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[Continued on next page]

- (54) Title: ENDODONTIC INSTRUMENT WITH NARROW RADIAL LANDS

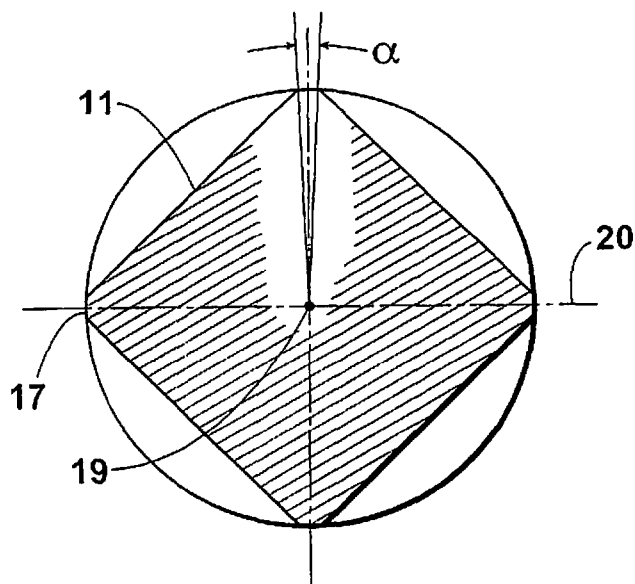


Fig. 2

(57) **Abstract:** An improved endodontic instrument that has a uniform tapered working length portion (24) with at least two helical shaped flutes (11) and spiraled lands (17) having a land width no greater than 0.101 mm as measured in a plane perpendicular the central axis of rotation (19) of the instrument. The land width is preferably constant along the working length portion (24) but may vary provided it does not exceed 0.101 mm. The instrument resists mid-root transportation and exhibits superior fatigue performance and cutting efficiency compared to prior art instruments..



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- *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

ENDODONTIC INSTRUMENT WITH NARROW RADIAL LANDS

BACKGROUND OF THE INVENTION

1. **Field of the Invention.** This invention relates generally to the field of dentistry
5 and more particularly to endodontic files or reamers used in the cleaning of material present
in the root canal of human teeth and for enlarging and shaping the root canal so that it is
prepared for receiving filling material.

2. **Description of the Related Art.** Instruments that enable an endodontist to clear
and clean the root canal of a tooth are well-known in the art. Because of the geometry of a
10 root canal, these instruments—typically referred to as endodontic files—experience
significant flexing and twisting while in use, making them susceptible to breakage. Because
of the breakage problem and the danger that it poses to a patient, nickel-titanium alloy (NiTi
or Nitinol™) generally is viewed as a better material for use in manufacturing these
instruments than is stainless steel. Relative to stainless steel, NiTi is able to withstand a far
15 greater amount of twisting or bending without experiencing permanent deformation or
breaking.

The design challenge is multi-dimensional: to provide a NiTi instrument that is
flexible, resists torsional breakage and cyclic fatigue, cuts efficiently, and does not transport
the root canal during cutting. Unfortunately, these design objectives run counter to one
20 another. Therefore, prior art instrument designs represent the various tradeoffs made among
these objectives. To date, all the prior art instrument designs teach away from providing
narrow radial land widths along the entire working length of a straight or uniform taper
instrument.

The prior art has assumed that radial lands in the range of at least 0.004 to 0.006
25 inches (about 0.102 to 0.152 mm) are required to get optimum cutting yet prevent mid-root
transportation when a standard K-file or reamer is employed in a curved root canal. See e.g.,

U.S. Pat. Nos. 4,934,934 to Arpaio, Jr. et al.; Re. 34,439 (reissue of 4,871,312) and 5,762,497 to Heath; and 5,941,760 to Heath et al. To achieve this performance, the land width selected in this range should be held constant along the working length of the instrument.

5 Where lands having a width below 0.004 inches (about 0.102 mm) are disclosed, the instrument shape is altered from a uniform or straight taper shape and the narrow lands are only located at the tip and shank portions of the instrument. For example, U.S. Pat. App. Pub. No. 2007/0026360 to Buchanan discloses a land width below that of Arpaio, Jr. and Heath, in the range of 0 to 0.004 inches, except for lands located along an under-contoured
10 (narrower) intermediate or middle waist portion of the working length. The lands in the waist portion are relatively wide—for example, in the range of 0.004 to 0.006 inches—compared to those in the tip and shank portions. Buchanan claims that the combination of multiple contours or heights and multiple land width variations along the working length reduces taper lock, increases cutting efficiency, and minimizes or eliminates transportation.
15 See Buchanan at para. 0030 (noting “the wider land in the mid-region of the instrument prevents or minimizes straightening of curved canals at their mid-points.”) Similar to Arpaio, Jr. and Heath, Buchanan also discloses that a wide land width prevents transportation of the root canal path but increases the likelihood of breakage due to cyclic fatigue because of reduced cutting efficiency (therefore requiring more revolutions to
20 accomplish a certain shaping objective). On the other hand, a narrow land width reduces the likelihood of breakage because of increased cutting efficiency but increases the chances of mid-root transportation.

Buchanan also found that a straight taper instrument having narrow land widths toward the shank end of the instrument and relatively wider land widths toward the tip end
25 increases mid-root transportation to unacceptable levels. See Buchanan at para. 0006. This transportation is most likely the result of stiffness created by the increasing land widths in

the waist portion of the instrument. Additionally, as the width of the radial land increases, torque strength increases but so does drag.

Subsequent testing by the Applicant has discovered that a straight taper instrument having narrow land widths in the shank and tip portions but wider lands in the waist portion
5 does lead to stiffness, which is evidenced by stress concentrations in the waist portion as the instrument traverses a curved portion of a root canal. The Applicant also has conducted experimentation with instruments having a wider waist portion relative to the shank and tip end portions and narrow lands along the length of the instrument. These instruments also experienced unacceptable mid-root transportation. The Applicant then decided to
10 manufacture a straight taper K-file having narrow radial lands along its entire length. Unexpectedly and surprisingly, the instrument exhibited no mid-root transportation in addition to superior cutting performance and resistance to cyclic fatigue. Preferred embodiments of this file is disclosed herein.

SUMMARY OF THE INVENTION

An improved endodontic instrument made according to this invention has a uniform tapered working length that includes spiraled lands having a land width no greater than 0.101 mm as measured in a plane perpendicular the central axis of rotation of the instrument. The land width may vary along the working length provided that it does not exceed 0.101 mm. The taper is preferably in the range of 0.02 to 0.08 mm per mm, with the instrument size being in the range of 8 to 70.

An object of this invention is to provide an improved endodontic instrument that provides superior cutting performance and resistance to cyclic fatigue. Another object of this invention is to provide an endodontic instrument that does not transport the root canal as the instrument navigates and shapes a curved portion of the canal.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a view of a preferred embodiment of an endodontic instrument according to this invention. The instrument has a uniform taper, at least two helical flutes, and narrow radial lands located between the helical flutes along the entire working length of the instrument.

FIG. 2 is a view taken along section line 2–2 of FIG. 1 illustrating a preferred embodiment of the endodontic instrument. The instrument has four substantially straight helical flute surfaces with narrow radial lands located between each adjacent pair of flutes.

FIG. 3 is a view taken along section line 3–3 of FIG. 1 illustrating another preferred embodiment of the endodontic instrument. The instrument has four concave-shaped helical flutes with narrow radial lands located between each adjacent pair of flutes.

FIG. 4 is a view taken along section line 4–4 of FIG. 1 illustrating yet another preferred embodiment of the endodontic instrument. The instrument has three substantially straight helical flute surfaces with narrow radial lands located between each adjacent pair of flutes.

FIG. 5 is a view taken along section line 5–5 of FIG. 1 illustrating yet another preferred embodiment of the endodontic instrument having three concave-shaped helical flutes defined by a radius of curvature and forming narrow radial lands between each adjacent flute.

5 FIG. 6 is a view taken along section line 6–6 of FIG. 1 illustrating another preferred embodiment of the endodontic instrument. The instrument has three convex-shaped helical flutes with narrow radial lands located between each adjacent pair of flutes.

FIG. 7 is a graphical depiction of a prior art endodontic instrument having wide lands in the mid-portion of the working length—or alternatively narrow lands in a wider mid-
10 portion of the working length—as the working length of the instrument would appear when traversing a curved root canal.

FIG. 8 is a graphical depiction of the endodontic instrument of FIG. 1 as its working length would appear when traversing a curved root canal.

FIG. 9 is an enlarged view of the curved and stressed mid-portion of the working
15 length of the prior art endodontic instrument of FIG. 7. Because of the wide lands (or the wider waist portion) the mid-portion experiences severe and moderate stress concentrations which make it prone to cyclic fatigue and breakage.

FIG. 10 is a view an enlarged view of the mid-portion of endodontic instrument of FIG. 8. The narrow lands in the mid-portion eliminate the areas of stress concentration
20 which are experienced by the wider landed or wider waist instrument of FIG. 9.

FIG. 11 is a view of the prior art endodontic instrument of FIG. 7 as it traverses a curved root canal and experiences mid-root transportation.

FIG. 12 is a view of the instrument of FIG. 1 as it traverses a curved root canal. The instrument experiences no mid-root transportation.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Preferred embodiments of an endodontic instrument made according to this invention will now be described in reference to the drawings and the following element numbering:

5	10	Endodontic instrument	20	Plane perpendicular to 19
	11	Flute surfaces	21	Handle portion
	13	Shank or proximal end	23	Depth calibration grooves
	14	Waist or mid-portion	24	Working length
	15	Tip or distal end	25	Transportation
10	17	Radial land	27	Area of moderate stress concentration
	19	Central axis of rotation	29	Area of severe stress concentration

Referring first to FIG. 1, an endodontic instrument 10 includes two or more continuously spiraled flute surfaces 11 extending between the shank end 13 and tip end 15 of the instrument 10. Adjacent flute surfaces 11 form a radial land 17 that provides an edge for cutting or scraping the wall of a root canal in order to shape the canal as the instrument 10 is manually or mechanically manipulated about its central axis of rotation 19. Therefore, the radial lands 17 are located along the active portion or working length 24 that lies between the shank and tip ends 13, 15. Working length 24 is preferably about 16 mm to 25 mm in length and follows a predetermined straight or uniform taper so that the diameter at its tip end 15 is less than the diameter at its the shank end 13. Although not forming a part of this invention, the handle portion 21 of instrument 10 may be configured for manual or mechanical manipulation and includes depth calibration grooves 23.

Referring now to FIGS. 2 to 6, the flute surfaces 11 may be straight, convex or concave surfaces that form radial lands 17. The cross-sectional shape of the working length 24 is preferably constant. That is to say, the desired number and shape of flute surfaces 11 do not change from one cross-section to the next along working length 24. Central to this invention is that the radial lands 17 are narrow lands, meaning that their width as measured in a plane 20 lying perpendicular to the central axis of rotation 19 is no greater than about

0.0039 inches (0.101 mm). In one preferred embodiment, the radial lands 17 were so narrow as to appear to form a sharp point.

Measured in terms of degrees of arc α , the maximum degrees of arc α at each diameter D_n for various sizes of instruments having a 0.02 mm per mm taper does not exceed those as listed in Table 1, where n is the distance in millimeters from tip end 15. For example, a size 8 instrument having a 0.02 taper has a D_1 diameter of 0.08 mm and a D_2 of 0.10. A size 8 instrument having a 0.08 taper has a D_1 and D_2 diameter of 0.08 and 0.16 mm, respectively. To calculate the maximum degrees of arc " α " at any given cross-section " n " so as to not exceed a predetermined maximum land width " w " at that cross-section " n " for any given size instrument " s " and taper " t ", the following formula may be used:

$$\text{Max } \alpha_n = \frac{360w_n}{\pi[(n-1)t + s]}$$

where " n " is measured from the tip end of the instrument and " s " is the instrument size in hundredths (e.g., size 8 equates to an " s " of 0.08 mm).

It has always been assumed by the designers of endodontic instruments that wider radial lands are needed in the waist portion 14 of the instrument to keep the instrument from transporting the root canal. The waist portion 14 generally begins about 9 to 11 mm from proximal end 13 and ends about 2-1/2 to 3 mm from the tip end 15, respectively (or about 9 to 11 mm from the distal end. However, referring now to FIGS. 7, 9 & 11, digital photography reveals that a prior art endodontic instrument having narrower radial lands at the shank and tip portions 13, 15 and wider radial lands at the waist portion 14 still experiences unacceptable levels of mid-root transportation 25 as the instrument navigates about a 45° curvature of a simulated root canal R in a resin block B. Thermal spectroscopy also reveals areas of moderate 27 and severe 29 stress concentration in the waist portion 14 as the prior art instrument traverses the curvature of canal R. These areas of stress concentration 27, 29 negatively affect the cyclic fatigue performance of the instrument. These findings are in line

with those of Buchanan, as was discussed in the Background section. However, Buchanan, in keeping with conventional wisdom, tried to solve the problem by keeping the wider lands in the waist portion 14 but altering the contour of the instrument.

Table 1. Maximum degrees of arc to achieve an arc length no greater than 0.101 mm at the D₁ to D₁₆ diameters for various instrument sizes having a 0.02 taper.

Instrument Size	Working length diameter D _n															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
8	145	116	96	83	72	64	58	53	48	45	41	39	36	34	32	30
10	116	96	83	72	64	58	53	48	45	41	39	36	34	32	30	29
15	77	68	61	55	50	46	43	40	37	35	33	31	30	28	27	26
20	58	53	48	45	41	39	36	34	32	30	29	28	26	25	24	23
25	46	43	40	37	35	33	31	30	28	27	26	25	24	23	22	21
30	39	36	34	32	30	29	28	26	25	24	23	22	21	21	20	19
35	33	31	30	28	27	26	25	24	23	22	21	20	20	19	18	18
40	29	28	26	25	24	23	22	21	21	20	19	19	18	18	17	17
45	26	25	24	23	22	21	20	20	19	18	18	17	17	16	16	15
50	23	22	21	21	20	19	19	18	18	17	17	16	16	15	15	14
55	21	20	20	19	18	18	17	17	16	16	15	15	15	14	14	14
60	19	19	18	18	17	17	16	16	15	15	14	14	14	13	13	13
70	17	16	16	15	15	14	14	14	13	13	13	13	12	12	12	12
80	14	14	14	13	13	13	13	12	12	12	12	11	11	11	11	11
90	13	13	12	12	12	12	11	11	11	11	11	10	10	10	10	10
100	12	11	11	11	11	11	10	10	10	10	10	9	9	9	9	9
110	11	10	10	10	10	10	9	9	9	9	9	9	9	9	8	8
120	10	9	9	9	9	9	9	9	9	8	8	8	8	8	8	8
130	9	9	9	9	8	8	8	8	8	8	8	8	8	7	7	7
140	8	8	8	8	8	8	8	8	7	7	7	7	7	7	7	7
150	8	8	8	7	7	7	7	7	7	7	7	7	7	7	7	6

Although Buchanan saw the need for narrow radial lands at the tip and shank end of the instrument, he avoided narrow radial lands in the waist portion 14 because conventional wisdom held that to provide narrow lands in this portion of the instrument would require that the waist portion 14 be widened. However, widening the waist portion 14 leads to similar transportation 25 and stress concentration 27, 29 because a wider waist causes stiffness. Therefore, Buchanan elected to narrow the waist portion but widen the lands relative to the tip and shank portions.

The prior art also teaches that an instrument having a straight or uniform taper but narrow radial lands 17 along its entire working length 14 would experience unacceptable levels of transportation 25 due to, for example, flexing of the waist portion as either the shank or tip ends 13, 15 thread into the root canal R or their cutting or scraping edges drag across the walls of canal R. Buchanan is indicative of the lengths that endodontic designers will go to in order to avoid narrow lands in the waist portion 14 of the instrument. Compared to the current invention, Buchanan's design is complex and more costly to manufacture.

Referring now to FIGS. 8, 10 & 12 a preferred embodiment of an endodontic instrument made according to this invention was tested in a simulated root canal R in a resin block B. Unexpectedly and surprisingly, the instrument 10 exhibited no mid-root transportation in its waist portion 14 as the instrument traversed a 45° curvature. Furthermore, thermal spectroscopy indicated no areas of severe or moderate stress concentrations in the waist portion 14 or along the working length 24.

The fact that improved endodontic instrument 10 experiences no mid-root transportation and has no areas of stress concentration was demonstrated in subsequent testing. Two PROFILE® instruments (DENTSPLY Tulsa Dental Specialties, Tulsa, Oklahoma) were made according to this invention and compared under the same set of test conditions to other prior art, sharp-cutting non-landed instruments. One of the PROFILE® instruments was made out of M-WIRE™ NiTi wire (DENTSPLY Tulsa Dental Specialties, Tulsa, Oklahoma) and the other was made out of NiTi wire. The advantage of the M-WIRE is in enhanced resistance to cyclic fatigue. The straight taper of instrument 10 in combination with the narrow radial lands 17 along its working length 24 improved cutting efficiency by a factor of about 1.4.

Table 2. Cyclic fatigue and cutting efficiency of various endodontic instruments having a 0.04 taper and a 25 mm working length.

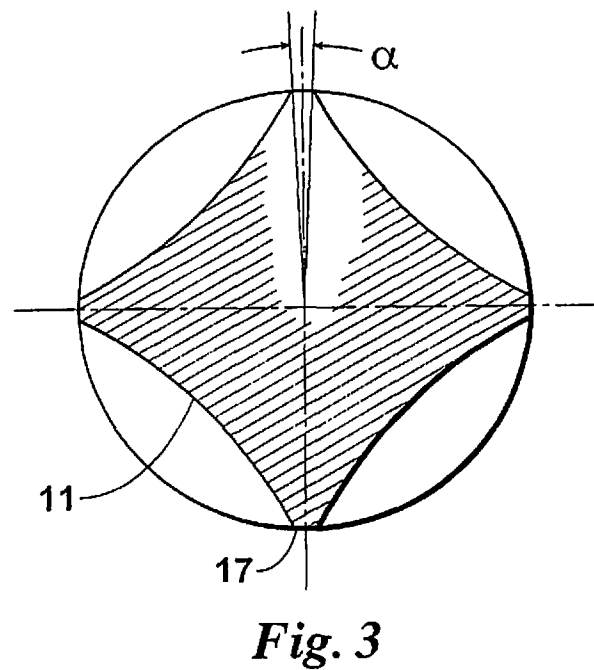
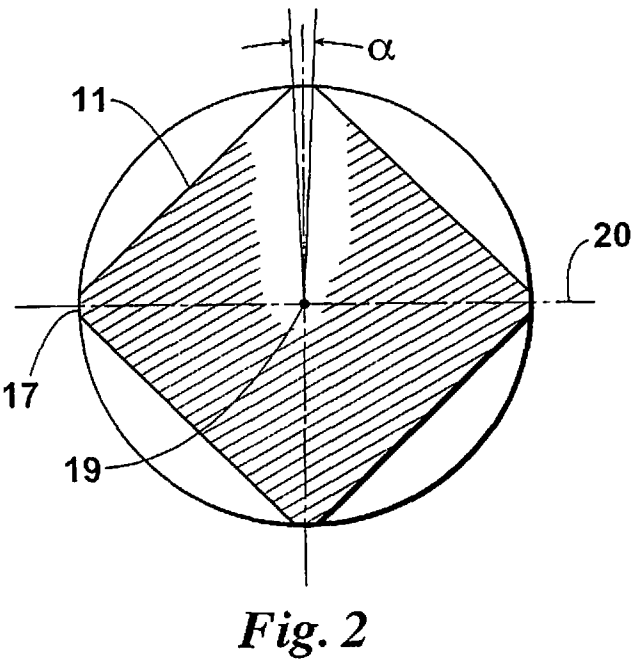
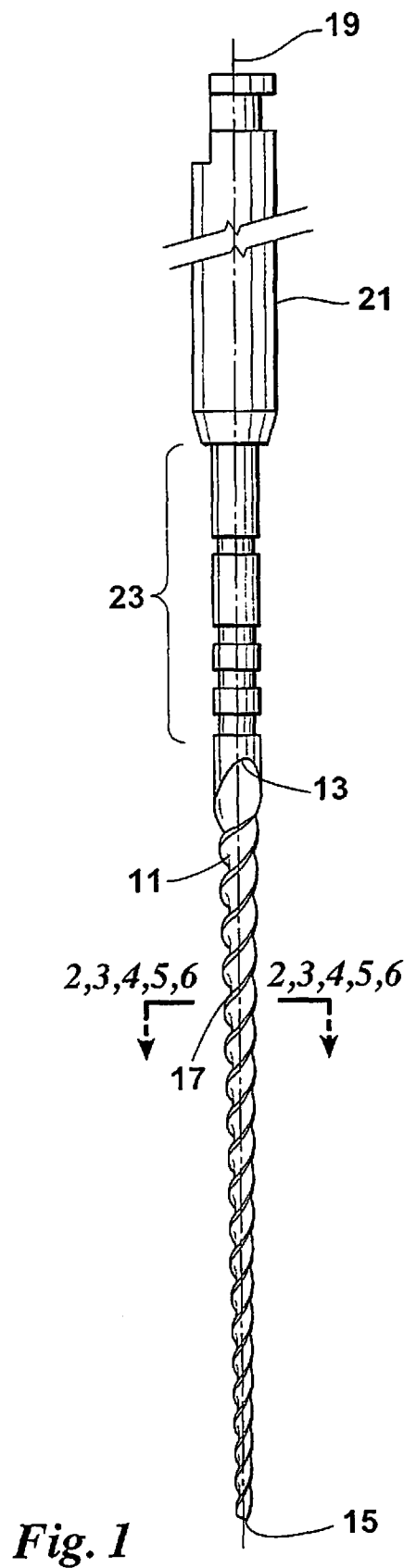
	M-WIRE™ NiTi Wire			NiTi Wire		
	Non-Landed K-File (sharp Δ)	FLEX- MASTER® (sharp convex Δ)	Landed PROFILE® (land width < 0.101 mm)	Non-Landed Twisted File (sharp Δ)	K-File (sharp Δ)	Landed PROFILE® (land width ≈ 0.102 mm)
Cyclic Fatigue (min)	16.16	3.45	4.73	2.88	2.00	2.31
Efficiency (mm/sec)	2.24	1.41	1.47	1.43	1.43	1.08

While an endodontic instrument having narrow radial lands along its entire working

5 length has been described with a certain degree of particularity, many changes may be made in the details of construction and the arrangement of components without departing from the spirit and scope of this disclosure. An endodontic instrument according to this disclosure, therefore, is limited only by the scope of the attached claims, including the full range of equivalency to which each element thereof is entitled.

WHAT IS CLAIMED

1. An improved endodontic instrument comprising:
a longitudinal body (10) having a uniform tapered working length portion
5 (24) extending between a shaft end (13) and a tip end (15) of said longitudinal body
(10) and including at least two helical shaped flutes (11) with spiraled lands (17)
between said flutes;
said spiraled lands (17) having a land width no greater than 0.101 mm as
measured in a plane perpendicular a central axis of rotation (19) of said longitudinal
10 body.
2. An improved endodontic instrument according to Claim 1 wherein the land width of
said spiraled lands is a constant land width between said tip and shaft ends.
- 15 3. An endodontic instrument according to Claim 1 wherein the endodontic instrument is
a size 8 (0.08 mm) endodontic instrument.
4. An endodontic instrument according to Claim 1 wherein the endodontic instrument is
in a range of a size 10 (0.10 mm) to a size 60 (0.60 mm) endodontic instrument.
- 20 5. An endodontic instrument according to Claim 1 wherein the endodontic instrument is
a size 70 (0.70 mm) endodontic instrument.
6. An endodontic instrument according to Claim 1 further comprising the uniform
25 tapered working length portion tapers in a range of +0.00 and +0.08 mm/mm from
said tip end to said shaft end.



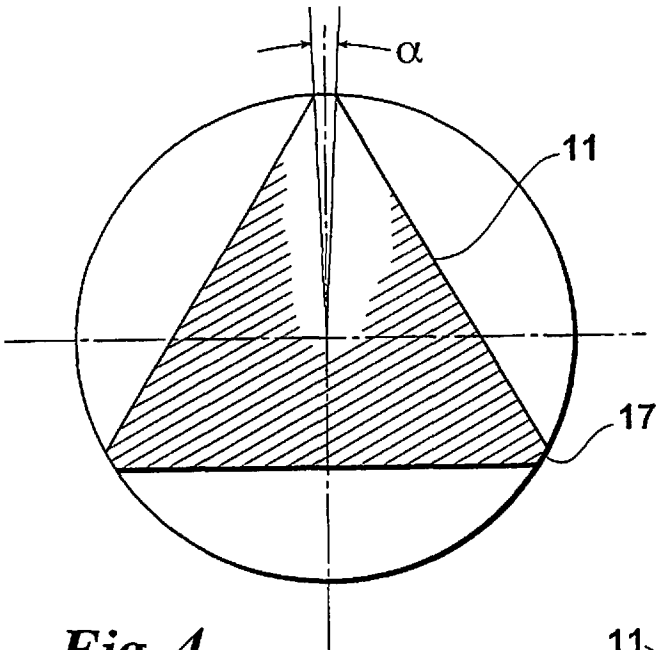


Fig. 4

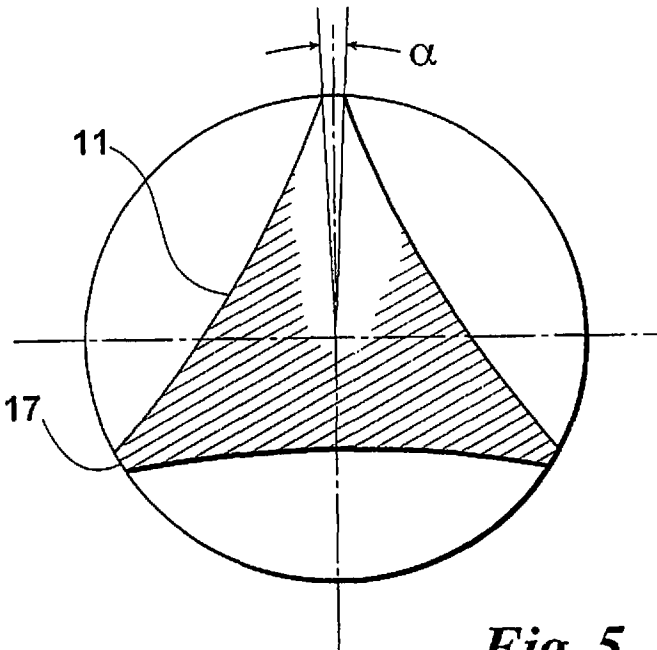


Fig. 5

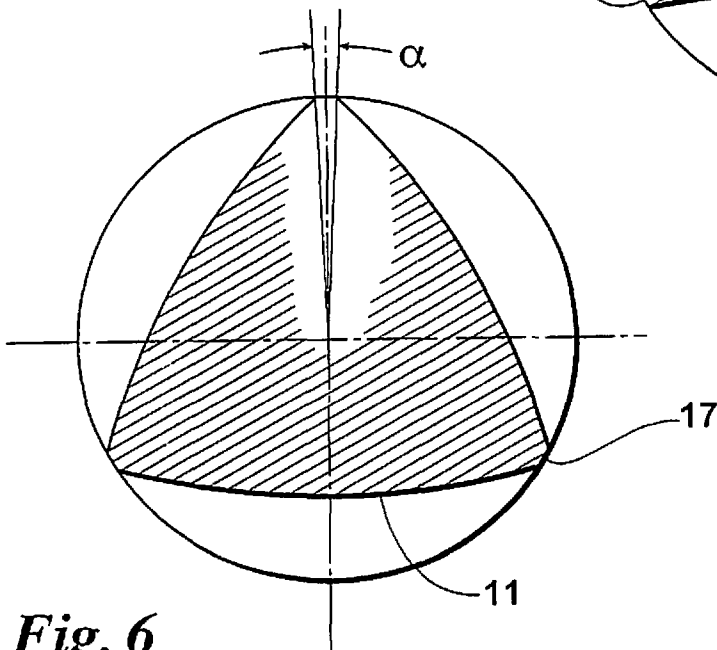
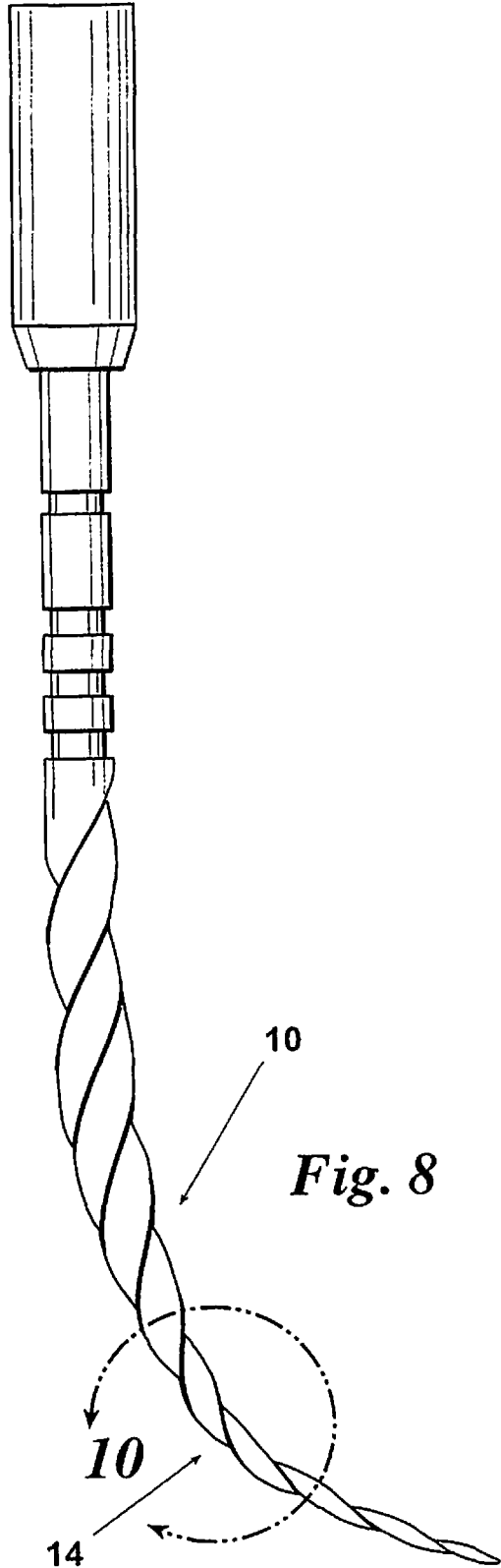
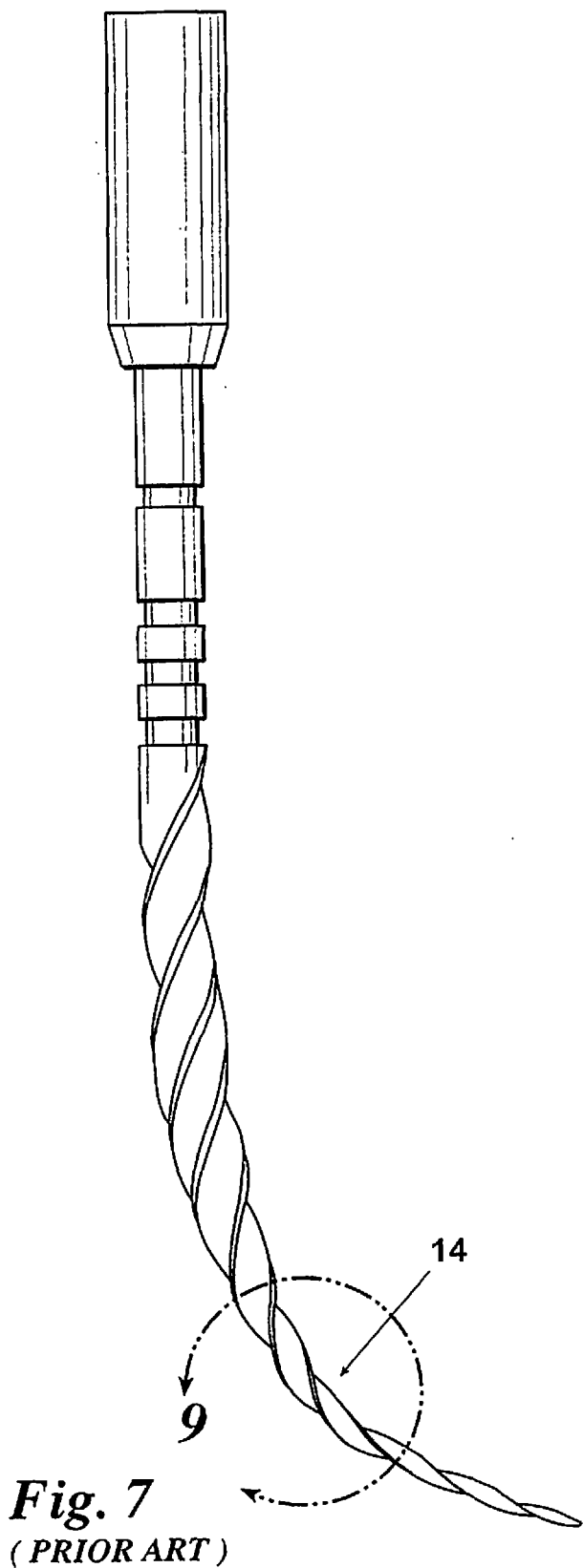
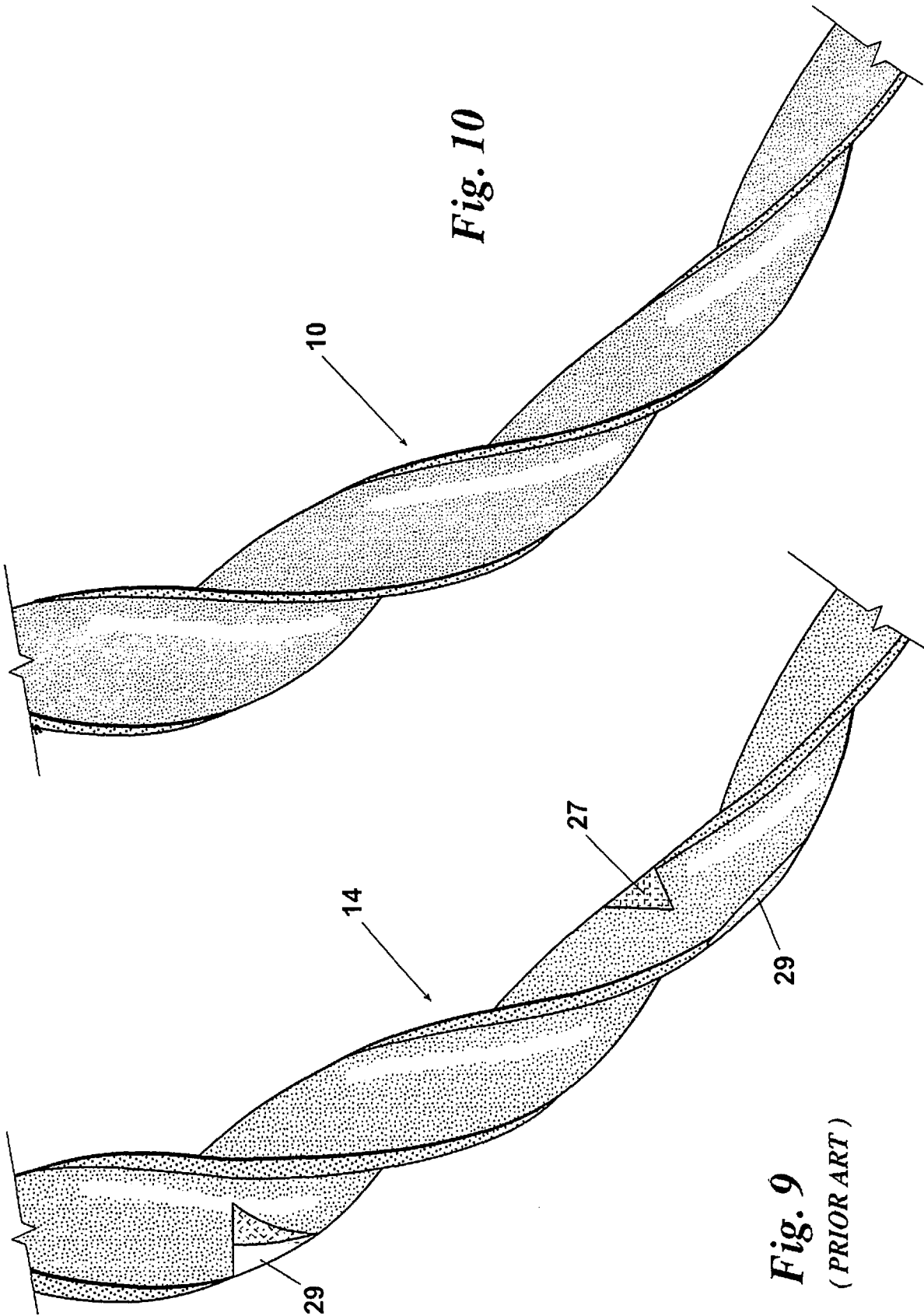


Fig. 6





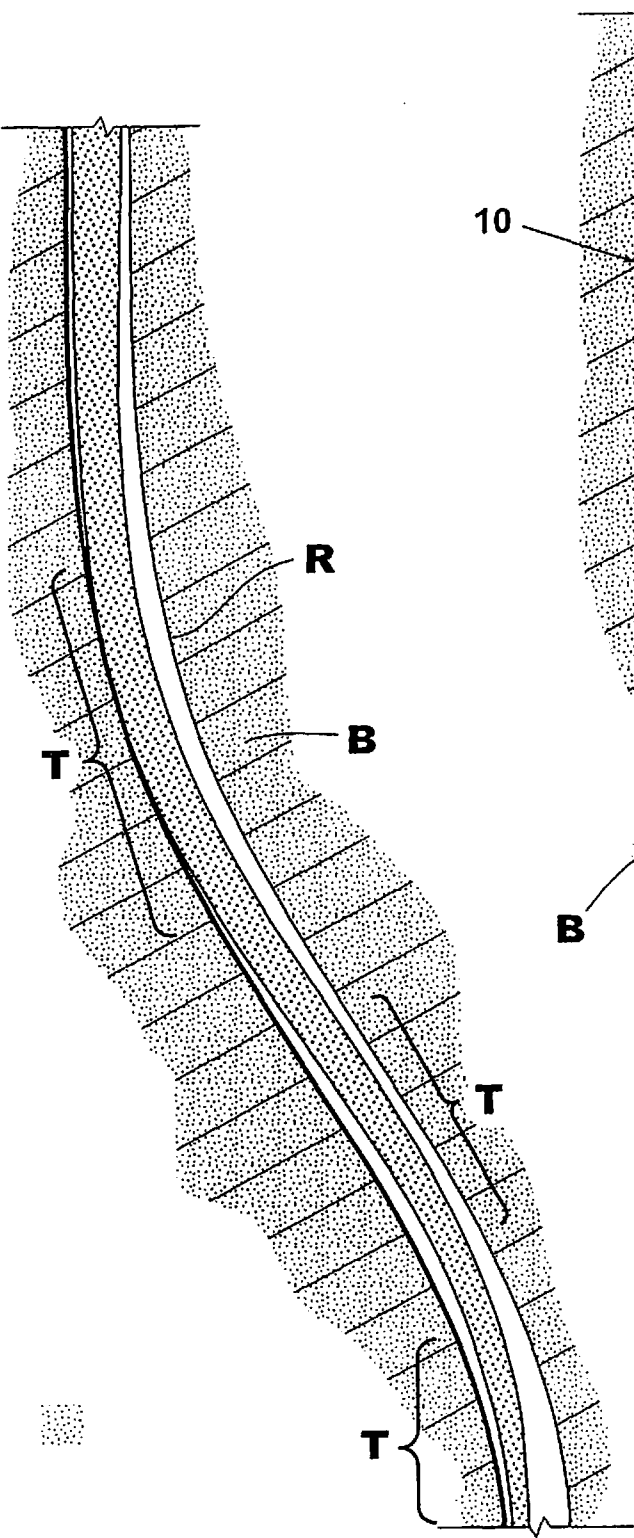


Fig. 11
(PRIOR ART)

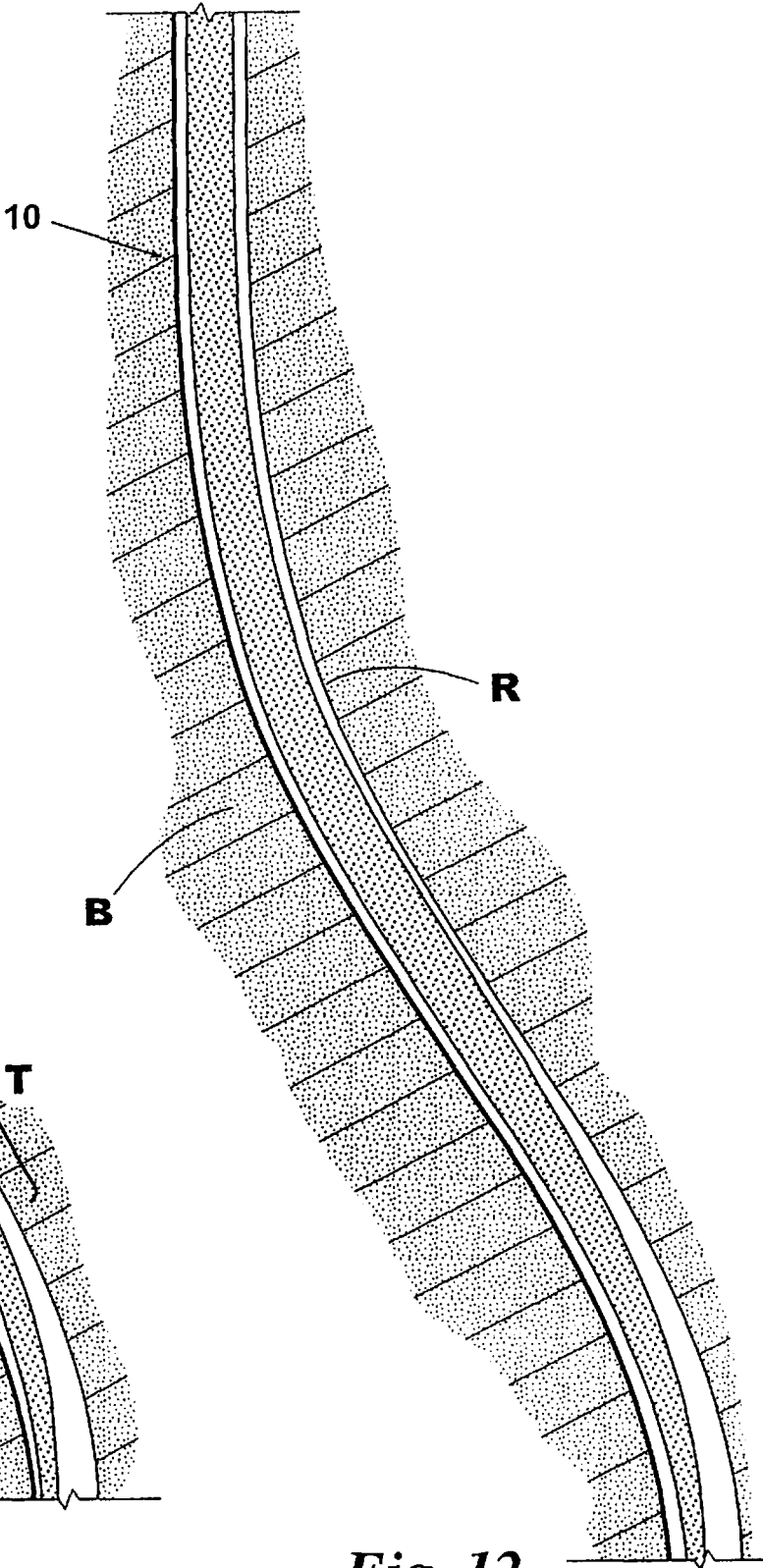


Fig. 12

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2014/046832

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61C5/02
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data, COMPENDEX, INSPEC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 83/01565 A1 (INVENTIVE TECH INT [US]) 11 May 1983 (1983-05-11) figures 1-4 page 4, line 5 - page 9, line 12 -----	1-6
X	US 2006/210947 A1 (LAMPERT CHRISTOPHER J [US]) 21 September 2006 (2006-09-21) figures 10-20 paragraph [0042] - paragraph [0048] paragraph [0045] claims 1, 4 -----	1-6



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

6 November 2014

Date of mailing of the international search report

18/11/2014

Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2014/046832

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