112. Figure 3D of McSpadden, which is a cross-sectional view of the working portion of the instrument depicted in Figures 3A through 3C, shows a triangle with three cutting edges. Ex. 1003, ¶112.

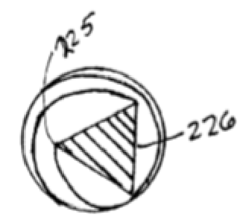


FIG. 3D

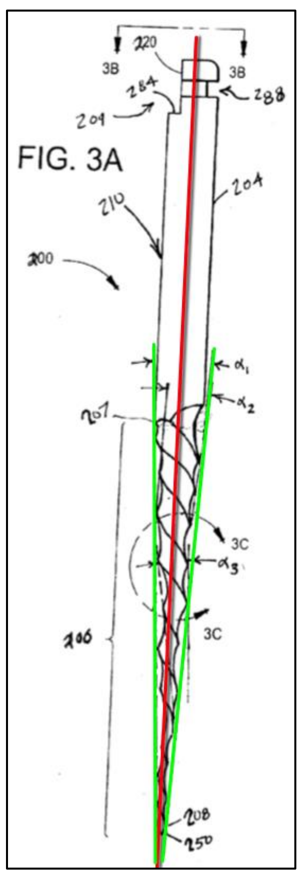
McSpadden teaches that, while a "triangular cross-section is particularly preferred," "those skilled in the art will readily appreciate that a wide variety of other [polygonal] shapes may also be used with efficacy." Ex. 1004, ¶47; Ex. 1003, ¶113. Figures 4A through 4I depict polygonal cross-sections, with multiple cutting edges, of "additional alternative embodiments of a multi-tapered endodontic instrument having features and advantages of the present invention." Ex. 1004, ¶26; Ex. 1003, ¶113.

A POSITA would understand McSpadden's disclosures to teach that the polygonal cross-section extends over the entire working portion, *i.e.*, to the tip portion. Ex. 1003, ¶114. McSpadden further teaches that that cross-section "wind[s] cork-screw-like from the proximal end 207 to the distal end 208." Ex. 1004, ¶59; Ex. 1003, ¶114. Thus, the entire length of the working portion of

McSpadden's instrument may have a "cork-screw-like" shape and cutting edges, which extends to the tip portion. Ex. 1003, ¶114.

Further, McSpadden teaches that "[t]he tip 250 of the instrument 200 may assume any number of a variety of possible configurations," "depending upon the preference of the endodontist and manufacturing conveniences." Ex. 1004, ¶58; Ex. 1003, ¶115. Regarding "the preference of the endodontist," a POSITA would have understood that some endodontists prefer a cutting tip. Ex. 1003, ¶115. Regarding "manufacturing conveniences," a POSITA would have understood that it would likely be just as, if not more, convenient to manufacture an instrument that has a polygonal cross-section forming at least two cutting edges extending the entire length of the active part, *i.e.*, to the point, than to manufacture an instrument that does not have cutting edges extending to the point. Ex. 1003, ¶115. Figure 3A of McSpadden depicts explicitly such configuration. *Id*. Relatedly, McSpadden discloses that the tip may assume, for example, a chisel configuration. Ex. 1004, ¶58; Ex. 1003, ¶115. A chisel tip, as the label implies, cuts and removes material from the root canal. Ex. 1003, ¶115.

McSpadden's instrument has an "active part terminating by a point and being defined by an envelope of a cylindrical or conical shape along its entire length." Ex. 1003, ¶116. McSpadden states, "[t]he working portion 206 extends from a proximal end 207 adjacent the base of the shank 204 to a distal end 208 terminating in a tip 250," Ex. 1004, ¶49, Ex. 1003, ¶116, and that "[t]he outer envelope of the working portion 206 is preferably shaped in accordance with a first taper function from the proximal [end] 207 to the distal end 208, as shown," Ex. 1004, ¶51, Ex. 1003, ¶116. McSpadden further discloses that "the first taper function is an elongated cone having a substantially uniform angle of conicity α_1—that is, the rate of taper or cone angle is substantially constant along the working portion 206." Ex. 1004, ¶51, Ex. 1003, ¶116. Additionally, as seen in Figure 3A of McSpadden reproduced below, the longitudinal axis of the envelope (envelope annotated in green) coincides with the axis of rotation of the instrument (axis of rotation annotated in red).



Ex. 1003, ¶117.

c. [1.b] "wherein for any cross-section of the active part, at least one of the at least two cutting edges is located on the envelope, said active part has a first portion extending from the point and a second portion extending following the first portion towards the rear of the active part"

In the cross-section of the working portion depicted in Figure 3D of McSpadden reproduced below, one of the cutting edges is on the envelope (identified by an annotated red arrow):

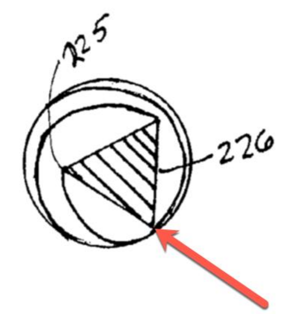
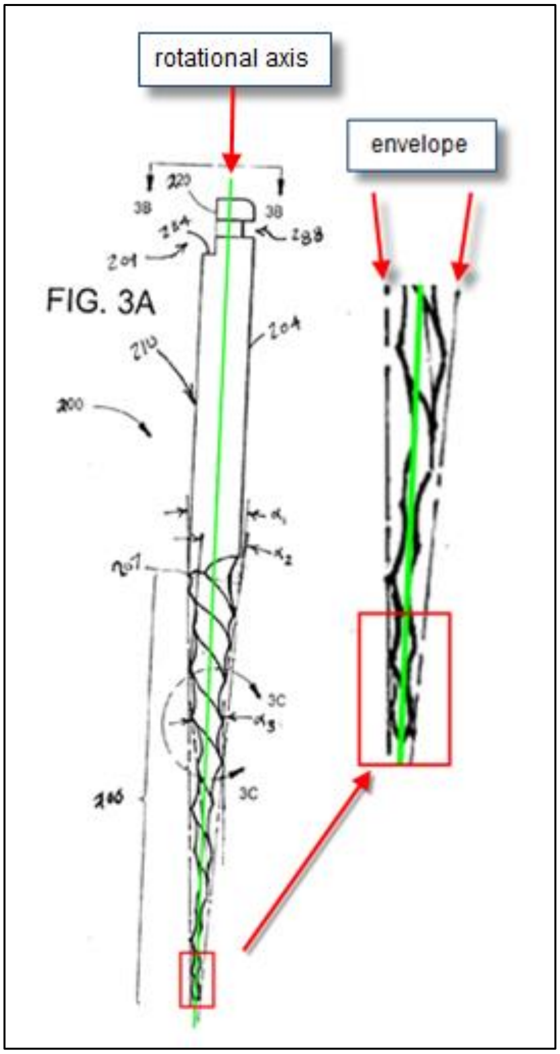


FIG. 3D

Ex. 1003, ¶119. As the cross-sectional polygon winds cork-screw-like across the working portion of the instrument, from the rear of the working portion (closer to the handle of the instrument) towards the point of the instrument depicted in Figure 3A, that cutting edge revolves around the longitudinal axis of the envelope, all the while remaining on the envelope. Ex. 1003, ¶¶120-121. McSpadden's endodontic instrument has a tip portion, which is the "first portion" of the active part that extends from the point, *i.e.*, the tip. Ex. 1004, ¶49, Fig. 3A; Ex. 1003, ¶122. The remainder of the working portion of McSpadden's instrument is the "second portion" of the active part. Ex. 1003, ¶122. Further details of these two portions of the active part of McSpadden's instrument are described below with respect to the remaining claim limitations.

d. [1.c] "any cross-section of the first portion has a center of mass located on the axis of rotation, said at least two cutting edges defined by said cross-section of the first portion being located on the envelope"

As shown in Figure 3A reproduced below (with annotations), McSpadden discloses that the tip, *i.e.*, the first portion of the active part, is located on the axis of rotation.



Ex. 1003, ¶124 (tip portion encompassed in the annotated red rectangle). A POSITA would have understood that it is desirable to locate the center of mass of any cross-section of the tip on the axis of rotation, in order for the tip to be able to effectively guide the instrument into the canal and to avoid the tip "screwing-in" to the canal wall, a common problem identified by McSpadden. Ex. 1004, ¶8; Ex. 1003, ¶125.

As discussed above, *see supra* Section VII.B.1.b., a POSITA would understand McSpadden's disclosures, Ex. 1004, ¶¶52, 53, 59, to teach that the cross-sectional polygon defining the cutting edges may extend to the tip portion of the instrument, and that such a design may be in accord with the preference of the endodontist and manufacturing conveniences. Ex. 1003, ¶126. For a cross-section having a symmetrical shape, such as the equilateral triangle depicted in Figure 3D of McSpadden, and a center of mass located on the axis of rotation, at least two of the cutting edges would be located on the envelope. Ex. 1003, ¶127.

e. [1.d] "at least one cross-section of the second portion has a center of mass offset with respect to the axis of rotation, at least one cutting edge defined by said cross-section of the second portion being located set back within the envelope"

As discussed above, *see supra* Section VII.B.1.c., the second portion of the active part of McSpadden's instrument follows the tip portion. Ex. 1003, ¶129. As the cross-sectional polygon winds cork-screw-like across the working portion of the instrument depicted in Figure 3A, one of the cutting edges remains on the envelope. *Id.* at ¶130. Similarly, as the cross-sectional polygon winds, the center of mass of the cross-section of the second portion remains offset with respect to the axis of rotation, and two of the cutting edges of the triangular cross-section remain set back within the envelope as depicted in Figure 3D. *Id*. at ¶¶130-131.

As the foregoing demonstrates, McSpadden anticipates and/or renders obvious claim 1 of the '696 patent.

2. Dependent claim 2

Claim 2 requires that for the instrument of claim 1, "any of the cross-sections of the second portion has a center of mass offset with respect to the axis of rotation, and at least one cutting edge defined by said cross-section of the second portion is located set back within the envelope." As discussed above, *see supra* Section VII.B.1.e., as the cross-sectional polygon winds cork-screw-like across the working portion of the instrument depicted in Figure 3A of McSpadden, each cross-section of the second portion has a center of mass offset with respect to the axis of rotation, and two cutting edges defined by each said cross-section of the second portion located set back within the envelope. Ex. 1003, ¶133.

3. Dependent claim 5

Claim 5 requires that for the instrument of claim 2, "one of the cross-sections of the second portion of the active part that is located close to the point has a center of mass proportionally closer to the axis of rotation than the center of mass of one of the cross-sections of said second portion that is located at the rear of the active part." As discussed above, McSpadden's instrument has a conical helix design. Ex. 1003, ¶135. In this design, since the amplitude of the helicoidal path of the cross-sectional centers of mass would be bounded by the conical envelope, the cross-sectional center of mass of the second portion of the active part located closest to the point would necessarily be closer to the axis of rotation than the cross-sectional center of mass of the second portion located at the rear of the active part. Ex. 1003, ¶135. Further, since the envelope would get gradually smaller from the rear to the tip end, the offset of the cross-sectional centers of mass from the axis of rotation would change gradually between those two centers of mass. Ex. 1003, ¶135.

4. Dependent claim 8

Claim 8 requires that for the instrument of claim 1, "the active part has over its entire length a polygonal cross-section with straight sides." As mentioned above, *see supra* Section VII.B.1.b., McSpadden teaches that the cross-sections of the working portion may assume any of a variety of polygonal shapes. McSpadden specifically teaches that such cross-sectional polygonal shapes may have straight sides. Ex. 1003, ¶137. For example, in the instrument depicted in Figures 3A through 3D, discussed above, the cross-section is an equilateral triangle with straight sides. Ex. 1004, Fig. 3D; Ex. 1003, ¶137. McSpadden alternatively depicts a hexagonal cross-section with straight sides in Figure 4B. Ex. 1004, ¶¶26, 48; Ex. 1003, ¶138. McSpadden discloses other embodiments, depicted in Figures 5A and 5B, having a tapered rod with "a generally square cross section" that "remains substantially square" "throughout its length." Ex. 1004, ¶¶62, 63; Ex. 1003, ¶139. In Figure 5C, McSpadden depicts a similar embodiment that instead has a "generally triangular cross section with three flats and preferably three sharp corners." Ex. 1004, ¶64; Ex. 1003, ¶139.

5. Dependent claim 10

Claim 10 requires that for the instrument of claim 1, "the first portion of the active part has a length between 1 and 3 millimeters." McSpadden discloses that the working portion may have "a length ranging from about 3 mm to about 18 mm," and that a "preferred length is about 16 mm." Ex. 1004, ¶36; Ex. 1003, ¶142. For an instrument that has a working portion with a length of approximately 16 millimeters, it would have been not only reasonable, but rather, likely, for a POSITA to select a length of the centered tip portion that is between 1 and 3 millimeters. Ex. 1003, ¶142.

A POSITA would have understood that in order to avoid the screwing-in effect discussed by McSpadden, *see supra* Section VII.B.1.d., the tip portion should be of sufficient length, but at the same time, it need not encompass a significant length of the working portion. Ex. 1003, ¶143. A POSITA would further have understood that it would be desirable to minimize the length of the tip portion as much as possible, without losing the benefit of avoiding the screwing-in effect, because a centered tip portion would not provide the benefits of an offset-center of mass, as in the remainder of the working portion. Ex. 1003, ¶144. It would be well within the capability of a POSITA to optimize the length of the tip portion, *i.e.*, to make it just as long as needed to avoid the screwing-in effect. Ex.

1003, ¶145. A POSITA could have performed basic experimentation and testing, and arrived at an appropriate length of the tip portion based on routine trial and error. *Id*. The appropriate length of the tip portion for an instrument with a working portion that is 16 mm long is likely to be between 1 and 3 millimeters. *Id*; *see also id*. at ¶146.

C. Ground 3: Claim 9 is Obvious Over McSpadden in View of Garman

Claim 9 requires that for the instrument of claim 1, "the first portion of the active part has a square cross-section, and the second portion of the active part has a rectangular cross-section."

As set forth above, Garman discloses endodontic instruments wherein the geometry of the cross-sections across the working length changes in order to optimize flexibility and strength. *See supra* VII.A.5. Garman specifically discloses an endodontic instrument that has a quadrilateral cross-section defined by two diameters—a minor diameter, "d," and a major diameter, "D." Ex. 1005, Fig. 6; Ex. 1003, ¶153. Garman further discloses that that this allows the minor diameter to be maintained substantially constant along the working length, while the major diameter has a taper. Ex. 1005, 2:46-54, 4:43-52, 5:44-49; Ex. 1003, ¶153.

A cross-section of the first portion of the active part of the rod differs from a cross-section of the second portion and, more specifically, the ratio of height and width differs for the two cross-sections. Ex. 1003, ¶153. As shown in the below color annotated reproduction of Garman's Figure 6, this changing ratio may result in the instrument having, for example, a square cross-section at its tip end (annotated in blue) and a rhomboid cross-section at the other end (annotated in orange). Ex. 1005, 5:52-55, Figs. 4-6; Ex. 1003, ¶153.

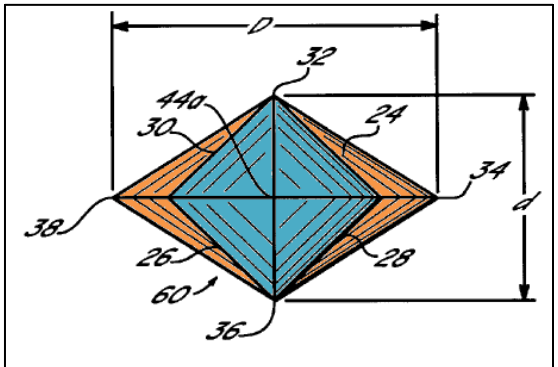


FIG. 6

While Figure 6 of Garman depicts a particular rhomboid cross-sectional shape towards the rear of the active part of the instrument, a POSITA would have readily understood that a rectangle could be employed just as well to obtain the benefits of a changing cross-sectional geometry. Ex. 1003, ¶154. When selecting from the finite number of possibilities for a symmetrical four-sided shape, it would have been a simple design choice to use a rectangular cross-sectional shape towards the rear of the active part of the instrument instead of a rhomboid one. *Id.*

In fact, a POSITA would have been motivated to use a rectangle, knowing that a rectangular cross-section will provide a more durable file than a rhomboid cross-section. Ex. 1003, ¶154. A POSITA would also have recognized it would be no more difficult to manufacture an instrument with a rectangle substituted for the rhomboid depicted in Figure 6 of Garman. *Id.* In some instances, it would be easier to design and develop an instrument with a rectangular cross-section instead of a rhomboid one. *Id.*

McSpadden teaches that its instrument may have a square cross-section. Ex. 1004, ¶¶26, 48, 62, 63, Figs. 4F, 5A, 5B; Ex. 1003, ¶¶148-149. McSpadden also specifically teaches that those skilled in the art would readily appreciate that a wide variety of other shapes, including a rectangle, may be used with efficacy. Ex. 1004, ¶47; Ex. 1003, ¶149. In view of Garman, it would have been obvious to modify McSpadden's instrument to incorporate the features recited in claim 9 of the '696 patent. Ex. 1003, ¶¶147-155.

A POSITA would have had ample reasons to consider the teachings of Garman for manufacturing McSpadden's instrument. Ex. 1003, ¶¶151-152. McSpadden is concerned with increasing the flexibility of the instrument, without sacrificing overall strength, Ex. 1004, ¶¶44, 60, and this goal is the essence of Garman, Ex. 1005, 1:50-59, 2:1-16, 2:36-38, 2:51-54, 4:52-55. Ex. 1003, ¶155. A person of ordinary skill in the art would have been motivated to apply Garman's teachings of the cross-sectional geometry changing over the working length to McSpadden's instrument, which teaches a square or a rectangular cross-section, in order to further increase the instrument's flexibility without sacrificing its strength. *Id.*

A POSITA would have had a reasonable expectation of success in combining the teachings of McSpadden and Garman. *Id.* It would have been straightforward for a POSITA to employ Garman's disclosed grinding process to obtain a tapered rod that changes from a square-cross section to a rectangular cross-section along its length, and to follow that with a twisting step disclosed in McSpadden to give the cutting edges a helical shape and arrive at the invention recited by claim 9 of the '696 patent. *Id.*

D. Ground 4: Claims 1, 2, 5, 8, and 10 are Obvious Over Scianamblo

1. Independent claim 1

a. "An instrument for drilling dental root canals comprising"

To the extent the Board determines that the preamble of claim 1 is limiting, Scianamblo explains that "the present invention provides methods and apparatus for providing swaggering endodontic instruments for preparing an endodontic cavity space." *See, e.g.,* Ex. 1006, ¶17; Ex. 1003, ¶159; *see also* Ex. 1006, ¶¶3, 10, 19, 60, and 97.

b. [1.a] "a tapered rod defined by a single continuous taper function and having over at least an active part of its length a polygonal cross-section forming at least two cutting edges, said active part terminating by a point and being defined by an envelope of a cylindrical or conical shape along its entire length, the longitudinal axis of the envelope coinciding with the axis of rotation of the instrument"

Scianamblo's instruments have a tapered body such that the tip end has a smaller diameter than the shank end, giving the body a cone-like shape. Ex. 1006, ¶¶18, 20, 26, 97; Figs. 11A-D, 21A-C; Ex. 1003, ¶161. Scianamblo further discloses instruments with a working portion, which is the portion of the instrument that has cutting edges, *i.e.*, an active part. Ex. 1006, ¶97; Figs. 21A-C; Ex. 1003, ¶162. The cross-section over the working portion is a polygon (*e.g.*, trapezoidal, rectangular, square, or triangular). Ex. 1006, ¶¶112, 201, 204, 210, 216, 222, 229, 230; Figs. 21D-E, 24D-E; Ex. 1003, ¶162. The working portion may terminate by a point, which is the tip end of the instrument, such that the tip has an active or cutting surface confluent the working surface. Ex. 1006, ¶¶18, 20, 26, 97, 204, Figs. 11A-D, 21A-C; Ex. 1003, ¶163.

Scianamblo further explains that "[i]n cases where an endodontic instrument includes a working portion that runs to the tip of the instrument, the cone like shape is a cone." Ex. 1006, ¶98; Ex. 1003, ¶164. The active part of such an instrument is defined by an envelope of a cylindrical or conical shape along its entire length. Ex. 1003, ¶164. In such an instrument, the diameter of the rod of the instrument gets gradually smaller from the rear toward the tip end. *Id*. at ¶165. Instruments having a single continuous taper function and a conically-shaped active part are depicted in Figures 11A-D and 21A-C. *Id*. at ¶166. In such an instrument, the longitudinal axis of the envelope coincides with the axis of rotation of the instrument, as indicated in this annotated reproduction of Figure 11A:

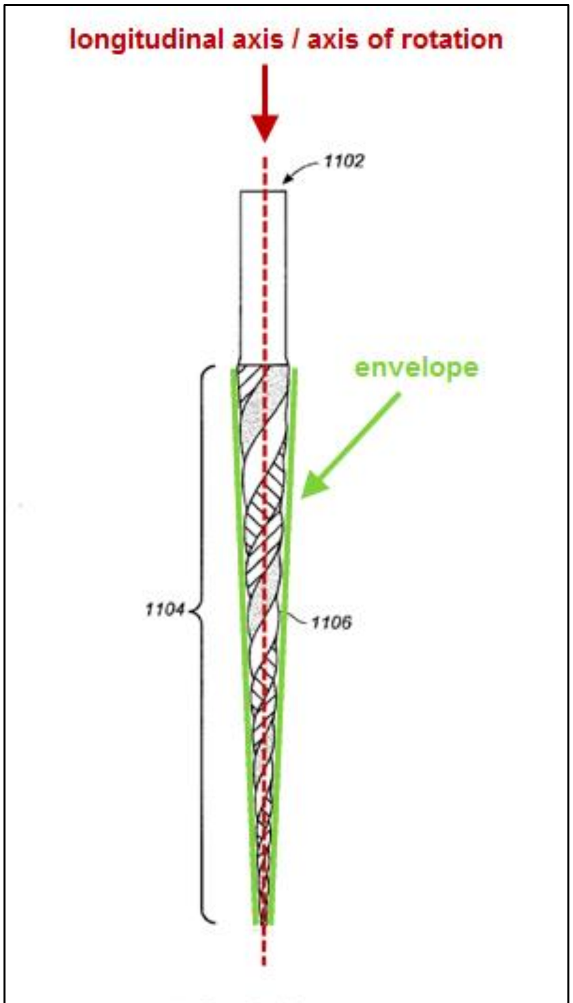


FIG. 11A

Id.

c. [1.b] "wherein for any cross-section of the active part, at least one of the at least two cutting edges is located on the envelope, said active part has a first portion extending from the point and a second portion extending following the first portion towards the rear of the active part"

Scianamblo discloses that along the length of the tapered body, there is at least one cutting surface along the outer diameter that is configured to remove material when the body is rotated within a canal. Ex. 1006, ¶20; Ex. 1003, ¶168.

This teaches the claim requirement that "for any cross-section of the active part, at least one of the at least two cutting edges is located on the envelope." Ex. 1003, ¶168.

Scianamblo's instrument has a tip portion, which is the "first portion" of the active part that extends from the point, *i.e.*, the tip end. Ex. 1006, ¶¶18, 21, 70; Ex. 1003, ¶169. And, the remainder of the working portion of Scianamblo's instrument is the "second portion" of the active part. *Id.* Further details of these two portions of the active part of Scianamblo's instrument are described below with respect to the remaining limitations of claim 1.

d. [1.c] "any cross-section of the first portion has a center of mass located on the axis of rotation, said at least two cutting edges defined by said cross-section of the first portion being located on the envelope"

Scianamblo generally discloses instruments wherein at least one cross-section of the body is located on the axis of rotation and at least one cross-section of the body is offset from the axis of rotation. *See, e.g.*, Ex. 1006, ¶20, claim 18; *see also id.* at ¶¶19, 21, 22, 25, 202. From this disclosure, a POSITA would have understood that the tip portion could have a center of mass located on the instrument's axis of rotation, as is the case for most endodontic instrument designs. Ex. 1003, ¶171.

A POSITA would also have understood that it is desirable to locate the center of mass of any cross-section of the tip on the axis of rotation, in order for the tip to be able to effectively guide the instrument into the canal, as well as to avoid the tip "binding" with the canal wall—an adverse effect that Scianamblo explains is common for instruments having a "screw like configuration." Ex. 1006, ¶58; Ex. 1003, ¶172.

Scianamblo more specifically explains that "the tip can be on the axis of rotation." Ex. 1006, ¶21; Ex. 1003, ¶173; *see also* Ex. 1006, ¶232, claim 28. A POSITA would have understood that being "on the axis of rotation" means that the center of mass of the tip coincides with the axis of rotation. Ex. 1003, ¶173. A number of Scianamblo's figures depict instruments that have a tip centered on the axis of rotation. *Id.* (citing Ex. 1006, Figs. 6A, 6B, 9A, 11A-B, 21A-C, 23A-C, 24A-C, 25A-C, 27, 28, 30A, 31A).

As discussed above, *see supra* Section VII.D.1.b., Scianamblo discloses that the working portion, including its cutting edges, may run to the tip of the instrument. Ex. 1003, ¶174. Scianamblo also discloses that the cross-sections of the tip portion may be symmetrical. Ex. 1006, ¶234; Ex. 1003, ¶174. A POSITA would have understood that for a symmetrical cross-section of the tip portion with a center of mass located on the axis of rotation, at least two of the cutting edges would be located on the envelope. Ex. 1003, ¶175.

e. [1.d] "at least one cross-section of the second portion has a center of mass offset with respect to the axis of rotation, at least one cutting edge defined by said cross-section of the second portion being located set back within the envelope"

As discussed above, the second portion of the active part of Scianamblo's endodontic instrument follows the tip portion. *See supra* Section VII.D.1.c. Scianamblo generally discloses an instrument wherein at least one cross-section of the body is located on the axis of rotation and at least one cross-section is offset from the axis of rotation. Ex. 1006, ¶20, claim 18; Ex. 1003, ¶171; *see also* Ex. 1006, ¶¶19, 21, 22, 25, 202. From this disclosure, a POSITA would have understood that any cross-section of second portion of the active part could have a center of mass offset with respect to the instrument's axis of rotation. Ex. 1003, ¶178.

Scianamblo specifically discloses an instrument with a curved portion, the curve being defined by the centroids of the cross-sections. Ex. 1006, ¶232; Ex. 1003, ¶179. Such an instrument is depicted in Figures 30A (reproduced below with annotations) and 30B of Scianamblo. Ex. 1003, ¶179.

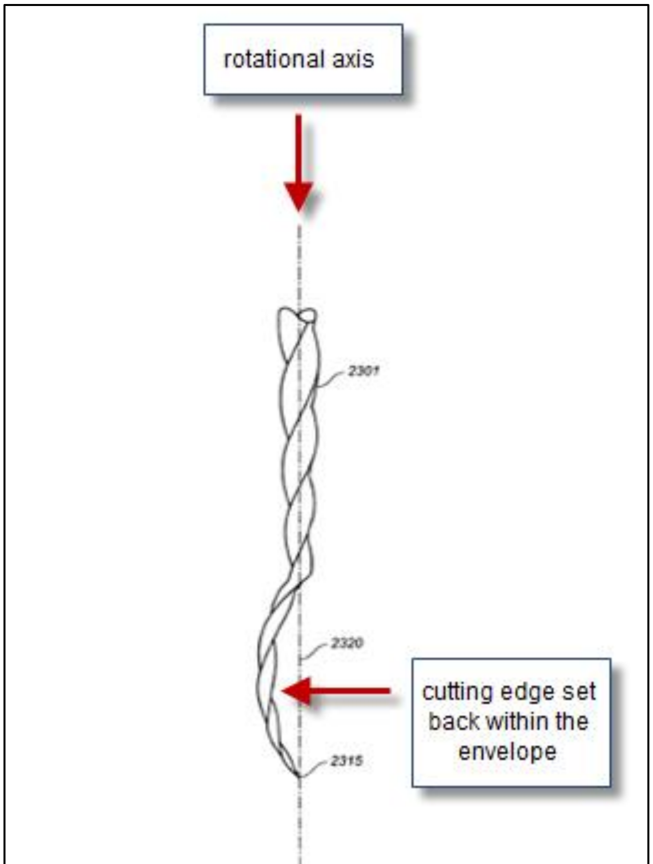


FIG. 30A

As seen in Figure 30A, the tip portion coincides with the axis of rotation, while the second portion of the working surface immediately following the tip portion has at least one cross-section with a center of mass offset from the instrument's axis of rotation and at least one cutting edge defined by said cross-section being located set back within the envelope. *Id.* Scianamblo further discloses that the working surfaces depicted in its Figures 21 through 25 can be used with this embodiment. Ex. 1006, ¶233; Ex. 1003, ¶180.

Although this instrument does not appear to have a single continuous taper function creating a cylindrical or conical shape of the active part of the instrument, it would have been obvious for a POSITA to modify it to incorporate such features, and a POSITA would, in fact, have been motivated to do so. Ex. 1003, ¶181. Scianamblo discloses a number of embodiments having a conical shape. Ex. 1006, Figs. 6A, 6B, 9A, 11A-B, 21A-C, 23A-C, 24A-C, 25A-C, 27, 28, 31A; Ex. 1003, ¶181. Endodontic instruments are usually conical shaped since endodontic cavity spaces or root canals, are wider near the top of the canal and narrow to a point at the bottom of the canal, much like a cone. Ex. 1003, ¶182. The benefit of the conical aspect of such a design, a POSITA would have understood, is that the instrument would effectively follow the general shape of, and clean, endodontic cavity spaces. *Id*.

An endodontic instrument design that incorporates both a curvature as well as a conical shape would have been within the scope of knowledge of a POSITA. An example of such a design is one in which the centroids of the cross-sections of the second portion of the working portion follow a helicoidal or cork-screw path. Ex. 1003, ¶183. A benefit of the helicoidal or cork-screw design, a POSITA would have understood, is that it would have multiple offset cross-sectional centers of mass, thereby further effectively cleaning the endodontic cavity space by accounting for variations or deviations in the space from the general conical shape. Ex. 1006, ¶203; Ex. 1003, ¶183.

Such a helicoidal or cork-screw-like design is disclosed in various prior art references, for example, McSpadden, *see infra* Section VII.B.1., as well as Exhibit 1016 ("Rouiller"), 7:11-17, Figs. 1, 2, 4. Ex. 1003, ¶184. The instrument described in a French language counterpart of Rouiller (EP 1 361 831) is referenced as one of numerous instruments developed in response to the problems discussed in the '696 patent. Ex. 1001, 1:25-50; Ex. 1003, ¶184. Alleviating these problems would be another benefit of the helicoidal cork-screw-like design. Ex. 1003, ¶184. In order to achieve these benefits, a POSITA would have been motivated to incorporate a helicoidal or cork-screw-like shape into the instruments described in Scianamblo. Ex. 1003, ¶185. Further, a POSITA would have had a reasonable expectation of success in incorporating this feature into Scianamblo's instrument. *Id.*

2. Dependent claim 2

Claim 2 requires that for the instrument of claim 1, "any of the cross-sections of the second portion has a center of mass offset with respect to the axis of rotation, and at least one cutting edge defined by said cross-section of the second portion is located set back within the envelope." As discussed above, *see supra* Section VII.D.1.e., a POSITA would have been motivated to modify Scianamblo's instrument to obtain an instrument having a conical helix shape. In this design, each cross-section of the second portion would necessarily have a center of mass offset with respect to the axis of rotation, and at least one cutting edge defined by each said cross-section of the second portion would necessarily be located set back within the envelope. Ex. 1003, ¶¶187-188.

3. Dependent claim 5

Claim 5 requires that for the instrument of claim 2, "one of the cross-sections of the second portion of the active part that is located close to the point has a center of mass proportionally closer to the axis of rotation than the center of mass of one of the cross-sections of said second portion that is located at the rear of the active part." As discussed above, *see supra* Sections VII.D.1.e. and VII.D.2., a POSITA would have been motivated to modify Scianamblo's instrument to have a conical helix shape. Ex. 1003, ¶190. In this design, since the amplitude of the helicoidal path of the cross-sectional centers of mass would be bounded by the conical envelope, the cross-sectional center of mass of the second portion of the active part located closest to the point would necessarily be closer to the axis of rotation than the cross-sectional center of mass of the second portion located at the rear of the active part. *Id.* Further, since the instrument is tapered, and the envelope would get gradually smaller from the rear to the tip end, the offset of the cross-sectional centers of mass from the axis of rotation would change gradually between those two centers of mass. *Id.*

4. Dependent claim 8

Claim 8 requires that for the instrument of claim 1, "the active part has over its entire length a polygonal cross-section with straight sides." As mentioned above, *see supra* Section VII.D.1.b., Scianamblo teaches that the cross-sections of the working portion may assume any of a variety of polygonal shapes. For example, Scianamblo discloses that "the instrument may have a square cross-section at the shank end and a triangular cross-section at the tip end." Ex. 1006, ¶201; Ex. 1003, ¶192. Scianamblo also discloses an endodontic instrument that "includes three sides, is triangular in transverse cross-section, and can be utilized to remove tissue and/or dentin from an ECS." Ex. 1006, ¶204; Ex. 1003, ¶192. Scianamblo further discloses an instrument that is "four sided or rectilinear in transverse cross-section." Ex. 1006, ¶210; Ex. 1003, ¶192; *see also* Ex. 1006, ¶¶216, 222.

Notwithstanding that the figures in Scianamblo depict cross-sectional shapes with curved sides, a POSITA would have understood from these disclosures that the sides of the various polygonal shapes discussed could be straight. Ex. 1003, ¶193. A POSITA would have understood that Scianamblo teaches its instruments may have either straight or curved sides. Ex. 1006, ¶230; Ex. 1003, ¶193.

Employing a straight-sided polygon is a simple design choice that a POSITA would have understood is readily available, including for instruments having a helicoidal or cork-screw shape. Ex. 1003, ¶194. A POSITA would have known that it is highly common to employ a straight-sided polygonal cross-section in endodontic instruments. *Id*. One motivation for a POSITA to have done so is that instruments with a straight-sided cross-sectional shape are typically easier to manufacture than instruments with a curved-sided cross-sectional shape. *Id.*

5. Dependent claim 10

Claim 10 requires that for the instrument of claim 1, "the first portion of the active part has a length between 1 and 3 millimeters." As discussed above, s*ee supra* Section VII.D.1.c., for Scianamblo's instrument, the first portion of the active part is the tip portion of the working portion. Scianamblo discloses that the "tip of the implementation ends in a pyramidal or parabolic shape and is at least 0.05 mm in diameter and 1-3 mm in length." Ex. 1006, ¶70; Ex. 1003, ¶197. Further, a POSITA would have understood that, for endodontic instruments with a cutting tip, the length of the tip portion typically falls within the range of 1 and 3 millimeters. Ex. 1003, ¶198.

E. Ground 5: Claim 9 is Obvious Over Scianamblo in View of Garman

Claim 9 requires that for the instrument of claim 1, "the first portion of the active part has a square cross-section, and the second portion of the active part has a rectangular cross-section." With reference to Fig. 23D, Scianamblo teaches that its instrument may have a "generally square shaped" core. Ex. 1006, ¶212; Ex. 1003, ¶200. Similar to the discussion above regarding the combination of McSpadden and Garman, *see supra* Section VII.C., in view of Garman, it would have been obvious to modify Scianamblo's instrument having a generally square-shaped core to incorporate the feature of a rectangular cross-section in the second portion of its active part. Ex. 1003, ¶201.

A POSITA would have had ample reasons to consider the teachings of Garman for manufacturing Scianamblo's instrument. Ex. 1003, ¶202. Particularly germane to claim 9 of the '696 patent, Scianamblo discloses that endodontic instruments may employ a changing geometry across their length in order make them "more flexible and less likely to fracture," Ex. 1006, ¶12; *see also id.* at ¶230, and this concept is the essence of Garman, Ex. 1005, 1:50-59, 2:1-16, 2:36-38, 2:51-54, 4:52-55. Ex. 1003, ¶203. Garman teaches the steps to accomplish this. Ex. 1005, 5:12-6:51; Ex. 1003, ¶203. As discussed above, *see supra* Section VII.C., the result of Garman's process is an instrument that has, for example, a square cross-section at the tip end and a rhomboid cross-section towards the other end, and a POSITA would have been motivated, in certain instances, to substitute a rectangle in place of the rhomboid. Ex. 1003, ¶¶204-205.

A person of ordinary skill in the art would have been motivated to apply Garman's teachings of the cross-sectional geometry changing over the working length, to Scianamblo's instrument having a generally square-shaped core, in order to optimize the instrument's flexibility and strength. Ex. 1003, ¶206. A POSITA would have had a reasonable expectation of success in combining the teachings of Scianamblo and Garman. *Id.* It would have been straightforward for a POSITA to employ Garman's disclosed grinding process to obtain a tapered rod that changes from a square-cross section to a rectangular cross-section along its length, and to follow that with a twisting step to give the cutting edges a helical shape and arrive at the invention recited by claim 9 of the '696 patent. *Id.*

F. Ground 6: Claims 1, 2, 5, and 10 are Obvious Over Badoz in View of Taylor

1. Independent claim 1

a. "An instrument for drilling dental root canals comprising"

To the extent the Board determines that the preamble of claim 1 is limiting, Badoz is directed to "endodontic instruments for the preparation of root canals," such as a root-canal reamer. Ex. 1008, Abstract, 1:1-5; Ex. 1003, ¶211. Similarly, Taylor is directed to reamers and files, which it explains are "used to remove diseased tissue from the canal." Ex. 1009, 1:6-11; Ex. 1003, ¶211.

b. [1.a] "a tapered rod defined by a single continuous taper function and having over at least an active part of its length a polygonal cross-section forming at least two cutting edges, said active part terminating by a point and being defined by an envelope of a cylindrical or conical shape along its entire length, the longitudinal axis of the envelope coinciding with the axis of rotation of the instrument"

Badoz teaches that the "prior art already includes root-canal instruments comprising a working section including three flutes forming three cutting lips," the working section called a "blade," Ex. 1008, 1:1-7, and that its disclosed instruments comprise the same, Ex. 1008, 1:25-28. Ex. 1003, ¶213. The cross-sections along the length of the active part of Badoz's instrument take the shape of a triangle that is isosceles rather than equilateral. Ex. 1008, 1:25-28, 2:12-15, 4:4-6, Fig. 2; Ex. 1003, ¶213.

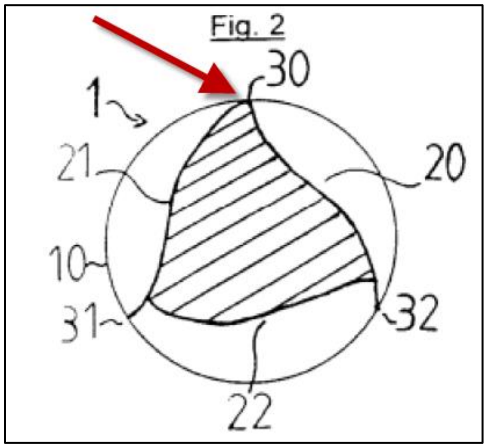
Badoz's instrument has a conical shape, Ex. 1008, 2:16-18, which a POSITA would understood to mean that it is tapered, and has an envelope of conical shape with a longitudinal axis coinciding with the instrument's rotational axis. Ex. 1003, ¶214. Badoz teaches that the conical shape can be obtained by gradually moving the grinding wheel away from the rotational axis as one moves away from the tip, Ex. 1008, 2:18-20, which a POSITA would have understood to mean that the diameter of the rod gets gradually smaller toward one end. Ex. 1003, ¶214. Such an instrument, a POSITA would have understood, generally terminates by a point, *i.e.*, a tip. Ex. 1003, ¶214.

As discussed above, *see supra* Section VII.B.1.b., the fact that some endodontists prefer a cutting tip and the fact that it would likely be just as, if not more, convenient to manufacture an instrument that has cutting edges extending to the tip would have led a POSITA to provide cutting edges on the tip of an instrument, including Badoz's instrument. Ex. 1003, ¶215. Taylor provides further evidence of the motivation for the provision of a cutting tip based on the endodontist's preference, based on the discovery that "providing at least some cutting ability on the tip can increase the overall cutting efficiency and clinical efficacy of the instrument without significantly increasing the likelihood of canal wall transportation. Ex. 1009, 5:36-50; Ex. 1003, ¶215.

A POSITA would have recognized all of these features as highly common in endodontic instruments for years, if not decades, prior to January 30, 2013, as evidenced by not only the disclosures of McSpadden and Scianamblo, *see supra* Sections VII.B.1.b. and VII.D.1.b., but also those of Taylor, which describes an instrument having a rod that is uniformly tapered, with multiple cutting edges formed over an active part that is defined by a conical envelope and terminates by a cutting tip, and the envelope coinciding with the instrument's rotational axis. Ex. 1009, 3:19-23, 5:36-50, 6:9-26, 7:22-32, Figs. 2A, 2D, 2E; Ex. 1003, ¶216.

c. [1.b] "wherein for any cross-section of the active part, at least one of the at least two cutting edges is located on the envelope, said active part has a first portion extending from the point and a second portion extending following the first portion towards the rear of the active part"

Badoz teaches that the isosceles triangular cross-section of its instrument is obtained by milling two flutes identically, and then milling a third flute deeper than the first two. Ex. 1008, 2:26-3:1, 4:7-10; Ex. 1003, ¶218. As seen in Figure 2 of Badoz (reproduction below annotated with red arrow showing one cutting edge on the envelope), due to such milling operation, two of the three cutting edges (elements 31, 32) are set back within the envelope, while the third cutting edge (element 30) is on the envelope.



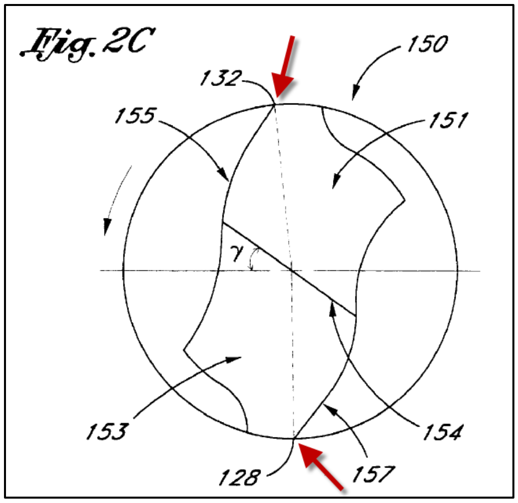
Ex. 1003, ¶219. Additionally, the cross-sectional center of mass is offset from the longitudinal axis of the envelope (which, as discussed above, coincides with the instrument's rotational axis). Ex. 1008, Fig. 2; Ex. 1003, ¶220. A POSITA would have understood that upon using conventional methods of milling blanks in order to form flutes and cutting edges, in accordance with Badoz's teachings, the offset cross-sectional shape depicted in Figure 2 would rotate around the rotational axis such that the third cutting edge would remain on the envelope for the length of such portion of the active part. Ex. 1003, ¶221-222. This portion of the active part of Badoz's instrument corresponds to the claimed "second portion extending following the first portion towards the rear of the active part." Ex. 1003, ¶223.

The cutting tip portion corresponds to the claimed "first portion [of the active part] extending from the point." Ex. 1003, ¶224.

Taylor similarly teaches that its instrument has at least one cutting edge located on the envelope. Ex. 1009, 6:17-27; Figs. 2C, 2D; Ex. 1003, ¶225.

d. [1.c] "any cross-section of the first portion has a center of mass located on the axis of rotation, said at least two cutting edges defined by said cross-section of the first portion being located on the envelope"

Badoz teaches that the tip of its disclosed instrument "is able to search for the root canal and penetrate it naturally." Ex. 1008, 1:21-24; Ex. 1003, ¶227. The ability of an endodontic instrument to follow the natural path of the root canal would have been a concern to a POSITA in designing an endodontic instrument, as further evidenced by Taylor. Ex. 1009, 1:45-51, 2:22-24, 3:25-28, 8:13-18, 10:49-54; Ex. 1003, ¶227. A POSITA would have understood that locating the center of mass of any cross-section of the tip on the axis of rotation and shaping the cross-section at the tip to be symmetrical would help ensure that "the tip of the instrument is able to search for the root canal and penetrate it naturally," and further avoid the possibility of "a directional mishap" or "a perforation of the canal," as Badoz discusses, Ex. 1008, 1:16-24. Ex. 1003, ¶228. A POSITA would have understood that at least two of the cutting edges of such a tip would be located on the envelope. Ex. 1003, ¶229. Further, as shown in the annotated figure reproduced below, Taylor discloses a tip portion with the features of this claim limitation. Ex. 1009, Figs. 2A-2C; Ex. 1003, ¶230; *see also* Ex. 1009, 5:36-50.



Ex. 1003, ¶230 (annotated red arrows pointing to the cutting edges located on the envelope). A POSITA would have been motivated to incorporate these features into the tip portion for the reasons discussed above, and would have had a reasonable expectation of success in doing so. Ex. 1003, ¶231.

e. [1.d] "at least one cross-section of the second portion has a center of mass offset with respect to the axis of rotation, at least one cutting edge defined by said cross-section of the second portion being located set back within the envelope."

As discussed above, *see supra* Section VII.F.1.c., as the cross-sectional shape rotates around the longitudinal axis of the envelope (and the instrument's axis of rotation) across the second portion of the active part of the instrument depicted in Figure 2 of Badoz, one of the cutting edges remains on the envelope. Ex. 1003, ¶¶233-234. Similarly, as the cross-sectional shape rotates, the center of mass of the cross-section remains offset with respect to the axis of rotation, and two of the cutting edges of the cross-section remain set back within the envelope, as also depicted in Figure 2. Ex. 1003, ¶235. Taylor similarly depicts its instrument as having edges being set back within the envelope, which it refers to as "trailing edges." Ex. 1009, 6:17-28, Figs. 2C, 2D; Ex. 1003, ¶236.

2. Dependent claim 2

Claim 2 requires that for the instrument of claim 1, "any of the cross-sections of the second portion has a center of mass offset with respect to the axis of rotation, and at least one cutting edge defined by said cross-section of the second portion is located set back within the envelope." As discussed above, *see supra* Section VII.F.1.e., each of the cross-sections of the second portion of the instrument depicted in Figure 2 of Badoz would have a center of mass offset with respect to the axis of rotation, and two cutting edges that are set back within the envelope. Ex. 1003, ¶238.

3. Dependent claim 5

Claim 5 requires that for the instrument of claim 2, "one of the cross-sections of the second portion of the active part that is located close to the point has a center of mass proportionally closer to the axis of rotation than the center of mass of one of the cross-sections of said second portion that is located at the rear of the active part." As discussed above, *see supra* Sections VII.F.1.b. and VII.F.1.c., Badoz's instrument would have a conical envelope and a rotating and offset cross-sectional center of mass across the length of the second portion of the active part. Ex. 1003, ¶240. In this design, since the amplitude of the path of the cross-sectional centers of mass would be bounded by the conical envelope, the cross-sectional center of mass of the second portion of the active part located closest to the point would necessarily be closer to the axis of rotation than the cross-sectional center of mass of the second portion located at the rear of the active part. Ex. 1003, ¶240. Since the diameter of the rod of Badoz's instrument gets gradually (*i.e.*, proportionally) smaller from the rear to the tip end, *see supra* Section VII.F.1.b., the offset of the cross-sectional centers of mass from the axis of rotation would change gradually between those two centers of mass. Ex. 1003, ¶240.

4. Dependent claim 10

Claim 10 requires that for the instrument of claim 1, "the first portion of the active part has a length between 1 and 3 millimeters." A POSITA would have understood that endodontic instruments have working portions generally spanning between 15 and 20 millimeters in length. Ex. 1003, ¶243. For example, Taylor discloses that the working portion may have "a length ranging from about 3 mm to about 18 mm," and that a "preferred length is about 16 mm." Ex. 1009, 7:22-24; Ex. 1003, ¶243. For an instrument that has an active part with a length in this range, it would have been not only reasonable, but rather, likely, for a POSITA to select a length of the centered tip portion that is between 1 and 3 millimeters. Ex.

1003, ¶243.

A POSITA also would have understood that in order to ensure that "the tip of the instrument is able to search for the root canal and penetrate it naturally," and further avoid the possibility of "a directional mishap" or "a perforation of the canal," discussed by Badoz*, see supra* Section VII.F.1.d., the tip portion should be of sufficient length, but at the same time, that it need not encompass a significant length of the active part. Ex. 1003, ¶244. A POSITA would further have understood that it would be desirable to minimize the length of the tip portion as much as possible, without losing the benefits discussed above, because a centered tip portion would not provide the benefits of an offset-center of mass, as in the remainder of the active part. Ex. 1003, ¶¶245-246. A POSITA would have understood that the appropriate length of the tip portion for an instrument with a working portion that is approximately 15-20 millimeters long is between 1 and 3 millimeters. Ex. 1003, ¶246.

Indeed, the prior art, including Scianamblo and another McSpadden patent, is replete with disclosures of lengths between 1 and 3 millimeters for the tip portion of an endodontic instrument. Ex. 1003, ¶247.

G. Ground 7: Claims 8 and 9 are Obvious Over Badoz in View of Taylor and in Further View of Garman

1. Dependent claim 8

Claim 8 requires that for the instrument of claim 1, "the active part has over its entire length a polygonal cross-section with straight sides."

As discussed above, *see supra* Sections VII.F.1.b. and VII.F.1.c., Badoz discloses an instrument having a triangular (*i.e.*, polygonal) cross-section. Ex. 1003, ¶250. Neither Badoz nor Taylor specifically discusses whether the cross-sections of their instruments have curved or straight sides. *Id.* But Garman teaches the steps of forming cutting edges on an instrument by grinding, Ex. 1005, Figs. 3A-3F, 4-7, 8A-8D, 9-12, 15, 16, resulting in a polygonal cross-section with straight sides, Ex. 1005, 5:52-59, 6:46-51. Ex. 1003, ¶250.

Employing a straight-sided polygon cross-section over the active part of the instrument is a simple design choice that a POSITA would have understood is readily available, including for instruments having a helicoidal or cork-screw shape. Ex. 1003, ¶251. A POSITA would have been motivated to do so since instruments with a straight-sided cross-sectional shape were typically easier to manufacture than instruments with a curved-sided cross-sectional shape. Ex. 1003, ¶¶248, 251-252.

2. Dependent claim 9

Claim 9 requires that for the instrument of claim 1, "the first portion of the active part has a square cross-section, and the second portion of the active part has a rectangular cross-section." Similar to the discussion above regarding the combination of McSpadden and Garman, *see supra* Section VII.C., in view of

Garman, it would have been obvious to modify Badoz's instrument such that the active part includes a first portion with a square cross-section and a second portion with a rectangular cross-section. Ex. 1003, ¶254.

It would have been obvious to a POSITA to substitute square cross-sections for the triangular cross-sections of Badoz's instrument. Ex. 1003, ¶255. Quadrilaterals, such as a square, have been known in the art, since well before April 8, 2005, to be effective for the cross-sections of endodontic instruments. *Id.* In fact, of the limited number—a handful—of potential polygonal cross-sectional shapes that a POSITA would have considered, a square was one of the most commonly used, and it would have been a simple design choice to select it. *Id.* That McSpadden and Scianamblo also disclose a square cross-section is further evidence that it was well within the knowledge of a POSITA at the time of the alleged invention. *See supra* Sections VII.C. and VII.E.; Ex. 1003, ¶255. The motivation to select a square cross-section instead of a triangular one is that the former generally provides greater resistance to breakage of the instrument. Ex. 1003, ¶255.

Badoz and Taylor are concerned with making a more easily maneuverable instrument that follows the natural curve of an endodontic cavity, Ex. 1008, 1:10-24, Ex. 1009, 1:45-51, 2:22-24, 3:25-28, 8:13-18, 10:49-54, and Garman shares this goal, Ex. 1005, 1:50-59, 2:1-16, 2:36-38, 2:51-54, 4:52-55. Ex. 1003, ¶256.

Garman also teaches the steps to accomplish this. Ex. 1005, 5:12-6:51; Ex. 1003, ¶256. As discussed above, *see supra* Section VII.C., the result of Garman's process is an instrument that has, for example, a square cross-section at the tip end and a rhomboid cross-section towards the other end, and a POSITA would have been motivated, in certain instances, to substitute a rectangle in place of such rhomboid. Ex. 1003, ¶¶257-259. A person of ordinary skill in the art also would have been motivated to apply Garman's teachings of the cross-sectional geometry changing over the working length, to the modified Badoz instrument having a square cross-section, in order to further increase the instrument's flexibility, maneuverability, and ability to follow the natural curve of an endodontic cavity without sacrificing strength. Ex. 1003, ¶¶248, 260.

A POSITA would have had a reasonable expectation of success in combining the teachings of Badoz, Taylor, and Garman. *Id.* It would have been straightforward for a person of ordinary skill in the art to incorporate Garman's disclosed grinding steps into Badoz's disclosed milling process to obtain a tapered rod that changes from a square cross-section to a rectangular cross-section along its length and arrive at the invention recited in claim 9 of the '696 patent. *Id*.

H. No Secondary Considerations of Non-obviousness

Petitioner is not aware of any evidence of secondary considerations, let alone evidence that would rebut the strong obviousness grounds presented herein.

Petitioner asks that the Board wait to undertake evaluation of secondary consideration evidence, if any, presented by Patent Owner until Petitioner has been given an opportunity to test or respond to such evidence. *Amneal Pharms., LLC v. Supernus Pharms., Inc.*, IPR2013-00368, slip op. at 12-13 (PTAB Dec. 17, 2013) (Paper 8).

VIII. CONCLUSION

For the foregoing reasons, claims 1, 2, 5, and 8-10 of the '696 patent are unpatentable. Petitioner respectfully petitions for their cancellation.

Respectfully submitted,

Dated: July 3, 2018

/s/ *Jeffrey S. Ginsberg*

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CERTIFICATE OF COMPLIANCE

I hereby certify that this paper complies with the type-volume limitation of 37 C.F.R. §42.24(d) because it contains 13,411 words (as determined by the Microsoft Word word-processing system used to prepare this paper), excluding the parts of the paper exempted by 37 C.F.R. §42.24(a).

Respectfully submitted,

Dated: July 3, 2018

/s/ *Jeffrey S. Ginsberg*

Jeffrey S. Ginsberg (Reg. No. 36,148)
Lead counsel for Petitioner Edge Endo, LLC

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§42.6(e) and 42.105, the undersigned certifies that on July 3, 2018, a complete and entire copy of this Petition for *Inter Partes* Review along with complete and entire copies of Exhibits 1001 through 1016 were served via FedEx Express on the Patent Owner at the following correspondence address of record for the '696 patent:

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